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HIPAA, Physicians and Photographs: Legal vs. Illegal

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Sexting during surgery? Selfies with an anesthetized celebrity patient? Snapping explicit photos of female patients in exam rooms?

Do not become a headline!

Anyone who has worked in a physician's office, hospital or other medical facility has undoubtedly seen and heard various scenarios and situations involving a physician and a patient. Clearly, the aforementioned scenarios are precluded by the Health Insurance Accountability and Affordability Act ("HIPAA")¹ and other related laws; however, what is not precluded? This article will address the HIPAA standard, scenarios that have resulted in physician liability, and steps physicians can take to obtain pictures, if they are legitimate and related to treatment and the medical record.

In the text of the original legislation, Congress articulated the following guideline, "Confidentiality. Such guidelines shall include procedures to assure that such information is provided and utilized in a manner that appropriately protects the confidentiality and the privacy of individuals receiving healthcare services and items."² This fundamental concept of confidentiality, as well as integrity and availability of the protected health information ("PHI") has been woven into every facet of the subsequent rules,³ information technology standards⁴ and the Health Information Technology for

Economic and Clinical Health Act ("HITECH Act").⁵ Building on the notion of confidentiality, the HIPAA Privacy Rule forms the foundation for protecting PHI⁶. The U.S. Department of Health and Human Services (HHS) provided an explanation of what the Privacy Rule encompasses:

[U]sing or disclosing protected health information unless authorized by patients, except where this prohibition would result in unnecessary interference with access to quality health care or with certain other important public benefits or national priorities. Ready access to treatment and efficient payment for health care, both of which require use and disclosure of protected health information, are essential to the effective operation of the health care system. In addition, certain health care operations — such as administrative, financial, legal, and quality improvement activities — conducted by or for health care providers and health plans, are essential to support treatment and payment. Many individuals expect that their health information will be used and disclosed as necessary to treat them, bill for treatment, and, to some extent, operate the covered entity's health care business. To avoid interfering with an individual's access to quality health care or the efficient payment for such health care, the Privacy Rule permits a covered entity to use and disclose protected health information, with certain limits and protections, for treatment, payment, and health care operations activities.⁷

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MISSION STATEMENT

The Nevada State Board of Medical Examiners serves the state of Nevada by ensuring that only well-qualified, competent physicians, physician assistants, respiratory therapists and perfusionists receive licenses to practice in Nevada. The Board responds with expediency to complaints against our licensees by conducting fair, complete investigations that result in appropriate action. In all Board activities, the Board will place the interests of the public before the interests of the medical profession and encourage public input and involvement to help educate the public as we improve the quality of medical practice in Nevada.

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HIPAA, Physicians and Photographs: Legal vs. Illegal

Nowhere within the various state and federal laws are there exceptions carved out to allow physicians to arbitrarily take pictures of patients under anesthesia without the prior, express, written consent of the patient. This goes beyond violating the doctor-patient relationship as well as HIPAA. Unable to respond, the patient is placed in a situation that may impact him or her in the same way as if he or she had been raped u nder anesthesia. This, in turn, may implicate other laws, including common law claims for intentional infliction of emotional distress.

As indicated from the outset, certain highlighted scenarios in this article are for educational purposes. So, what are some common ways physicians violate HIPAA?⁸

- Texting pictures or other PHI to others who are not members of the care team.
- Texting pictures to members of the care team, that are not done through encrypted, secure apps and other IT so-lutions as well as texting pictures that do not fall within the scope of treatment.
- Taking pictures of patients without consent.
- Not reporting a lost or stolen device that contains PHI.
- Not reporting a breach.

In California, the San Diego District Attorney's Office is involved in a criminal case where a physician is accused of taking explicit photos of female patients. It is more likely than not, a reasonable person would be mortified by having a physician, "inserted his finger into her vagina for the exam [of pain in the belly button]. Records show that [the physician] pulled out a cell phone from his doctor's coat and took a picture of her belly button area and five pictures of her naked body."9 The (California) Medical Board Expert Reviewer described that both the exam and photos were "extreme departures from the standard of care."¹⁰ And, in addition, were HIPAA violations.

In Washington State, an anesthesiologist sexted images during surgery not only of himself, with his pants down, but, also, pictures of anesthetized patients, which he used for sexual purposes. "According to the Washington State Department of Health, anesthesiologist Arthur Zilberstein 'compromised patient safety due to his preoccupation with sexual matters while he was on hospital duty between at least April and August 2013," KOMO-TV News reported. "The state Medical Quality Assurance Commission says Zilberstein repeatedly sent sexually explicit text messages during surgeries in which he was the responsible anesthesiologist. During one August 6 surgery, Zilberstein exchanged 45 sexually-related messages, according to the Commission."¹¹

The late Joan Rivers is an example of a violated celebrity. In addition to the fact that one of her procedures was not authorized and consented to, the physician "took a selfie photo in the procedure room while Rivers was under anesthesia".¹²

These types of examples are endless and unfortunate. To protect themselves, physicians should do the following:

- 1. Do not take pictures of anything patient related, unless it is for a legitimate medical purpose (i.e., skin disorder, before and after pictures of various types of reconstruction) and if it is for a legitimate medical purpose, make sure the exact area and purpose are express in the consent form.
- 2. Obviously, do not engage in any of the activities highlighted previously in this article.
- 3. If you have any questions about how pictures may be used for legitimate purposes (i.e., grand rounds, medical education or course of treatment), consult an attorney or the Board for further information.

To preserve the confidentiality, integrity and availability of the PHI, the bodily integrity of the patient as well as the physician's medical license, both common sense and proactive steps should be taken to avert becoming another headline.

² *Id.* § 1128C(3)(B)(ii) (noting 42 USC 1320a-7c) ³ 78 Fed. Reg. 5565 (Jan. 25, 2013).

National Institute of Standards and Technology, http://www.nist.gov (last accessed, Feb. 28, 2015). ⁹ Pub. L. 111-5 (Feb. 17, 2009).

Ibid.

Disclaimer: The opinions expressed in the Guest Contributor's article are those of the author, and do not necessarily reflect the opinions of the Board members or

staff of the Nevada State Board of Medical Examiners.

About the Author

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⁴⁵ CFR 164.506

U.S. Department of Health and Human Services. Uses and Disclosures for Treatment. Payment and Health Care Operations, http://www.hbs.gov/ocr/privacy/hipaa/understanding/coveredentities/usesanddisclosuresfortpo.html (last accessed. Feb. 28. 2015) See, http://www.ismanet.org/news/ViewArticle.aspx?ArticleId=8684/PHIRCktLKB (last accessed, Feb. 28, 2015). See, http://www.cbs8.com/story/26853458/doctor-accused-of-taking-explicit-photos (last accessed, Feb. 28, 2015)

¹¹ See, http://www.inquisitr.com/1293003/is-that-sanitary-sexting-doctors-medical-license-suspended-after-sending-nude-selfies-taken-during-surgery/#7FeJ7ITwhGUG2bi.99 (last accessed, Feb. 28, 2015). ¹² CNN News, Joan Rivers' Doctor Took Selfie, Began Biopsy Before Her Cardiac Arrest, available at, http://www.cnn.com/2014/09/16/showbiz/joan-rivers-clinic/.

BOARD NEWS

BEFORE YOU RENEW!

MEDICAL DOCTORS: Pursuant to Nevada Revised Statute 630.30665, you are required to submit to the Board of Medical Examiners the requisite in-office surgery reporting form for the period of January 1, 2013 through December 31, 2014, **prior** to renewing your license in 2015, and you will be required to attest on your renewal application that you have submitted the form. Forms are available on the Board's website. Further information can be found on pages 4 and 5 of this Newsletter for reporting instructions.

HOW TO RENEW!

You must renew your license before 5:00 PDT, July 1, 2015. Please ensure the Board has your <u>current</u> mailing address! Licensees will receive a postcard which includes **individual** renewal information. Please retain your postcard for renewal purposes, as you will need the information contained thereon (such as your Renewal I.D.) in order to renew your license online. There is a \$10 administrative processing fee included for online renewals and a \$30 administrative processing fee for renewals by paper application. The administrative processing fee will be waived for those licensees who are not eligible to renew online in 2015. Once renewed, licenses are valid from July 1, 2015 – June 30, 2017*.

Fees are as follows:	Online Renewal Fee	Paper Renewal Fee
Active Medical Doctors	\$760	\$780
Inactive Medical Doctors	\$385	\$405
Physician Assistants	\$385	\$405
Perfusionists	N/A	\$375
Practitioners of Respiratory Care	\$195	\$215

Online, you can pay with American Express, Discover, MasterCard or Visa. By paper, you can pay with personal check, money order, cashier's check or the above-listed credit cards (no cash please).

Perfusionists are not eligible for online renewal in 2015 and will receive their renewal applications in the mail. The administrative processing fee will be waived for these licensees in 2015.

All licensees are subject to a random audit of their CME/CE, which includes licensees who are renewing by paper application. If you are selected to provide proof of completion of your continuing medical education (CME)/continuing education (CE) at the time you renew online, and cannot satisfy the CME/CE requirement, your license <u>will not</u> be renewed, and will be mandatorily audited the next renewal period. <u>Word to the wise</u>: please have your CME/CE up to date. Further information regarding CME/CE requirements can be found on the Board's website: <u>www.medboard.nv.gov</u>.

*Renewing licensees who currently hold a Visa, Employment Authorization or Conditional Resident Alien Card are required to fax proof of extension of their immigration status to licensing staff at (775) 688-2551, prior to renewal of their licenses. Licenses are only valid for the duration of the existing immigration status, which is verified through USCIS, and if extended by USCIS may be valid until June 30, 2017.

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BOARD MEMBERS	NOTIFICATION OF ADDRESS CHANGE,
Michael J. Fischer, M.D., <i>President</i> Theodore B. Berndt, M.D., <i>Vice President</i> Valerie J. Clark, BSN, RHU, LUTCF, <i>Secretary-Treasurer</i> Beverly A. Neyland, M.D. Bashir Chowdhry, M.D. Wayne Hardwick, M.D.	PRACTICE CLOSURE AND LOCATION OF RECORDS Pursuant to NRS 630.254, all licensees of the Board are required to "maintain a permanent mailing address with the Board to which all communications from the Board to the licensee must be sent." A licensee must notify the Board in writing of a change of permanent mailing address within 30 days after the change. Failure to do so may result in the imposition of a fine or initiation of disciplinary proceedings against the licensee.
Ms. Ann Wilkinson Rachakonda D. Prabhu, M.D.	Please keep in mind the address you provide will be viewable by the public on the Board's website.
Ms. Sandy Peltyn	Additionally, if you close your practice in Nevada, you are required to notify the Board in writing within 14 days after the closure, and
Edward O. Cousineau, J.D., <i>Executive Director</i>	for a period of 5 years thereafter, keep the Board apprised of the location of the medical records of your patients.

Mandatory In-Office Surgery Reporting 2013-2014

INSTRUCTIONS FOR REPORTING IN-OFFICE SURGERIES OR PROCEDURES INVOLVING CONSCIOUS SEDATION, DEEP SEDATION OR GENERAL ANESTHESIA, AND ANY ASSOCIATED SENTINEL EVENTS, FOR 2013-2014

Instructions and forms are available on the Board's website (<u>www.medboard.nv.gov</u>) by clicking the red "In-Office Surgery Reporting" link on the home page.

All allopathic physicians licensed in the state of Nevada are required by Nevada Revised Statute 630.30665 to report to the Nevada State Board of Medical Examiners, **prior** to licensure renewal, all in-office surgeries or procedures that involved the use of conscious sedation, deep sedation or general anesthesia, and the occurrence of any sentinel event arising from any such surgeries or procedures, between January 1, 2013 and December 31, 2014.

This reporting requirement, to include negative reporting, is mandatory. Your failure to submit a report or knowingly filing false information in a report is grounds for disciplinary action under Nevada's Medical Practice Act. You will be required to attest on your 2015 license renewal application that you have completed the applicable reporting form, either:

Form A: Which is to be completed and signed by you if you <u>DID</u> perform surgeries or procedures which involved the use of conscious sedation, deep sedation or general anesthesia, and any associated sentinel events, in your office or other location within the state of Nevada, other than those excepted facilities which are listed on page 5.

Form B: Which is to be completed and signed by you if you <u>DID NOT</u> perform any surgeries or procedures which involved the use of conscious sedation, deep sedation or general anesthesia, in your office or other location within the state of Nevada, other than those excepted facilities which are listed on page 5. <u>Again, negative reporting is required by law</u>.

Definitions:

Conscious Sedation

"Conscious sedation" means a minimally-depressed level of consciousness, produced by a pharmacologic or non-pharmacologic method, or a combination thereof, in which the patient retains the ability independently and continuously to maintain an airway and to respond appropriately to physical stimulation and verbal commands.

You must report <u>the number (how many)</u> and <u>type (name of the surgery or procedure)</u> of surgeries/procedures in which you used **con**scious sedation on a patient on Form A.

You must also report <u>any sentinel event</u> associated with any surgery or procedure, while a patient was under **conscious sedation**, on Form A.

Deep Sedation

"Deep sedation" means a controlled state of depressed consciousness, produced by a pharmacologic or non-pharmacologic method, or a combination thereof, and accompanied by a partial loss of protective reflexes and the inability to respond purposefully to verbal commands.

You must report **the number (how many)** and **type (name of the surgery or procedure)** of surgeries/procedures in which you used **deep sedation** on a patient on Form A.

You must also report any sentinel event associated with any surgery or procedure, while a patient was under deep sedation, on Form A.

General Anesthesia

"General anesthesia" means a controlled state of unconsciousness, produced by a pharmacologic or non-pharmacologic method, or a combination thereof, and accompanied by partial or complete loss of protective reflexes and the inability independently to maintain an airway and respond purposefully to physical stimulation or verbal commands.

You must **report the number (how many)** and **type (name of the surgery or procedure)** of surgeries/procedures in which you used **general anesthesia** on a patient on Form A.

You must also report any sentinel event associated with any surgery or procedure, while a patient was under **general anesthesia**, on Form A.

Sentinel Event

A "sentinel event" is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof, including, without limitation, any process variation for which a recurrence would carry a significant chance of serious adverse outcome. The term includes loss of limb or function, and includes any case in which the patient requires hospitalization within 72 hours after the conclusion of the in-office procedure.

Examples of reportable sentinel events:

- 1. Death that is related to a procedure or surgery that takes place in the office setting or within 14 days of discharge.
- 2. Transfer to a hospital or emergency center for a period exceeding 24 hours.

3. Unscheduled hospital admission for longer than 24 hours, within 72 hours of an office procedure and which is related to that procedure.

4. Other serious events: A serious or life-threatening event, occurrence or situation in the office setting, involving the clinical care of a patient that compromises patient safety and results in unanticipated injury requiring the delivery of additional health services to the patient.

These events include, but are not limited to, the following examples:

- surgery performed on the wrong body part
- surgery performed on a wrong patient
- wrong surgical procedure performed on a patient
- unintentional retention of a foreign object in a patient after surgery or other procedure
- perforation or laceration of a vital organ
- serious disability associated with a medication error
- serious disability associated with a burn incurred from any source
- serious disability associated with equipment malfunction
- anesthesia-related complication/event, such as anaphylaxis, shock, prolonged hypoxia, hypertensive crisis, malignant hyperthermia, severe hyperthermia, renal failure, aspiration, severe transfusion reaction or unanticipated anesthesia awareness
- cardiac or respiratory complication/event, such as cardiac arrest, respiratory arrest, myocardial infarction, prolonged life-threatening arrhythmia, pneumothorax or pulmonary embolism
- neurological complication/event, such as CVA, prolonged seizure, prolonged unresponsiveness, significant nerve injury, coma, paralysis, brain or spinal injury
- infectious complication/event such as septic shock or deep site wound abscess/infection
- fracture or dislocation of bone or joints.

Reminders:

The physician's signature is required, whether you submit Form A or Form B. Do not provide a report for a group practice as a whole -<u>a report is required from each and every physician within a group practice</u>. Report only those surgeries/procedures performed within the state of Nevada, **as you do not have to report any surgeries or procedures performed at one of the following facilities, or outside the state of Nevada**:

- 1. A surgical center for ambulatory patients;
- 2. An obstetric center;
- 3. An independent center for emergency medical care;
- 4. An agency to provide nursing in the home;
- 5. A facility for intermediate care;
- 6. A facility for skilled nursing;
- 7. A facility for hospice care;
- 8. A hospital;
- 9. A psychiatric hospital;
- 10. A facility for the treatment of irreversible renal disease;
- 11. A rural clinic;
- 12. A nursing pool;
- 13. A facility for modified medical detoxification;
- 14. A facility for refractive surgery;
- 15. A mobile unit; and
- 16. A community triage center.

Submission of Forms:

Please submit all completed applicable forms to the Nevada State Board of Medical Examiners:

By mail to:	P.O. Box 7238, Reno, NV 89510	By hand delivery:	1105 Terminal Way, Suite 301, Reno, NV 89502
By fax to:	(775) 688-2553	By email to:	<pre>surgeryreport@medboard.nv.gov</pre>

Despite Broad Awareness, Only Half of Doctors Surveyed Use Prescription Drug Monitoring Programs

USABILITY BARRIERS DAMPEN PARTICIPATION YET NEARLY THREE-QUARTERS WHO USE STATE DATABASES REPORT PRESCRIBING FEWER OPIOIDS

In a new survey, researchers at the Johns Hopkins Bloomberg School of Public Health found that physicians report relatively high awareness of state databases that track drug prescriptions but more than one-fifth indicated they were not aware of their state's program at all.

In a survey of 420 primary care physicians published in the March issue of the journal *Health Affairs*, the researchers found that 72 percent indicated they were aware of their state's program, and 53 percent reported they had used their state's program. Another 22 percent indicated they had no knowledge of their state's program.

This is believed to be the first national survey examining physicians' awareness and use of Prescription Drug Monitoring Programs and state-run databases that track prescriptions classified as federal controlled substances, including opioids. The programs are considered an important intervention aimed at curtailing prescription drug abuse and misuse, which has reached epidemic proportions in the United States. An estimated one-third of people aged 12 or older who used opioids for the first time in 2009 began by using a prescription drug without a prescription.

The databases allow prescribing physicians to identify "doctor shoppers" - people who obtain prescriptions from multiple physicians, either to use or to sell or both -- and other potentially illicit or abusive behaviors. Every state but Missouri has a prescrip-



tion drug-monitoring program in place.

The survey also assessed physicians' perceptions of program usability, ease of accessing the data as well as barriers to using the data. Nearly three-quarters - 74 percent - found accessing the data to be "very easy" (31 percent) or "somewhat easy" (38 percent). But when it came to using the data, 58 percent reported that the information was too time-consuming to retrieve and 28 percent indicated that the information was not in an easy-to-use format.

"The success of these programs depends on physicians' knowledge, impressions and use of them," says study leader Lainie Rutkow, JD, PhD, an associate professor in the Department of Health Policy and Management at the Bloomberg School. "While awareness of the programs is relatively high, barriers exist. The information in our report about the barriers physicians face will give states something to focus on."

The programs are relatively new, with the earliest introduced in the past decade and newer programs in various stages of rollout. In the past three years, 12 states introduced prescription drug monitoring programs. They vary from state to state, but by and large require doctors and/or pharmacists to enter information about prescriptions and dispensing of drugs so they can be tracked. In some states, law enforcement has access to the databases.

As for the 22 percent who reported not knowing about the programs, Rutkow says the figure is not as alarming as it might suggest because in many states the programs are new and physicians may not be aware of the rollout. Still, Rutkow notes that this finding represents an opportunity for states to communicate with physicians about their programs.

One challenge the programs face is the lack of information sharing between states. "It's a goal of course to ultimately have interstate interaction, especially in large urban areas that span multiple states," says Rutkow.

The authors note that physicians might use the programs more frequently if states addressed barriers to use. For instance, some states only give physicians access to the systems, which puts the burden of use on the doctor. Other states allow physicians to appoint a proxy, so someone else can do the work. Another problem is that in some state databases, the data is not clearly presented, making the databases difficult to access and interpret.

In addition to addressing the prescription drug epidemic, the state programs could have the unintended consequence of serving other valuable functions, including preventing adverse drug interactions. Given the widespread use of prescription drugs to treat chronic diseases, these programs may be useful for monitoring other types of prescriptions.

"Most Primary Care Physicians Are Aware Of Prescription Drug Monitoring Programs, But Many Find Data Difficult To Access" was written by Lainie Rutkow, Lydia Turner, Catherine Hwang and G. Caleb Alexander.

The research was supported by the Robert Wood Johnson Foundation Public Health Law Research Program. Alexander is also supported by the Lipitz Public Health Policy Award from the Johns Hopkins Bloomberg School of Public Health.

AAMC Report: New Physician Workforce Projections Show Doctor Shortage Remains Significant

Solution Requires Delivery Innovation, Team-Based Care, Federal Support

Washington, D.C., March 3, 2015—The nation will face a shortage of between 46,000-90,000 physicians by 2025, according to a report released today by the AAMC (Association of American Medical Colleges). The study, which is the first comprehensive national analysis that takes into account both demographics and recent changes to care delivery and payment methods, projects shortages in both primary and specialty care, with specialty shortages particularly acute.

"The doctor shortage is real – it's significant – and it's particularly serious for the kind of medical care that our aging population is going to need," said AAMC President and CEO Darrell G. Kirch, MD.

The study, conducted for the AAMC by the Life Science division of <u>IHS Inc.</u>, a global information company, presents projections in ranges that reflect the potential impact of a variety of health care delivery and policy scenarios, including the rapid growth in non-physician clinicians and new payment and delivery models such as patient-centered medical homes (PCMH) and accountable care organizations (ACO).



Projections for individual specialties were aggregated into four broad categories: primary care, medical specialties, surgical specialties, and "other" specialties. Within the overall projected physician shortage, the study estimates a shortage of 12,000-31,000 primary care physicians, and a shortfall of 28,000-63,000 non-primary care physicians, most notably among surgical specialists.

"The trends from these data are clear - the physician shortage will grow over the next 10 years under every likely scenario," said Kirch. "Because training a doctor takes between five and 10 years, we must act now, in 2015, if we are going to avoid serious physician shortages in 2025. The solution requires a multi-pronged approach: Continuing to innovate and be more efficient in the way care is delivered as well as increased federal support for graduate medical education to train at least 3,000 more doctors a year to meet the health care needs of our nation's growing and aging population."

The Complexities of Physician Supply and Demand: Projections from 2013 to 2025 View the complete report.

The Association of American Medical Colleges is a not-for-profit association representing all 141 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and nearly 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 148,000 faculty members, 83,000 medical students, and 115,000 resident physicians. Additional information about the AAMC and U.S. medical schools and teaching hospitals is available at www.aamc.org/newsroom. Contact - Susan Beach - 202-828-0983 sbeach@aamc.org

Physician Supply and Demand Through 2025: Key Findings

In March 2015, the economic modeling and forecasting firm IHS Inc. released a new study, *The Complexities of Physician Supply and Demand: Projections from 2013 to 2025*, at the request of the AAMC. Projections for individual specialties were aggregated into four broad categories for reporting: primary care, medical specialties, surgical specialties, and "other" specialties. To reflect future uncertainties in health policy and care use and delivery patterns, the study presents ranges for the projected shortage of physicians rather than a specific shortage number.

Demand for physicians continues to grow faster than supply. Although physician supply is projected to increase modestly between 2013 and 2025, demand will grow more steeply.

• Total physician demand is projected to grow by up to 17 percent, with population aging/growth accounting for the majority. Full implementation of the Affordable Care Act accounts for about 2 percent of the projected growth in demand.

• By 2025, demand for physicians will exceed supply by a range of 46,000 to 90,000. The lower range of estimates would represent more aggressive changes secondary to the rapid growth in non-physician clinicians and widespread adoption of new payment and delivery models such as patient-centered medical homes (PCMHs) and accountable care organizations (ACOs).

• Total shortages in 2025 vary by specialty grouping and include:

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- A shortfall of between 12,500 and 31,100 primary care physicians.
- A shortfall of between 28,200 and 63,700 non-primary care physicians, including:
 - 5,100 to 12,300 medical specialists
 - 23,100 to 31,600 surgical specialists
 - 2,400 to 20,200 other specialists

The physician shortage will persist under every likely scenario, including increased use of advanced practice nurses (APRNs); greater use of alternate settings such as retail clinics; delayed physician retirement; rapid changes in payment and delivery (e.g., ACOs, bundled payments); and other modeled scenarios.

Addressing the shortage will require a multi-pronged approach, including innovation in delivery; greater use of technology; improved, efficient use of all health professionals on the care team; and an increase in federal support for residency training. The study's results confirm that no single solution will be sufficient on its own to resolve physician shortages.

Because physician training can take up to a decade, a physician shortage in 2025 is a problem that needs to be addressed in 2015.

For More Information - https://www.aamc.org/download/426260/data/physiciansupplyanddemandthrough2025keyfindings.pdf

FDA Releases Final Guidance on Reprocessing of Reusable Medical Devices

Agency to hold panel meeting to discuss recent cases associated with duodenoscopes



The U.S. Food and Drug Administration today announced new actions to enhance the safety of reusable medical devices and address the possible spread of infectious agents between uses.

The new recommendations are outlined in a final industry guidance aimed at helping device manufacturers develop safer reusable devices, especially those devices that pose a greater risk of infection.

Medical devices intended for repeated use are commonplace in health care set-

tings. They are typically made of durable substances that can withstand reprocessing, a multi-step process designed to remove soil and contaminants by cleaning and to inactivate microorganisms by disinfection or sterilization. While the majority of reusable devices are successfully reprocessed in health care settings, the complex design of some devices makes it harder to remove contaminants.

FDA's guidance document, titled "<u>Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling</u>" includes recommendations medical device manufacturers should follow pre-market and post-market for the safe and effective use of reprocessed devices.

A device manufacturer's reprocessing instructions are critical to protect patients against the spread of infections. As part of its regulatory review for reusable medical devices, the FDA reviews the manufacturer's reprocessing instructions to determine whether they are appropriate and able to be understood and followed by end users. The guidance lists six criteria that should be addressed in the instructions for use with every reusable device to ensure users understand and correctly follow the reprocessing instructions.

The guidance also recommends that manufacturers consider reprocessing challenges early in device design. Manufacturers will be expected to conduct validation testing to show with a high degree of assurance that their cleaning and disinfection or sterilization instructions will consistently reduce microbial contamination.

"Despite the recent concerns about multi-drug resistant bacteria infections associated with duodenoscopes, patients and health care providers should know that the risk of acquiring an infection from a reprocessed medical device is low" said William Maisel, M.D., M.P.H., Deputy Director for Science and Chief Scientist at the FDA's Center for Devices and Radiological Health. "This guidance is an important step toward further enhancing the safety margin by outlining for manufacturers the steps they should undertake to make their reprocessing instructions effective and clear to the healthcare community that uses them. Doing so should provide greater assurance to patients that the devices used on them are safe and effective."

The FDA issued a draft guidance discussing the reprocessing of reusable medical devices in 2011, and considered almost 500 comments before issuing the final guidance. The final guidance provides more clarity about testing protocols and what data should be submitted to the agency for a premarket submission, such as the data FDA needs to evaluate substantial equivalence for a 510(k) premarket submission.

Manufacturers seeking to bring to market certain reusable devices, such as duodenoscopes, bronchoscopes and endoscopes, should submit to the FDA for review their data validating the effectiveness of their reprocessing methods and instructions.

Separately, the FDA also announced in the *Federal Register* that the agency's Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee will hold a <u>public meeting</u> on May 14 and 15, 2015 to discuss recent reports and epidemiologic investigations of transmission of infections associated with the use of duodenoscopes in endoscopic retrograde cholangiopancreatography (ERCP) procedures in hospitals in the United States.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

FDA Final Guidance: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling

DEA Issues Nationwide Alert on Fentanyl as Threat to Public Health and Safety

(WASHINGTON) - The United States Drug Enforcement Administration (DEA) today issued a nationwide alert about the dangers of fentanyl and fentanyl analogues/compounds. Fentanyl is commonly laced in heroin, causing significant problems across the country, particularly as heroin abuse has increased. This alert was issued through the multi-agency El Paso Intelligence Center (EPIC) to all U.S. law enforcement.

"Drug incidents and overdoses related to fentanyl are occurring at an alarming rate throughout the United States and represent a significant threat to public health and safety," said DEA Administrator Michele M. Leonhart. "Often laced in heroin, fentanyl and fentanyl analogues produced in illicit clandestine labs are up to 100 times more powerful than morphine and 30-50 times more powerful than heroin. Fentanyl is extremely dangerous to law enforcement and anyone else who may come into contact with it. DEA will continue to address this threat by directly attacking the drug trafficking networks producing and importing these deadly drugs. We have lost too many Americans to drug overdoses and we strongly encourage parents, caregivers, teachers, local law enforcement and mentors to firmly and passionately educate others about the dangers of drug abuse, and to seek immediate help and treatment for those addicted to drugs."

In the last two years, DEA has seen a significant resurgence in fentanyl-related seizures. According to the National Forensic Laboratory Information System (NFLIS), state and local labs reported 3,344 fentanyl submissions in 2014, up from 942 in 2013. In



addition, DEA has identified 15 other fentanyl-related compounds.

Fentanyl is a Schedule II narcotic used as an analgesic and anesthetic. It is the most potent opioid available for use in medical treatment – 50 to 100 times more potent than morphine and 30 to 50 times more potent than heroin. Fentanyl is potentially lethal, even at very low levels. Ingestion of small doses as small as 0.25 mg can be fatal. Its euphoric effects are indistinguishable from morphine or heroin.

DEA has also issued warnings to law enforcement as fentanyl can be absorbed through the skin and accidental inhalation of airborne powder can also occur. DEA is concerned about law enforcement coming in contact with fentanyl on the streets during the course of enforcement, such as a buy-walk, or buy-bust operation.

Fentanyl cases in 2014 have been significant, particularly in the northeast and in California, including one 12-kilogram seizure. The fentaryl from these seizures originated from Mexican drug trafficking organizations.

Globally, fentanyl abuse has increased the past two years in Russia, Ukraine, Sweden and Denmark. Mexican authorities have seized fentanyl labs there, and intelligence has indicated that the precursor chemicals came from companies in Mexico, Germany, Japan, and China.

Historically, this is not the first time fentanyl has posed such a threat to public health and safety. Between 2005 and 2007, over 1,000 U.S. deaths were attributed to fentanyl – many of which occurred in Chicago, Detroit, and Philadelphia. The source of that fentanyl was traced to a single lab in Mexico. When that lab was identified and dismantled, the surge ended.

The current outbreak involves not just fentanyl, but also fentanyl analogues. The current outbreak is wider geographically and involves a wide array of individuals including new and experienced abusers.

Some recent examples of the fentanyl surge across the United States:

- New Hampshire State Laboratory recently reported four fentanyl overdose deaths within a two-month period.
- New Jersey saw a huge spike in fentanyl deaths in 2014, reporting as many as 80 in the first six months of the fiscal • year.
- Rhode Island and Pennsylvania have also seen huge increases since 2013. In a 15-month period, about 200 deaths were . reported in Pennsylvania related to fentanyl.
- In the St. Louis area, based on information provided by medical examiners over a 10-year period, fentanyl was the only drug attributed as a primary death factor in 44 percent of overdose cases.
- In June 2014, DEA New York dismantled a heroin and fentanyl network and arrested the two heads of the organization. • These individuals were linked to at least three overdose deaths from heroin and fentanyl they sold.

For more information on fentanyl, visit: http://www.deadiversion.usdoj.gov/drug chem info/fentanyl.pdf DEA Public Affairs Office: (202) 307-7977

SAMHSA Issues New Guidance on Extended-Release Injectable Naltrexone



The Substance Abuse and Mental Health Services Administration (SAMHSA) has issued new guidance on the clinical use of extended-release injectable naltrexone for treatment of opioid use disorder. *Clinical Use of Extended-Release Injectable Naltrexone in the Treatment of Opioid Use Disorder: A Brief Guide* is based on a review of the current evidence on the effectiveness of available medications for the treatment

of opioid use disorders, including a summary of the key differences between extended-release injectable naltrexone, methadone, and buprenorphine.

The guidance provides key information on assessing the patient's need for treatment, and initiating medicationassisted treatment (MAT). It also advises on how to monitor patient progress, adjust the treatment plan, and decide whether and when to end MAT.

The problem of non-medical use of prescription opioids has widened the need for opioid treatment services. Many people with an opioid use disorder – whether from heroin use or non-medical use of prescription opioids - do not receive MAT because of limited treatment capacity, financial obstacles, social bias, and other barriers to care.

Researchers, federal health agencies, and pharmaceutical manufacturers have focused on developing medications such as extended-release injectable naltrexone that can be used to expand access to treatment of an opioid use disorder in medical office settings, rather than limiting use to specialized opioid treatment programs.

These new medications can help fill the unmet need for treatment through the largely untapped resource of primary care clinicians. Many studies show that treatment of an opioid use disorder can be successfully integrated into general office practice by physicians and healthcare providers who are not addiction specialists.

The brief guide is available to download from the SAMHSA Store website at <u>http://store.samhsa.gov</u>.

The Substance Abuse and Mental Health Services Administration (SAMHSA) is the agency within the U.S. Department of Health and Human Services (DHHS) that leads public health efforts to advance the behavioral health of the nation. SAMHSA's mission is to reduce the impact of substance abuse and mental illness on America's communities.

For more information about SAMHSA visit: <u>http://www.samhsa.gov/</u>

Media Contact: SAMHSA Press Office (240) 276-2130

Telephone Hotlines

All hotline numbers are toll-free

SAMHSA's National Helpline 800-662-HELP (800-662-4357) TTY: 800-487-4889 Suicide Prevention Lifeline 800-273-TALK (800-273-8255) TTY: 800-799-4889 Disaster Distress Hotline 800-985-5990 TTY: 800-846-8517 Text TalkWithUs to 66746

HHS Secretary: It's Time to Act to Reduce Opioid-Related Injuries and Death

By: Sylvia Mathews Burwell, HHS Secretary

We lose too many of our fellow Americans to drug overdoses. In fact, drug overdose deaths are the leading cause of injury death in the United States – more than even car crashes – because they have increased five-fold since 1980.

Especially alarming is the high rate of prescription drug overdose and the rising rate of overdoses due to heroin use. In 2012 alone, 259 million opioid prescriptions were written -- enough for every American adult to have a bottle.

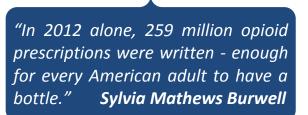
Rural America, including my home state of West Virginia, knows this issue all too well. Opioid injuries and overdoses are very real and affect many families. The situation is urgent – but there is reason for optimism: there are targeted actions we can take to save lives and turn these trends around. But we need all stakeholders at the table. Therefore, I am asking federal, state and local government officials, doctors, treatment providers, drug companies, individuals and family members to work together to address this nationwide crisis.

Fortunately, many are already doing so – Republicans, Democrats, and Independents alike – because they recognize our common interest in defeating this epidemic.

At the U.S. Department of Health and Human Services, we're working to develop the most effective solutions to reverse this trend. We've used the best evidence to determine where to focus our attention and turn the tide against opioid drug-related overdose and dependence.

Our efforts focus on three promising areas: informing opioid prescribing practices, increasing the use of naloxone - a drug that reverses symptoms of a drug overdose, and using medication-assisted treatment to slowly move people out of opioid addiction. At the same time, it is critical to balance combatting opioid misuse with supporting health care professionals in providing appropriate pain management.

States, health care providers, and pharmacists are key partners for safe prescribing and dispensing of prescription opioids. That's why we plan to focus on increasing investments in state-based prescription drug monitoring programs (PDMPs), developing guidelines for opioid prescribing, and training providers. PDMPs are electronic prescription tracking systems run by states. PDMPs such as those in Kentucky and New York are showing great potential for identifying people at high risk for dependence, addiction and overdose and changing prescribing behaviors.



Given the unique role of naloxone as an opioid overdose reversal treatment, getting it into the hands of more first responders is a top priority. Our efforts will continue to support the development and distribution of this life-saving drug. We are also expanding the use of medication-assisted treatment (MAT), which combines the use of medication with counseling and behavioral therapies to treat substance abuse disorders - and is a comprehensive way to effectively reduce opioid dependence and overdose.

Our intention is clear: to save lives by preventing the misuse and abuse of prescription opioids and heroin use.

Our efforts are not "one size fits all," nor do they encompass every activity happening in this space. Our focus is on the activities and interventions with the strongest evidence base and the greatest potential for impact. We will work together with equally committed partners and use the tools available to us to combat this crisis.

We share common interests and therefore have an opportunity to work together in common cause. Whether we happen to work at state, local, or federal level – and regardless of whether we are in the private or public sector -- this is an issue that knows no geographic or ideological boundaries. We all have a stake in saving more lives and we all have a role to play in building safer, stronger, and healthier communities.

For more information, <u>click here</u>.

FSMB Offers Free CME/CPE Activity "Internet Drug Sellers: What Providers Need to Know"



The Federation of State Medical Boards (FSMB) and the Alliance for Safe Online Pharmacies (ASOP) recently announced a free online continuing education program (CME/CPE) for physicians and pharmacists focused on the growing problem of illegal online drug sales.

BOARDS This program, entitled "Internet Drug Sellers: What Providers Need To Know," is a learning activity that encourages participants to discuss the risks and patient safety issues involved with purchasing medications from a rogue Internet pharmacy.

The program is available at: www.fsmb.org/free-online-cme-cpe-activity.

The course will guide participants through understanding the common characteristics of illegal online drug sellers while raising awareness about the issue. After completing the program physicians and pharmacists will have a proficient understanding of this issue and be armed with the current tools and resources to identify fraudulent online pharmacies.



Recent studies found that nearly 97% of online drug sellers are operating illegally, and one in two websites selling medicine online peddle counterfeit drugs. Consumers, lured by the cheap drugs promised on rogue websites, may end up paying a higher price than anticipated, as medications may be counterfeit, ineffective, or adulterated with other ingredients, including potentially toxic chemicals. The problem is significant, with an estimated one in six Americans purchasing drugs online without a valid prescription at some point.

Experts agree that education is the key to combating the problem effectively. As trusted health care providers, physicians and pharmacists play a key role in educating consumers regarding the risks associated with purchasing medications online from an unverified source. This program offers providers the information necessary to protect patients from illegal online drug sales. Input for this activity was provided by the U.S. Food and Drug Administration, faculty from the University of California at San Diego, LegitScript and the Federation of State Medical Boards.



University of Nevada School of Medicine

Earn up to 2 Ethics CME Credits

Medical Marijuana: From Theory to Practical Application

Tuesday, May 5 Las Vegas, NV 7:30 am – 12:15 pm

The University of Nevada School of Medicine and the PACT Coalition will present an in-depth look at how medical marijuana has impacted other communities. This program will help prescribers and law enforcement prepare for dispensaries opening in Nevada.

For more information or to register, please visit: <u>http://medicine.nevada.edu/cme/medmlv2015</u>

WHOM TO CALL IF YOU HAVE QUESTIONS

Management:	Edward O. Cousineau, J.D. Executive Director
	Todd C. Rich Deputy Executive Director
	Donya Jenkins Finance Manager
Administration:	Laurie L. Munson, Chief
Legal:	Erin L. Albright, J.D. General Counsel
	Alexia M. Emmermann, J.D. General Counsel
Licensing:	Lynnette L. Daniels, Chief
Investigations:	Pamela J. Castagnola, CMBI, Chief

Nevada State Medical Association

3660 Baker Lane #101 Reno, NV 89509 775-825-6788 http://www.nsmadocs.org website

Clark County Medical Society

2590 East Russell Road Las Vegas, NV 89120 702-739-9989 phone 702-739-6345 fax http://www.clarkcountymedical.org website

Washoe County Medical Society

3660 Baker Lane #202 Reno, NV 89509 775-825-0278 phone 775-825-0785 fax http://www.wcmsnv.org website

2015 BME MEETING & HOLIDAY SCHEDULE

January 1 – New Year's Day holiday January 19 – Martin Luther King, Jr. Day holiday February 16 – Presidents' Day holiday March 6-7 – Board meeting May 25 – Memorial Day holiday June 5-7 – Board meeting July 3 – Independence Day holiday (observed) September 7 – Labor Day holiday September 11-12 – Board meeting October 30 – Nevada Day holiday November 11 – Veterans' Day holiday November 26 & 27 – Thanksgiving/family day holiday December 4-5 – Board meeting December 25 – Christmas holiday

Nevada State Board of Pharmacy

431 W. Plumb Lane Reno, NV 89509 775-850-1440 phone 775-850-1444 fax http://bop.nv.gov/ website pharmacy@pharmacy.nv.gov email

Nevada State Board of Osteopathic Medicine

2275 Corporate Circle, Ste. 210 Henderson, NV 89074 702-732-2147 phone 702-732-2079 fax www.bom.nv.gov website

Nevada State Board of Nursing

Las Vegas Office 4220 S. Maryland Pkwy, Bldg. B, Suite 300 Las Vegas, NV 89119 702-486-5800 phone 702-486-5803 fax Reno Office 5011 Meadowood Mall Way, Suite 300, Reno, NV 89502 775-687-7700 phone 775-687-7707 fax www.nevadanursingboard.org website

Unless otherwise noted, Board meetings are held at the Reno office of the Nevada State Board of Medical Examiners and videoconferenced to the conference room at the offices of the Nevada State Board of Medical Examiners/Nevada State Board of Dental Examiners, 6010 S. Rainbow Blvd., Building A, Suite 1, in Las Vegas.

Hours of operation of the Board are 8:00 a.m. to 5:00 p.m., Monday through Friday, excluding legal holidays.

DISCIPLINARY ACTION REPORT

ARMITAGE, David R., PA-C (620)

Cottonwood, Idaho

- Summary: Mr. Armitage voluntarily surrendered his license to practice medicine in Nevada.
- Statutory Authority: NRS 630.240 [voluntary surrender of license].
- Disposition: On March 6, 2015, the Board accepted Mr. Armitage's voluntary surcine in Nevada while under investigation.

ESTELA, Cesar A., M.D. (9610)

Henderson, Nevada

- Summary: Alleged malpractice and failure to maintain appropriate medical records related to his treatment of a patient.
- *Charges*: One violation of NRS 630.3062(1) [failure to maintain timely, legible, accurate and complete medical records relating to the diagnosis, treatment and care of a patient]; one violation of NRS 630.301(4) [malpractice].
- Disposition: On March 6, 2015, the Board accepted a Settlement Agreement by which it found Dr. Estela violated NRS 630.301(4), as set forth in Count II of the Complaint, and imposed the following discipline against him: (1) public reprimand; (2) reimbursement of the Board's fees and costs associated with investigation and prosecution of the matter. Count I of the Complaint was dismissed.

LYNCH, Douglas S., PA-C (PA1486) Las Vegas, Nevada

- Summary: Reasonable belief that the health, safety and welfare of the public was at imminent risk of harm.
- Statutory Authority: NRS 630.326(1) [risk of imminent harm to the health, safety or welfare of the public or any patient served by the physician assistant].
- Action Taken: On March 19, 2015, the Investigative Committee summarily suspended Mr. Lynch's license until further order of the Investigative Committee or the Board of Medical Examiners.

PHILANDER, Peter H., M.D. (8535)

Las Vegas, Nevada

- Summary: Alleged malpractice, practicing beyond the scope permitted by law and/or performing services that were beyond the scope of his training, and failure to maintain appropriate medical records related to his treatment of six patients.
- render of his license to practice medi- Charges. One violation of NRS 630.3062(1) [failure to maintain timely, legible, accurate and complete medical records relating to the diagnosis, treatment and care of a patient]; one violation of NRS 630.301(4) [malpractice]; one violation of NRS 630.306(2)(b) [engaging in any conduct which the Board has determined is a violation of the standards of practice established by regulation of the Board]; one violation of NRS 630.306(5) [practicing beyond the scope permitted by law or performing services which the licensee knows he is not competent to perform or which are beyond the scope of his training].
 - Disposition: On March 6, 2015, the Board accepted a Settlement Agreement by which it found Dr. Philander violated NRS 630.3062(1), as set forth in Count I of the Complaint, and imposed the following discipline against him: (1) public reprimand; (2) reimbursement of the Board's fees and costs associated with investigation and prosecution of the matter. Counts II, III and IV of the Complaint were dismissed.

VALENCIA, Arlyn M., M.D. (10340) Las Vegas, Nevada

Summary: Settlement of summary suspension of license to practice medicine. Disposition: On March 6, 2015, the Board accepted a Settlement Agreement in settlement of the summary suspension that was in place against Dr. Valencia and ordered that Dr. Valencia's license to practice medicine be revoked, with said revocation stayed and Dr. Valencia placed on probation for a period of 60 months, subject to various terms and conditions, including reimbursement of the Board's fees and costs associated with investigation and prosecution of the matter.

Public Reprimands Ordered by the Board

Cesar A. Estela, M.D.

March 9, 2015

Cesar A. Estela, M.D. c/o Anastasia Noe, Esq. 7201 W. Lake Mead Blvd., Ste. 570 Las Vegas, NV 89128

Dr. Estela:

On March 6, 2015, the Nevada State Board of Medical Examiners (Board) accepted the Settlement Agreement (Agreement) between you and the Board's Investigative Committee in relation to the formal Complaint filed against you in Case Number 14-19407-1.

In accordance with its acceptance of the Agreement, the Board entered an Order finding you violated Nevada Revised Statute 630.301(4), malpractice, and dismissing the remaining count. For the same, you shall receive a public reprimand and pay the fees and costs related to the investigation and prosecution of this matter within sixty (60) days of the Board's acceptance of the Agreement.

Accordingly, it is my unpleasant duty as President of the Board to formally and publicly reprimand you for your conduct which has brought professional disrespect upon you and which reflects unfavorably upon the medical profession as a whole.

Sincerely,

Michael J. Fischer, M.D., President Nevada State Board of Medical Examiners

Peter H. Philander, M.D.

March 9, 2015

Peter H. Philander, M.D. c/o John J. Savage, Esq. 7900 W. Sahara, Ste. 200 Las Vegas, NV 89117

Dr. Philander:

On March 6, 2015, the Nevada State Board of Medical Examiners (Board) accepted the Settlement Agreement (Agreement) between you and the Board's Investigative Committee in relation to the formal Complaint filed against you in Case Number 14-12104-1.

In accordance with its acceptance of the Agreement, the Board entered an Order finding you violated Nevada Revised Statute 630.3062(1), failure to maintain timely, legible, accurate and complete medical records relating to the diagnosis, treatment and care of a patient, and dismissing the remaining counts. For the same, you shall receive a public reprimand and pay the fees and costs related to the investigation and prosecution of this matter within sixty (60) days of the Board's acceptance of the Agreement.

Accordingly, it is my unpleasant duty as President of the Board to formally and publicly reprimand you for your conduct which has brought professional disrespect upon you and which reflects unfavorably upon the medical profession as a whole.

Sincerely,

Michael J. Fischer, M.D., President Nevada State Board of Medical Examiners

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NEVADA STATE BOARD OF MEDICAL EXAMINERS

1105 Terminal Way, Ste. 301

Reno, NV 89502-2144