NEVADA STATE BOARD OF MEDICAL EXAMINERS

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Time to Talk About Mental Health

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Mental health issues in America have not been elevated to the same level of concern and public discourse given to physical health issues. However, mental health issues are becoming a public health matter and should be discussed with as much ease, concern, and regularity as other public health issues such as obesity, influenza, smoking, or food-borne illnesses. For example, currently more than 18% (41 million) of adults in America have a mental health illness and 8% (20 million) have a substance abuse disorder (Substance Abuse and Mental Health Services Administration [SAMHSA], 2013). Between 1996 and 2010, the number of prescriptions filled to treat adults for mental illness increased dramatically, with the most common medication being antidepressants. Likewise, in 2011, more than one in eight adults received some level of mental health intervention or service (SAMHSA, 2013). These numbers are likely to increase due to a number of factors, such as improved mental health insurance coverage and parity.

Another public health concern is the extent to which mental and behavioral health disorders negatively impact the daily functioning of Americans. Serious mental illness is a classification often used to differentiate between conditions that are persistent and disabling to one's day-to-day functioning versus those mental conditions that result in less severe impairments to routine daily functioning. Individuals who suffer from serious mental illness tend to experience difficulty sustaining employment, housing, and good physical health. They can be frequent users of emergency and public services, typically experiencing regular contacts with law enforcement (SAMHSA, 2013). About 4% of the adult U.S. population experiences serious mental illness (SAMHSA, 2012a), and a meta-analysis of the literature found that adults with serious mental illness are victimized more often than individuals who do not have serious mental illnesses (Choe, Teplin, & Abram, 2008). Thus, these victimized mentally-ill individuals are more likely to experience related physical health injuries and the need for physical health care. In the future, when these vulnerable citizens need concomitant psychological/medical treatments, there will be an increasing number of options for access to and payments for needed services. Now is the time to discuss those options.

Through implementation of the Mental Health Parity and Addiction Equity Act and the Affordable Care Act, the federal government has helped expand the health and mental health insurance protections for the vast majority of Americans, paving the way for improved access to needed care and treatment for individuals with mental and substance abuse disorders. The 2014 federal budget provides millions of dollars to enhance and expand the workforce that will specifically be trained to serve vulnerable groups experiencing mental illness within our society, such as children enrolled in primary schools and military veterans and their families. For example, the health professions programs of the Health Resources Services Administration (HRSA) will receive $39 million to increase the mental health workforce of social workers and psychologists who work in rural

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FEATURED IN THIS ISSUE:

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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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areas and who serve military personnel, veterans, and their families (U.S. Department of Health and Human Services, 2013b). An additional $35 million is provided within SAMHSA for a collaboration with HRSA to increase the workforce of mental health professionals as part of President Obama's "Now is the Time" proposal, which was initiated as a response to the 2012 shooting tragedy at Sandy Hook Elementary School. Additionally, there has been a steady increase in efforts to train and certify peers to support the recovery of people with mental and behavioral health problems and substance abuse problems. The SAMHSA National Registry of Evidence-Based Programs and Practices, a searchable online system, includes descriptions of dozens of SAMHSA-funded, evidence-based mental health and substance abuse prevention and treatment interventions that include peer advocates, peer educators, or specialists.

Mental health and substance abuse conditions are treatable and manageable in ways similar to medical conditions like diabetes or high blood pressure. Thus, people with diabetes or high blood pressure, like people with mental illness and substance abuse disorders, are encouraged to seek formal care from qualified professionals as well as informal social support from family members and peers. Research has shown that social support in the form of a knowledgeable confidant or empathetic peer can assist with the coping and recovery of various challenges such as mental illness, cancer, or physical disability (Swarbrick, 2013; Swarbrick et al., 2011; Vestal, 2013). Such confidants and peers often accompany or serve as catalysts for people seeking treatment and, thus, they should be targeted for increased awareness of the signs and symptoms of mental health and substance abuse challenges and conditions.

Physicians are in contact with a large number of individual patients and their spouses, parents, children and other relative caregivers of patients. Physicians can notify their patients and patient caregivers of the expanded access to essential health and mental health care benefits now available to them. Physicians can alert their patients and patient caregivers regarding recent federal legislation that individuals with mental health needs have increasing opportunities to obtain treatment through expanded private health care insurance options, improved mental health benefits and lowered costs associated with mental health co-payments. And although not yet a mandate, the federal government has urged states to continue efforts to expand mental health parity to those receiving Medicaid in an effort to facilitate timely and appropriate behavioral health care for this population as well. It is significant to note that social workers are well positioned to inform the mental health workforce, and child, and adult, as serving social services agencies, and to reach former foster youth who may not know of their new eligibility for Medicaid coverage until age 26. However, there are many youth and adults that do not come in contact with social service agencies and, thus, we need help from physicians that come in contact with individuals via urgent care facilities, private practice offices, emergency rooms, specialty clinics, etc. Thus, now is the time for physicians and social workers alike to encourage widespread use of the new mental and behavioral health parity coverage provisions. We encourage physicians to increase and improve their initial screening for mental health and substance abuse problems, and to make it more routine and customary to refer patients to local social service agencies for further assessment, diagnosis and treatment. Now is the time to partner and turn the health and mental health parity discussion into action to improve the overall health and mental health status of patients in the United States. *For more details, see the expanded article at the UNLV Lincy Institute Website:* http://www.unlv.edu/news-story/time-talk-mental-health-adults-nevada.

About the Authors

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Dr. Sandra Owens *is an Associate Professor in the School of Social Work at the University of Nevada Las Vegas, and is a Hartford Faculty Scholar of Gerontological Social Work. Dr. Owens completed her PhD in Social Welfare at the University of California, Berkeley. Prior to her academic career, Dr. Owens' clinical experience was gained working with children and adults admitted to inpatient psychiatric units in Monte Vista Hospital, Charter Hospital, and Southern NV Adult Mental Health Services. Dr. Owens' research has focused on family caregiving, cross-cultural competency, and the mental health and social functioning of Black, White, and Latino female caregivers of the elderly. Dr. Owens is committed to assisting agencies with meeting their organizational goals and to helping address the myriad of problems facing individuals, groups, and communities. Dr. Owens is actively involved in leadership roles in a variety of community organizations, and she recently served as President's Fellow on the cabinet of UNLV President Neal Smatresk.*

About The Lincy Institute

Established in 2009, The Lincy Institute conducts and supports research that focuses on improving Nevada's health, education, and social services. This research is used to build capacity for service providers and enhance efforts to draw state and federal money to greater Las Vegas. The Lincy Institute also highlights key issues that affect public policy and quality-of-life decisions on behalf of children, seniors, and families in Nevada. The Lincy Institute has been made possible by the generous support of The Lincy Foundation. Robert E. Lang, Ph.D., serves as the Institute's Executive Director. To learn more, visit: http://www.unlv.edu/lincyinstitute

Additional Recommended Reading

Behavioral Health, United States, 2012; http://www.samhsa.gov/data/2012BehavioralHealthUS/Index.aspx
MentalHealth.gov; http://www.mentalhealth.gov/talk/index.html
National Survey on Drug Use and Health; http://samhsa.gov/data/NSDUH/2012SummNatFindDetTables/Index.aspx

Disclaimer: The opinions expressed in the Guest Authors' article are those of the authors, and do not necessarily reflect the opinions of the Board members or staff of the Nevada State Board of Medical Examiners.

BOARD MEMBER NEWS

ADVISORY OPINION OF THE BOARD OF MEDICAL EXAMINERS
NO. 14-1 Adv. Op.
JUNE 2014

Participation of Licensee as a Shareholder, Officer or Managing Member of Any Medical Marijuana Cultivation Facility, Dispensary or other Establishment or Entity Authorized Under NRS 453A.

All licensees of the Nevada State Board of Medical Examiners (Board) are hereby advised that participating as a shareholder, officer or managing member of any medical marijuana cultivation facility, dispensary or other establishment or entity authorized under Nevada Revised Statutes (NRS) Chapter 453A is currently a violation of federal law under the Controlled Substances Act, 28 U.S.C. 801 et seq., because marijuana: 1) is classified as a Schedule I drug; 2) has not been fully evaluated and approved by the Food and Drug Administration for medicinal purposes, i.e., contraindications, dosages, potency, quantity and side effects; 3) lacks accepted safety standards for use; and 4) has a high potential for abuse.

Board licensees are further advised that licensees will not be investigated by the Board based solely on their participation as a shareholder, officer or managing member of any medical marijuana cultivation facility, dispensary or other establishment or entity authorized under NRS Chapter 453A. However, if the Board receives a complaint alleging misconduct or other possible violations regarding a licensee's participation as a shareholder, officer or managing member of any medical marijuana cultivation facility, dispensary or other establishment or entity authorized under NRS Chapter 453A, the Board is obligated by law to investigate the allegations contained in the Complaint. Additionally, if a licensee is convicted of violating the Controlled Substances Act, or any other federal or state law regarding the possession, distribution or use of any controlled substance or any dangerous drug as defined in Chapter 454 of the NRS, the Board is obligated by law to investigate the matter (NRS 630.301(11)(f)). Thus, licensees are further advised, whether they participate or not as a shareholder, officer or managing member of any medical marijuana cultivation facility, dispensary or other establishment or entity authorized under NRS Chapter 453A, that they may be subject to potential disciplinary action by the Board for the following violations: 1) directly or indirectly receiving from any person, corporation or other business organization any fee, commission, rebate or other form of compensation which is intended or tends to influence the physician's objective evaluation or treatment of a patient – NRS 630.305(1)(a); 2) referring a patient to a health facility or commercial establishment in which the licensee has a financial interest – NRS 630.305(1)(c); 3) failing to disclose to a patient any financial or other conflict of interest – NRS 630.305(1)(g); 4) administering, dispensing or prescribing any controlled substance, or any dangerous drug to or for himself/herself or others except as authorized by law – NRS 630.306(3); and 5) willful failure to perform a statutory or other legal obligation imposed upon a licensed physician – NRS 630.3065(3).

Board licensees act at their own legal peril as a shareholder, officer or managing member of any medical marijuana cultivation facility, dispensary or other establishment or entity authorized under NRS Chapter 453A. Accordingly, all licensees of the Board are encouraged to consult with their own legal counsel to explore all possible legal and/or criminal implications of such actions and/or relationships.

NEVADA STATE BOARD OF MEDICAL EXAMINERS
Michael J. Fischer, M.D., President

Review Document Here:
http://www.medboard.nv.gov/Advisory%20Opinions/No.%2014-1%20Adv.%20Op..pdf

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NOTIFICATION OF ADDRESS CHANGE, 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.

Please keep in mind the address you provide will be viewable by the public on the Board's website.

Additionally, if you close your practice in Nevada, you are required to notify the Board in writing within 14 days after the closure, and for a period of 5 years thereafter, keep the Board apprised of the location of the medical records of your patients.

What Physicians Should Consider When Retaining or Disposing of Medical Records

Part Two of a Two-Part Series

Guest Author: Mistee Arias, Esq.

This is the second part of a two-part series discussing the retention and disposal of medical records, with a focus on Nevada law.

There are plenty of compelling reasons for Nevada practitioners to be attentive to the rules relating to the retention of patient records: (1) to maintain compliance with HIPAA regulations so as to avoid onerous enforcement penalties (discussed more fully in part one); (2) to avoid disciplinary action from the Medical Board; and (3) to enhance patient care. Ultimately, the responsibility for retention of patient health care records lies with the patient's physician.

Overview of Nevada Law

Health care records are afforded considerable protections under Nevada law. Health care records, as defined by Nevada Statutes, are comprised of any information, in whatever form retained, which is received or produced by a health care provider containing information related to the medical history, examination, diagnosis or treatment of the patient. Reports, notes, orders, photographs and x-rays are all examples of what health care records encompass[1]. Under this definition, medical records from one health care provider may be considered the official medical record of another health care provider, if received in the course of treating the patient. Legal correspondence or other documentation relating to lawsuits and/or Board investigations are not part of the medical record, and should be maintained separately from the patient chart.

The retention period for health care records is 5 years, with the beginning time frame being the date that the information was created, received or produced[2]. For patients with chronic conditions and other long-term, ongoing physician-patient relationships, it is likely that health care records of current patients may span a time frame greater than 5 years. Under these circumstances, practitioners should assess the impact record disposal may have on patient care. While state law does not permit the early destruction of records, it does not limit the practitioners' discretion to retain records for longer periods of time.

The purpose of retaining records is to make them available to patients for review and reproduction. Common uses include production for treating physicians, regulatory agencies, litigants or for the patient himself or herself. Under Nevada law, a health care provider must be prepared to provide records to an authorized requestor within 10 days if the records are retained in Nevada or within 20 days if the records are retained elsewhere. [3]

Failure to follow the standards set forth by statute has several negative consequences, including exposure to enforcement penalties by the Office of Civil Rights (the regulatory agency charged with enforcing the provisions of HIPAA), [4] potential disciplinary action by the Nevada State Board of Medical Examiners, and an interruption in the continuity of patient care.

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[1] NRS 629.021.
[2] See NRS 629.051- however, note that records for pediatric patients should be retained for a minimum of 5 years after the age of majority, or until age 23.
[3] See NRS 629.061- however, note that production within 5 days may be mandated if the circumstances warrant an abbreviated timeframe.
[4] See Part One, "What Physicians Should Consider When Retaining or Disposing of Medical Records," Nevada State Board of Medical Examiners Newsletter, Vol. 50, March 2014, Rachel V. Rose, JD, MBA.

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Medical Board Oversight

The Legislature has empowered the Nevada State Board of Medical Examiners to enforce certain statutory provisions,[5] including those relating to maintaining medical records and making them available to patients as mandated by statute.[6] As part of its oversight, the Medical Board can investigate, and ultimately impose sanctions where warranted, based on medical records infractions. Patients who are unable to secure copies of their records, or who have to wait long periods of time for the production of records may not always make their frustration known to their physicians before contacting the Board seeking intervention. The result can be a time-consuming and stress-producing inquiry by the Board. Even where sanctions are not imposed, the loss of productivity, the breach of the relationship with the patient, and the added stress of such scrutiny is taxing for a medical provider.

Patient Care

The most compelling reason for compliance with the state and federal regulations regarding medical records has little to do with the threat of legislative penalties. The most compelling reason is the patient himself or herself. The obligation to safeguard a patient's personal and most private information entrusted to a health care provider is not born out of HIPAA. Rather, it arises directly from the fiduciary nature of the physician-patient relationship. Likewise, memorializing (in a medical record) the measures taken in treating a patient, ensuring continuity of care from one visit to another, and often from one practitioner to another, has the same genesis. Optimizing the patient's ability to be restored to wellness should be the focus. That is, after all, the art of medicine, and the aspiration that draws many physicians to the practice of medicine.

Medical Records Check-Up

A strong proactive approach for practitioners to adopt is to conduct a periodic check-up of their current medical records protocol, focusing on the following queries:

- **Are you retaining records for the requisite period of time?**
- **Are you safeguarding records appropriately?**
- **Are you restricting release to the appropriate parties?**
- **Are you able to retrieve records and produce records in a timely manner (within 10 days)?**
- **If your patient is a minor, have you retained records long enough?**
- **If you plan to retire or relocate, do you have a strategy in place for retaining records securely and in a fashion that would allow you to retrieve them if requested?**

[5] NRS 630.130.
[6] NRS 630.3062.

About the Author
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The Role of Informed Consent in Utilizing Medical Devices and the FDA's Humanitarian Device Exemption

Guest Author: Rachel V. Rose, JD, MBA

The Food and Drug Administration has various avenues for a company to obtain approval for a medical device or biologic. One route favored by companies is the 510(k) process[1], which requires less testing because it is substantially similar to another device already on the market. While this process is a prudent course to take in some instances, it can be a disaster if used for the improper purpose of circumventing the correct course in order to cut costs and testing requirements, and in return get a product approved more quickly. Hence, for consumers, just because a device received approval, does not mean that it was properly tested.

Recently, the FDA released guidance about Humanitarian Use Devices (HUDs) and the Humanitarian Device Exemption (HDE) expressed in section 520(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act)[2]. HUDs are a very narrow exception to the regular course of FDA regulatory approval. These devices are "intended to benefit patients in the treatment or diagnosis of disease or conditions that affect or are manifested in fewer than 4,000 individuals in the United States per year." [3] The HDE application represents the second step in the process.

Regardless if the medical device is a HUD, a biologic, other device seeking a pre-market submission 510(k) approval (i.e., a submission made to the FDA demonstrating that it is at least as safe and effective as a substantial similar, predicate device already on the market), or an experimental device, the discussion of the nature of, and the status of, the device in obtaining informed consent from a patient is crucial. Explaining the status of the device being used and the risks to the individual patient can mitigate liability on the part of the physician, the hospital, and the manufacturer. As a matter of public policy, we want medical devices and biologics to have reasonable assurances of being safe. A cornerstone of this public policy is the FDA's oversight and a physician's educating the patient in order to obtain informed consent to perform a procedure utilizing the item. Therefore, the focus of this article is to: (1) provide an overview of the FDA's approval process; (2) appreciate the nature and nuances of HUD approvals; and (3) understand the importance of disclosure and informed consent in utilizing medical devices and biologics.

Overview of the FDA's Approval Process

For medical device approval, the first step is determining the classification of the device. The Medical Device Amendments of 1976 ("MDA") mark the beginning of the "modern era" of device regulation[4]. The present system, while originating in the MDA, was refined by the Safe Medical Devices Act of 1990 ("SMDA") [5]. Device classifications fall into three general categories. [6] In 1976, MDA established the FDA's review of all types of medical devices in existence required the placement into Class I, II or III. [7] Class I devices are subject to various general post-market controls (e.g., establishment registration, device listing, or good manufacturing practice ("GMP")). Class II devices are subject to FDA established performance standards and general post-market controls. [8] Class III requires Premarket Approval ("PMA") application or a completed product development protocol ("PDP"). [9] A popular route of obtaining approval is the 510(k) pre-market approval process. This route of application submission requires the submitter to provide the requisite information for review to the FDA. Until a substantial equivalent ("SE") order is received from the FDA, a company is precluded from marketing the device.

> ***An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification 510(k) submission to FDA. Clinical studies with devices of significant risk must be approved by FDA and by an Institutional Review Board (IRB) before the study can begin. Studies with devices of nonsignificant risk must be approved by the IRB only before the study can begin.*** [10]

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[1] "Each person who wants to market in the U.S., a Class I, II, and III device intended for human use, for which a Premarket Approval (PMA) is not required, must submit a 510(k) to FDA unless the device is exempt from 510(k) requirements of the Federal Food, Drug, and Cosmetic Act (the Act) and does not exceed the limitations of exemptions in .9 of the device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9)." http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/premarketnotification510k/default.htm.

[2] The Food and Drug Administration Safety and Innovation Act (FDASIA), Pub. L. 112-144 (Jul. 9, 2012) (amending section 520(m) of the FDCA).

[3] U.S. Food and Drug Administration, *Humanitarian Device Exemption (HDE): Questions and Answers*, p. 1 (Mar. 18, 2014) (citing, 21 CFR 814.3(n)).

[4] Pub. L. No. 94-295, 90 Stat. 539 (1976).

[5] Pub. L. No. 101 629, 104 Stat. 4511 (1990).

[6] 21 CFR 807(E); 21 CFR 814. In addition to these three broad classifications, the exception exists for an Investigational Device Exemption ("IDE"). *See* 21 CFR 812.

[7] *See* 90 Stat. 540-41.

[8] *See* 90 Stat. 546 552.

[9] *See* 90 Stat. 553 59.

[10] U.S. Food and Drug Administration, *Overview of Medical Device Regulation*, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/overview/#510k (last accessed, Apr. 4, 2014) citing, 21 CFR Part 812.

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Unlike other submission routes available to applicants, the PMA is a detailed, multifaceted process that can take multiple years. The 510(k) route is considered an "exception" to the PMA requirements. Another exception, with a different set of requirements, is HUDs in relation to the HDE. An Institutional Review Board (IRB) plays a role in both HDEs and IDEs. Therefore, appreciating the category of device, as well as the category of exemption, is crucial.

Humanitarian Use Devices

In March 2014, the Food and Drug Administration, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research, Office of Orphan Products Development (CDRH), issued draft guidance, *Humanitarian Device Exemption (HDE): Questions and Answers*, which, when final, will supersede guidance issued in 2010. [11] Identifying the HUD is the first step and the HDE application is the second step, in gaining approval for a HUD designation. The HDE is a 'Premarket Approval application' submitted to [the] FDA …"seeking a humanitarian device exemption from the effectiveness requirements sections 514 and 515 of the [FD&C Act] as authorized by section 520(m)(2) of the [FD&C Act]." [12] Some of the criteria that is relied upon by the FDA includes: the likelihood of an unreasonable risk of illness or injury; whether the benefit outweighs the risk, and the alternative forms of treatment[13]. More importantly, to be considered for approval, the determination must be made as to whether any other options (i.e., existing comparable device or IDE) exist for the diagnosis or treatment of the condition. [14]

One crucial element of HDEs, as well as IDEs, is the role of Institutional Review Boards (IRBs). IRBs perform a crucial role in obtaining and monitoring the patient's informed consent. In the *Draft Guidance,* the FDA addressed the role of IRBs in relation to HDEs and IDEs. Specifically:

If a HUD meets the HDE standards for approval, it is exempt from the requirement of establishing a reasonable assurance of effectiveness that would otherwise be required under sections 514 and 515 of the FD&C Act. See section 520(m).

A device being used under an approved IDE is a device that has not been cleared or approved by FDA for marketing but has been authorized for investigational use in an FDA-regulated clinical investigation (i.e., an IDE is an investigational exemption). With this exemption, the investigational device can be shipped lawfully for purposes of conducting clinical investigations of the device without complying with certain other requirements that would apply to devices in commercial distribution. See 21 CFR Part 812.

The standards of IRBs in the context of either HDEs or IDEs are very stringent and the FDA can inspect the IRB. Depending on the nature of the device and the number of centers, there could be a national IRB and a facility IRB. One of the main roles IRBs play is the oversight and reporting of adverse events to the FDA. [15] And, the applicant should monitor if other comparable devices have cleared the PMA or 510(k) approval process. [16] Obtaining informed consent from the patient is also vital. [17]

The Role of Informed Consent

The pivotal question as to whether the informed consent of the patient *must* be obtained under federal law, in accordance with FDA regulations, hinges on whether or not it is a clinical investigation.[18] While "[n]either the FD&C Act nor the regulations require informed consent from patients for the use of a HUD for its HDE-approved indication(s),[a]n IRB may, however, choose to require informed consent that is consistent with the approved labeling when the IRB approves use of the HUD in a facility." [19] Once a physician elects to study a HUD for a new indication, the clinical investigation process begins. The investigational protocol must accord with 21 CFR Parts 812, 50, 54, and 56.

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[11] Food and Drug Administration, *Humanitarian Device Exemption (HDE): Questions and Answers – Draft Guidance for HDE Holders, Institutional Review Boards, Clinical Investigators, and Food and Drug Administration Staff – DRAFT GUIDANCE* (Mar. 18, 2014). Indicating that when finalized, this document will supersede *Guidance for HDE holders, Institutional Review Boards (IRBs), Clinical Investigators, and Food and Drug Administration Staff, Humanitarian Device Exemptions (HDE) Regulation: Questions and Answers* (Jul. 8, 2010).

[12] *Ibid*. at 2, citing 21 CFR 814.3(m) and Subpart A.

[13] 21 CFR 814.104(b)(3).

[14] FD&C Act § 520(m)(B)(2), 21 CFR 814.104(b)(2). Notably, a "comparable device" need not "be identical to the device submitted under the HDE application. In determining whether a comparable device exists, the FDA may consider: the device's indications for use and technological characteristics; the patient population to be treated or diagnosed with the device; and whether the device meets the needs of the identified patient population." *Supra* n. 11 at 5.

[15] 21 CFR 814.126(b)(1).

[16] 21 CFR 814.118(a).

[17] *Grimes v. Kennedy Krieger Inst., Inc.,* 366 Md. 29, 38-39, 782 A.2d 807, 813 (2001) (relaying the history of IRBs); *Pomona Valley Hosp. Med. Ctr.*, 209 Cal. App. 4th 687, 691 (2012) ("the IRB's responsibilities include requiring documentation of informed consent from subjects (21 C.F.R. § 56.109(b), (c)."(…"It is the IRB's duty to require that each patient be adequately informed of the nature of the study and the possible side effects, risks and consequences of an investigational drug or device. It is also the IRB's duty to require that each patient sign an informed consent.").

[18] 21 CFR Part 50.

[19] *Supra*, n. 11 at 23.

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A recent example of the role of informed consent in a clinical trial is *Cabana v. Stryker Biotech, LLC; Stryker Corporation; Medtronic Sofamor Danek USA, Inc.; Medtronic, Inc.*, Case No. BC 465 313 (CA Superior Court, Jul. 13, 2011). Here, the injured patient filed suit and the Court ruled on summary judgment that "OP-1 [a bone morphogenetic protein] was approved by the FDA under a rare classification known as Humanitarian Use Device (HUD), meaning, *inter alia*: (a) the FDA had not determined the efficacy of OP-1; (b) due to its experimental nature, it could only be implanted in less than 4,000 patients annually; and importantly (c) prior to being implanted, the hospital's Institutional Review Board ("IRB") (i.e., research committee) needed to approve and monitor the use of OP-1 and renew the approval on an annual basis." [20] Complimentary to the FDA standard for informed consent set forth above, the widely cited California Supreme Court case, *Moore v. Regents of Univ. of California*, 51 Cal. 3d 120, 129-131 (1990), held a common law duty exists to obtain informed consent. While a HUD was not at issue, the use of a patient's cells to develop a patented and commercially viable cell treatment without obtaining the patient's informed consent was a crucial item. The California Supreme Court held:

> *"Our analysis begins with three well-established principles. First, 'a person of adult years and in sound mind has the right, in the exercise of control over his own body, to determine whether or not to submit to lawful medical treatment.' Second, 'the patient's consent to treatment, to be effective, must be an informed consent.' Third, in soliciting the patient's consent, a physician has a fiduciary duty to disclose all information material to the patient's decision.*
>
> *Accordingly, we hold that a physician who is seeking a patient's consent for a medical procedure must, in order to satisfy his fiduciary duty and to obtain the patient's informed consent, disclose personal interests unrelated to the patient's health, whether research or economic, that may affect his medical judgment."*

Therefore, informed consent is essential to comporting with state laws as it is in comporting with federal laws.

Conclusion

The FDA approval process and the regulations and guidance associated with various exceptions is dynamic. The one area that remains constant is the need to obtain a patient's informed consent and to disclose outside interests unrelated to the patient's health. Keeping vigilant on all fronts can ensure a better quality of care, a clean conscience and the potential reduction of an unfavorable outcome in a legal proceeding.

[20] *See* Plaintiff's Opposition to Defendant Pomona Valley Hospital Medical Center's Motion for Summary Adjudication of Issues; Memorandum of Points and Authorities, p. 2, Case N. BC 465 313 (filed Oct. 11, 2013).

About the Author

***Rachel V. Rose**, JD, MBA is a Principal with Rachel V. Rose – Attorney at Law, PLLC, located in Houston, TX. Ms. Rose holds an MBA with minors in health care and entrepreneurship from Vanderbilt University, and a law degree from Stetson University College of Law, where she graduated with various honors, including the National Scribes Award and The William F. Blews Pro Bono Service Award. Ms. Rose is licensed in Texas. Currently, she is Vice Chair of Publications for the Federal Bar Association's Corporations and Associations Counsel Division, the Co-Editor of the American Health Lawyers Association's "Enterprise Risk Management Handbook for Healthcare Entities" (2nd Edition), Vice Chair of the Book Publication Committee for the Health Law Section of the American Bar Association and Co-Author of the ABA's publication, "The ABCs of ACOs." Ms. Rose is an Affiliated Member with the Baylor College of Medicine's Center for Medical Ethics and Health Policy. She can be reached at rvrose@rvrose.com.*

Consent for Student Participation and Observation of Patient Care in the Physician's Office

By: Jerry C. Calvanese, MD

Periodically, the Board receives complaints from patients concerning a physician or physician assistant and their student participation/observation of his/her care in physician offices. These complaints are centered on the manner in which the patient's permission is obtained.

Complaints to the Board have centered on the fact that the patient often "feels pressured" when consent is sought verbally at the time when both the physician or physician assistant and their student enter the exam room. Not wanting to be perceived as "disagreeable", the patient will reluctantly agree to the student's participation/observation of their care.

In an attempt to help minimize these complaints, protect the patient, and protect the physician or physician assistant as well as the student, we suggest a different approach. Consider that the patient be informed of the student's presence and participation/observation at the time of registration with front office staff. Any questions and comments by patients can be addressed at that time by a qualified staff member. If a patient agrees to the student's participation/observation of his/her in-office care, we suggest a consent form be signed; thus, providing documentation in the patient's chart and allowing for the same documentation to be utilized to protect both the physician, physician assistant and the student. If a patient objects and no consent form is signed, a notation or flag may be used as a way to indicate the patient declined the student's participation/observation at that time. A final consideration for the patient's file is an entry documenting their wish to reject any student participation/observation requests by the physician or physician assistant during future visits.

FDA Reminds Health Care Professionals to Stop Dispensing Prescription Combination Drug Products with More Than 325mg of Acetaminophen

The FDA is reminding health care professionals to stop prescribing, and pharmacists to stop dispensing, prescription combination drug products that contain more than 325 milligrams (mg) of acetaminophen per tablet, capsule, or other dosage unit. If a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit, the FDA recommends that he/she contact the prescriber to discuss a product with a lower dose of acetaminophen. These products are no longer considered safe by FDA and have been voluntarily withdrawn. We encourage pharmacists to return them to the wholesaler or manufacturer.

These products were voluntarily withdrawn by the manufacturers at the FDA's request to protect consumers from the risk of severe liver damage, which can result from taking too much acetaminophen.

The FDA also asks wholesalers to remove the product codes for all prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit from their ordering systems and return all products to the manufacturers.

Health care professionals who have questions are encouraged to contact the Division of Drug Information at: ***888.INFO.FDA (888-463-6332)*** *or druginfo@fda.hhs.gov.*

Secondary Stroke Prevention

Guest Author:
J. Ivan Lopez, MD, FAAN, FAHS
Director, Stroke Center, Renown Regional Medical Center, and Professor of Medicine and Pediatrics, University of Nevada, Reno

Stroke is the fourth leading cause of death and a leading cause of disability in the United States. The long-term consequences of stroke are devastating for the individual, the families involved, and our society in general. Strokes can be divided into two groups - ischemic strokes, which represent around 85% of all strokes, and hemorrhagic strokes, comprising around 15% of all strokes. Only one drug has been approved to treat ischemic strokes in the acute setting and only a minority of patients are eligible to receive the medication.

This brief article focuses on secondary stroke prevention, and will try to clarify the best use of available medications to prevent a stroke once the individual has already experienced a stroke or has had a transient ischemic attack (TIA).

It is useful to classify stroke risk factors into non-modifiable and modifiable. Non-modifiable stroke risk factors include age (strokes are more common after age 50), ethnicity (strokes are more common among the black population), family history, and others. Modifiable risk factors are mostly based on lifestyle and include: high blood pressure, diabetes, cigarette smoking, obesity, sedentary lifestyle, and others.

Once the clinician has intervened and counseled the patient regarding these modifiable risk factors, he or she will have to decide what medications should be used in addition to the changes implemented through diet, exercise, and smoking cessation. *The best way to classify medications used in secondary stroke prevention is:*

- ***Medications that interfere with blood coagulation***
  - *Anti-platelet agents*
    - Aspirin
    - Clopidogrel (brand name - Plavix)
    - Extended release dipyridamole/aspirin combination (brand name - Aggrenox)
  - *Anticoagulants*
    - Vitamin K antagonists
      - Warfarin (the most commonly used)
    - Thrombin inhibitors
      - Dabigatran (brand name - Pradaxa)
    - Factor Xa inhibitors
      - Rivaroxaban (brand name - Xarelto)
      - Apixaban (brand name - Eliquis)
      - Edoxaban (not on the market as of yet)
- ***Other medications***
  - *Statins (several of them on the market)*
  - *Angiotensin receptor blockers (ARBs)*
  - *Angiotensin converting enzyme inhibitors (ACEIs)*

Both the American Heart Association and the American Academy of Neurology recommend that every patient who has sustained an ischemic stroke or a TIA be discharged from the hospital on an anti-platelet agent and a statin. Statins have been shown in multiple studies to be efficacious in secondary stroke prevention. The use of ARBs or ACEIs for secondary stroke prevention is supported by mounting evidence in the literature, but not widely accepted yet, and their use is not included in current guidelines. It is unclear which one of the available

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anti-platelet agents is best. The decision of which one to prescribe depends on patient tolerance, co-morbidities, insurance coverage, etc.

When it comes to the use of anti-platelet agents, the exception is when the patient has atrial fibrillation (AF) or a prosthetic cardiac valve. In these cases, barring special circumstances, an anticoagulant is indicated. Warfarin is indicated in patients with either AF or a prosthetic cardiac valve. Warfarin has a very narrow therapeutic window and recent studies show that a sizable number of patients never achieve therapeutic levels of this drug. The newer anti-coagulants, thrombin inhibitors and factor Xa inhibitors have shown in clinical trials to be non-inferior and safer than warfarin in cases of AF. These newer medications are not indicated in cases when the patient has a prosthetic cardiac valve, in which case, warfarin is the drug of choice.

Oftentimes the clinician feels tempted to use dual anti-platelet therapy (clopidogrel and aspirin combined). Several clinical trials have shown that the use of dual anti-platelet therapy for secondary stroke prevention in the long term offers no benefit over either of these medications used alone and only increases the risk of serious bleeding. The use of this combination in the short-term (for up to 90 days after the index event) is being studied at this time. The exception is dipyridamole/aspirin combination, which has been shown to be superior to aspirin for secondary stroke prevention.

Complicated? Maybe - to some extent. The one thing to remember is that stroke specialists are available in the state of Nevada and it is always a good idea to seek advice when in doubt.

As I say to my students and residents: "The best treatment for stroke is not to have one."

***Disclaimer:** The opinions expressed in the Guest Author'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.*

Aging and Disability Virtual Resources and Information at your Fingertips!

As part of the enhancement to Nevada's Care Connection: An Aging and Disability Resource Center (ADRC) program, the Aging and Disability Services Division (ADSD) has developed a virtual resource center to connect seniors, people with disabilities and their families to information and resources about long term services and support. This virtual resource center is available now and includes:

- **Resource Directory** – resource listings for organizations across Nevada that serve our target population.
- **Learn About Library** – a collection of web links from a variety of sources with information pertinent to our population.
- **Training and Education** – a collection of learning modules for service providers and the general public on a range of topics.
- And many, many more features!

ADSD encourages you to explore, register and share the virtual resource center. Visit www.nevadaadrc.com.

For more information, you may also contact:
Cheyenne Pasquale, ADRC Project Manager, by email at cpasquale@adsd.nv.gov.

One More Advance Directive or Something Else?

The Nevada POLST Program is Different and Makes a Difference

Paul loved life, retired from a very successful company he built from scratch. He now enjoyed golf, playing the piano, card tricks and spending time with friends and family, and, they all loved being with this fun-loving man. Then, at 77 Paul was diagnosed with aortic stenosis. He slowed down some, but otherwise enjoyed life as before. He also completed an advance directive and talked to his family and doctor, making it very clear that he didn't want any heroic measures nor to live like an invalid; he had enjoyed life and when it was time, he wanted to go naturally without any machines or tubes. It was 6 months later that Paul collapsed. His wife called 911 and an ambulance arrived. Because an advance directive is not a medical order, the paramedics, by law, had to attempt resuscitation. Max survived with several broken ribs and another four years with significant cognitive and cardiac impairment requiring full-time care.

Advance directives are important in changing these statistics, but in the case of the severely ill or frail or those diagnosed with a life-limiting illness, medical orders with specifics about what treatments a patient wants are necessary to assure health care professionals provide an appropriate level of care.

The Nevada Physician Orders for Life-Sustaining Treatment (POLST) form, a medical order that is bright pink for easy recognition, is at the center of the Nevada POLST Program launched in Nevada in March. Other states have adopted the POLST program with significant improvements in end-of-life care. A three-state study demonstrated that nursing home residents with POLST forms requesting comfort measures only were less likely to receive medical interventions than residents with traditional DNR orders or residents with traditional full-code orders. Another study showed that consistency rates between actual treatment and POLST orders were 98% for resuscitation orders and 91% for medical interventions.

The Nevada POLST Program (http://www.nevadapolst.org) involves 4 steps:

1. A physician recognizes that a patient qualifies for the POLST (severely ill with a life-limiting disorder or is very frail) and initiates a conversation about the patient's goals of treatment and what specific treatments a patient might want at the end of life. This discussion covers the implications of the choices the patient makes and what the burdens or benefits are of those choices.
2. The physician completes the POLST form with the patient or his/her agent, choosing treatments that align with the patient's wishes. The physician then signs and dates the POLST to legally validate it.
3. The POLST stays with the patient and only a copy is taken for the patient's medical record. If the patient is transferred, the POLST goes with the patient regardless of setting: home, nursing facility, hospital or hospice.
4. Emergency medical services are trained to request a POLST when responding to a medical call and to honor its orders. The POLST is a bona fide do-not-resuscitate order whether at a residence, in transport or in the field.

The Nevada POLST legislation (AB344) was unanimously passed in both houses of the 2013 legislative session and the form approved without objection by the Division of Health and Wellness in December 2013. Nevada POLST, a Nevada nonprofit, was established to introduce the Nevada POLST Program and the Nevada POLST form. These are now available to providers throughout Nevada with the support of the Nevada POLST Coalition, a group of 25 patient and health care advocates.

Information about the program is being sent to hospitals, physicians, nursing homes, senior centers and hospices across the state. You can follow POLST developments and stories on Facebook or Twitter; links can be found on the Nevada POLST website.

For more information, please contact:

Sally Hardwick, MS, Chair, Nevada POLST
775-742-6766; mailto:sph@nevadapolst.org

Mary-Ann Brown, RN, MSN, Director, Renown Hospice and Palliative Care
775-982-7046; mailto:mbrown3@renown.org

Steve Phillips, MD, Geriatric Specialty Care
775-398-1981; mailto:gcnreno@gmail.com

WHOM TO CALL IF YOU HAVE QUESTIONS

Management:	Douglas C. Cooper, CMBI Executive Director
	Edward O. Cousineau, J.D. Deputy Executive Director/Legal
	Donya Jenkins Finance Manager
Administration:	Laurie L. Munson, Chief
Legal:	Bradley O. Van Ry, J.D. General Counsel
	Erin L. Albright, J.D. General Counsel
Licensing:	Lynnette L. Daniels, Chief
Investigations:	Pamela J. Castagnola, CMBI, Chief

2014 BME MEETING & HOLIDAY SCHEDULE

January 1 – New Year's Day holiday
January 20 – Martin Luther King, Jr. Day holiday
February 17– Presidents' Day holiday
March 7-8 – Board meeting
May 26 – Memorial Day holiday
June 6-7 – Board meeting
July 4 – Independence Day holiday
September 1 – Labor Day holiday
September 5-6 – Board meeting
October 31 – Nevada Day holiday
November 11 – Veterans' Day holiday
November 27 & 28 – Thanksgiving/family day holiday
December 5-6 – Board meeting
December 25 – Christmas holiday

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

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
901 American Pacific Dr., Unit 180
Henderson, NV 89014
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

ABDELLA, Thomas, M.D. (7589)
Las Vegas, Nevada

Summary: Alleged failure to maintain appropriate medical records related to Dr. Abdella's 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].

Disposition: On March 7, 2014, the Board accepted a Settlement Agreement by which it found Dr. Abdella violated NRS 630.3062(1), as set forth in the First Amended Complaint, and imposed the following discipline against him: (1) public reprimand; (2) $1,000 fine; (3) 10 hours of continuing medical education regarding the subject of record keeping and/or preeclampsia; (4) reimbursement of the Board's costs and fees associated with investigation and prosecution of the matter.

BOHMAN, Van, M.D. (6760)
Las Vegas, Nevada

Summary: Alleged malpractice and failure to maintain appropriate medical records related to Dr. Bohman's treatment of a patient.

Charges: One violation of NRS 630.301(4) [malpractice]; 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].

Disposition: On March 7, 2014, the Board accepted a Settlement Agreement by which it found Dr. Bohman violated NRS 630.3062(1), as set forth in Count II of the Complaint, and imposed the following discipline against him: (1) $1,500 fine or completion of 6 hours of continuing medical education regarding the subject of electronic health care records and/or ethics; (3) reimbursement of the Board's costs and fees associated with investigation and prosecution of the matter. Count I of the Complaint was dismissed.

CLAYSON, Darby-Annette, M.D. (11502)
Pahrump, Nevada

Summary: Alleged failure to adequately supervise a physician assistant, malpractice, and failure to ensure her physician assistant maintained appropriate medical records related to treatment of patients.

Charges: One violation of NAC 630.375(1) [a physician assistant is considered to be and is deemed the agent of her supervising physician in the performance of all medical activities]; one violation of NAC 630.230(1)(i) [failure to provide adequate supervision of a physician assistant]; one violation of NRS 630.301(4) [malpractice]; one violation of NRS 630.301(9) [engaging in conduct that brings the medical profession into disrepute]; one violation of NRS 630.306(2)(b) engaging in conduct which the Board has determined is a violation of the standards of practice established by regulation of the Board]; one violation of NRS 630.3062(1) [failure to maintain timely, legible, accurate and complete medical records relating to the diagnosis, treatment and care of a patient].

Disposition: On June 6, 2014, the Board accepted a Settlement Agreement by which it found Dr. Clayson violated NAC 630.230(1)(i), as set forth in Count II of the Complaint, and imposed the following discipline against her: (1) public reprimand; (2) 10 hours of continuing medical education on professional boundaries and/or medical ethics; (3) reimbursement of the Board's costs and fees associated with investigation and prosecution of the matter. All remaining counts of the Complaint were dismissed.

DUDEK, John J., Jr., M.D. (3293)
Las Vegas, Nevada

Summary: Alleged aiding, assisting, employing or advising an unlicensed person to engage in the practice of medicine, allowing dangerous drugs to be ordered, administered and dispensed in a manner not authorized by law, practicing beyond the scope of his training, and failure to maintain appropriate medical records related to treatment of patients.

Charges: One violation of NRS 630.305(1)(e) [aiding, assisting, employing or advising, directly or indirectly, any unlicensed person to engage in the practice of medicine]; multiple violations of NRS 630.306(3) [administering, dispensing or prescribing any controlled substance or dangerous drug except as authorized by law]; one violation of NRS 630.306(5) [practicing or offering to practice beyond the scope permitted by law or performing services which the licensee knows or has reason to know that he is not competent to perform or which are beyond the scope of his training]; ten violations 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].

Disposition: On June 6, 2014, the Board accepted a Settlement Agreement by which it found Dr. Dudek violated NAC 639.742(4)(b), as set forth in Count IX of the Second Amended Complaint [only the dispensing practitioner may remove drugs from stock], which constitutes a violation of NRS 630.306(3), and imposed the following discipline against him: (1) public reprimand; (2) 8 hours of continuing medical education on cosmetic medicine; (3) reimbursement of the sum of $6,500, a negotiated amount of the Board's costs and fees associated with investigation and prosecution of the matter. All remaining counts of the Second Amended Complaint were dismissed.

ETEBAR, Ramin, M.D. (6788)
Las Vegas, Nevada

Summary: Alleged failure to maintain appropriate medical records related to Dr. Etebar's treatment of a patient.

Charges: Two violations 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].

Disposition: On June 6, 2014, the Board accepted a Settlement Agreement by which it found Dr. Etebar violated NRS 630.3062(1) (2 counts), as set forth in the First Amended Complaint, and imposed the following discipline against him: (1) $2,000 fine; (2) 15 hours of continuing medi-

Continued from page 14

cal education on medical records and/or ethics; (3) reimbursement of the Board's costs and fees associated with investigation and prosecution of the matter.

FOOTE, Ronald, M.D. (9240)
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].

Action Taken: On May 30, 2014, pursuant to stipulation, the Investigative Committee summarily suspended Dr. Foote's license until further order of the Investigative Committee, order of the Board of Medical Examiners or written agreement between Dr. Foote and the Investigative Committee.

GANSERT, Gary, M.D. (3204)
Reno, Nevada

Summary: Alleged malpractice and failure to maintain appropriate medical records related to Dr. Gansert's 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 7, 2014, the Board accepted a Settlement Agreement by which it found Dr. Gansert 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) $1,500 fine; (3) 10 hours of continuing medical education regarding the subject of diagnosing and/or treating sepsis and associated conditions; (4) reimbursement of the Board's costs and fees associated with investigation and prosecution of the matter. Count I of the Complaint was dismissed.

GARRISON, Thomas, M.D. (10304)
Scottsdale, Arizona

Summary: Disciplinary action taken against Dr. Garrison's medical licenses in California, Washington, Arizona, Utah and Illinois.

Charges: Multiple violations of NRS 630.301(3) [disciplinary action taken against his medical license in another state].

Disposition: On March 7, 2014, the Board accepted a Settlement Agreement by which it found Dr. Garrison violated NRS 630.301(3) (1 count) and imposed the following discipline against him: (1) public reprimand; (2) not supervise any cosmetic procedures in Nevada for a period of 3 years; (3) $2,500 fine; (4) 12 hours of continuing medical education in emergency medicine and/or dermatology; (5) reimbursement of the Board's costs and fees associated with investigation and prosecution of the matter. All remaining counts of the Complaint were dismissed.

KUTHURU, Mahesh, M.D. (12101)
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].

Action Taken: On March 25, 2014, the Investigative Committee summarily suspended Dr. Kuthuru's license until further order of the Investigative Committee or the Board of Medical Examiners.

LONG, Nancy, M.D. (5916)
Henderson, Nevada

Summary: Alleged malpractice related to Dr. Long's treatment of a patient.

Charges: One violation of NRS 630.301(4) [malpractice].

Disposition: On March 7, 2014, the Board accepted a Settlement Agreement by which it found Dr. Long violated NRS 630.301(4), as set forth in the Complaint, and imposed the following discipline against her: (1) public reprimand; (2) 5 hours of continuing medical education regarding the subject of preeclampsia signs, symptoms and treatments; (3) reimbursement of the sum of $5,000, a negotiated amount of the Board's costs and fees associated with investigation and prosecution of the matter.

SMITH, Kathleen D., M.D. (10735)
Las Vegas, Nevada

Summary: Alleged malpractice and failure to maintain appropriate medical records related to Dr. Smith's 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 June 6, 2014, the Board accepted a Settlement Agreement by which it found Dr. Smith violated NRS 630.301(4), as set forth in Count II of the Complaint, and imposed the following discipline against her: (1) $2,500 fine; (2) 15 hours of continuing medical education on liposuction and/or cosmetic procedures; (3) reimbursement of the Board's costs and fees associated with investigation and prosecution of the matter. Count I of the Complaint was dismissed.

SPERO, Bruce, M.D. (7904)
Keizer, Oregon

Summary: Alleged malpractice, continual failure to exercise the skill or diligence or use methods ordinarily used under the same circumstances by other physicians practicing in the same specialty or field and failure to maintain appropriate medical records related to Dr. Spero's treatment of six patients.

Charges: Six violations of NRS 630.301(4) [malpractice]; six violations 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]; six violations of NRS 630.306(7) [continual failure to exercise the skill or diligence or use the methods ordinarily exercised under the same circumstances by physicians in good standing practicing in the same specialty or field].

Disposition: On March 7, 2014, the Board accepted a Settlement Agreement by which it found Dr. Spero violated NRS 630.3062(1) (3 counts), as set forth in Count II of the Complaint, and imposed the following discipline against him: (1) public reprimand; (2) $1,000 fine; (3) 45 hours community service in a medically related field; (4) reimbursement of the Board's fees and costs of investigation

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and prosecution. Counts I, III, and three of the six counts in Count II of the Complaint were dismissed.

SU, Sean, M.D. (9013)
Las Vegas, Nevada

Summary: Alleged malpractice and failure to maintain appropriate medical records related to Dr. Su's treatment of 11 patients.

Charges: Eleven violations 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]; 8 violations of NRS 630.301(4) [malpractice].

Disposition: On March 7, 2014, the Board accepted a Settlement Agreement by which it found Dr. Su violated NRS 630.3062(1) (10 counts), as set forth in Count I of the Complaint, and NRS 630.301(4) (4 counts), as set forth in Count II of the Complaint, and imposed the following discipline against him: (1) public reprimand; (2) $2,500 fine; (3) reimbursement of the Board's fees and costs of investigation and prosecution.

VO, Ngoc, M.D. (12533)
Las Vegas, Nevada

Summary: Alleged malpractice and failure to maintain appropriate medical records related to Dr. Vo's treatment of a patient.

Charges: One violation of NRS 630.301(4) [malpractice]; 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].

Disposition: On March 7, 2014, the Board accepted a Settlement Agreement by which it found Dr. Vo violated NRS 630.3062(1), as set forth in Count II of the Complaint, and imposed the following discipline against her: (1) $2,000 fine or completion of 8 hours of continuing medical education regarding the subject of electronic health care records and/or ethics; (2) reimbursement of the Board's costs and fees associated with investigation and prosecution of the matter. Count I of the Complaint was dismissed.

YARBRO, Donald, M.D. (4777)
Henderson, Nevada

Summary: Alleged malpractice and failure to maintain appropriate medical records related to Dr. Yarbro's treatment of a patient.

Charges: One violation of NRS 630.301(4) [malpractice]; 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].

Disposition: On March 7, 2014, the Board accepted a Settlement Agreement by which it found Dr. Yarbro violated NRS 630.3062(1), as set forth in Count II of the First Amended Complaint, and imposed the following discipline against him: (1) public reprimand; (2) 6 hours continuing medical education regarding the subject of electronic health records; (3) reimbursement of the Board's costs and fees associated with investigation and prosecution of the matter. Count I of the Complaint was dismissed.

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Public Reprimands Ordered by the Board

Thomas N. Abdella, M.D.

March 19, 2014

Thomas N. Abdella, M.D.
c/o Brent Vogel, Esq.
Lewis Brisbois Bisgaard & Smith LLP
6385 S. Rainbow Blvd., Ste 600
Las Vegas, NV 89118

Dr. Abdella:

On March 7, 2014, 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 First Amended Complaint filed against you in Case Number 12-11024-1.

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. For the same, you shall pay a $1,000 fine within sixty (60) days of the Board's acceptance of the Agreement; complete ten (10) hours of Continuing Medical Education regarding the subject of record keeping and/or preeclampsia; receive a public reprimand and pay the 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

Darby-Annette Clayson, M.D.

June 13, 2014

Darby-Annette Clayson, M.D.
c/o John A. Hunt, Esq.
500 South Rancho Drive, Suite 17
Las Vegas, NV 89106-4847

Dr. Clayson:

On June 6, 2014, the Nevada State Board of Medical Examiners (Board) accepted the Settlement Agreement between you and the Investigative Committee of the Board in Case No. 13-30595-1 and found that you committed a violation of the Medical Practice Act (MPA) of the state of Nevada, more specifically: one count of failure to adequately supervise a physician assistant, a violation of Nevada Administrative Code 630.230(1)(i).

As a result of its finding that you violated the MPA, the Board entered its **Order** as follows: that you shall be publicly reprimanded; that you shall reimburse the Board the fees & costs incurred in the investigation and prosecution of this case within thirty (30) days; and that you shall complete ten (10) hours of Continuing Medical Education in professional boundaries and/or medical ethics within one (1) year.

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

Sincerely,

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

John Joseph Dudek, Jr., M.D.

June 13, 2014

John Joseph Dudek, Jr., M.D.
c/o William A. Maupin, Esq.
300 South Fourth Street, Ste. 1700
Las Vegas, NV 89101

Dr. Dudek:

On June 6, 2014, the Nevada State Board of Medical Examiners (Board) accepted the Settlement Agreement between you and the Investigative Committee of the Board in Case No. 12-4879-1, wherein you did not contest a violation of the Medical Practice Act (MPA) of the state of Nevada, more specifically: one (1) count of failure to properly supervise Ms. Frey, and others, in connection with the removal of Botox, Dysport, Radiesse, Restylane, Juvederm and Latisse from stock on numerous occasions, a violation of Nevada Administrative Code 639.742(4)(b).

As a result of its finding that you violated the MPA, the Board entered its **Order** as follows: that you shall be publicly reprimanded; that you shall reimburse the Board the fees & costs incurred in the investigation and prosecution of this case within thirty (30) days; and you shall complete eight (8) hours of Continuing Medical Education in cosmetic medicine within one (1) year.

Accordingly, it is my unpleasant duty as President of the Board to formally and publicly reprimand you for your conduct which has brought personal and 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

Gary G. Gansert, M.D.

March 19, 2014

Gary G. Gansert, M.D.
c/o Ed Lemons, Esq.
Lemons, Grundy & Eisenberg
6005 Plumas St., Third Floor
Reno, NV 89519

Dr. Gansert:

On March 7, 2014, 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 13-4774-1.

In accordance with its acceptance of the Agreement, the Board entered an Order finding you violated Nevada Revised Statute 630.301(4), malpractice as defined by NAC 630.040. For the same, you shall pay a $1,500 fine within sixty (60) days of the Board's acceptance of the Agreement; complete ten (10) hours of Continuing Medical Education regarding the subject of diagnosing and/or treating sepsis and associated conditions within one (1) year of the Board's acceptance of the Agreement; re-

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ceive a public reprimand and pay the 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

Thomas Garrison, M.D.

March 17, 2014

Thomas Garrison, M.D.
c/o Constance L. Akridge, Esq., Kelly S. McIntosh, Esq.
Holland & Hart
5441 Kietzke Lane, 2nd Floor
Reno, NV 89511

Dr. Garrison:

On March 7, 2014, the Nevada State Board of Medical Examiners (Board) accepted the Settlement Agreement between you and the Investigative Committee of the Board in Case No. 13-26118-1 and found that you committed a violation of the Medical Practice Act (MPA) of the state of Nevada, more specifically: one count of any disciplinary action, including, without limitation, the revocation, suspension, modification or limitation of a license to practice any type of medicine, taken by another state, a violation of Nevada Revised Statute 630.301(3).

As a result of its finding that you violated the MPA, the Board entered its **Order** as follows: that you shall be publicly reprimanded; that you shall not supervise any cosmetic procedures in Nevada for a period of three (3) years; that you shall pay a fine of $2,500; that you shall reimburse the Board the reasonable costs and expenses incurred in the investigation and prosecution of this case; and that you shall complete 12 hours of CME in emergency medicine and/or dermatology.

Accordingly, it is my unpleasant duty as President of the Board to formally and publicly reprimand you for your conduct which has brought personal and 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

Nancy Long, M.D.

March 17, 2014

Nancy Long, M.D.
c/o Marie Ellerton, Esq.
Mandelbaum, Ellerton & McBride
2012 Hamilton Lane
Las Vegas, NV 89106

Dr. Long:

On March 7, 2014, the Nevada State Board of Medical Examiners (Board) accepted the Settlement Agreement between you and the Investigative Committee of the Board in Case No. 11-9612-1 and found that you committed a violation of the Medical Practice Act (MPA) of the state of Nevada, more specifically: one count of the failure to use the reasonable care, skill, or knowledge ordinarily used under the same or similar circumstances, a violation of Nevada Revised Statute 630.301(4) and Nevada Administrative Code 630.040.

As a result of its finding that you violated the MPA, the Board entered its **Order** as follows: that you shall be publicly reprimanded; that you shall reimburse the Board a negotiated amount of the reasonable costs and expenses incurred in the investigation and prosecution of this case; and that you shall complete 5 hours of CME in Preeclampsia.

Accordingly, it is my unpleasant duty as President of the Board to formally and publicly reprimand you for your conduct which has brought personal and 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

Bruce A. Spero, M.D.

March 19, 2014

Bruce A. Spero, M.D.
c/o Hal Taylor, Esq.
223 Marsh Ave.
Reno, NV 89509

Dr. Spero:

On March 7, 2014, 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 12-10270-1.

In accordance with its acceptance of the Agreement, the Board entered an Order finding you guilty of three (3) violations of 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. For the same, you shall pay a $1,000 fine within one hundred eighty (180) days of the Board's acceptance of the Agreement; complete forty-five (45) hours of community service in a medically related field within one (1) year of the Board's acceptance of the Agreement; receive a public reprimand; and pay the costs related to the investigation and prosecution of this matter within one hundred eighty (180) 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

Sean Phong-Quoc Su, M.D.

March 19, 2014

Sean Phong-Quoc Su
2451 Professional Court, #110
Las Vegas, NV 89128

Dr. Su:

On March 7, 2014, the Nevada State Board of Medical Examiners (Board) accepted the

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settlement agreement proposed between you and the Board's Investigative Committee in relation to the formal complaint filed against you regarding case number 13-11344-1.

In accordance with their acceptance, the Board has entered an **ORDER** as follows: that you are guilty of four counts of malpractice, violations of Nevada Revised Statute 630.301(4), and that you are guilty of ten counts of failure to maintain timely, legible, accurate and complete medical records, a violation of Nevada Revised Statute 630.3062(1). Further, the settlement agreement called for you to be publicly reprimanded, fined in the amount of $2,500.00, and to reimburse the Board for its costs in investigating and prosecuting the underlying matter. The fine and costs are to paid to the Board within one year of the acceptance of the settlement agreement.

Accordingly, it is now 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 also reflects unfavorably upon the medical profession as a whole.

Sincerely,

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

Donald Yarbro, M.D.

March 14, 2014

Donald Yarbro, M.D.
c/o David J. Mortensen, Esq.
Alverson, Taylor, Mortensen & Sanders
7401 West Charleston Blvd.
Las Vegas, NV 89117

Dr. Yarbro:

On March 7, 2014, the Nevada State Board of Medical Examiners (Board) accepted the Settlement Agreement between you and the Investigative Committee of the Board in Case No. 12-6960-1 and found that you committed a violation of the Medical Practice Act (MPA) of the state of Nevada, more specifically: one count of the failure to maintain timely, legible, accurate and complete medical records relating to the diagnosis, treatment and care of a patient, a violation of Nevada Revised Statute 630.3062(1). As a result of its finding that you violated the MPA, the Board entered its **Order** as follows: that you shall be publicly reprimanded; that you shall reimburse the Board the reasonable costs and expenses incurred in the investigation and prosecution of this case; and that you shall complete 6 hours of CME in electronic health records.

Accordingly, it is my unpleasant duty as President of the Board to formally and publicly reprimand you for your conduct which has brought personal and 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