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ISSUES and ANSWERS

Oklahoma State Board
of Medical Licensure
and Supervision

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"Would you know it if you saw it"?

by Lyle Kelsey, Executive Director

In 1964, [Supreme Court] Justice Potter Stewart tried to explain pornography, or what is obscene, by saying, "I shall not today attempt further to define the kinds of material I understand to be embraced . . . but I know it when I see it"!

Some 40+ years later, the level of some physician advertising raises the question as to whether we know what "decent medical advertising" is when we see it. I am not a prude (I was in the military)…but frankly, some of the medical advertising I have seen in magazines, newspapers and the free press leaves me and others to wonder what exactly is being advertised. I'm not even going to talk about "cheesy" advertising with coupons and 2 for 1 offers.

"...frankly, some of the medical advertising I have seen ... leaves me and others to wonder what exactly is being advertised."

Now, before you get all defensive about the FTC and freedom in advertising (there are some senior physicians that think the FTC did the profession no big favor by opening the advertising door), I am not saying that advertising is unnecessary or even bad in 2009. However, I am saying we need to raise the bar on medical advertising to a level at which we consider the integrity and image of the profession… high.

I have had the privilege to have worked for and with doctors for over 30 years and through the thick and thin (more thick than thin) I have maintained a high regard for the medical profession and those who wear the initials "MD". While I am not a physician, I still call physicians "Doctor" and not "Doc", I like the term "patients" rather than "clients" and I still have a great deal of respect for the medical education, training and commitment it takes to achieve the goal of Doctor. It is a highly respected field of endeavor and still commands veneration.

Okay, here's my point. "Doctors, review your ads before they hit the print, airwaves and websites and give them one last glance to see "if you know it when you see it."

This article is part of a collective effort by the OSMA, OOA, Oklahoma Medical Board and Osteopathic Board to raise awareness and encourage more decorous and ethical advertising.

Medical Spa & Aesthetic Procedure Guidelines

After much discussion and input, the Medical Board has adopted guidelines to give physicians (MDs) some direction when practicing in or considering this medical area. These are very broad guidelines as there is no way to keep up with every type of laser or new procedure that comes on the market. The main issue is still the involvement of the physician with the patient in the delivery of care whether personally done or through the supervision of another health professional. Do your research before entering into any practice that may have negative consequences on your license.

Board of Medical Licensure and Supervision
Policy and Guidelines for Medical Spas & Aesthetic Procedures

Definitions (Oklahoma Law & Rules)

Practice of Medicine - Every person shall be regarded as practicing allopathic medicine within the meaning and provisions of this act, who shall append to his or her name the letters "M.D.", "Physician" or any other title, letters or designation which represent that such person is a physician, or who shall for a fee or any form of compensation diagnose and/or treat disease, injury or deformity of persons in this state by any allopathic legend drugs, surgery, manual, or mechanical treatment unless otherwise authorized by law.

Doctor/Patient Relationship - Means a person has a medical complaint/issue, which has been addressed by the doctor and there is a correlation between the complaint/issue and the treatment/procedure performed or drug given/prescribed/dispensed.

Surgery - The ablation or alteration of any human tissue by any means including but not limited to the use of sharp surgery, heat, cold, abrasion, laser, chemicals, injection/placement of substances subcutaneous, or the use of FDA approved devices *that can only be initially purchased by physicians* is the practice of medicine as defined in Title 59 O.S. Section 492. Lasers are instruments of surgery. No matter what type of laser is being utilized, a physician involved in the process should following these guidelines.

Guidelines

The practice of medicine and surgery as defined above is grounded upon the **doctor/patient relationship** which at a minimum requires a face-to-face evaluation of the patient by the physician or a physician assistant under a physician's supervision, prior to the determined treatment or procedure, development of a patient chart, providing patient informed consent and the process for the patient's follow up care.

There are several important guidelines to follow when supervising other practitioners.

- If the physician is utilizing unlicensed, trained assistants under their control and supervision, the physician must be on-site (premise) before, during and after the medical treatment or procedure.
- If the physician is utilizing an Oklahoma licensed physician assistant (PA), the physician can delegate any of the defined medical services to that licensed PA under general supervision, which does not require the physician to necessarily be on-site.
- If the physician is utilizing an Oklahoma licensed nurse, [RN, LPN, APN (advance practice nurse) or APN with prescriptive authority] and **IF** they are functioning within the scope of their practice act, then the physician may delegate any of the defined medical services to that licensed nurse under general supervision, which may not require the physician to be on-site. It is imperative that the physician contact the Oklahoma Board of Nursing (405-962-1800) to find out the nurse's scope of practice and level of physician supervision required.
- If the physician is utilizing any other Oklahoma recognized practitioner such as a certified micropigmentologist or licensed aesthetist, the physician must contact the Oklahoma Department of Health (405-271-6576) or the Board of Cosmetology (405-521-2441) respectively and find out the scope of their practice act and level of medical supervision required.

Medical Spa, cont from page 2

- In no instance may a physician allow one of the aforementioned practitioners to further delegate the medical service to another practitioner.
- Physicians who are medical directors for one or multiple medical spa and aesthetic facilities are subject to these guidelines.

When in doubt of a specific medical procedure/treatment and the corresponding level of supervision, the physician should contact the Oklahoma Board of Medical Licensure and Supervision or appropriate regulatory agency before potentially placing their medical license in jeopardy.
Approved 11/7/08

Concurrent Respiratory Therapy Treatments

Because of increasing financial constraints, facilities may be tempted to cut costs by stacking respiratory care treatments. The following is the Board's position statement on Concurrent Therapy.

Oklahoma State Board of Medical Licensure and Supervision

Position Statement on Concurrent Therapy

Adopted March 27, 2003

Concurrent therapy occurs when one Respiratory Care Practitioner administers treatments to multiple patients simultaneously. It is the position of the Oklahoma State Board of Medical Licensure and Supervision that concurrent therapy may subject the licensee to a heightened risk of prosecution for unprofessional conduct violations. Potential liability exists for the following reasons.

1) **Medical Errors:** The potential exists for jeopardizing patient safety, including inadequate assessment and monitoring of the patient.

2) **Billing Errors:** The potential exists for fraud and abuse in reimbursement billing in that the Centers for Medicare and Medicaid Services (CMS) does not recognize services rendered during concurrent therapy.

Any of the above, if proven, would be considered unprofessional conduct under the Respiratory Care Practice Act and rules of the Board.

The Board understands there may be situations where concurrent therapy is a valid treatment method, i.e., in the intensive care unit where simultaneous physiological monitoring and direct supervision of the patient is available. Otherwise, policies and procedures should be in place to ensure adequate assessment and monitoring of patients by appropriate clinicians possessing sufficient knowledge and skill. Further, care should be taken to comply with all local, state and federal regulations when filing for reimbursement to avoid billing errors.

Board Meeting March 26, 27, 2009

The Board met on March 26, 27, 2009 to consider licensing and disciplinary matters.

Five full medical licenses were issued after personal appearances. One medical license was reinstated after a short period of retirement. One medical license was reinstated under a lifelong probation requiring monitoring for relapse to alcohol abuse and continuing involvement in a 12-Step program.

A Dietitian was licensed under agreement for monitoring and 12-step participation due to history of CDS abuse.

Two applications for MD licenses were tabled, one until the applicant obtains an ECFMG certificate and the other until practice restrictions on another state's license are lifted. One application was denied due to a history of disruptive hospital behavior in several locations.

One probation was altered to require inpatient and follow-up treatment for disruptive behavior.

Two MD licenses were surrendered: one for felony conviction of unlawful distribution of CDS and the other for sexual misconduct.

One MD license was revoked after a lengthy hearing for sexual misconduct (soliciting sex from a patient) and prescribing in excess of medical need.

New Question on Renewal Application

We are interested in tabulating statistical numbers of the status of doctors licensed by the Oklahoma Medical Board. During the renewal process, you will be asked a question about the status of your clinical practice.

It is a mandatory question as the statistical information will be of little value unless all respond. There is a lot of misinformation floating around about physician availability in Oklahoma. We would like to get an idea of how much direct patient care is accessible either by physicians practicing in Oklahoma or by outside telemedicine. If you are "going to cut back your hours or retire soon" answer as to what your status is at the time of renewal NOT what you plan to do (plans change). We plan to have this as an on-going question so it will update the information on a monthly basis as doctors renew their licenses. NOTE: This has NO IMPACT on your license. You may retire and keep your full license if you choose and this question will not be utilized to change the current process. Please call the Board if you have any questions. We will post statistics on the website.

The questions is asked in this fashion:

New Renewal Question

Main Menu / Patient Care

How much time do you spend in patient care to Oklahomans? (This information is for statistical use only - will not affect licensure status)

Select one of the following:

- ☐ Full Time
- ☐ Part Time (20 hours or less per week)
- ☐ Fully Retired (No Patient Care)
- ☐ Volunteer Medicine *
- ☐ Out of State via Telemedicine
- Out of State N/A

**Volunteer Medical License available at no cost or CME.*

Administering & Dispensing

The Medical Board has received several calls about patients wanting the physician to accept drugs directly from the pharmaceutical manufacturer and administering or dispensing the drug to the patient. A number of physicians have been doing this under "patient convenience" but some doctors are hesitant to do so. The following is an excerpt from the minutes of the Pharmacy Board that discussed this very topic. Hopefully, this will help some of you in making this decision. NOTE: Even with this information, a physician can still choose not to do this.

MINUTES
OKLAHOMA STATE BOARD OF PHARMACY
4545 N Lincoln Boulevard, Suite 112
Oklahoma City, OK 73105-3488
January 16, 2008
(Excerpt)

A discussion was held regarding the sending of prescriptions to physician's offices for administration. There had been several companies indicating that the FDA is requiring their product to be administered in the doctor's office because of the severity of reaction to the drug by some patients. Some have "Black Box Warning" on the product requiring the administration by a physician. The Board came up with a workable solution and set a Policy for prescriptions that are required to be administered by a physician.

Interpretation of 353.24.4 - Policy for "Drop Off" Statute

The Board determined that in the interest of safety of the patients regarding prescription products, that the FDA and Manufacturers required administration by a physician, be allowed exemption to the 353.24.4 "Drop Off" Statute.

Motion was made by Bill Osborn and seconded by Gordon Richards that the Policy for the pharmacy products requiring administration by a physician, be exempt from the 353.24.4 Statute and allow pharmacies to send filled "patient specific" prescriptions to physician's office for administration. These prescriptions are to be billed to the patient or their insurance and may not be billed to the physician. Motion passed on roll call vote.

Dispensing Physicians

Physicians may now select to be a ***dispensing physician** anytime during the year. The dispensing option used to be an option only at renewal time. Now physicians can elect this option anytime by going on the "Update Your Personal Profile Information". **Dispensing** is not the same as prescribing nor does it have anything to do with giving out samples.

- All physicians can prescribe legend (non-controlled) drugs without having a permit from DEA or BNDD.
- All physicians can give patients samples as long as they are in the original container from the pharmaceutical company. Under no circumstances can samples be sold.
- Only physicians who have current federal DEA and Oklahoma BNDD permits can prescribe controlled drugs (Schedules II through V)
- *Physicians who choose to dispense drugs from their practice location must register with the Medical Board by checking the dispensing box on their personal profile information on the Medical Board website. Again, dispensing has nothing to do with prescribing or handing out samples.

While registering to be a dispensing physician requires no additional license, certification or training, it does require that the physician abide by certain parts of the Oklahoma Pharmacy Act and the Bureau of Narcotics and Dangerous Drugs (BNDD), which are not minor. A dispensing physician can purchase medications in bulk from a pharmaceutical company or compound medicines in their office, such as ointments, and then "dispense" them to their patients with or without a fee. The medication must be properly labeled according to the Pharmacy Act. (See Below)

Any fees charged need to be at reasonable rate commensurate with local pharmacies. The physician's office needs to let the patient know that there are other options to obtain the medicine. In cases where a physician may have a special compound (example: dermatology) that they feel works better than some of the known prescription or OTC medicines, they still need to inform the patient of those other options and let the patient choose.

Pharmacy Law

(Note: The Pharmacy law uses "dangerous drug" for scheduled and non-scheduled drug)

355.1. Dispensing dangerous drugs - Procedure - Registration - Exemptions

A. Except as provided for in Section 353.1 et seq. of this title, only a licensed practitioner may dispense dangerous drugs to such practitioner's patients, and only for the expressed purpose of serving the best interests and promoting the welfare of such patients. The dangerous drugs shall be dispensed in an appropriate container to which a label has been affixed, such label to include the name and office address of the licensed practitioner, date dispensed, name of patient, directions for administration, prescription number, the trade or generic name and the quantity and strength, not meaning ingredients, of the drug therein contained; provided, this requirement shall not apply to compounded medicines. The licensed practitioner shall keep a suitable book, file or record in which shall be preserved for a period of not less than five (5) years a record of every dangerous drug compounded or dispensed by the licensed practitioner.

Continued on page 6

Dispensing, continued from page 5

B. A licensed practitioner desiring to dispense dangerous drugs pursuant to this section shall register annually with the appropriate licensing board as a dispenser, through a regulatory procedure adopted and prescribed by such licensing board.

C. A licensed practitioner who dispenses professional samples to patients shall be exempt from the requirement of subsection B of this section if:

1. The licensed practitioner furnishes the professional samples to the patient in the package provided by the manufacturer;

2. No charge is made to the patient; and

3. An appropriate record is entered in the patient's chart.

D. This section shall not apply to the services provided through the State Department of Health, city/county health departments, or the Department of Mental Health and Substance Abuse Services.

E. This section shall not apply to organizations and services incorporated as state or federal tax-exempt charitable nonprofit entities and/or organizations and services receiving all or part of their operating funds from a local, state or federal governmental entity; provided, such organizations and services shall comply with the labeling and recordkeeping requirements set out in subsection A of this section.

475:30-1-4. Manner of issuance of prescriptions

(c) (3) Each scheduled drug shall be written on a single prescription form, and no other prescriptions (controlled or non-controlled) shall be written on the same prescription form.

475:45-1-2. Required reporting of certain information

Every pharmacy or dispensing practitioner filling any schedule II, III, or IV prescriptions must report the following information to a central repository maintained by the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control (OBN). The information must include, but not be limited to, the following:

(1) Recipient's name;

(2) Recipient's identification number;

(3) National Drug Code number of the substance dispensed,

(4) Date of the dispensation;

(5) Quantity of the substance dispensed;

(6) Prescriber's U.S. Drug Enforcement Agency registration number; and,

(7) Dispenser's registration number and location.

475:45-1-3. Method of reporting

Each pharmacy or dispensing practitioner must transmit the information required in 475:45-1-2 in the following manner: On an electronic device which is compatible with the receiving device of the central repository or by computer diskette, magnetic tape, or other electronic medium.

475:45-1-5. Time limit for reporting

The information required by this section must be reported to the central repository within thirty (30) days of the time that the controlled dangerous substance was dispensed.

"Buyer (and Seller) Beware"

We recently obtained a copy of a FAX from Alliance Healthcare (Pharmakind) application sent to an Oklahoma physician, urging him to "partner with us and earn unlimited income". The application involved filling prescriptions for patients after reviewing an online questionnaire completed by someone who wanted medications from Pharmakind. No need to examine, diagnose or even see one of their applicants.

One Oklahoma doctor was recently fined close to $2 million and is in Federal prison for similar behavior. Another was fined and had his license suspended. The DEA has "...taken the position that any written prescription based on an online questionnaire is invalid, and if you have an invalid prescription for a controlled substance, that is drug dealing." (Patrick Egan, Chicago-based Healthcare/Criminal Law Attorney). New federal law is making its way to the President's desk for signature controlling online prescribing and giving new authority to the States to enforce physician prescribing.

If something seems too good to be true, it probably is.

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Website Provides Prescribers Unbiased Information on Pharmaceutical Industry Marketing Practices

A new Web-based tool provides U.S. physicians with access to free, accredited CME courses about pharmaceutical industry marketing techniques and their effect on prescribing practices. Located at www.fsmb.org/re/open/modules.html, the website is part of the Attorney General Consumer and Prescriber Education Grant Program, which provides prescribers tools for accessing unbiased sources of information about drugs.

For example, two modules developed by the Georgetown University Medical Center (GUMC) discuss requirements regarding new drug approvals and how generic drugs are tested and approved.

"We want to educate doctors about the fact that generic drugs are held to exactly the same standard as different batches of branded drugs," said Adriane Fugh-Berman, M.D., associate professor of Physiology and Biophysics at GUMC.

Although pharmaceutical sales representatives may misinform doctors that generic drugs may contain 20 percent less drug than brand-name medications, said Dr. Fugh-Berman, different batches of drugs may differ slightly in potency, but allowable variability never approaches 20 percent.

"Doctors want to take the best care of their patients, but misinformation from drug reps can interfere with good medicine," said Dr. Fugh-Berman. "We want to prevent doctors from increasing the dose of generics to compensate for their supposedly weaker effect, a practice that increases the risk of adverse medication effects."

CME courses on the portal are accredited and available free of charge to all U.S. prescribers. Courses currently available include:

- Drug Approval in the U.S.: How Drugs Get to Market
- Generic Drugs: Prescribing Sensibly
- What's Hype? What's Right? Assessing New Information from Pharm Reps to the Latest Journals
- Why and how are drugs approved?
- There's no such thing as a free lunch ... or dinner
- A Clinician's Guide to Critical Appraisal of Clinical Trials
- Pharmaceutical Marketing: Its Goal is to Influence Your Prescribing Practices
- Principles of Rational Prescribing

The Federation of State Medical Boards Research and Education Foundation developed and implemented the website to disseminate educational courses developed by grant recipients. These include the Kaiser Foundation Health Plan of Colorado, Georgetown University Medical Center, the Lovelace Clinic Foundation, Massachusetts General Hospital (MGH) Institute of Health Professions, the Meyers Primary Care Institute, Northeastern Ohio University College of Medicine and Pharmacy, the University of California, San Francisco, and Wake Forest University Health Sciences.

FDA Update

Fentanyl Transdermal System

The FDA issued an update that highlights important information on appropriate prescribing, dose selection, and the safe use of the Fentanyl transdermal system (patch). FDA previously issued a Public Health Advisory and information for Healthcare Professionals in July 2005 regarding the appropriate and safe use of the transdermal system. However, the Agency continues to receive reports of death and life-threatening adverse events related to Fentanyl overdose that have occurred when the Fentanyl patch was used to treat pain in opioid-naïve patients and when opioid-tolerant patients have applied more patches than prescribed, changed the patch too frequently, and exposed the patch to a heat source. The Fentanyl patch is only indicated for use in patients with persistent, moderate to severe chronic pain who have been taking a regular, daily, around-the-clock narcotic pain medicine for longer than a week and are considered to be opioid-tolerant.

Patients must avoid exposing the patch to excessive heat as this promotes the release of Fentanyl from the patch and increases the absorption of Fentanyl through the skin which can result in fatal overdose. Directions for prescribing and using the Fentanyl patch much be followed exactly to prevent death or other serious side effects form Fentanyl overdose.

Read the complete 2007 Med Watch Safety Summary including a link to the FDA Public Health Advisory and Information for Heathcare Professionals Sheet regarding this issue at:

http://www.fda.gov/medwatch/safety/2007/safety07.htm#Fentanyl

Medical Board Rule on use of Board Certification Debated

In late 2008, a group of physicians presented to the Board their concerns about deceptive and misleading physician advertising in the state. They raised concerns about the quality and accuracy of physician credentialing information being presented to patients and the public. The discussion brought to light the Medical Board Rule allowing the Board to approve specialty certifications other than those granted by the American Board of Medical Specialties. After much debate, comment, and a public hearing, the Medical Board decided on March 26th that the current rule language allows enough flexibility for the Board to determine the quality of the certification and grant permission to use the terms "Board Certified" or "Certified by" or a "Diplomat" or "Fellow". Efforts to amend the rule were dropped. This issue will continue with further study.

Warning Regarding Investigational Drugs

It has been brought to the attention of the Oklahoma State Board of Medical Licensure and Supervision that some physicians have been ordering Domperidone for their patients when the physicians are not part of an investigational team and the use is not part of an Investigational New Drug (IND). This is not a legal prescription and whether the active ingredient is factory or locally compounded makes no difference.

This practice is illegal unless part of an IND.

Board member, **Curtis Harris, MD, JD** has been nominated to the Federation of State Medical Boards Board of Directors. The Board of Directors guides the Federations policy-making for the nation's 70 state medical and osteopathic boards. Congratulations, Dr. Harris!

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