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Medical Licensure Commission

Newsletter and Report

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Inside:

Male infertility – A common side effect of testosterone therapy

by Michael P. Steinkampf, MD, and
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The increasing use of testosterone (androgen) therapy in adult men has brought to light a common but little-known side effect of this treatment – infertility. Recently, we saw a couple in our fertility clinic that was typical of this problem. The wife was 35 years old and had conceived by her present husband without difficulty five years ago. She used birth control pills for several years after her delivery, but she stopped them two years ago to attempt another pregnancy. Her menses were regular and she was in good health. Her husband, 42 years old, also described himself as being in good health, with no current medical problems or treatment, but his semen analysis showed no sperm. On further questioning, he admitted to problems with fatigue and decreased libido for several years, but he said these problems resolved when he began receiving injections from his personal physician. A call to his physician revealed that the husband was receiving injections of testosterone cypionate.

How does testosterone therapy cause infertility in men?

The effect of androgens on male fertility can be deceiving, since men receiving testosterone often have improved libido and sexual function. However, testosterone treatment suppresses the production of follicle stimulating hormone and luteinizing hormone by the pituitary gland. These hormones are necessary for sperm production, and men receiving testosterone often show shriveling and atrophy of their testes.

See Testosterone Therapy, page 3

Registration required for office based surgery

Effective Oct. 27, 2011, registration will be required for physicians:

1) Performing or offering to perform liposuction when infiltration methods such as the tumescent technique are used, and
2) Performing or offering to perform any procedure in which **propofol** is administered given or used.

Beginning in January 2012, annual registration will be required for all office based surgery/procedures physicians.

Physicians are required to register with the Board if they perform or offer to perform in an office setting:

- Any procedure that requires moderate sedation, deep sedation or general anesthesia.
- Liposuction when infiltration methods such as the tumescent technique are used.
- Any procedure in which **propofol** is administered, given or used.

In January 2012, every licensed physician will receive by mail a notification of the registration requirement. Registration is due by March 1 of each year and will be accomplished online. There is no charge associated with the registration.

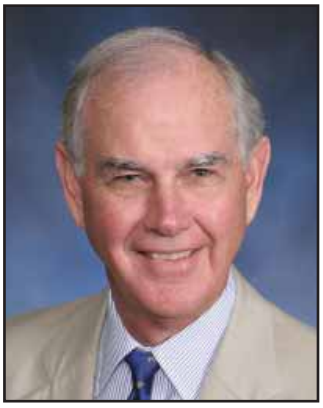
Requirements for office based surgery/procedures physicians include physician registration, equipment and supplies, training and assistance of other personnel.

See Office Based Surgery, page 5

A Message from the Executive Director

Office based surgery rules

by Larry Dixon, Executive Director



Larry Dixon

On Oct. 27, 2011, new rules regarding office based surgery and physicians performing surgery or certain procedures in their offices became effective. Those new rules require the physicians performing or offering to perform liposuction utilizing infiltration methods such as the tumescent technique and performing or offering to perform any procedure in which **propofol** is administered, given or used must register as office based surgery/procedures physicians with the Alabama Board of Medical Examiners.

In addition to the above change, beginning in January 2012, every physician performing office based surgery will be required to register annually with the Alabama Board of Medical Examiners. Prior to this rule change, registration was only required initially. However, the Board determined that the number of complications arising from procedures/surgery performed in an office based setting required annual registration. There will be no charge for this registration; however, any physician utilizing any procedure in the office that requires moderate sedation, deep sedation or general anesthesia, or liposuction using infiltration methods such as the tumescent technique and any procedure in which **propofol** is administered, must indicate that on their registration form.

Requirements for office based surgery/procedures include physician registration, a listing of the equipment and supplies on hand, the training of assistants in the office. Requirements also include listing of the recovery area and the assessment to be done before the patient is discharged. The physician will also have to list ABMS/AOA specialty board certification, procedures performed using moderate/conscious sedation and/or general anesthesia. The Board will be paying close attention to these registration forms, checking certain items, in particular, for physicians who are performing procedures in the office outside the core curriculum of the physician's specialty training. If that is occurring, the physician must list the training received that qualifies that individual to perform the procedure in his or her office.

At the bottom of the form, the physician will be required to certify that he or she has read and understands the requirements for office based surgery as stated in the rules. Any physician with questions can check the Board's web page concerning office based surgery where these rules are listed. In an attempt to notify every physician of these requirements, the Board has ordered that every licensed physician in the state of Alabama receive by mail a notification of the registration requirement at the beginning of next year. The registration is due by March 1 of each year and must be accomplished online.

Your Medical License

As a physician, your license to practice medicine in the State of Alabama is one of your most important assets. It allows you to apply what you learned during years of school and post-graduate training to earn a livelihood to support your family. Exercise care to protect this asset.

Testosterone Therapy, cont.

Why isn't this complication more widely known?

The ability of testosterone to diminish sperm production has been known for many years, but since most men receiving testosterone are older and not interested in fertility, this side effect hasn't been emphasized. Two recently published reviews of testosterone therapy don't even mention infertility as a potential complication,[1,2] and the prescribing information for testosterone gel has this complication listed inconspicuously among many other potential side effects.[3]

Which androgen preparations are most likely to result in infertility?

Long-acting, injectable testosterones seem to be the most potent inhibitors of sperm production, but we have also seen this problem with transdermal gels and oral formulations.

What should be done for a man on testosterone therapy who desires fertility?

Obviously, stop the testosterone. Keep in mind that it takes at least three months for sperm production to resume, and it may take much longer if long-acting androgens were used. (We currently have one husband in our practice with a previously normal semen analysis who now has **no** sperm production 10 months after discontinuing injectable testosterone pellets.) Men whose semen analyses do not normalize within six months of discontinuing testosterone should be referred to a fertility specialist for additional testing and treatment. Of course, it is preferable to ask men being considered for androgen therapy about their interest in fertility **before** the treatment begins.

What about "natural" hormone replacement therapy for men?

Male hormone treatment that is promoted as "natural" often consists of long-acting testosterone pellets. As noted above, we have found this formulation to be a very potent and long-lasting inhibitor of sperm production.

Can testosterone treatment be used as a male contraceptive?

Testosterone treatment shouldn't be relied on as a contraceptive. It takes 2-3 months after beginning testosterone for sperm concentrations to be severely affected, and even with injectable androgens, the rates of azoospermia (no sperm) are only about 40-90 percent, depending on the individual's ethnic background (Asian men treated with testosterone exhibit higher rates of azoospermia than men in Europe or North America[4]) and which formulation is administered. The use of combinations of hormones to reliably prevent sperm production continues to be an area of research interest.

References

1. Winters SF. Current status of testosterone replacement therapy in men. *Archives of Family Medicine* 1999;8:257-263.
2. Anonymous. Testosterone topical. AHFS Consumer Medication Information (Internet). Bethesda MD: American Society of Health-System Pharmacists; 2000-2011. Accessed 9/28/2011.
3. Anonymous. AndroGel full prescribing information. Abbott Laboratories, North Chicago, IL. Rev March 2011.
4. Roth MY and Amory JK. Pharmacologic Development of Male Hormonal Contraceptive Agents. *Clinical Pharmacology & Therapeutics* 2011;89(1):133-136.

Rules clarified for e-prescribing of controlled substances

On Oct. 19, 2011, the Drug Enforcement Agency (DEA) issued a clarification and notification concerning electronic prescriptions for controlled substances. DEA emphasized that third-party audits of software applications for Electronic Prescriptions for Controlled Substances (EPCS) must encompass all applicable DEA regulations, including security, and must address "processing integrity" as set forth in the DEA regulations. When there are questions in reviewing a particular application, DEA recommends consulting federal guidelines set forth in NIST Special Publication 800-53A.

DEA also announced the first DEA approved certification process for EPCS. Certifying organizations with a certifying process approved by DEA pursuant to the regulations are posted on DEA's website once approved. At this date, only Supervalu pharmacies in Virginia and California have met DEA certification requirements to utilize electronic controlled substances prescriptions. **There are currently no approved systems in Alabama for utilizing electronic prescriptions for controlled substances.**

The following information comes from DEA's web page with general questions and answers about EPCS:

What is DEA's rule "Electronic Prescriptions for Controlled Substances?"

DEA's rule, "Electronic Prescriptions for Controlled Substances" revises DEA's regulations to provide practitioners with the option of writing prescriptions for controlled substances electronically. The regulations will

see Electronic Prescribing, page 5

Electronic Prescribing, cont.

also permit pharmacies to receive, dispense, and archive these electronic prescriptions. The rule was published in the *Federal Register* March 31, 2010, and became effective on June 1, 2010.

When can a practitioner start issuing electronic prescriptions for controlled substances?

A practitioner will be able to issue electronic controlled substance prescriptions only when the electronic prescription or electronic health record (EHR) application the practitioner is using complies with the requirements in the interim final rule.

As a practitioner, until I have received an audit/certification report from my application provider indicating that the application meets DEA's requirements, how can I use my electronic prescription application or EHR application to write controlled substances prescriptions?

Nothing in this rule prevents a practitioner or a practitioner's agent from using an existing electronic prescription or EHR application that does not comply with the interim final rule to prepare and **print** a controlled substance prescription, so that EHR and other electronic prescribing functionality may be used. Until the application is compliant with the final rule, however, the practitioner will have to print the prescription for manual signature. Such prescriptions are paper prescriptions and subject to the existing requirements for paper prescriptions.

Is identity proofing of individual prescribing practitioners still required and who will conduct it?

Identity proofing is still required. It is critical to the security of electronic prescribing of controlled substances that authentication credentials used to sign controlled substances prescriptions are issued only to individuals whose identity has been confirmed. Individual practitioners will be required to apply to certain federally approved credential service providers (CSPs) or certification authorities (CAs) to obtain their two-factor authentication credential or digital certificates. The CSP or CA will be required to conduct identity proofing that meets National Institute of Standards and Technology Special Publication 800-63-1 Assurance Level 3. Both in person and remote identity proofing will be acceptable. Institutional practitioners will have the option to conduct in-person identity proofing in-house as part of their routine credentialing process.

What two-factor credentials will be acceptable?

Under the interim final rule, DEA is allowing the use of two of the following – something you know (a knowledge factor), something you have (a hard token stored separately from the computer being accessed), and something you are (biometric information). The hard token, if used, must be a cryptographic device or a one-time-password device that meets Federal Information Processing Standard 140-2 Security Level 1.

How will the two-factor credential be used?

The practitioner will use the two-factor credential to sign the prescription; that is, using the two-factor credential will constitute the legal signature of the

DEA-registered prescribing practitioner. When the credential is used, the application must digitally sign and archive at least the DEA-required information contained in the prescription. Because the record will be digitally signed and archived at that point, the proposed requirement for a lock-out period is not needed and is not part of the interim final rule.

May a practitioner use his own digital certificate to sign an electronic controlled substance prescription?

Yes, the interim final rule allows any practitioner to use his own digital certificate to sign electronic prescriptions for controlled substances. If the practitioner and his application provider wish to do so, the two-factor authentication credential can be a digital certificate specific to the practitioner that the practitioner obtains from a Certification Authority that is cross-certified with the Federal Bridge Certification Authority at the basic assurance level.

Must a practitioner separately attest to each prescription?

No, the application must include, on the prescription review screen, a statement that the use of the two-factor credential is the legal equivalent of a signature, but no keystroke is required to acknowledge the statement.

Is it permissible to have a staff person in the practitioner's office complete all of the required information for a controlled substance prescription and then have the practitioner sign and authorize the transmission of the prescription?

Yes. However, if an agent of the practitioner enters information

see Electronic Prescribing, page 6

Utilizing controlled substances for weight reduction

Effective Jan. 20, 2012, Board rules provide guidelines for physicians utilizing controlled substances for weight reduction. The entire text of the rules can be accessed through our website. The following represents some of the major points, but should not be taken on their own; instead, the entire text of Chapter 540-X-17 should be reviewed by all physicians who prescribe or contemplate prescribing controlled substances for the purposes of weight reduction.

- Schedule II controlled substances may not be prescribed, dispensed or otherwise administered to any person for the purpose of weight control, weight loss, weight reduction or treatment of obesity.
- Only a licensed physician may prescribe, dispense or otherwise administer Schedule III, IV or V controlled substances to a person for the purpose of weight control, weight loss, weight reduction or treatment of obesity.
- The prescribing/ordering physician must be present at the facility when prescribing, ordering or dispensing a controlled substance for a patient for the purpose of weight reduction or treatment of obesity.
- Before initiating treatment for weight reduction or obesity utilizing a Schedule III, IV or V controlled substance, there should be an initial evaluation conducted by and recorded by the prescribing physician, to include an appropriate physical and complete history, appropriate testing, and appropriate medical referrals.
- The patient should have a BMI of 30 or above, or greater than 25 with at least one comorbidity factor, or a measurable body fat content of 25% for men or 30% for women, or an abdominal girth of at least 40 inches for men or 35 inches for women.
- Controlled substances should not be prescribed, ordered or dispensed in greater than a 35 day supply.
- Within the first 35 days following initiation of a controlled substance, the patient should be seen by the prescribing physician, a PA supervised by the prescribing physician, or a CRNP collaborating with the prescribing physician, and a recording should be made of weight, blood pressure, pulse and any other tests deemed necessary.
- There should be an in-person re-evaluation at least once every 35 days. If this is delegated to a PA or CRNP, the prescribing physician should personally review the resulting medical records before continuing the controlled substance for weight reduction.
- Medical records should be maintained in compliance with the Medical Licensure Commission's minimum standards for medical records.
- Controlled substances should not be initiated or should be discontinued if the patient has failed to progress towards medically established goals, has developed tolerance to the anorectic effects of the controlled substance, has a history of or shows a propensity for alcohol or drug abuse, has consumed or disposed of a controlled substance not in compliance with directions, has repeatedly failed to comply with treatment recommendations, or is pregnant.

The Board has adopted these rules to protect the public health and safety of the citizens of Alabama. The Board recognizes that inappropriate prescribing of controlled substances may lead to drug diversion and abuse, and physicians should be diligent in preventing the diversion of drugs for illegitimate purposes. Utilizing controlled substances for weight reduction or the treatment of obesity should be based on accepted scientific knowledge and sound clinical grounds.

On the net:
Full text of Board Rules Chapter 540-X-17, Guidelines and Standards for the Utilization of Controlled Substances for Weight Reduction: www.albme.org/csforweight.html
Commission Rule 545-X-4-.09, Minimum Standards for Medical Records: http://www.albme.org/medrecminstds.html

Office Based Surgery, cont.

Requirements also include recovery area and assessment for discharge.

The annual registration form will require the registrant to list ABMS/AOA specialty board certification, procedures performed using moderate/conscious sedation and/or general anesthesia, indicate if liposuction with infiltration methods is performed, and indicate if **propofol** is administered, given or used in any procedures.

If any procedures are performed that are outside the core curriculum of the physician's specialty training, the physician must list the training received that qualifies the physician to perform the procedure. There is also a certification that Board rules have been read and the physician meets the requirements stated in the rules.

For more information, please see the Board's web page concerning office based surgery.

On the net:
Board's web page for office based surgery: www.albme.org/obs.html

Electronic Prescribing, cont.

at the practitioner's direction prior to the practitioner reviewing and approving the information, the practitioner is responsible in the event the prescription does not conform in all essential respects to the law and regulations.

Can a practitioner print a copy of any electronic prescriptions for controlled substances?

Yes, the electronic prescription application may print copies of the transmitted prescription(s) if they are clearly labeled: "Copy only – not valid for dispensing." Data on the prescription may be electronically transferred to medical records, and a list of prescriptions transmitted may be printed for patients if the list indicates that it is for informational purposes only and not for dispensing. The copies must be printed after transmission. If an electronic prescription is printed prior to attempted transmission, the electronic prescription application must not allow it to be transmitted.

Will a practitioner be allowed to simultaneously issue multiple prescriptions for multiple patients with a single signature?

A practitioner is not permitted to issue prescriptions for multiple patients with a single signature. However, a practitioner is allowed to sign multiple prescriptions for a single patient at one time. Each controlled substance prescription will have to be indicated as ready for signing, but a single execution of the two-factor authentication protocol can then sign all prescriptions for a given patient that the practitioner has indicated as being ready to be signed.

Who can conduct an audit or certify an application?

Application providers must obtain a third-party audit or certification to certify that each electronic prescription and pharmacy application to be used to sign, transmit, or process controlled substances prescriptions is in compliance with DEA regulations pertaining to electronic prescriptions for controlled substances. The application may undergo a WebTrust, SysTrust, or SAS 70 audit conducted by a person qualified to conduct such an audit. The application may undergo an audit conducted by a Certified Information System Auditor who performs compliance audits as a regular ongoing business activity. The application may have a certification organization whose certification has been approved by DEA verify and certify that the application meets DEA's requirements.

When must a third-party audit or certification be conducted?

The third-party audit or certification must be conducted before the electronic prescription application is used to sign or transmit electronic prescriptions for controlled substances, or before the pharmacy application is used to process electronic prescriptions for controlled substances, respectively. Thereafter, a third-party audit or certification must be conducted whenever a functionality related to controlled substance prescription requirements is altered or every two years, whichever occurs first.

To whom does the third-party audit/ certification requirement apply?

The requirement for a third-party audit applies to the application provider, not to the individual practitioner, institutional practitioner, or pharmacy that uses the application. Unless an individual practitioner, institutional practitioner, or pharmacy has developed its own application, the practitioner or pharmacy is not subject to the requirement.

On the net:

DEA Federal Register clarification and notification: http://www.gpo.gov/fdsys/pkg/FR-2011-10-19/pdf/2011-26738.pdf

NIST Special Publication 800-53A: http://csrc.nist.gov/publications/nistpubs/800-53A-rev1/sp800-53A-rev1-final.pdf

Educational Opportunities for 2012

Feb. 10-11	**MISSION IMPOSSIBLE III - Optimizing Technology**
March 31-April 1	**Prescribing and Pharmacology of Controlled Drugs: Critical Issues and Common Pitfalls**
April 13	**Ensuring Quality in the Collaborative Practice**
April 13-14	**MASA's Annual Session: Ready. Set. *Lead.***
August 10-12	**Prescribing and Pharmacology of Controlled Drugs: Critical Issues and Common Pitfalls**
November 17-18	**Prescribing and Pharmacology of Controlled Drugs: Critical Issues and Common Pitfalls**
November 29	**Ensuring Quality in the Collaborative Practice**
December 15	**Ethics**

Report of Public Actions of the Medical Licensure Commission and Board of Medical Examiners

MLC – September 2011

◆ On Sept. 20, the Commission entered an Order placing on indefinite probation the license to practice medicine in Alabama of **Scott Hull Boswell, MD**, license number MD.16975, Jasper, AL.

◆ On Sept. 28, the Commission entered an Order summarily suspending the license to practice medicine in Alabama of **Wade A. Young, MD**, license number MD.14717, Demopolis, AL, until such time as the Administrative Complaint of the Board shall be heard and a decision rendered thereon.

◆ On Sept. 28, the Commission accepted the voluntary surrender of the license to practice medicine or osteopathy in Alabama of **Christopher P. Gay, DO**, license number DO.687, Sheffield, AL.

BME – September 2011

◆ On Sept. 21, the Board accepted the Voluntary Restriction on the certificate of qualification and license to practice medicine in Alabama of **Melvyn V. Mahon, MD**, license number MD.29855, Columbia, SC.

◆ On Sept. 21, the Board accepted the Voluntary Surrender of certificate of qualification and license to practice medicine in Alabama of **Marla Shaver, MD**, license number MD.27380, Coral Springs, FL.

MLC – October 2011

◆ On Oct. 14, the Commission entered an Order reinstating to full, unrestricted status the license to practice medicine in Alabama of **Michael A. Schwartz, MD**, license number MD.11378, Warrior, AL.

◆ On Oct. 17, the Commission entered an Order denying the application for reinstatement of the license to practice medicine in Alabama of **Allie C. Boyd, III, MD**, license number MD.3883, Tuscaloosa, AL.

◆ On Oct. 17, the Commission entered an Order removing all restrictions on the license to practice medicine in Alabama of **Samia S. Moizuddin, MD**, license number MD.24363, Jasper, AL, and reinstating the license to full, unrestricted status.

◆ On Oct. 17, the Commission entered an Order revoking the license to practice medicine in Alabama of **Jeffrey H. Rudell, MD**, license number MD.7095, Kissimmee, FL.

BME – October 2011

◆ On Oct. 12, the Board entered an Order revoking the Alabama Controlled Substances Certificate of **Kenneth Eugene Roberts, MD**, license number MD.9562, Dothan, AL. Dr. Roberts is not authorized to prescribe controlled substances in Schedules II - V in the state of Alabama.

◆ On Oct. 19, the Board accepted the Voluntary Restriction on the certificate of qualification and license to practice medicine in Alabama of **Jarrod S. Roberts, MD**, license number MD.29094, Auburn, AL.

MLC – November 2011

◆ On Nov. 7, the Commission entered an Order lifting the summary suspension of the license to practice medicine in Alabama of **Andrew M. Osborne, MD**, license number MD.18034, Dothan, AL, and imposing certain conditions.

◆ On Nov. 7, the Commission entered an Order denying the Motion to Reconsider the Commission's Order of June 27, 2011, which denied the application for reinstatement of the license to practice medicine in Alabama of **Sumathi Paturu, MD**, license numer MD.18590, Birmingham, AL.

◆ On Nov. 7, the Commission entered an Order terminating all restrictions on the license to practice medicine in Alabama of **Janie T. Bush Teschner, MD**, license number MD.14227, Gadsden, AL.

Actions taken regarding failure to comply with 2010 CME requirements (fine, additional CME required):

• **Delsadie P. Callins, MD**, MD.4380, Bessemer, AL. Consent Order dated Sept. 28, 2011.

• **Francene A. Gayle, MD**, MD.25786, Huntsville, AL. Commission Order dated Oct. 14, 2011.

• **Steven P. Seidel, MD**, MD.18179, Cullman, AL. Commission Consent Order dated Oct. 26, 2011.

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Look inside for important news from the Board of Medical Examiners that pertains to your license to practice medicine in Alabama.

All current licensees receive the Board of Medical Examiners *Newsletter and Report* at their address of record at no charge. Licensees may also choose to receive the newsletter by e-mail. Non-licensee subscriptions to the newsletter are by e-mail only.

If you would like to receive the newsletter by e-mail, please send a request to masa@masalink.org.

Change of Address

Alabama law requires that every licensed physician notify the Board of Medical Examiners in writing within 15 days of a change of the physician's practice location address and/or mailing address.