DEA rules for electronic prescribing of controlled substances

by Ed Munson Jr., Senior Investigator

On June 1, 2010, Drug Enforcement Administration (DEA) rules regarding “Electronic Prescriptions for Controlled Substances” became effective. This does not mean that physicians may immediately start prescribing controlled substances electronically. The following information is intended to provide a summary of the important aspects of this rule change.

Implementation of the rule
The DEA’s Rule “Electronic Prescriptions for Controlled Substances” does not mandate that practitioners prescribe controlled substances using only electronic prescriptions. Nor does this rule require pharmacies to accept electronic controlled substance prescriptions. This is a matter of choice and convenience. Practitioners can continue to write controlled substance prescriptions and manually sign them. Practitioners may also continue to phone in controlled substance prescriptions in Schedules III-V. Nothing in the rule prevents practitioners from using all three methods. Pharmacies will continue to fill prescriptions issued under all three methods.

Application/device compliance
Physicians and other practitioners will be able to issue electronic controlled substance prescriptions only after the electronic prescription, or electronic health record being used, complies with the requirements set forth in the DEA’s rule. The same holds true for the pharmacists who will be receiving the electronic prescriptions. To determine application compliance, the application provider (software vendor) must either hire a qualified third party to audit the application or have the application certified by an “approved certification body.” The rule goes on to state that the auditor, or certification body, will issue a report that states whether the software complies with the DEA’s requirements and whether there are any limitations on its use for controlled substance prescriptions. The vendor will be required to provide a copy of the report to practitioners and pharmacists to allow them to determine whether or not the application is compliant and meets the specifications.

Nothing in the rule prevents a practitioner from using an existing electronic prescription application (that does not comply with the rule) to prepare and print a controlled substance prescription. Until the software meets the requirements of the rule, a controlled substance prescription will have to be printed out and manually signed by the practitioner. This will hold true for prescriptions being provided to the patient directly, or those that are faxed to a pharmacy to be filled. Once printed out, that prescription becomes an original prescription (paper prescription) and will have to meet all of the requirements specified under state and federal law. That would include the double signature line; one line with “product selection permitted” and one line with “dispense as written.” The physician must manually sign above the appropriate line.

Identity proofing
Identity proofing will be of major importance in implementation of this concept. It is critical to the security of electronic prescribing that the authentication credentials used to sign the prescriptions are reliable.
In 2010 there was an increase in the number of newly licensed physicians in Alabama, with 669 approved applicants by endorsement and 126 approved applicants by examination, which constitutes 65 more approved applicants than in 2009. This was the first year to report the issuance of Qualified Alabama Controlled Substances Certificates, with 57 issued in 2010. The Board of Medical Examiners and its staff have compiled the following Annual Report for your information.

### A. APPLICANTS CERTIFIED TO MEDICAL LICENSURE COMMISSION
1. Applicants by endorsement ......................................................... 669
   a. Non-disciplinary Citation with Administrative Charge .............. 15
2. Applicants by examination .......................................................... 126

### B. APPLICANTS CERTIFIED FOR LIMITED LICENSE .................... 189

### C. APPLICANTS TAKING SPEX EXAMINATIONS
1. Applicants passing examinations ................................................. 10
2. Applicants failing examinations .................................................. 3

### D. APPLICANTS FOR OUT OF STATE ENDORSEMENT ...................... 0

### E. ADVANCED PRACTICE NURSES (CRNP/CNM)
1. Certified Registered Nurse Practitioner Collaborations Approved .... 676
2. Certified Nurse Midwife Collaborations Approved ......................... 2

### F. PHYSICIAN ASSISTANTS
1. Physician Assistants Licensed .................................................. 59
2. Physician Assistants Registered to Physicians (new applications) .... 200
3. Physician Assistants Granted Temporary Licensure ....................... 20
4. Temporary Licensure Converted to Full Licensure (after passing exam) ... 19
5. Temporary Licensees Granted Registration .................................... 17
6. Anesthesiologist Assistants Licensed ......................................... 0
7. Anesthesiologist Assistants Granted Temporary License .................. 0
8. Anesthesia Assistants Registered to Physicians (new applications) .... 0

### G. ACSC ISSUED/RENEWED ................................................. 12,166

### H. DISCIPLINARY/CONFIDENTIAL ACTIONS
1. ACSC Surrender/Revocation/Restriction/Reinstatement .................. 5
   ACSC Restriction Terminated ..................................................... 1

*see Annual Report, page 3*
Board stresses importance of PDMP

The Prescription Drug Monitoring Program (PDMP) administered by the Alabama Department of Public Health has two purposes for physicians:

- Physicians who dispense medications to patients from their offices must register and report to the PDMP all dispensed controlled substances; and
- Physicians may register for the service which allows practitioners to obtain a report of all the controlled substances dispensed or prescribed to a current or prospective patient – the prescriber/dispenser, the pharmacy/site dispensed, the name, strength and quantity of the drug, and the date.

The data bank is not just for physicians who practice pain control. All physicians can check to be sure a patient who is prescribed controlled substances isn’t also receiving them from other physicians, using multiple pharmacies or overlapping refills, all signs of possible drug abuse or diversion. However, there is a possibility that the information in the data bank is inaccurate – we have seen instances of reports made under the wrong physician and other data input errors – but a quick check with the pharmacy and/or other prescriber will confirm the data.

What if you discover a patient is abusing or diverting medications? You can contact the Board of Medical Examiners and discuss your situation “off the record.” Senior Investigator Ed Munson can be reached at (334) 242-4116 or emunson@albme.org.

On the Net:
PDMP website: http://www.adph.org/pdmp

AMA policy for use of social media

In November 2010, the American Medical Association (AMA) adopted a policy to help physicians maintain a positive online presence and ensure that the physician patient relationship is appropriate and confidential.

The new policy encourages physicians to weigh a number of considerations when maintaining an online presence:

- Know the standards of privacy and confidentiality that must be maintained in all situations, as well as online, and do not post identifiable patient information online.
- Use privacy settings when using the Internet for social networking.
- Maintain appropriate boundaries just as in any other context, and consider separating personal and professional online content.
- Recognize that actions and content posted online could negatively affect your reputation, have consequences for your medical career, and undermine public trust in the medical profession.

On the Net:

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H. DISCIPLINARY/CONFIDENTIAL ACTIONS, cont.
2. Certificates of Qualification Denied/Surrendered ................................ 9
3. Certificates of Qualification with Agreements/Restrictions ......................... 8
   Certificate of Qualification Restrictions Terminated ..................................... 0
4. Letters of Concern .................................................................................. 199
5. Complainant Inquiries Received ............................................................... 558
6. Complainant Inquiries Resolved ............................................................... 434
7. Complainant Inquiries Pending ................................................................. 11
8. Complainant Formal Investigations ......................................................... 135
   Formal Investigations Completed .............................................................. 113
   Formal Investigations Pending .................................................................. 22
9. Collaborative Practice Inspections ........................................................... 142
10. Collaborative Practice Compliance Seminars ............................................ 1
11. Interviews Conducted ........................................................................... 67
12. Complaints filed with Medical Licensure Commission ............................. 19
13. Evaluations Ordered ............................................................................. 10
14. Voluntary Agreements Entered Into ..................................................... 12
    Voluntary Agreements Removed ............................................................. 5
15. Voluntary Restrictions Entered Into ..................................................... 3
    Voluntary Restrictions Removed ............................................................. 0
16. Flag File for Reinstatement ..................................................................... 6
17. Impaired Physician Coordinator Monitoring .......................................... 70
    Number monitored since 1990 ................................................................. 993
18. Requested CME Course Attendance ..................................................... 31
19. Sent for Expert Review ......................................................................... 8
20. Assessments (MLC/BME) ...................................................................... 22
    Administrative Fines .................................................................................. 11
    Administrative Costs .................................................................................. 11
21. Summary Suspensions .......................................................................... 2
    Summary Suspension B Surrendered ......................................................... 1
    Summary Suspension B Pending a Hearing before the MLC ..................... 1
22. Voluntary Surrender of Alabama Medical License .................................. 4
Be courteous when communicating with pharmacies

by Richard M. Freeman, MD,
Vice Chairman,
Alabama Board of Medical Examiners

The Board periodically receives complaints from pharmacists who have problems communicating with physicians and their offices. They are often told the doctor doesn’t have time to talk to the pharmacist, and occasionally a physician will speak very inappropriately to the pharmacist, even to the point of shouting and using obscenities.

These sorts of outbursts and refusals to speak with pharmacists are not only unprofessional, but they could be detrimental to your patient. The pharmacist may be calling about a potential drug interaction or a possible forged prescription. Pharmacists have more resources at their command to be warned if there is a potential harmful interaction, and they can be of great assistance by noting such things.

The Board takes it very seriously when a physician puts a patient at risk because he or she is unable to maintain a professional demeanor in communicating with pharmacists and other healthcare professionals.

Richard M. Freeman, MD
*Dr. Freeman is a board certified pediatrician who practices in Auburn.

Electronic prescribing
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are issued only to individuals whose identity has been confirmed. Individual practitioners will be required to apply to federally approved credential service providers (CSPs) or certification authorities (CAs) to obtain their two-factor authentication credential or digital certificates. The CSP and/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.

The two-factor credentialing authentication allowed by DEA under the rule, involves two of the following:
1. Something you know (knowledge factor).
2. Something you have, such as a hard token stored separately from the computer being accessed.
3. Something that you are (biometric information/intrinsic physical traits).

In the case of using the “hard token,” it must be a cryptographic device or a one-time password device that will meet the “Federal Information Processing Standard 140-2, Security Level 1.” The practitioner will use the “two-factor credential” to sign the prescription. Thus, the “two-factor credential” will constitute the prescriber’s signature. When this is done, the software must digitally sign the prescription and must archive at a minimum the DEA required information contained in the prescription. Once the digital signature is accepted and the information archived, there will be no need for the prescriber to attest to each prescription. The software application device must include, on the prescription screen, a statement that the use of the two-factor credential is the legal equivalent of a signature. Acknowledgment of the statement will be understood (without any additional keystroke).

Application access

Under the DEA rule, it will be permissible for the practitioner to have a designated staff person complete all of the required information for a controlled substance prescription and then have the practitioner “sign” and authorize the transmission of the prescription. In allowing this, the practitioner assumes full responsibility for the prescription conforming to all aspects of correctness, including compliance with federal and state laws.

After transmission of an electronic prescription for a controlled substance prescription may be printed out. That printed copy must contain the written statement/label “Copy Only – Not Valid For Dispensing.” Prescription data may be electronically copied to medical records and/or a list of prescriptions may be provided to the patient. That list must indicate that it is for informational purposes only and not for dispensing. If the practitioner intends to provide the list to the patient, the list must first be transmitted to the patient record. The list should not be printed out for the patient until that has been accomplished. Bear in mind that if the electronic prescription is printed prior to transmission, the electronic prescription application must not allow it to be transmitted for filling. This prevents possible “double filling.” As stated previously, once the prescription is printed out it becomes a paper/hard copy prescription and must conform with all laws, rules and regulations.

Application limitations and provisions

A practitioner will not be allowed to issue multiple prescriptions for multiple

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Prescribing and Pharmacology of Controlled Drugs: Critical Issues and Common Pitfalls

The 2011 Series

The Intensive Course in Prescribing Controlled Drugs is designed for physicians and physician assistants in all specialties who need or wish to increase their knowledge and ability to effectively prescribe and control medications without the potential for abuse.

Controlled substances are prescribed and dispensed today at an increasing rate to help patients cope with pain, insomnia, anxiety, depression, obesity and myriad other disorders. Studies show that most practitioners are rather conservative when prescribing controlled drugs while a small number are at times overly aggressive. In addition, controlled prescription medications are falling into the hands of increasing numbers of prescription drug abusers.

How can the practitioner more effectively understand the pharmacologic profiles for controlled drugs, identify diagnostic criteria for appropriate prescribing and consider the therapeutic implications of specific substance use by individual patients? This special intensive course has been developed to enhance the physician’s ability to effectively prescribe controlled medications, while minimizing their misuse whenever possible.

The Medical Foundation of Alabama designates this educational activity for a maximum of 12 AMA PRA Category 1 Credits™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

This activity has been planned and implemented in accordance with the Essential Areas and policies of the Medical Association of the State of Alabama through the joint sponsorship of the Medical Foundation of Alabama and the Medical Association of the State of Alabama. The Medical Foundation of Alabama is accredited by the Medical Association of the State of Alabama to provide continuing medical education to physicians.

Visit www.masalink.org/prescribing for more seminar details including full agenda.

The registration fee includes all course materials and meals. All registration fees must be paid at time of registration. Attendees will not be allowed to pay or register at the door. Please see below for registration deadlines. A fee of $75 will apply if registration or payment is received after registration deadline.

Cancellation/Refund Policy: If you cancel two weeks before the seminar, you will be refunded half of your registration fee and receive course materials. If you cancel less than two weeks before the seminar, you will receive NO refund and NO course materials.

MASA members may register online at www.masalink.org.

Name: ___________________________________________________________________________   Designation: ____________________________

Company: ________________________________________________________________________________________________________________

Address: _________________________________________________________________________________________________________________

City, State, Zip: ____________________________________________________________________________________________________________

Phone:______________________________   Fax: _______________________________   E-mail: _________________________________________

Payment: o Check   o Visa   o MasterCard   o American Express

Cardholder:________________________________________________ Card Number:____________________________________________________

Exp. Date:_______________ 3 or 4-Digit Security Code:_______________ Amount:_________________ Billing Zip Code: _____________________

Signature: ________________________________________________________________________________________________________________

Note: Your signature constitutes an agreement to pay the amount indicated.
Ensuring Quality in the Collaborative Practice
Working together to deliver quality healthcare.

The Medical Association of the State of Alabama, the Alabama Board of Medical Examiners, and the Alabama Board of Nursing have partnered to present a seminar for physicians, advanced practice nurses and certified nurse midwives who are involved in or considering a collaborative practice agreement.

Registration Fee: $100. The fee includes all course materials and meals (Dothan and Birmingham only). Please see below for registration deadlines. Note: All registration fees must be paid at time of registration. Attendees will not be allowed to pay or register at the door.

Cancellation/Refund Policy: If you cancel two weeks before the seminar, you will be refunded half the registration fee and will receive course materials. If you cancel less than two weeks before the seminar, you will receive NO refund and NO course materials.

MASA members can register online at www.masalink.org.

May 27 (Registration Deadline: May 13)
Baytowne Conference Center, Destin, Fla.
Room Block Deadline: April 25
Call (800) 320-8115 – Room Code: 22628B
Note: This presentation is part of MASA’s Annual Session and is offered at no charge to members of MASA and AMASA. Cost for Non-members (including spouses who are not members of AMASA): $100

Sept. 1 (Registration Deadline: Aug. 18)
Hilton Garden Inn, Dothan
Call (334) 671-7676
Cost: $100

Dec. 1 (Registration Deadline: Nov. 17)
Birmingham Marriott
Call (205) 968-3775
Cost: $100

Name: ______________________________________________________   Check One:  MD  DO  CRNP  CRNM  Other __________
Company:  _______________________________________________________________________________________________________________
Address: ________________________________________________________________________________________________________________
City, State, Zip: ___________________________________________________________________________________________________________
Phone:______________________________   Fax: ________________________________   E-mail: _______________________________________
Payment:   o Check  o Visa  o MasterCard  o American Express
Cardholder:_______________________________________________ Card Number:____________________________________________________
Exp. Date:_________________ 3- or 4-Digit Security Code:_________________ Amount:__________________ Billing Zip Code: ________________
Signature: ________________________________________________________________________________________________________________

Note: Your signature constitutes an agreement to pay the amount indicated.

Return completed registration form and payment to:
Medical Association of the State of Alabama • Attn: Education Department
PO Box 1900 • Montgomery, AL 36102-1900 • Phone: (334) 954-2500 • Fax: (334) 269-5200
On Nov. 30, the Commission entered an Order lifting the suspension of the license to practice medicine in Alabama of Oscar V. Fadul, MD, license number MD.9585, Huntsville, AL, subject to the condition that he may not practice medicine until submitting a detailed plan of practice for prior approval.

On Dec. 7, the Commission entered an Order denying the reinstatement application of John A. King, DO, a/k/a Christopher W. Martin, DO, license number DO.127, Orlando, FL.

Effective Dec. 30, the Commission issued an Order summarily suspending the license to practice medicine in Alabama of Bryant H. Hudson III, MD, license number MD.4228, Montgomery, AL, until such time as the Administrative Complaint of the Board shall by heard by the Commission and a decision rendered thereon.

On Dec. 15, the Board accepted the voluntary surrender of the certificate of qualification and license to practice medicine in Alabama of John A. Kreisberg, MD, license number MD.22819, Mobile, AL.

On Jan. 7, the Commission entered an Order approving the plan of practice of Michael A. Schwartz, MD, license number MD.11378, Warrior, AL.

On Jan. 7, the Commission entered an Order approving the plan of practice of Ervin Wells, MD, license number MD.28241, Augusta, GA.

On Jan. 26, pursuant to the stipulation of the parties, the Commission entered an Order placing on three-year probation the license to practice medicine in Alabama of George R. Storey, MD, license number MD.15022, Talladega, AL.

On Feb. 3, the Commission entered an Order reinstating to full, unrestricted status the license to practice medicine in Alabama of William T. Hall Jr., MD, license number MD.8930, Birmingham, AL.

On Feb. 3, the Commission entered an Order placing on probation the license to practice medicine in Alabama of Thomas Baldwin Lank, MD, license number MD.13282, Severna Park, MD.

On Feb. 3, the Commission entered an Order requiring certain conditions to be met concerning the license to practice medicine in Alabama of Jose G. Zavaleta, MD, license number MD.22305, Pineville, LA.

Electronic prescribing

Patients by use of a single signature. The practitioner will be 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 that patient.

Application certification and auditing

The aspect of application/appliance certification and auditing is not an issue for individual practitioners, institutional practitioners, or pharmacies and pharmacists who use the application. Unless the individual practitioners, institutional practitioners, or pharmacists develop their own application, the practitioner or pharmacist is not subject to the Certification and Auditing Requirements, but their vendors are. The ultimate users of the applications (practitioners) must ensure that the vendors are recognized/authorized providers who are complying with the DEA’s regulations as set forth in 1311.120, Electronic prescription application requirements, contained in the rule.

Note

E-prescribing of controlled substances will not be permissible by any practitioner until the DEA makes the determination that the providers of the systems to be used meet all application requirements. That means that e-prescribing of controlled substances has not immediately begun. It will commence only after the DEA has determined that the systems providers have met all of the requirements specified in the rule.

On the Net:
DEA’s web site on electronic prescriptions:
http://www.deadiversion.usdoj.gov/ecomm/e_rx/index.html
Look inside for important news from the Board of Medical Examiners that pertains to your license to practice medicine in Alabama.

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.

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.