

TEMPORARY LICENSES
(Issued since last board meeting)

Walgreens

Danielle Shannon

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RE: Anthem Institute Las Vegas

LARRY L. PINSON

Sent: Tuesday, July 26, 2011 2:51 PM

To: Delgado, Tijeria [TDelgado@anthem.edu]

Cc: Carolyn J. Cramer; Pharmacy Board

Tijeria,

Good move! A wise decision, and one that I am certain will please the Board.

Thanks you,

Larry

Larry L. Pinson, Pharm. D.
Executive Secretary
Nevada State Board of Pharmacy
(775) 850-1440
(775) 850-1444 (fax)

From: Delgado, Tijeria [TDelgado@anthem.edu]

Sent: Tuesday, July 26, 2011 2:49 PM

To: LARRY L. PINSON

Subject: Anthem Institute Las Vegas



Hi Larry,

I just wanted to inform you and the board of an important change that we are making as an educational facility in reference to our pharmacy technician students. We have decided to obtain background checks on all students who enroll in school for the PT program. This will begin immediately. We are hoping that this change can help eliminate students with background problems from having to go before the board. We have also changed the process on drug testing to be more random and for it to occur more than just one time during the program. Any feedback or additional ideas are more than welcomed from you and the Board.

Thank You!

Tijeria Delgado, CPhT
Pharmacy Technician Program Chair
Anthem Institute-Las Vegas
702-366-4132
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Live the 3 Rs

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Governor

MICHAEL J. WILLDEN
Director



RICHARD WHITLEY, MS
Administrator

TRACEY D. GREEN, MD
State Health Officer

STATE OF NEVADA
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HEALTH DIVISION
BUREAU OF HEALTH CARE QUALITY AND COMPLIANCE

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August 4, 2011

Nevada State Board of Pharmacy
431 W. Plumb Lane
Reno, NV 89509

RE: Senate Bill 37

Dear Board Members:

The purpose of this letter and attached bulletin is to ensure we all have full knowledge on the requirements of Senate Bill 37, which became effective July 1, 2011.

Please review the bulletin, and the full language of the new law if necessary. If you have any questions, or if we need to discuss improved mechanisms for sharing complaint information, please don't hesitate to contact our office.

Sincerely,

A handwritten signature in blue ink that reads "Chad Westom".

Chad Westom, Health Facilities Surveyor III
For: Wendy Simons, Bureau Chief

Encl: SB 37 Technical Bulletin

AUG - 8 2011



Nevada State Health Division Technical Bulletin



Topic: Referral of Complaints Received by Health Care Licensing Boards per Senate Bill 37

Section/Program/Contact: Bureau of Health Care Quality and Compliance/ Chad Westom

Date: June 2011

TO: All Nevada Health Care Licensing Boards


The purpose of this bulletin is to notify all Nevada Health Care Licensing Boards of changes concerning complaints received by a health care licensing board, with the passage of Senate Bill 37. These changes will be in effect July 1, 2011.

The new law requires each health care licensing board to refer to another health care licensing board any complaint that concerns a matter within the jurisdiction of the other health care licensing board, within 5 days of making the determination.

Each health care licensing board is required to notify the appropriate health authority if the board determines that the complaint concerns certain public health emergencies or other health events, per NRS 439.970.

The new law provides a definition for the term "health care licensing board" to include licensing boards which license, certify or otherwise regulate a provider of health care or other person who may retain health care records. The definition now includes the Health Division of the Department of Health and Human Services, which licenses health care facilities.

If any further clarification is needed, please contact the Bureau of Health Care Quality and Compliance at 775-684-1030.

Signed: 
Tracey Green, MD, State Health Officer
Nevada State Health Division

Date: May 25, 2011

Signed: 
Richard Whitley, MS, Administrator
Nevada State Health Division

Date: May 25, 2011

Electronic Prescribing of Controlled Substances in California

Please see more detailed information on this subject at "Transmission and Receipt of Electronic Controlled Substance Prescriptions," on the Board's Web site under "What's New."

Since at least 2001, California has allowed e-prescribing for controlled substances, excluding Schedule II, subject to "... if authorized by federal law and in accordance with regulations promulgated by the Drug Enforcement Administration." (Health and Safety Code 11164.5[a]). However, the DEA did not permit DEA registrants to e-prescribe controlled substances. Nevertheless, as prescribers, pharmacies, and payers increasingly turn to e-prescribing technology to increase efficiency and reduce expenses, the DEA has searched for ways to reconcile its e-prescribing regulations of controlled substances with those of individual states. Subsequently, the DEA published on June 27, 2008, a proposed rule to permit e-prescribing of controlled substances under specific, fairly detailed requirements. Comment period on the rulemaking closed in September 2008, and the Interim Final Rule (IFR) on e-prescribing of controlled substances became effective and was published in the Federal Register on June 1, 2010. What follows is a very brief summary of the rule.

The DEA's basic prescribing structure has remained consistent: whereas it has previously allowed controlled substances to be prescribed only by using (secure) paper prescriptions, the IFR will make it possible to prescribe Schedules II through V controlled substances by using electronic prescription applications (software systems), transmitted either directly or through intermediaries to pharmacies.

The new IFR requirements affect:

- The companies that develop, sell, and host electronic prescription software applications, electronic health record applications, and pharmacy applications;
- Any DEA-registered prescriber, including any mid-level practitioner who wants to sign and transmit controlled substance prescriptions electronically;
- Any DEA-registered pharmacy that wants to process electronic prescriptions for controlled substances;
- Software application providers must undergo third-party audit or certification to determine whether the application meets DEA's requirements;
- Prescribing practitioners must select application, submit to identity proofing, set access controls; and sign prescriptions; and
- Pharmacies must select software application, set access controls, process prescriptions, and archive prescriptions.

The requirements to participate in e-prescribing include, but are not limited to the following factors:

Identity Proofing: The IFR continues the requirement that practitioners be subject to identity proofing before they are issued authentication credentials (the password[s] and hard token or biometric that permits them to issue e-prescriptions).

Two Factor Authentication: Practitioners must be authenticated to the e-prescribing system by using two of the following three factors: knowledge-based (i.e., password), a hard token, (e.g., a security card that gives a user access to a computer system), and/or a biometric (e.g., scanned iris, fingerprint, etc.).

Creating and Signing E-Prescriptions: Controlled substance prescriptions are required to contain the same data elements as paper prescriptions, but the prescriber is only required to review the patient name, drug information, refill/fill information, and the prescriber's information on-screen before approving/signing the prescription. It will be possible to authorize multiple prescriptions for a single patient with one transaction.

Digital Signatures: The application will apply a digital signature to and archive the required controlled substance prescription information when the practitioner completes the two-factor authentication process (this is his or her way of "signing" the prescription). For those practitioners who have private keys for digital signatures (e.g., those practicing in federal facilities), the private key infrastructure may be used to digitally sign the prescription. The prescription need not be transmitted immediately, because it has been digitally signed (and therefore locked). The IFR also requires the pharmacy or the last intermediary before pharmacy receipt to digitally sign the prescription, and the pharmacy to archive the digitally signed record.

Recordkeeping: All records related to controlled substance e-prescriptions must be retained for two years.

Participation in the transmission and receipt of electronic prescriptions is not mandatory: it is voluntary. The regulations do not mandate that prescribers use only electronic prescribing for controlled substances, nor do they require pharmacies to accept electronic controlled substance prescriptions. Written prescriptions are still acceptable, as are oral prescriptions for Schedule III-V controlled substances. If used, electronic prescriptions for Schedule II-V controlled substances must meet DEA regulatory requirements.

DEA Interim Final Rule on Electronic Prescribing and Receiving Controlled Substance Prescriptions

Questions and Answers for Pharmacies [as of 03/31/2010]

The questions and answers below are intended to summarize and provide general information for pharmacies regarding the Drug Enforcement Administration Interim Final Rule on electronic prescriptions for controlled substances.

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

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

Q. Is the use of electronic prescriptions for controlled substances mandatory?

A. No, the new regulations do not mandate that practitioners prescribe controlled substances using only electronic prescriptions. Nor do they require pharmacies to accept electronic prescriptions for controlled substances for dispensing. Whether a practitioner or pharmacy uses electronic prescriptions for controlled substances is voluntary from DEA's perspective. Prescribing practitioners are still able to write, and manually sign, prescriptions for schedule II, III, IV, and V controlled substances and pharmacies are still able to dispense controlled substances based on those written prescriptions. Oral prescriptions remain valid for schedule III, IV, and V controlled substances. Electronic prescriptions for controlled substances are only permissible if the electronic prescription and the pharmacy application meet DEA's requirements. In addition, electronic prescriptions for controlled substances may be subject to state laws and regulations. If state requirements are more stringent than DEA's regulations, the state requirements would supersede any less stringent DEA provision.

Q. When can a pharmacy start processing electronic prescriptions for controlled substances?

A. A pharmacy will be able to process electronic controlled substance prescriptions only when the application the pharmacy is using to process prescriptions complies with the requirements in the interim final rule.

Q. What must a pharmacy application be able to do to process electronic controlled substance prescriptions?

A. The application requirements are detailed in 21 C.F.R. 1311.205. Generally, the application must be able to import, display, and store the required contents of a controlled

substance prescription accurately and consistently. The application must be able to digitally sign and archive the controlled substance prescription or import and archive the record that the last intermediary digitally signed. The application must electronically accept and store all of the information that DEA requires to be annotated to document the dispensing of a prescription. The application must allow the pharmacy to limit access for the annotation, alteration (to the extent such alteration is permitted by DEA regulations), or deletion of controlled substance prescription information to specific individuals or roles. The application must have an internal audit trail that documents whenever a prescription is received, altered, annotated, or deleted. The application must conduct an internal audit that identifies any potential security problems daily and generate a report for review by the pharmacy if a problem is identified. Many of these requirements are standard functionalities for pharmacy applications.

Q. How will a pharmacy be able to determine that an application complies with DEA's rule?

A. The application provider must either hire a qualified third party to audit the application or have the application reviewed and certified by an approved certification body. The auditor or certification body will issue a report that states whether the application complies with DEA's requirements and whether there are any limitations on its use for controlled substance prescriptions. (A limited set of prescriptions require information that may need revision of the basic prescription standard before they can be reliably accommodated, such as hospital prescriptions issued to staff members with an identifying suffix.) The application provider must give a copy of the report to pharmacies that use or are considering use of the pharmacy application to allow them to determine whether the application is compliant with DEA's requirements.

Q. Until a pharmacy has received an audit/certification report from the pharmacy application provider indicating that the application meets DEA's requirements, how can the pharmacy application be used to process controlled substance prescriptions?

A. A pharmacy cannot process electronic prescriptions for controlled substances until its pharmacy application provider obtains a third party audit or certification review that determines that the application complies with DEA's requirements and the application provider gives the audit/certification report to the pharmacy. The pharmacy may continue to use its pharmacy application to store and process information from paper or oral controlled substances prescriptions it receives, but the paper records must be retained.

DEA Interim Final Rule

Continued from Page 22

Q. What is a pharmacy's responsibility if the pharmacy's application cannot accommodate special DEA requirements, such as extension data for institutional-based practitioners?

A. The audit report the pharmacy will receive from the pharmacy application provider will indicate if the application is capable of importing, displaying, and storing such information accurately and consistently. If the audit or certification report indicates that the pharmacy application cannot accurately and consistently import, store, and display this information, the pharmacy must not process electronic prescriptions for controlled substances that require such information. For example, until the audit or certification report indicates that the pharmacy application can import, display, and store both a hospital DEA number and the individual practitioner's extension number, the pharmacy must not accept electronic prescriptions that include only a hospital DEA registration. The pharmacy may, however, use the application to process other controlled substance prescriptions if the audit or certification report has found that the pharmacy application meets all other requirements.

Q. How does a pharmacy limit access to the pharmacy application?

A. The pharmacy application has to allow the pharmacy to set access controls. These controls may be set either by name or by role (e.g., pharmacist, pharmacy technician). The controls define who has permission to annotate, alter (where such alteration is permitted by DEA regulations), or delete controlled substance prescription information.

Transmission of Prescriptions to Pharmacies

Q. What is an intermediary?

A. An intermediary means any technology system that receives and transmits an electronic prescription between the practitioner and the pharmacy.

Q. If transmission of an electronic prescription fails, may the intermediary convert the electronic prescription to another form (e.g. facsimile) for transmission?

A. No, an electronic prescription must be transmitted from the practitioner to the pharmacy in its electronic form. If an intermediary cannot transmit the electronic data file of a controlled substance prescription to the pharmacy, the intermediary must notify the practitioner. Under such circumstances, if the prescription is for a schedule III, IV, or V controlled substance, the practitioner can print the prescription, manually sign it, and fax the prescription directly to the pharmacy. This prescription must indicate that it was originally transmitted to, and provide the name of, a specific pharmacy, the date and time of transmission, and the fact that the electronic transmission failed.

Q. What are the restrictions regarding alteration of a prescription during transmission?

A. The (DEA-required) contents of a prescription must not be altered during transmission between the practitioner and pharmacy. However, this requirement only applies to the content (not the electronic format used to transmit the prescription). This requirement applies to actions by intermediaries. It does not apply to changes that occur after receipt at the pharmacy. Changes made by the pharmacy are governed by the same laws and regulations that apply to paper prescriptions.

Q. What should a pharmacist do if he/she receives a paper or oral prescription that was originally transmitted electronically to the pharmacy?

A. The pharmacist must check the pharmacy records to ensure that the electronic version was not received and the prescription dispensed. If both prescriptions were received, the pharmacist must mark one as void. The pharmacy is responsible for verifying that the prescription was not received electronically and that no controlled substances were dispensed pursuant to the electronic prescription prior to filling the paper prescription. The paper prescription must comply with all DEA requirements for any paper prescription, including a manual signature.

Q. What should a pharmacist do if he/she receives a paper or oral prescription that indicates it was originally transmitted electronically to another pharmacy?

A. The pharmacist must check with the other pharmacy to determine whether the prescription was received and dispensed. If the pharmacy received the original electronic prescription, but had not dispensed the prescription, that pharmacy must mark the electronic version as void or canceled. If the pharmacy that received the original electronic prescription dispensed the prescription, the pharmacy with the paper version must not dispense the paper prescription and must mark the prescription as void.

Records

Q. What are the DEA requirements regarding the storage of electronic prescription records?

A. Once a prescription is created electronically, all records of the prescription must be retained electronically. As is the case with paper prescription records, electronic controlled substance prescription records must be kept for a minimum period of two years.

Q. Are electronic prescription records required to be backed-up, and if so, how often.

A. Yes, pharmacy application service providers must back up files daily. Also, although it is not required, DEA recommends as a best practice that pharmacies store their back-up copies at another location to prevent the loss of the records in the event of natural disasters, fires, or system failures.

DEA Interim Final Rule*Continued from Page 23***Reporting Security Incidents**

- Q. Is a person who administers logical access controls required to report security incidents?**
- A. Yes, the application is required to run an internal audit for potential security incidents daily and generate a report of any such incidents. If the application generates a report and, upon investigation, the person(s) designated to administer logical access controls for the pharmacy determine that the issuance or records of controlled substance prescriptions has been compromised or could have been compromised, it must be reported to the application provider and DEA within one business day. In general, the security incidents that should be reported are those that represent successful attacks on the application or other incidents in which someone gains unauthorized access.

Audits and Certification of Applications

- Q. Who can conduct an audit or certify an application?**
- A. 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.

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

- A. 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.

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

- A. 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.



Nevada State Board of Pharmacy

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NEVADA STATE BOARD OF PHARMACY

ACTIVITIES REPORT

JULY 13 & 14, 2011 BOARD MEETING HELD IN LAS VEGAS, NEVADA

This report is prepared and presented to keep interested legislators and others abreast of the activities of the Nevada State Board of Pharmacy. Following is a summary of the July, 2011 Board meeting.

Licensing Activity:

- 18 licenses were granted for Out-of-State MDEG (Medical Devices, Equipment and Gases) companies.
- 8 licenses were granted for Out-of-State pharmacies.
- 14 licenses were granted for Out-of-State wholesalers.
- 4 licenses were granted for a Nevada pharmacy (pending inspection).
- 3 licenses were granted for a Nevada MDEG company.
- 1 pharmacist license was reinstated and 1 denied after review of substance abuse progress.
- 1 pharmaceutical technician in training license was approved; 1 tabled; 1 denied after review of prior substance abuse issues.
- 1 pharmaceutical technician license was approved and 1 denied for prior drug abuse issues.
- 2 physician controlled substance registrations were granted after review of previous drug abuse issues (with restrictions).

Disciplinary Action:

- Pharmacist JC was ordered into Your Success Rx (remedial training) for a second misfill. She was put on probation for 2 years as well as other restrictions.
- Pharmaceutical technician YJ was suspended for 120 days and fined \$2500 for working unregistered.
- Pharmacy WG was fined \$750 and ordered a letter of reprimand for dispensing an un-reconstituted antibiotic and not counseling the patient.
- Pharmaceutical technicians RT, CW, TM, DJ and VR were all revoked for the removal of controlled substances for either for personal use or for resale.
- Pharmacists JO was revoked for diversion of controlled substances for use by his wife.

- Pharmacist ED was fined \$1000 for a calculation error on a prescription that resulted in a sub-therapeutic dose in a child with leukemia.
- Pharmaceutical technician FA was fined \$1000 and put on probation for 65 days for working unregistered.

Other Activity:

- The usual Board business reports were given, including recent and future speaking engagements.
- The budget for Board of Pharmacy for fiscal 2011-2012 was presented and accepted; personnel evaluation, including evaluation of the Executive Secretary, was conducted, resulting in very positive comments. There were no COLA or merit raises awarded at the request of the Executive Secretary.
- A discussion was conducted on computerized physician order entry in the hospital setting as well as electronic prescribing progress.