



Washington State Pharmacy Quality Assurance Commission

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No. 1191 Clarification of Newsletter Article No. 1186: Voice Messages Regarding Controlled Substances

Drug Enforcement Administration (DEA) representatives recently clarified that voice messages received from prescribers or their agents for new or refill prescriptions for Schedule III-V controlled substances (CS) may be allowed. The pharmacist has a corresponding responsibility to verify that the prescription received by voice mail is valid and the agent or prescriber is authentic.

Title 21 Code of Federal Regulations (CFR) Section 1306.04(a) states that “[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.” CFR 1306.05 requires that all prescriptions for CS shall be dated and bear the name and address of the patient, drug name, strength, dosage form, quantity prescribed, directions, and the name, address, and DEA number of the practitioner. Voice messages may not always include this required information. Furthermore, CFR 1306.21(c) requires that the pharmacist must promptly reduce to writing an oral prescription from a practitioner containing all information required by CFR 1306.05 (except for the signature of the practitioner).

If you are going to use voice messaging to accept prescriptions for controlled medications, you must be able to verify the prescription information and prescriber as legitimate within the corresponding responsibility of the pharmacist.

No. 1192 Changes Permitted With Hydrocodone/APAP Prescriptions

There have been numerous questions from pharmacists since the October 6, 2014 rescheduling of hydrocodone combination products regarding what can be changed on a Schedule II CS prescription with respect to hydrocodone/acetaminophen (APAP) products. A pharmacist is not permitted to change the name of a drug on a Schedule II prescription. This has created much confusion because of the various brand names and

strengths by which hydrocodone/APAP products are available commercially. The Seattle DEA office has jointly consulted with the Washington State Pharmacy Quality Assurance Commission regarding this issue. The Commission supports the Seattle DEA office regarding permitting the pharmacist to verbally change the milligram amount of APAP contained in a hydrocodone/APAP product, provided there is appropriate documentation by the pharmacist on the hard copy. The pharmacist is permitted to make this change under the following conditions:

1. The prescription is signed on the left side as substitution permitted.
2. The only portion the pharmacist may verbally change is the acetaminophen milligram content. The hydrocodone strength must remain the same.
3. The acetaminophen strength may be verbally changed only after the pharmacist has direct consultation with the actual prescriber. Speaking to a prescriber’s delegate is not permitted.
4. The pharmacist must document on the prescription the direct interaction with the prescriber.

No. 1193 ‘Non-Dispensed’ Prescriptions That Are Returned to Stock

The following guidelines should be considered when the patient has not picked up a prescription ready for dispensing.

- ◆ The pharmacist should inspect the prescription vial and contents to determine whether it is suitable for redispensing.
- ◆ Prescriptions that are deemed appropriate to be returned to stock should never be mixed with stock bottles of different lot numbers or expiration dates. The only way a pharmacist can safely return a medication to the stock bottle is in a pharmacy that tracks all lot numbers and expiration dates on the prescription label.
- ◆ In those instances in which a medication cannot be properly and safely returned to the original stock bottle because of lack of tracking, the pharmacy may hold the medication in the container in which it has been repackaged.

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DEA Finalizes Rule on CS Prescription Drug Disposal

In September 2014, Drug Enforcement Administration (DEA) published its final rule, titled the Disposal of Controlled Substances, that allows some DEA registrants to modify their registration to become authorized collectors. Under the new rule, some DEA registrants, including retail pharmacies, hospitals/clinics with an on-site pharmacy, manufacturers, distributors, reverse distributors, and narcotic treatment programs, may modify their registration with DEA to become authorized collectors. The final rule implements the Secure and Responsible Drug Disposal Act of 2010, which authorized DEA to develop and implement regulations that would allow authorized entities other than law enforcement to collect unused and unwanted prescription drugs, including controlled substances (CS), for disposal purposes. Proper disposal of unused prescription medication is a key method of preventing and reducing prescription drug abuse. The final rule took effect on October 9, 2014.

The full rule is available on the *Federal Register* website at www.federalregister.gov/articles/2014/09/09/2014-20926/disposal-of-controlled-substances.

System-Based Causes of Vaccine Errors

 This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at www.ismp.org. Email: ismpinfo@ismp.org.

Immunizations are widely recognized as one of the most successful and cost-effective health interventions ever introduced worldwide. However, errors with vaccines can result in an unintended and unrecognized source of vulnerability. While the immediate impact of a vaccine-related error on a patient may not be serious, such errors may render the vaccine ineffective or reduce its effectiveness, leaving patients unprotected against serious diseases such as hepatitis A, hepatitis B, diphtheria, tetanus, measles, cervical cancer, and many others. In September 2012, ISMP (in cooperation with the California Department of Public Health) established the ISMP National Vaccine Errors Reporting Program (VERP) to collect data about the type of vaccine errors occurring and the reasons they occur. In ISMP's November 28, 2013 newsletter (www.ismp.org/sc?id=307), ISMP provided a summary analysis of error reports submitted to the ISMP VERP during its first year. The vaccinations that are most frequently associated with errors included *Haemophilus influenzae* type b conjugate (Hib); diphtheria and tetanus toxoids, acellular pertussis

adsorbed, and inactivated poliovirus (DTaP-IPV); tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis adsorbed (Tdap); diphtheria, tetanus toxoid, and acellular pertussis adsorbed (DTaP); hepatitis A (HepA); hepatitis B (HepB); human papillomavirus quadrivalent (types 6, 11, 16, and 18), recombinant (HPV4); zoster; and measles, mumps, rubella, and varicella (MMRV). The most common contributing factors associated with the reported vaccine errors included mistakes in choosing age-dependent formulations of vaccines intended to prevent the same diseases; unfamiliarity with the vaccine, particularly its dose, dosing schedule, age specifications, route of administration, and the vaccine's various components (eg, combination vaccines, diluents, and powder); failure to check or verify the patient's age, health record, or state registry; similar vaccine names and abbreviations; similar and confusing vaccine labeling and packaging; unsafe storage conditions (eg, stored near other similar vaccines or unwanted temperature fluctuations); and expiration dates not noticed or misunderstood.

Practice Recommendations. Involve the patient or parent(s)/caregiver(s) in a vaccine verification process by:

- 1) Documenting the vaccine name, formulation (pediatric or adult, if applicable), lot number, and expiration date on the patient's vaccine record **prior** to preparation/administration of the vaccine,
- 2) Bringing the vial and syringe or the prefilled syringe along with the immunization record into the exam room,
- 3) Asking the patient or parent/caregiver to simultaneously verify the information on the immunization record while a health care provider reads the information on the label aloud,
- 4) Asking the patient or parent/caregiver if the verified vaccine is what he or she expected to be administered (based on an immunization schedule provided to the patient or parent/caregiver previously),
- 5) Preparing and administering the vaccine immediately after verification, and
- 6) Documenting the vaccine on the patient's medical record.

FDA Warns of Growing Network of Rogue Wholesale Drug Distributors

Through a new educational program called Know Your Source, Food and Drug Administration (FDA) is warning pharmacists and other health care providers to watch for counterfeit and unapproved drugs. Aimed at protecting patients from unsafe and ineffective drugs, the program advises providers to only purchase drugs from wholesale drug distributors licensed in their state. Further, FDA offers tips to providers to protect patients, including being wary of offers too good to be true, and ensuring that all drugs received are FDA-approved medications.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous



review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo a site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the United States drug supply.

Additional information about the VAWD program is available in the Programs section of the NABP website. Know Your Source is available at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm.

PTCB Implements Changes to CE Requirements

In 2015, the Pharmacy Technician Certification Board (PTCB) will implement two changes in recertification requirements for certified pharmacy technicians (CPhTs) in accordance with its certification program changes announced in 2013. First, any continuing education (CE) hours earned by a CPhT will need to be pharmacy technician-specific in order to qualify toward recertification. Second, PTCB will reduce the number of allowable "in-service" CE hours from 10 to five. PTCB's certification program changes are intended to support and advance improved patient care and safety throughout pharmacy practice, a PTCB press release indicates. The changes are the result of a PTCB initiative that began with a 2011 summit on future directions for pharmacy technicians.

Additional information can be accessed on the PTCB website at www.ptcb.org.

Security Guidelines Available as Rate of Pharmacy Robberies Still a Concern

Nationally, pharmacy robberies dipped slightly from 745 in 2012, to 713 in 2013, according to a report compiled by *Drug Topics* using DEA statistics. The 10 states that had the most robberies are in stark contrast to other states that had no robberies (South Dakota, North Dakota, and Alaska) or as few as one or two (such as Montana and Illinois), reports *Drug Topics*. However, fueled by the prescription drug abuse epidemic, pharmacy robberies still pose a threat to the safety of personnel and customers. The report lists the top 10 states that had the most pharmacy thefts in 2013. Arizona experienced the most pharmacy robberies in 2013 with 77 incidents, and Indiana took second place with 71 robberies. The report, titled "Top 10 states for pharmacy robberies," may be found at <http://drugtopics.modernmedicine.com/drug-topics/content/tags/arizona/top-10-states-pharmacy-robberies?page=full>.

NABP partnered with DEA to create an educational pamphlet identifying key strategies pharmacists can take to secure their stores against robberies, which can be downloaded at www.deadiversion.usdoj.gov/pubs/brochures/pharmtheft.pdf. In addition, some boards of pharmacy have identified best practices for preventing pharmacy theft, and have supported these practices through regulations or recommendations for their licensees. For example, the New Jersey State Board of Pharmacy's *Pharmacy Security Best Practices* document recommends that all Schedule II and III CS be stored in a "safe or substantially constructed steel cabinet that is locked at all times," with only licensed pharmacists having access.

Additional recommendations include annual pharmacist-in-charge self-assessments and interfacing with prescribers and customers, among others. The best practices document can be downloaded from the New Jersey Consumer Affairs website at www.njconsumeraffairs.gov/press/05012013.pdf.

Private organizations have also developed resources to assist pharmacies in improving security. One such resource is the RxPATROL program, which works with law enforcement, the pharmacy community, and security professionals to maintain a database containing detailed information about pharmacy robberies and other losses. In addition, the RxPATROL website, www.rxpatrol.com, provides training videos and a pharmacy security checklist.

Further, NABP members directed the Association to convene a task force to review strategies that states have taken to prevent theft and drug diversion. The Task Force to Examine Strategies for Preventing and Reacting to Pharmacy Robberies and Thefts met on October 22-23, 2014, to discuss these issues.

Assured Brand Naproxen Tablets Recalled Due to Packaging Error

In October 2014, Contract Packaging Resources of Greensboro, NC, a drug repackaging company, issued a voluntary recall of nearly 12,000 boxes of Assured brand naproxen sodium tablets because some cartons contain bottles of 200 mg ibuprofen softgels instead, a press release posted to the FDA website indicates. The packaging error affected boxes of Assured brand naproxen sodium tablets 220 mg, 15 count (Lot Number FH4102A), which were distributed to and sold at Dollar Tree stores and on the Dollar Tree website. Contract Packaging Resources is contacting customers to arrange for replacement of all recalled products. Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting Program.

More information is available on the FDA website at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm419769.htm.

Martin Avenue Pharmacy Issues Voluntary Recall for All Sterile Compounded Preparations

Martin Avenue Pharmacy, Inc. of Naperville, IL, issued a voluntary recall for all in-date compounded sterile preparations due to a lack of sterility assurance in August 2014. Following a recent FDA inspection that revealed "quality control procedures that present a risk to sterility assurance," the company issued the recall out of an abundance of caution, indicates a news release posted to the FDA website. Martin Avenue Pharmacy supplied compounded sterile preparations to offices of licensed medical professionals and individuals in multiple states including Illinois, Wisconsin, Ohio, Michigan, Florida, Alabama, and Texas until August 20, 2014. A full list of recalled products is available on the Martin Avenue Pharmacy website (registration required). FDA urges consumers and health care providers to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information Adverse Event Reporting Program.

More information is available on the FDA website at www.fda.gov/Safety/Recalls/ucm412431.htm.

- ◆ The expiration date given on the prescription vial shall become the new expiration date of the medication and should be pulled from stock accordingly. Lot numbers are not expected to be found on these return-to-stock vials.
- ◆ If the manufacturer or the United States Food and Drug Administration order a recall for a drug product, pharmacists should assume products held in containers without lot numbers are included in the recall and proceed accordingly.

No. 1194 Naloxone and Collaborative Drug Therapy Agreements

The Washington State Department of Health reports that opiate overdose deaths were level from 2012 through 2013, after the prior decade of increases. From 2008 to 2013, there was a significant decline in pharmaceutical opioid-involved overdose deaths and a significant increase in heroin-involved deaths, with the net result being no change over the past six years. In 2013, there were 381 pharmaceutical opioid-involved deaths and 227 deaths involving heroin.

In the past few years, the Department of Health has helped facilitate prevention tools to help health care professionals and consumers manage opioid use, while also addressing the opioid overdose epidemic. These include pain management rules for health care providers and the Washington State Prescription Monitoring Program, which helps providers see what medications patients are receiving.

The Department of Health, in conjunction with local health departments and law enforcement agencies, will work on expanding availability of naloxone during 2015. Naloxone is a powerful opioid overdose antidote that health care professionals can prescribe for those at risk of an overdose. Naloxone is available in opioid overdose reversal kits in about 12 pharmacies in Washington State in accord with collaborative drug therapy agreements (CDTAs). Pharmacists are encouraged to enter into CDTAs for opioid overdose reversal kits in order to make naloxone more readily available throughout Washington.

More information on opioid overdose reversal kits is available from the Washington State Pharmacy Association.

No. 1195 Wet Signature

What constitutes a wet signature on a CS prescription faxed to the pharmacy?

21 CFR 1306.05(d) states: "A practitioner may sign a paper prescription in the same manner as he would sign a check or legal document (e.g., J.H. Smith or John H. Smith). Where an oral order is not permitted, paper prescriptions shall be written with ink or indelible pencil, typewriter, or printed on a computer printer and shall be manually signed by the practitioner. A computer-generated prescription that is printed out or faxed by the practitioner must be manually signed."

Many electronically generated prescriptions have the capability of attaching a prescriber's signature that has been signed on a signature pad onto the prescription hard copy prior to printing. The signature image that is transmitted to the pharmacy via facsimile may appear pixelated or have slight broken lines. Some systems can save a prescriber's signature for use on pre-

scriptions, and the signature will be identical when transposed. Some prescribers have a stamp of their signature and will stamp prescriptions. These are not wet signatures. Pharmacists are tasked to exercise professional judgment in closely examining prescriptions to ensure that all the prescription requirements are met and, when in doubt, to contact the prescriber to verify.

No. 1196 Election of Commission Officers

Al Linggi, RPh, was elected as chair and Dan Rubin, MPP, was elected as vice chair when the Commission met on December 11, 2014.

Mr Linggi was appointed in 2008, and served previously as the chair of the Commission in 2010. Governor Jay Inslee reappointed him in November 2013, after a one-year hiatus. Mr Linggi chairs the Technology Rules Committee.

Then-Governor Christine Gregoire appointed Mr Rubin to the Commission in 2012. He will complete his first four-year term as a public member in January 2016. Mr Rubin chairs the Pharmacy Business Practices Committee.

No. 1197 Pharmacy Quality Assurance Commission Meetings – 2015

Mark your calendar with the following business meeting dates for the Commission.

- ◆ Thursday, January 29, 2015 – Tumwater, WA
- ◆ Thursday, March 12, 2015 – Des Moines, WA
- ◆ Thursday, April 30, 2015 – Bellingham, WA
- ◆ Thursday, June 11, 2015 – Tumwater
- ◆ Thursday, July 30, 2015 – Renton, WA
- ◆ Thursday, September 17, 2015 – Yakima, WA
- ◆ Thursday, October 29, 2015 – Renton
- ◆ Friday, December 11, 2015 – Des Moines

Commission meetings are open to the public. The Commission encourages pharmacists and auxiliary staff members to attend. Pharmacists and technicians are able to earn up to three contact hours (0.3 continuing education units) of continuing education credit each license renewal period for attending a Commission meeting. While the meetings have a formal structure, there is an open forum session for public comments.

If you are interested in receiving the meeting agenda, please join the interested parties list. Unless otherwise communicated, all meetings are scheduled to begin at 9 AM. Please verify the location address by visiting the [Commission's web page](#). Note: Scheduled locations may change.