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North Dakota State Board of Pharmacy News

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North Dakota 65th Legislative Assembly in Session

The 2017 North Dakota Legislature is currently in session and will continue through April. The North Dakota State Board of Pharmacy has introduced two pieces of legislation.

The first is the Board's customary revisions to the Uniform Controlled Substances Act. This includes new controlled substances (CS) added since the last session as well as updating the Schedule I CS with any illicit chemicals and future modification that could be made to help in protecting our citizens. To be noted, extensive work was done on the analogs of fentanyl, which has been a source of concern across the state recently.

The second is a bill to amend the reportable drugs to the prescription drug monitoring program to include the drug gabapentin. Gabapentin has increasingly become a drug of concern for many health care professionals, and reports increasingly show a trend of individuals obtaining the medication for illicit purposes. This addition will allow health care professionals to monitor and track a patient's history for making appropriate prescribing and dispensing decisions.

There are multiple other pieces of legislation that the Board is tracking and providing input on during the session that impact the Board and the profession of pharmacy. As always, the Board encourages you to stay informed and involved on bills that may impact your practice. Legislators appreciate hearing from their constituents on issues.

Dispensing Prescriptions Generated via Telemedicine Encounter

The North Dakota Board of Medicine is in the process of finalizing rules relative to telemedicine practices provided to our citizens. There are a few important tenets of care via a telemedicine encounter.

- The practice of medicine is deemed to occur in the state where the patient is located. The practitioner providing that care to North Dakota residents needs to be licensed to practice in North Dakota.
- The standard of care and ethics of medicine are uniform, whether practicing traditional face-to-face office visits or through telemedicine encounters. The Board of Medicine allows a patient-practitioner relationship to be developed through a telemedicine encounter. However, this examination must be equivalent to an in-person examination. There must be a video component for clear interaction, and utilization of the appropriate tests and diagnosis methods to ensure the same standard of care that would be expected in the traditional evaluation. Therefore, an examination consisting only of a questionnaire and/or audio conversation is not deemed to be appropriate or legitimate.
- After an appropriate, legitimate telemedicine encounter, the practitioner may prescribe the patient medication according to his or her discretion and judgment appropriate to his or her diagnosis.

For pharmacies and pharmacists, this expansion of medical care can certainly create consequences for determining the legitimacy of prescriptions being presented for patients who have acquired them through a telemedicine encounter.

The Board of Pharmacy's guidance to you in the case of determining the legitimacy of prescriptions being presented by patients who have acquired them through a telemedicine encounter includes the following potential actions.

- Have a discussion with the patient about the interaction with the prescriber. Should there be any concerns about the basis for the prescription, determine if there was a valid patient-practitioner relationship.
- In order to ascertain this, it may be appropriate to contact the prescriber to discuss the patient's prescription. It is not necessary to garner all diagnostic data, such as the patient's labs. However, you should feel comfortable that good patient care was administered. If for some reason you are unable to come to this conclusion, or you are unable to make contact with the prescriber or his or her representative for discussion, this should be cause for concern.
- Verifying the prescriber's licensure with the appropriate licensing board may also be necessary in these cases.

As with **any** pharmaceutical care rendered, the Board expects you to use your professional discretion for each prescription. In no way is there a hard and fast rule, checklist, or easy method to determine the absolute legitimacy of prescriptions given the multitude of ways a patient can receive medical care. A crucial responsibility is placed on you, as professionals, to make a duly diligent effort to feel comfortable

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National Pharmacy

The applicability of articles in the *National Pharmacy Compliance*
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FDA Issues Final Rule Amending List of Drug Products That May Not Be Compounded

Food and Drug Administration (FDA) issued a final rule amending FDA's list of drug products that may not be compounded under certain sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that allow the marketing of unapproved compounded drugs. Drug products on the list may not be compounded because the drug products have been withdrawn or removed from the market for safety or effectiveness reasons, indicates FDA. The list may be found in the Code of Federal Regulations at Title 21, Section 216.24, at *www.ecfr.gov.*

The final rule adds 24 types of drugs to the withdrawn or removed list; modifies the withdrawn or removed list to allow one type of drug product to be compounded under certain circumstances; and clarifies that the withdrawn or removed list applies to sections 503A and 503B of the FD&C Act. The final rule is available at *www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24333.pdf.* FDA provides more information online at *www.fda.gov/Drugs/DrugSafety/ucm524320.htm.*

Selected Medication Risks to Manage in 2017

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.*

Some medication safety risks are painfully apparent in an organization, while many others lie dormant in the system until an error or adverse event draws attention to them. ISMP thought it would be useful to describe selected medication safety risks for organizations to manage in 2017 that might otherwise fall off the radar screen.

Environmental Factors, Workflow, and Staffing Patterns – Poor Quality Lighting

Lighting is a crucial aspect of the physical environment that has been linked to medication safety.[1] Poor quality lighting has often impaired the highly visual tasks associated with medication use, thus leading to medication errors. Examples include tubing misconnections due to low lighting in a patient's room, infusion pumps that have been misprogrammed because of dim backlighting on the screens, and product selection errors in the pharmacy and patient care units caused by low lighting under a pharmacy hood or shadows around an automated dispensing cabinet (ADC).

Despite existing guidelines for lighting in health care, it has been a challenge to implement optimal lighting conditions for prescribing, dispensing, and administering medications. Recent literature reviews found that little system-wide action has been taken to increase staff awareness of the problem or improve the lighting.[1,2] This is largely because the tasks associated with medication use are varied and carried out under diverse physical conditions and in differing locations, and because there are differences in an individual's light requirements based on visual acuity and age. With an ever-increasing population of older health care providers, eye fatigue from computer work and task complexity, small font sizes on medication labels, poor background contrast, and glare or shadows have taken their toll on visual accuracy.[1,2]

Proper illumination improves both the accuracy and efficiency of medication-related tasks. Fluorescent cool white lamps or compact fluorescent lamps should be used in areas where critical tasks are performed, including on mobile medication carts, near ADCs, and in patients' rooms for nighttime administration of medications.[3,4] Administration of medications at night under low lighting to avoid disturbing the patient is an unsafe practice and should be avoided. Adjustable 50-watt high-intensity task lights are recommended when difficult-to-read prescriptions and product labels are encountered.[4] Illumination levels for computer order entry areas should be at least 75 foot-candles (fc), while 100-150 fc are needed when interpreting handwritten orders.[4] Medication preparation areas, medication verification areas, and patient counseling areas should have illumination levels between 90-150 fc.[4] Medication rooms should provide illumination at 100 fc.[4] Lighting levels should be increased if the workforce has an average age above 45 years. A magnifying glass and task light together can also significantly improve accuracy[3] and should be used on mobile medication carts (including those used with bar code medication verification systems)[4] and near ADCs.

References:

1. Chaudhury H, Mahmood A, Valente M. The effect of environmental design on reducing nursing errors and increasing efficiency in acute care settings: a review and analysis of the literature. *Environ Behav.* 2009;41(6):755-786.
2. Graves K. *Nurses' Decision Making Processes About Lighting During Medication Administration* [dissertation]. Denton: Texas Woman's University College of Nursing; 2014.
3. Grasha AF. Psychosocial factors, workload, and risk of medication errors. *US Pharm.* 2002;27(4):HS32-52.
4. United States Pharmacopeial Convention. Chapter <1066> Physical environments that promote safe medication use. *Revision Bulletin.* October 1, 2010;2-6. www.ismp.org/sc?id=1664.

DEA to Decrease Manufacturing Amount of Opioid Controlled Substances in 2017

Drug Enforcement Administration (DEA) is reducing the amount of almost every Schedule II opiate and opioid medication that may be manufactured in 2017 by 25% or more. Other medicines were reduced by more, such as hydrocodone, which will be 66% of last year's level, indicates the DEA news release. DEA notes that demand for these opioid medicines has declined based on sales data from IMS Health, a company that provides insurance companies with data on prescriptions written and prescription medications sold in the United States.

The aggregate production quota (APQ) established by the final order is the total amount of a controlled substance (CS) necessary to meet the estimated medical, scientific, research, industrial, and export needs for the year and for the maintenance

of reserve stocks. The 2017 APQ has been reduced for oxycodone, hydrocodone, fentanyl, hydromorphone, morphine, and other such medications. Much of this reduction is attributed to the elimination of a 25% buffer that was added to the APQ annually in 2013 through 2016 to guard against shortages. The purpose of quotas is to provide an adequate and uninterrupted supply for legitimate medical need of the types of Schedule I and II CS that have a potential for abuse, while limiting the amounts available to prevent diversion.

Additional details may be found in the DEA news release available at *www.dea.gov/divisions/hq/2016/hq100416.shtml* and in the final order available at *https://www.gpo.gov/fdsys/pkg/FR-2016-10-05/pdf/2016-23988.pdf*.

New CDC Brochure Offers Pharmacists Tips for Addressing Prescription Opioid Abuse and Overdose

Centers for Disease Control and Prevention (CDC) released a brochure encouraging pharmacists, who are an essential part of the health care team, to help prevent opioid abuse and overdose. The brochure, "Pharmacists: On the Front Lines," offers tips for communicating with patients who are receiving opioid therapy. In addition, the brochure offers tips on how to identify forged prescriptions and urges pharmacists to maintain collaborative working relationships with prescribers to improve patient outcomes. The brochure is available at *www.cdc.gov/drugoverdose/pdf/pharmacists_brochure-a.pdf*.

FDA Requires Boxed Warnings and Patient-Focused Medication Guides Indicating Serious Risks Related to Combined Use of Certain Opioid Medications and Benzodiazepines

FDA is requiring class-wide drug labeling changes to inform health care providers and patients of the serious risks associated with the combined use of certain opioid medications and benzodiazepines. Specifically, after an extensive review of the latest scientific evidence, FDA is requiring boxed warnings and patient-focused Medication Guides for prescription opioid analgesics, opioid-containing cough products, and benzodiazepines that provide information about the serious risks associated with using these medications at the same time. Risks include extreme sleepiness, respiratory depression, coma, and death.

FDA's news release indicates the changes are part of the agency's Opioids Action Plan, which focuses on policies aimed at reversing the prescription opioid abuse epidemic while providing patients in pain with access to effective and appropriate pain management. The public health crisis is evident through the significant rise of preventable overdose and death associated with the concurrent use of two drug classes, indicates FDA Commissioner Robert Califf, MD, in the press release, available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm*.

FDA's Division of Drug Information Offers CE Webinars for Students and Clinicians

FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information presents a series of continuing education (CE) webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of drug shortages and prescription drug promotion. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/DDIWebinars*.

FDA Approves Labeling Changes for All Prescription Testosterone Products

In October 2016, FDA approved class-wide labeling changes for all prescription testosterone products regarding the risks associated with abuse and dependence of the drug. The changes include adding a new warning as well as updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other anabolic androgenic steroids (AAS). The Anabolic Steroids Control Act of 1990 placed AAS, including testosterone, in Schedule III of the Controlled Substances Act.

Prescription testosterone products are FDA-approved as hormone replacement therapy for men who have low testosterone due to certain medical conditions. However, testosterone and other AAS are abused by adults and adolescents, including athletes and body builders, notes FDA. FDA indicates the new warning will "alert prescribers to the abuse potential of testosterone and the serious adverse outcomes, especially those related to heart and mental health that have been reported in association with testosterone/AAS abuse." In addition, new labeling information in the Warning and Precautions section advises prescribers of the importance of measuring serum testosterone concentration if abuse is suspected.

FDA explains that abuse of testosterone, usually at doses higher than those typically prescribed and usually in conjunction with other AAS, is associated with serious safety risks affecting the heart, brain, liver, mental health, and endocrine system. Reported serious adverse outcomes include heart attack, heart failure, stroke, depression, hostility, aggression, liver toxicity, and male infertility. Individuals abusing high doses of testosterone have also reported withdrawal symptoms, such as depression, fatigue, irritability, loss of appetite, decreased libido, and insomnia. The FDA announcement is available at *www.fda.gov/Drugs/DrugSafety/ucm526206.htm*.

Latest FDA Drug Info Rounds Training Videos Available

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, "Extortion Scam," pharmacists discuss steps a potential victim could take if they receive a call from individuals posing as FDA and DEA agents. Drug Info Rounds is developed with contributions from pharmacists in FDA's CDER, Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

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that the prescription is legitimate and appropriate. The most important final check is your responsibility to counsel the patient on each prescription.

It is important to report any concerns with prescribing activities to the Board of Pharmacy or the appropriate licensing board.

Should you have any concerns or questions, please feel free to contact the Board of Pharmacy.

The Philosophy of Ethics

By Howard C. Anderson, Jr, RPh

Ethics can be a very complicated topic.

As ethics intertwines with morality, it can change and shift as society changes and shifts. Ethics can be based on religion, what is perceived as common law, or the requirements set by laws, rules, or kings.

In health care, ethics has evolved from a common historical thread, which we call the "Hippocratic Oath." The language has changed somewhat with the times, but the original intention is clear. The Hippocratic Oath revolves around service to the patient and service to the profession.

The interplay between ethics, common morality, common laws, and conscience is an interesting one. Standards of practice in a profession or in life are based on what we see others doing and what we perceive as accepted practice.

A child who tells his first lie, steals his first candy bar, or trespasses in an area where he has been told not to go usually feels the pangs of conscience. This conscience may stem from his basic beliefs, but more often it stems from the basic beliefs of those around him. It is a reflection of what he believes will be accepted by others. If he does something in violation of ethical standards, he expects that if he gets caught, there will be some consequences. This may be simply the disapproval of those he respects, on up to more serious consequences that have been previously elucidated, or sometimes are yet unknown.

If the ethical breach is never discovered, the individual harbors that twinge of conscience and carries it forward into the rest of his activities. He may simply avoid other such activities because he does not want that twinge of conscience to rise again. Yet, he continues to know that the ethical standards are in place, that the punishment or disapproval, should this act come to light, remains the same.

If the breach of ethics that has been made by an individual comes to light and is ignored by others, or condoned by others, and the expected consequences are never forthcoming, it makes it easier for that individual to suppress his conscience or the twinge may go away altogether and subsequent activities become easier and easier until the practice becomes endemic.

On the other hand, if his small breach is never discovered, conscience remains a constant thorn and a reminder not to repeat the activity. Thus, it does not affect his ethical perspective on life or professional practice. He knows the activity was wrong, and if it should come to light, the consequences will be invoked. Thus, there is in fact a disincentive to repeat the unethical activity because of the fear that an additional episode may not only bring up that additional episode, but may even bring to light the previous episode as well. Only when the activity comes to light and then no consequences are applied do we begin to relearn that this breach is not as bad as we may have perceived than it might have been. The ethical standard then tends to shift, or move, as we perceive others to condone the practice, or perhaps do not even perceive it as unethical.

An additional aspect of ethics is that the perception of those around us tends to shift as they become aware that our action has come to light, but has not drawn the disapproval or consequences they might have anticipated had they been in our shoes. Thus, the fact that our actions have come to light and incurred no consequences makes it easier for others to perform the same ethical breaches and then not expect consequences that were previously envisioned.

In summary, I would say if we cheat and get caught, we should expect the consequences, and others should expect those consequences to happen to us as well. If the breach comes to light and is ignored or condoned, the practice becomes the standard and serves to shift the ethical base upon which we have pledged our oath.

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