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North Dakota State Board of Pharmacy News

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2019 Inspection Cycle

The North Dakota State Board of Pharmacy's compliance officers have finished the inspection cycle for 2019. This was the first year of utilizing an online inspection process, which, the Board hopes, was beneficial to everyone involved. This new, streamlined process gave pharmacies access to complete their self inspections and Board compliance officers access to finalize the inspection using a tablet device during the on-site visit. As with any new process, the Board identified further changes and updates that are planned to be implemented before the 2020 inspection cycle begins this summer.

Board compliance officers focused on the pharmacy inspections, which included:

- compounding standards;
- consultation – including the technician's ability to screen patients for consultation;
- utilization of quality assurance programs; and
- review of the new and revised administrative rules that impact your pharmacy operation.

The compliance officers did issue a few warning notices against pharmacies based on observed noncompliance with consultation standards. Overall, the cycle went well and reports generally showed pharmacies being compliant and having the desire to ensure that the highest level of care is provided to their patients.

The Importance of Continuous Quality Improvement Programs in Pharmacy Practice

By Mark J. Hardy, PharmD, Executive Director

The Board has recently wrapped up the pharmacy inspection cycle for the 2019 year. During the course of their visits, the compliance officers noted that some of the pharmacies had made stark improvements in various areas of practice, and the Board continues to see a dynamic profession across the state of North Dakota providing excellent care to patients and citizens. The Board thanks you for all your efforts!

I would like to highlight an important requirement that the Board continues to monitor through the compliance officers. This is North Dakota Administrative Code (NDAC) 61-02-09, which is the requirement for pharmacies to maintain an active continuous quality improvement (CQI) program.

While CQI programs are not new in health care, it is true that North Dakota is once again leading the country in ensuring that these programs are initiated, implemented, and working in all pharmacies across the state. The reason that the Board is requiring this in pharmacies is fairly simple. If your pharmacy makes an error, at the very least, the public should expect your pharmacy to learn from that error. This means taking the steps to document the incident, review how it happened, and discuss what can be done to prevent a repeat error in the future.

The compliance officers continue to witness variability in pharmacies complying with this rule of practice. They found pharmacies with vigorous CQI programs and heard great feedback on the improvements that these programs have made in their practice. They also found pharmacies that may not have vigorous CQI programs where the staff does not understand the function of CQI. This indicates leadership in the pharmacy not driving regular reporting of events or meetings to determine improvement of their practice. This finding is deeply concerning.

I want to highlight a few important points that are set forth in NDAC 61-02-09:

- There are three types of occurrences that a CQI program tracks:
  1. **Incident** – means a patient safety event that reached the patient, whether or not the patient is harmed.

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National Pharmacy Compliance News

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The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

DEA Proposes New Regulations to Address Opioid Epidemic

Drug Enforcement Administration (DEA) has announced proposed regulations to improve the agency's ability to oversee the production of opioids and other potentially dangerous drugs. The proposed regulation would further limit the quantities of medications that might be vulnerable to diversion and misuse. The proposal would also amend the manner in which DEA grants quotas to certain registered manufacturers to levels aligned with current manufacturing standards aimed at promoting quality and efficiency while also ensuring the country has sufficient quantities of Schedule II controlled substances (CS) necessary for medical, scientific, research, and industrial needs.

The proposal introduces several new types of quotas that DEA would grant to certain DEA-registered manufacturers. These use-specific quotas include quantities of CS for use in commercial sales, product development, packaging/repackaging and labeling/relabeling, or replacement for quantities destroyed. These quotas are intended to improve DEA's ability to respond quickly to drug shortages.

The proposed changes build on 2018 regulatory changes that gave a role to state attorney generals and other federal agencies in setting the aggregate production quotas for Schedule I and II CS. The proposed regulations are available in the October 23, 2019, *Federal Register* announcement at *https://www.federalregister.gov/documents/2019/10/23/2019-21989/management-of-quotas-for-controlled-substances-and-list-i-chemicals*.

FDA Issues Report on Root Causes and Solutions to Drug Shortages

Food and Drug Administration (FDA) has released a new report, *Drug Shortages: Root Causes and Potential Solutions,* which identifies root causes for drug shortages and recommends three "enduring solutions" to address the shortages. These recommendations include:

- creating a shared understanding of the impact of drug shortages on patients and the contracting practices that may contribute to shortages;
- developing a rating system to incentivize drug manufacturers to invest in quality management maturity for their facilities; and
- promoting sustainable private sector contracts (eg, with payers, purchasers, and group purchasing organizations) to make sure there is a reliable supply of medically important drugs.

In addition to these recommendations, the report outlines the agency's ongoing initiatives to mitigate drug shortages and legislative proposals in President Donald J. Trump's Fiscal Year 2020 budget. FDA also highlighted the need for international action, including global implementation of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use's (ICH's) *ICH Guideline Q12: Technical and Regulatory Consideration for Pharmaceutical Product Lifecycle Management,* which provides opportunities for regulatory flexibility in making post-approval changes to the product or its manufacturing process.

"We hope that the recommendations set forth in this report will help to set a framework that all stakeholders can assess and implement as we work together to further mitigate the public health impact that drug shortages have on American consumers," FDA stated. "In the meantime, the FDA's employees remain committed to working behind-the-scenes to anticipate and help mitigate shortages and make sure that patients have access to the drugs they need."

FDA's full statement is available at *https://www.fda.gov/news-events/press-announcements/statement-fdas-new-report-regarding-root-causes-and-potential-solutions-drug-shortages*.

HHS Announces Guide for Appropriate Tapering or Discontinuation of Long-Term Opioid Use

The United States Department of Health and Human Services (HHS) has published a new guide for clinicians intended to provide guidelines for tapering or discontinuing long-term opioid use. The guide, titled *HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*, covers important issues to consider when changing a patient's chronic pain therapy. The guide also lists issues to consider prior to making a change, when initiating the change, and as a patient's dosage is being tapered, including the need to treat symptoms of opioid withdrawal and provide behavioral health support.

"Care must be a patient-centered experience. We need to treat people with compassion, and emphasize personalized care tailored to the specific circumstances and unique needs

of each patient," said ADM Brett P. Giroir, MD, assistant secretary for health in a press release. "This Guide provides more resources for clinicians to best help patients achieve the dual goals of effective pain management and reduction in the risk for addiction."

FDA Releases Draft Best Practice Document for Postmarket Drug Surveillance

As part of FDA's efforts to enhance the efficiency of its postmarket drug safety surveillance, the agency has released a new best practices document, *Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff*. The draft document outlines FDA's approach for timely postmarket analyses of drugs and biologics, and includes a high-level overview of tools, methods, and signal detection and evaluation activities, using varied data sources, for drug safety. The goal is to provide a broader context and a general overview of ongoing efforts and commitments.

"Our best practices document incorporates the guiding principle that postmarket safety surveillance is a dynamic and constantly evolving field," FDA said in a statement announcing the document's release. "By using a risk-based approach, the FDA takes into account the nature of the drug, its potential adverse events, the intended population, and the potential for serious outcomes, as well as the impact on individuals and the overall potential impact on the health of the public."

The full draft document can be accessed at *https://www.fda.gov/media/130216/download*.

FDA Issues Revised Draft Guidance on Regulation of Homeopathic Products, Withdraws 1988 Compliance Policy Guide

FDA is taking two new steps to clarifying their approach to regulating drug products labeled as homeopathic: revising draft guidance previously published in 2017, and withdrawing the Compliance Policy Guide (CPG) 400.400 issued in 1988. These moves were announced in a statement published on the FDA website. Homeopathic products are often marketed as natural alternatives to approved prescription and nonprescription products and are widely available in the marketplace. Homeopathic products, however, are marketed without FDA review and may not meet modern standards for safety, effectivity, quality, and labeling. FDA uses a risk-based approach to monitor these products and to evaluate reports of adverse events.

The revisions to the 2017 draft guidance provide further information about FDA's approach. The guidance details a risk-based enforcement policy prioritizing certain categories of homeopathic products that could pose a higher risk to public health. These include products with particular ingredients and routes of administration, products for vulnerable populations, and products with significant quality issues. FDA has invited public comment on the guidance before it is finalized. The full guidance and instructions for providing comment are available in the *Federal Register* announcement.

CPG 400.400, Conditions Under which Homeopathic Drugs May be Marketed, is being withdrawn due to inconsistency with the agency's risk-based approach to regulatory and enforcement action and is therefore being withdrawn. Specifically, FDA states that it has encountered multiple issues with homeopathic drug products posing significant risk to patients, even though the products, as labeled, appeared to meet the conditions of CPG 400.400.

DEA Warns of Increase in Scam Calls Targeting Pharmacists and Other DEA-Registered Providers

DEA is warning health care providers and other members of the public of another increase in fraudulent phone calls attempting to extort money. Though the tactics change regularly, the callers typically claim to represent DEA and provide either fake names and badge numbers, or the names of well-known senior officials with DEA. The scammers then threaten legal action, including arrest, against the victim unless large fines are paid by wire transfer. Most recently, the scammers appear to be spoofing a DEA number based out of Salt Lake City, UT, according to a DEA press release.

The agency emphasizes that DEA will never contact practitioners by phone to demand money or any form of payment. DEA will not request any personal or sensitive information by phone, and notification of a legitimate investigation or legal action is always made via official letter or in person.

DEA asks anyone who receives a call from a person purporting to be a DEA special agent or other law enforcement official asking for money to refuse the demand and report the threat using the online form or by calling 877/792-2873. Reporting these calls will assist DEA in investigating and stopping this activity.

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2. **Near miss** – means a patient safety event that did not or could not have reached the patient.
3. **Unsafe condition** – means any circumstance that increases the probability of a patient safety event.

- Pharmacies get to set the policies and procedures around the incidents, near misses, and unsafe conditions that they may track in a CQI program. Some pharmacies may utilize a contract with a patient safety organization, such as Pharmacy Quality Commitment. Other pharmacies may use an internal program to document and evaluate events. Either solution can work. However, the second option involves a bit more commitment to ensure that tracking and evaluations are completed. The Board expects you to set and comply with policies and procedures around your CQI program.
- The CQI program requires the pharmacy to complete a review, at least quarterly, of the documented events and determine if any changes in the pharmacy's practice should occur to account for these events and prevent similar errors. Those changes are communicated to relevant staff to ensure that they are implemented.
- There are built-in protections for a pharmacy's CQI events from discovery, which are being tracked. These records are completely confidential and privileged information to the pharmacy, so third parties (including pharmacy benefits managers), legal proceedings, and others cannot access these records without the pharmacy's authorization. So, simply stated, this is used strictly to improve your practice, not as a punitive rule.
- The Board expects each pharmacist-in-charge to designate someone to be responsible to ensure that the reporting occurs, meetings happen, and discussions ensue in accordance with this rule of professional practice. This is often a delegated task to a registered pharmacy technician.

I cannot stress this enough – CQI programs are not meant to be punitive, but to be used as a way to track and prevent errors. This allows your pharmacy to learn from events and take the steps to prevent a future occurrence.

No professional likes to make a mistake, but the reality is that we are human and no one is perfect. However, taking steps to ensure that mistakes are minimized and not repeated is the professional way to practice and should be a public expectation of the profession.

A working CQI program may seem like just another duty and task in the long list that you need to complete. The reality of a working CQI program can ensure that error rates are low and ensure quality service to your patients and the citizens of North Dakota. It represents a true commitment to the profession and your patients.

From the large retail pharmacies and medical centers, to a critical access hospital and a small telepharmacy, CQI programs are truly impactful!

Dispensing Prescriptions Generated via Telemedicine Encounter

The North Dakota Board of Medicine has implemented laws and rules relative to telemedicine practices provided to North Dakotas's citizens. As we continue to see care provided in various "remote" mechanisms, there are a few important tenets of care to remember when assessing a prescription generated 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 via traditional face-to-face office visits or through telemedicine encounters. The Board of Medicine allows patient-practitioner relationships 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 diagnostic 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 the patient's 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 the prescriptions through a telemedicine encounter.

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The Board of Pharmacy's guidance to you in determining the legitimacy of patient's prescriptions acquired through a telemedicine encounter includes the following potential actions:

1. Have a discussion with the patient about the interaction with the prescriber. Should there be any concerns about the basis for the prescription, the Board of Pharmacy asks that you determine if there was a valid patient-practitioner relationship.
2. In order to determine this, it may be appropriate to contact the prescriber to discuss the patient's prescription with him or her. It may not be necessary to garnish all diagnostic data, such as lab tests; 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 representative for discussion, this should be cause for concern.
3. Verifying the practitioner's licensure with the appropriate licensing board may also be appropriate in these cases.

As with **any** pharmaceutical care rendered, the Board of Pharmacy expects you to use your professional discretion in each prescription. In no way is there a hard-and-fast rule, a checklist, or an 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 take due diligence efforts to feel comfortable 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.

Update on PDMP Registration

The number of pharmacy registrants and requests made by pharmacy registrants has increased quite substantially during the past year. The following charts show the number of pharmacy registrants and subsequent requests made in 2019. The Board is proud of the increase in utilization of the prescription drug monitoring program (PDMP), which continues to be the most powerful patient care tool to prevent and deter prescription drug abuse.

Much of the increase in the number of queries is attributed to the increase in integrations of the PDMP into pharmacy software systems through PMP Gateway. The Board will expect to see further increases in utilization for our profession to ensure compliance with the administrative rules for pharmacies to utilize the PDMP for all controlled substances.

2019 Registrants by Quarter		
Quarter	**Pharmacist**	**Pharmacy Technician**
First	1,256	471
Second	1,276	487
Third	1,254	509
Fourth	1,300	503

2019 Report Requests by Quarter	
Quarter	**Pharmacy Queries Requested**
First	21,052
Second	23,143
Third	28,646
Fourth	61,763

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