Pharmacy Law Update

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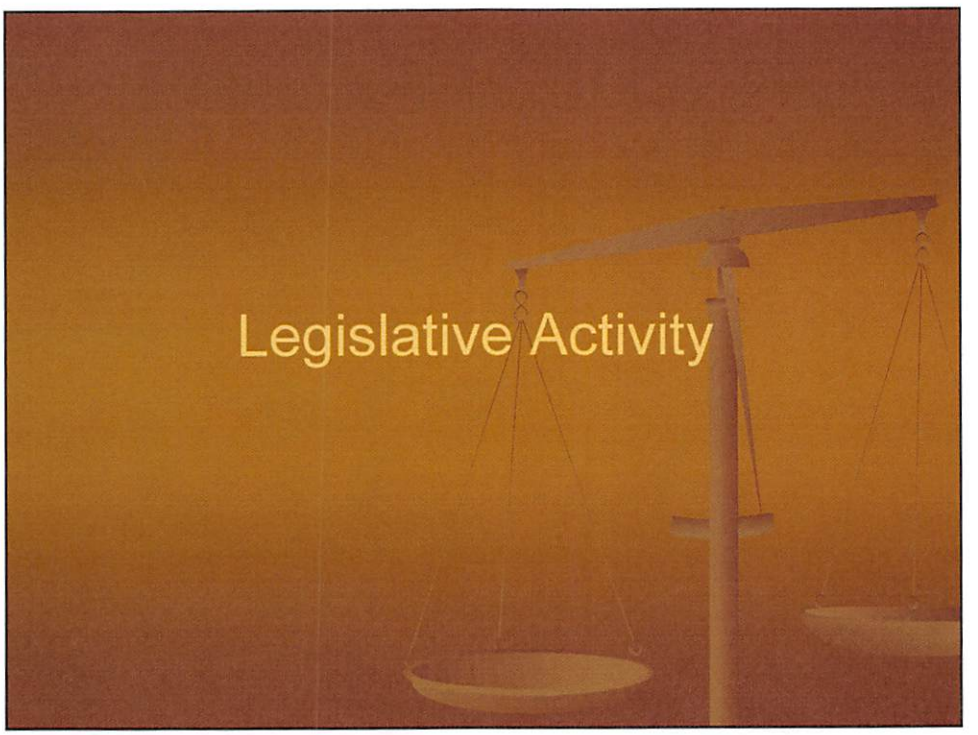
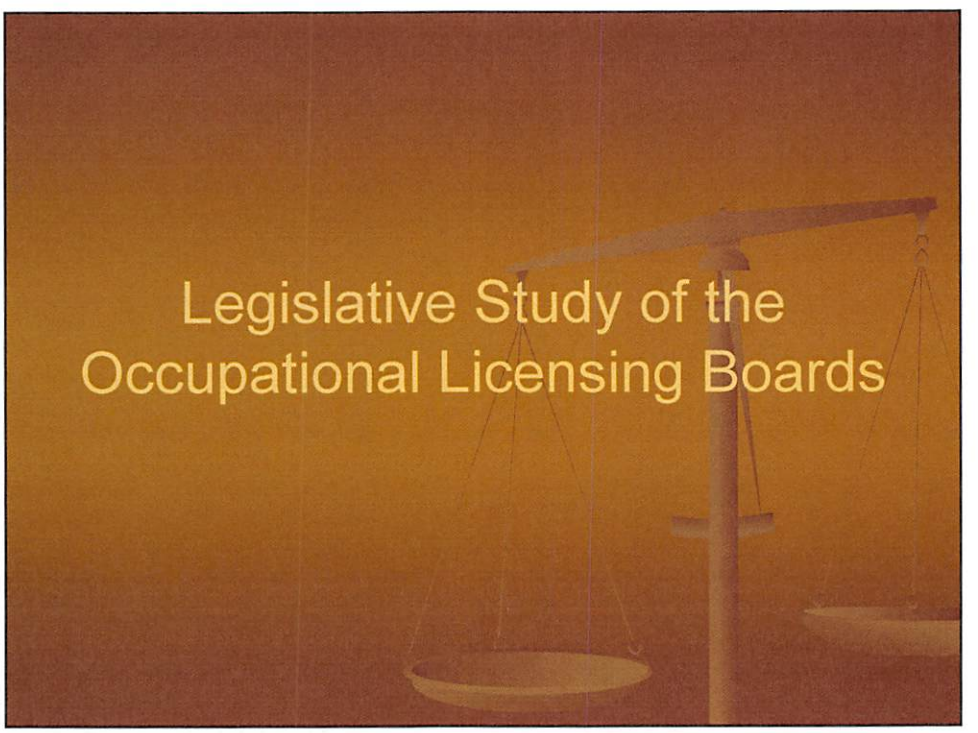

Legislative Activity


Legislative Study of the
Occupational Licensing Boards

2013 Regulatory Reform Law

- Work Plan for the Program Evaluation Division of the General Assembly includes:
  - A study to evaluate structure, organization, and operation of independent licensing boards
    - Determine feasibility of a single state oversight agency for "all or some" of the occupational licensing boards
    - Evaluate cost-effectiveness and efficiency of combining administrative functions, but not regulatory functions
    - Determine whether total number of boards should be reduced by either: combination or elimination

Study is Completed

- The Program Evaluation Division demanded, and received, a great deal of data and information from the occupational licensing boards.
- PED staff met with the licensing boards in late August and early September 2014
- A final report and recommendations was presented to a legislative committee in December 2014 and January 2015.

Key Study Recommendations

- "Stronger oversight" of licensing boards, but not "centralization"
- Consider eliminating 12 licensing boards and consolidating 10 others with other regulatory agencies
- Establish an "Occupational Licensing Commission" to perform certain oversight functions.

Proposed Occupational Licensing Commission

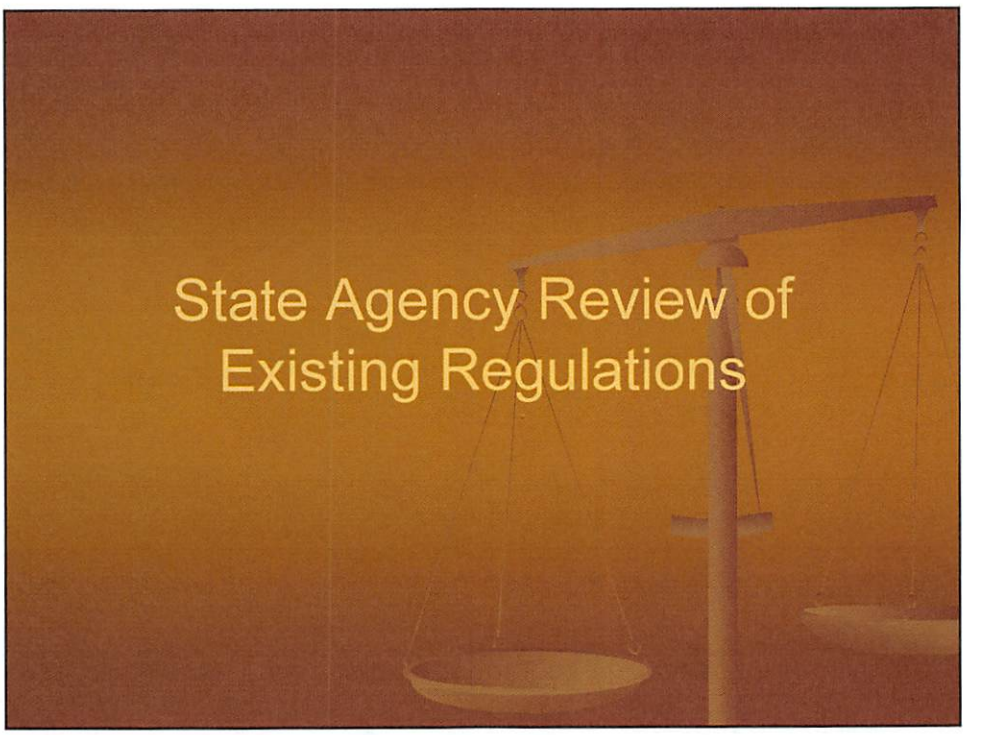
- Would "ensure that OLAs are cost-effectively achieving their objectives and receive proper oversight"
  - Facilitating the "sharing of services" among OLAs.
  - Identify "performance information" to determine whether an OLA is effectively protecting the public; collect and disseminate such information
  - Ensure that an OLA's "complaint resolution process" is effective
  - Mediate "scope of practice" disagreements among licensing boards (ed. note – legislators seem particularly weary of being pulled into these disputes)

Consideration of PED Report Has Heated Up

- Initial legislative reception to the PED report and recommendation appeared to be cool
- The US Supreme Court's decision *Federal Trade Commission v. North Carolina Dental Board*
  - Key holding: State occupational licensing boards are not automatically immune from antitrust liability by virtue of state agency status
  - To avoid potential antitrust liability for regulatory actions, the licensing board must either: (a) not be composed such that a "controlling number" of members are market participants; or (b) subject to "active supervision" of actions by a neutral, third-party state actor with power to reverse or modify decisions
- As a result of that decision, the PED report and recommendations have returned to the forefront of the legislative agenda.

Consideration of PED Report Has Heated Up

- H.765, the latest "regulatory reform" bill contains a provision directing the Joint Legislative Administrative Procedure Oversight Committee to recommend legislation to implement the PED report.
- Expect hearings by JLAPOC over the winter and legislation to be introduced in January.



2013 Regulatory Reform Law

- Periodic Review and Expiration of Rules
  - North Carolina agency, including occupational licensing boards, will have to conduct a review of each and every rule on the books periodically.
  - The Board of Pharmacy has devoted substantial time and effort to rule simplification over the past four years.
  - The Board of Pharmacy is on the Rules Review Commission schedule for a comprehensive review of regulations in 2018.

Bills Introduced in the 2015 Long Session That Touch on Pharmacy Issues

S. 197/H. 195, Biosimilars

- Has been signed into law.
- The Federal Food Drug and Cosmetic Act now provides for approval of "biosimilars" and "interchangeable biosimilars"
- "Interchangeable biosimilars" are, essentially, "generic" versions of biological drug products (e.g., proteins)
- Amends the "equivalent drug product" section of the Pharmacy Practice Act to clarify that, upon a presriber's authorization, a pharmacist could dispense an "interchangeable biosimilar"
- Law requires a pharmacist, after dispensing a biological product, to communicate the "product name and manufacturer of the specific biological product" dispensed to the prescriber "by making an entry into an interoperable electronic medical records system, or electronic prescribing technology, or a pharmacy benefit management system, or a pharmacy record that can be electronically accessible by the prescriber."
- Alternatively, the communication may be by "facsimile, telephone, electronic transmission, or other prevailing means."

S.154, Clarifying the Good Samaritan Law

- Has become law.
- In 2013, a "Good Samaritan" law became effective that allows prescribing of naloxone not only to the prescriber's patients, but to others who are not – e.g., caregivers or others who may be in a position to prevent an opioid overdose death by administering naloxone.
- This bill "clarifies" that pharmacists may dispense naloxone so prescribed (including by standing order). Ed. note– this is confusing as pharmacists plainly had this authority already.
- Clarifies that certain immunity from liability for prescribing or dispensing naloxone under the statute applies to pharmacists.

Further Discussion of Naloxone Distribution

- A number of states have authorized pharmacists to dispense naloxone on their own authority.
- Specific mechanisms vary, but most involve a quasi-prescriptive authority similar to protocol-based vaccine administration.
- The North Carolina Harm Reduction Coalition is interested in pursuing this legislatively.
- Initial reaction from medical groups has been cool. "Scope of practice" turf fighting.

Further Discussion of Naloxone Distribution

- Whether or not a quasi-prescriptive authority for pharmacists comes to pass, the "standing order" provision in current law has been broadly interpreted by Pharmacy and Dental Board staff.
- Public health officials are encouraging local health department medical directors to issue broad standing orders for naloxone, available to any pharmacy wishing to participate.

H.647 Prescribing of Epinephrine Auto-Injectors

- Authorizes prescribing and dispensing of epinephrine auto-injectors on an "entity" basis to any "child-serving businesses" – e.g., summer camps, day care centers
- Similar in some respects to the epinephrine auto-injector requirement for schools enacted last year.
- Personnel at such businesses must be trained to administer. NC DHHS tasked with "accrediting" training programs.
- Passed the House weeks ago. Sitting in a Senate committee.

H.437: Permit Exceptions for Renal Dialysis Products

- Has become law.
- Facilities where dialysate and drugs necessary to perform home renal dialysis are dispensed to patients do not need a pharmacy permit if:
  - Dialysate and drugs are held by a manufacture
  - Delivered to the facility in original manufacturer packaging pursuant to prescriber order
  - Delivered to the patient or to the facility

H.437: Permit Exceptions for Renal Dialysis Products

- Pharmacies may deliver renal dialysis products and drugs to a dialysis center (instead of the patient directly) for eventual dispensing to the patient if:
  - The patient authorizes, in writing, the dialysis facility to act as the patient's designated
  - The medications for home use are dispensed pursuant to a valid prescription order.
  - The delivered medication packages are held in a secure location in an area not accessible to the public.
  - Medication packages are individually labeled with the patient name.
  - The medications are not controlled substances.

H.437: Permit Exceptions for Renal Dialysis Products

- Note that alternative delivery arrangements for pharmacies are growing issue of discussion in a variety of contexts.

CSRS Activity

- Various amendments to the CSRS were floated again.
- None survived "crossover", but any or all could appear on budget bills and the like.
- The "mandatory check/criminal penalty" bill made a second appearance.
- Board expectations on use of CSRS: http://www.ncbop.org/PDF/NCBOPStatementConcerningCSRSUseOct2014.pdf

Board Rulemaking

- Recently completed amendment to Rule .3301.
- Technicians who practice solely at a free or charitable clinic must register with the Board of Pharmacy (previously, registration was not required).
- Such technicians, however, are exempt from the registration fee.
- Implementation requires a programming change. Pharmacists will be notified when the system is ready to receive these registrations.

Board Rulemaking

- Amendments to Rule .1801 concerning right to refuse prescriptions.
- Medical Board has amended its position on telemedicine-generated prescriptions.
- Amendments to .1801 are intended to make Pharmacy and Medical Board requirements consistent.
- Rulemaking complete. Awaiting final RRC clearance.

Board Rulemaking

- Proposed amendment to Rule .2615 regulating off-site storage DME facilities.
- Would allow a properly trained employee of a permitted DME facility to travel to the off-site storage facility, retrieve and deliver DME products directly to the patient.
- Comment period open. Public hearing at Board's September 15 meeting.

Board Rulemaking

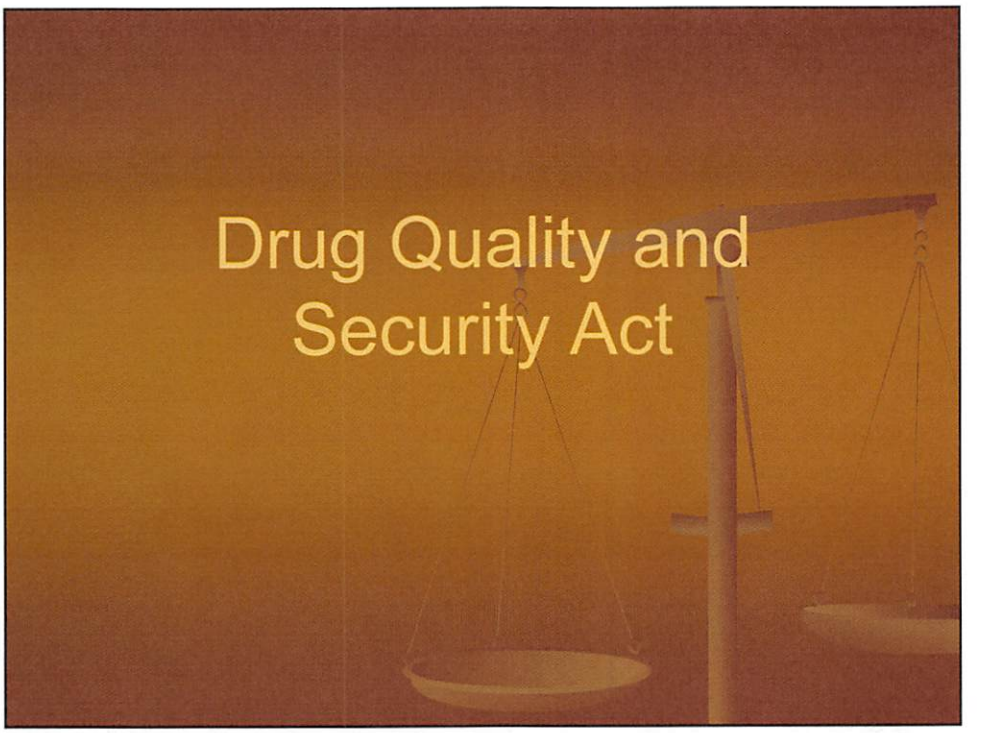
- Proposed amendment to Rule .1417 governing remote medication order entry for health-care facility pharmacies.
- Currently rule only allows "after hours" RMOE.
- Proposed amendment would allow "supplemental" RMOE when a health-care facility pharmacy is open.
- Publication was pursuant to a petition for rulemaking.
- Comment period open until October 15, 2015. Public hearing on September 15, 2015.

Pharmacist Manager Responsibilities

- In recent months, Board field staff saw an uptick in pharmacist-managers stating an inability (or unwillingness) to comply record production requests.
- Some attributed the refusal to various corporate policies.
- Pharmacist-managers are reminded that, by law, they have "accepted responsibility" for the pharmacy's lawful operation.
- A refusal to timely (typically within 48 hours) produce required records will be treated by Board staff as a disciplinary matter.

Pharmacist Manager Responsibilities

- Likewise, timely filing of drug disaster and loss reports required by North Carolina law are the responsibility of the pharmacist-manager.
- Not the responsibility of loss prevention officers, district managers, etc.
- More information is found in the January 2015 Board Newsletter.



DQSA's Focus

- Further refinement of the intersection between state and federal regulation of compounding pharmacy practices.

Section 503A Exempts Certain Compounded Drugs from Federal Requirements

- A pharmacy is exempted from FD&C Act requirements governing adequate labeling directions, cGMP compliance, and the new drug approval process if certain conditions are met.
  - Drug is compounded "on the prescription order for . . . an individual patient."
  - Drug is compounded in "limited quantities before the receipt of a valid prescription order" based on a "history of receiving valid prescription orders" for the compound, and the drug is not dispensed to a patient until a prescription order is received.

Section 503A and "Office Use" Compounding

- Section 503A does not grant an exemption from FD&C Act requirements for "office use" compounds.
- "Outsourcing facilities" under Section 503B (discussed shortly) may compound office use products.
- "Compounded positron emission tomography drugs" and "radiopharmaceuticals" are exempted from Section 503A.
- Section 503A does not apply to veterinary compounding.
- Board staff has prepared a summary guidance document: http://www.ncbop.org/faqs/FAQsDQSA030615.pdf

Section 503A and USP Standards

- Section 503A provides that compounded products must comply with "the United States Pharmacopeia chapter on pharmacy compounding."
- Some read this provision as requiring USP compliance only with respect to selection of ingredients for compounding.
- FDA interprets the provision as applying to the entire process of compounding and its guidance specifically notes that compliance with USP chapters <795> and <797> is required.
- In all events, North Carolina law explicitly requires compliance with USP chapters governing compounding.

Section 503A and Interstate Shipment

- Section 503A limits the ability of compounding pharmacies to ship products interstate.
- A state may enter into a "memorandum of understanding" with FDA to police the distribution of "inordinate amounts of compounded products interstate."
  - Section 503A charges NABP and FDA to work together on a proposed MOU.
- If a state does not enter into an MOU with FDA, compounding pharmacies in that state may not cause more than 5% of their total compounded products to be distributed interstate.

Draft MOU

- On February 13, 2015, the FDA published a draft MOU for commentary.
- It is found here: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm434270.htm
- The comment period ran through July 19, 2015.
- The Board prepared and submitted comments.

Cooperative Monitoring of Section 503A Compliance

- DQSA requires FDA to "immediately notify" a state board of pharmacy if it "makes a determination that a pharmacy is acting contrary to section 503A."
- DQSA requires FDA to receive reports from state boards of pharmacy "expressing concerns that a pharmacy may be acting contrary to section 503A."

Board of Pharmacy Actions

- The Board of Pharmacy has a completed a revision of its compounding rules chiefly aimed at ensuring that these rules do not conflict with federal law. More info: http://www.ncbop.org/rulemakings.htm
- Inspections of compounding pharmacies have long been focused on USP chapter compliance.
- Specific inspection intervals depend on the type of compounding being performed.
- This continues to be a high-priority inspection and enforcement area.
- Board has issued guidance on registration and permitting of 503B outsourcing facilities: http://www.ncbop.org/PDF/GuidancePermittingOutsourcingFacilities071514.pdf.

Board of Pharmacy Actions

- Board staff have noticed a rapid uptick in what appear to be kickback or referral-fee arrangements among prescribers and compounding pharmacists – particularly in the area of compounded topical products.
- North Carolina law expressly prohibits any health care provider from being financially compensated "in any manner" for securing a health care provider's employment by a patient or as a reward for having made a recommendation leading to such employment. NCGS Section 90-401.
- Violation of the referral-free prohibition is a basis for revocation of license.
- Many of these kickback schemes are clothed in bogus "study" garb.

Topical "Pain" Compounds

- Fraudulent prescribing, dispensing, and billing for topical "pain" compounds is endemic.
- Practice has been a focus of intense national news coverage.
- Board staff are active in this area and are working closely with federal law enforcement agencies on civil and criminal matters involving this practice.

Board of Pharmacy Actions

- Board staff is concerned that some pharmacies are not correctly reporting the type and scope of compounding practices performed.
- Accurate reporting of this information is crucial for at least two reasons:
  - Failure to provide accurate information in connection with seeking or renewing a permit is grounds to revoke or void a pharmacy permit.
  - The Board's risk-based inspection intervals are driven by the scope and type of service provided at a pharmacy, particularly compounding services.
- A guidance document is available here: http://www.ncbop.org/PDF/CompoundingRiskLevelsandCategoriesMar2015.pdf

Board of Pharmacy Election

- J. Andrew "Andy" Bowman elected to the Southeastern District seat for a five-year term to commence May 1, 2016.
- Andy is Director of Continuing Education and a Clinical Associate Professor of Pharmacy Practice at the Campbell University College of Pharmacy and Health Sciences.
- Andy is the first Campbell University pharmacy alum to be elected to the Board.

New Board Composition

- Robert Graves of Asheboro has been appointed to the public member position by Governor McCrory.
  - Mr. Graves had a 28-year career in the State Highway Patrol.
  - He is the director of security and emergency preparedness at Randolph Community College.
  - Also serves on the on North Carolina Criminal Justice Information Network Governing Board.

New Board Composition

- Stan Haywood, also of Asheboro, has returned to the Board as the Central District member.
- Stan served two previous terms on the Board and, therefore, brings a wealth of experience.
- Gene Minton has begun serving his second consecutive term as the Northeastern District member.

Board IT Systems

- The Board contracted for a thorough program review by the National Association of Boards of Pharmacy in Spring 2015.
- The review was largely positive, but recommended a number of ways that staff could better leverage technology to serve the public and licensees.
- Board staff is evaluating needs and vendors with an aim to execute a major IT systems upgrade in FY 2015-16.

WBOP – Broadcasting live each month!

- Board meetings are now live-streamed through a YouTube channel. Instructions for connecting are found on the Board's website.

Question, comments, concerns, postulates, theorems, axioms?