Ride the Consulting Wave
"The Presidents Corner"

I am pleased to bring you the Summer Edition of IPS Connect. The newsletter contains industry news, regulatory updates and practice orientated Board of Pharmacy references that may be of interest to members of the pharmacy community.

In this issue you will also find national and local pharmacy headlines, a summary of the recently enacted Massachusetts legislation concerning Massachusetts General Laws Chapter 159 "An Act relative to Pharmacy Practice in the Commonwealth" and other relevant information. I trust you will find this publication informative.

Best regards,

Michael J. Tocco, R.Ph., M.Ed.
President

NEXT ISSUE:

IMPLEMENTATION BREAKDOWN
Concerning New Massachusetts Legislation M.G.L. Chapter 159 "An Act relative to Pharmacy Practice in the Commonwealth"

340B DRUG PRICING PROGRAM TIPS
Self-Assessment is the key since HRSA Program Integrity Audits are on the rise
FY 2012 Audits (51) / FY 2013 Audits (19)
Increase No. of Audits Reported for 2015

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IPS Connect

2014 SUMMER EDITION

> "Quality is the result of high intention, sincere effort, and intelligent direction: which represents the wise choice of many alternatives. - William A. Foster"

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IPS Regulatory Updates In Brief

TRAMADOL CIV Eff. 8/31/2014

Effective August 18, 2014, the DEA has classified the pain reliever **Tramadol** as a **Schedule IV controlled substance**. Please be advised that DEA registered pharmacies that possesses Tramadol on this date shall take an **inventory** of on hand drug in accordance with 21 CFR 1304.03, 1304.04 and 1304.11 (a) and (d). If a **prescription** for Tramadol product was issued prior to 8/18/14, and refills were authorized by an eligible prescriber, as of 8/18/14, related refills must be **limited** to no more than five (5) and must be dispensed no later than six (6) months after the date the prescription was issued.

To open links right click and select open hyperlink
http://www.gpo.gov/fdsys/pkg/FR-2014-07-02/pdf/2014-15548.pdf

FDA DQSA Policy Documents

On July 1, 2014, the **FDA** issued several policy documents related to compounding of drug products for human use as part of the agency's continuing effort to implement the **Drug Quality and Security Act (DQSA**). The **policy documents include**; draft interim guidance regarding FDA expectations for compliance with cGMP requirements for compounding facilities registered as outsourcing facilities with FDA, a proposed rule that would revise FDA's current list of drug products that may not be compounded final guidance for individuals or pharmacies that intend to compound drugs under Section 503A and two federal register notices that reopen FDA's request for nominations for two lists of bulk drug substances (active pharmaceutical ingredients) that may be used to compound drug products.
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm

FDA SAFETY Notices

- June 26, 2014: Oral viscous **Lidocaine** 2% solution should **not be used to treat infants and children** with teething pain.
  http://www.fda.gov/Drugs/DrugSafety/ucm402240.htm
- May 15, 2014: FDA Lowers recommended starting dose of **Lunesta®** from 2mg to 1mg due to the risk of next day impairment.
  http://www.fda.gov/Drugs/DrugSafety/ucm397260.htm

Interchangeable BIOSIMILARS

On June 23, 2014, Massachusetts legislation entitled Chapter 143 "An Act Relative to the Substitution of Biosimilars" was enacted **allowing for the substitution of Interchangeable biosimilars**. According to the FDA, biosimilars are biological products that are "highly similar to a US-licensed reference biological product not-withstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product". Following any such substitution, the dispensing pharmacist or the pharmacist's designee shall notify the patient, or the patient's authorized representative, of the substitution. The **notification shall be written** and may be conveyed by facsimile, electronic transmission, a notation in the patients record system shared with the prescriber or another means consistent with prevailing pharmacy practice. Moving forward, the Massachusetts Department of Public Health may promulgate regulations for implementation and enforcement of this Chapter.
https://malegislature.gov/Laws/SessionLaws/Acts/2014/Chapter143

Legislative/Regulatory Awareness

"The Board shall establish a list of procedural criteria on which a retail sterile compounding pharmacy shall be evaluated at the time of inspection. The procedural criteria shall contain a predetermined list of standards and safeguards upon which a retail sterile compounding pharmacy shall be inspected, as well as a predetermined yet alternating list of variable criteria upon which the pharmacy may be inspected without prior notice as to which subset of these variable criteria shall be included in the inspection."

Can your pharmacy keep up? The true cost of regulatory non-compliance and its effect on your bottom line

"An Act relative to Pharmacy Practice in the Commonwealth"

In today's highly evolving and regulated marketplace, pharmacies are exposed to more risk than ever before. Moreover, with enactment on July 10, 2014, of M.G.L. Chapter 159 "An Act relative to Pharmacy Practice **in the Commonwealth",** https://malegislature.gov/Laws/SessionLaws/Acts/2014/Chapter159 risk management should be an utmost priority for all pharmacies operating in the Commonwealth of **Massachusetts**.

In response to these extensive legislative requirements, has your pharmacy measured operational risk exposure, and if so, instituted appropriate plans of correction and implementation strategies?

If not, consulting services are available to you on short notice wherein IPS can expertly quantify, prioritize and strategize your pharmacies compliance readiness level with both new and existing standards. If desired, IPS can formulate a customized regulatory compliance plan.

>> ADDITIONAL INFORMATION AVAILABLE ONLINE AT WWW.INTEGRATEDPHARMACYSOLUTIONS.COM

Be Familiar with these MA Web Resources:

- **To open links** right click and select open hyperlink
- **MA BOARD OF PHARMACY** (MA BOP)
  http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/
- **ALERTS**:
  http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/alerts/
- **Laws, Regulations & Policies**
  http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/
- **MANDATED REPORT FORMS**
  http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/mandated-reporting-forms-.html
- **APPLICATIONS & FORMS**
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- **Compliance Inspection Form**
  http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/compliance-inspection-tool.pdf
- **Plan of Correction Template**
  http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/plan-of-correction-template.pdf
- **Dispensing of Naloxone Rescue Kits by Standing Order**
  http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/dispensing-of-naloxone-by-standing-order-.html
- **Emergency Regulations Re Dispensing of Hydrocodone-only ER Products**
  http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/pha-247-cmr-8-00-9-00-memo-board-members.pdf
- **Zohydro® FAQ's**
  http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/zohydro-faq.pdf

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Legislative/Regulatory Awareness

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A confidential arrangement to conduct a customized pharmacy orientated compliance gap analysis is one sound solution to proactively, responsibly and effectively ensure compliance with the recent comprehensive legislative changes and preserve your fiscal good standing.

A **synopsis** of the legislation follows:

- The governor shall appoint **13 members** (formerly 11) to the board to include 8 registered pharmacists; 1 pharmacy technician; 1 rep. of the public with experience in health care service delivery, administration or consumer advocacy, 1 physician; 1 nurse; and 1 expert in patient safety and quality improvement
- at least 2 of the 8 pharmacist members shall be employed in the **independent pharmacy** setting
- at least 2 of the 8 registered pharmacist members shall be employed in the **chain pharmacy** setting
- at least 1 of the 8 registered pharmacist members shall have had at least 7 years of experience in a **hospital setting**
- at least 1 of the 8 registered pharmacist members shall have had at least 7 years of experience being employed in **a long-term care pharmacy** setting
- at least 1 of the 8 registered pharmacist members shall have had at least 7 years of experience in the practice of **sterile compounding**
- at least 1 of the 8 registered pharmacist members shall be employed in an **academic** or scholarly position related to the practice of pharmacy with an institution of higher learning

*"The Board may assess a pharmacy a penalty of not more than **$25,000 for each violation** of regulations or administrative rules governing the practice of pharmacy"*

- Board members shall be appointed and shall serve for a **term of 3 years**
- No member shall serve more than 2 consecutive terms on the board
- All drug preparations compounded, made or formulated by a pharmacy licensed by the board of registration in pharmacy shall have affixed to their container by the compounding pharmacy a **label** notifying prescribed users and practitioners that the drug is either a sterile or non-sterile compounded drug preparation
- All pharmacies engaged in sterile or complex non-sterile compounding and licensed under sections 39G to 39I, inclusive, of chapter 112 shall **provide a telephone number** to foster communication between patients in the commonwealth and a pharmacist employed by the pharmacy who has access to the patient's records
- New amended definition for "**Serious adverse drug event"**
- A facility that discovers a serious adverse drug event resulting from a patient's use, consumption or interaction with any pharmaceutical or drug preparation, **shall report** the event to the FDA's MedWatch Program, as well as the pharmacy from which the drug was produced, compounded or dispensed
- Board may **establish additional specialty pharmacy licensure** categories
- Board shall require each **RPH seeking renewal** of a personal registration **shall complete a minimum of 20 contact hours each calendar year of the 2 year renewal cycle**
- Any RPH overseeing or directly engaged in the practice of sterile compounding or practicing in a pharmacy licensed pursuant to section 39G or 39I shall devote **at least 5 of the 20 contact hours to the area of sterile compounding**
- Any RPH overseeing or directly engaged in the practice of complex non-sterile compounding or practicing in a pharmacy licensed pursuant to section 39H shall devote **at least 3 of the 20 contact hours to the area of complex non-sterile compounding**
- RPH not in compliance with **continuing education** requirements or who fail to provide the requested documentation within 7 days of receiving a request shall be **fined not more than $1,000**.
- New definition for "**accountability documentation**" including but not limited to evidence of receipt of patient-specific prescriptions prior to dispensing to facilitate tracing of a complex non-sterile drug preparation or sterile drug preparation back to the pharmacy where it was compounded

>> ADDITIONAL INFORMATION AVAILABLE ONLINE AT WWW.INTEGRATEDPHARMACYSOLUTIONS.COM

- A pharmacy **shall inform** MA DPH of any improper dispensing of a prescription drug that results in serious injury or death, as defined by the department in regulations, as soon as is reasonably and practically possible, but not later than **7 business days after discovery** of the improper dispensing
- Manager of Record of a pharmacy shall report any serious adverse drug event, as defined in section 51H of chapter 111, occurring as a result of the patient's interaction with any drug or pharmaceutical manufactured, produced or compounded at the manager of record's pharmacy, to the board, the federal Food and Drug Administration MedWatch Program and the Betsy Lehman center for patient safety and medical error reduction. This **data shall be reported to the board within 7 business days of the knowledge** of any serious adverse drug event by any pharmacy employee
- If a pharmacy knows or should have reason to know that a drug preparation compounded, dispensed or distributed by the pharmacy is or may be defective in any way, the pharmacy shall **immediately recall the drug preparation**
- A **defective drug preparation log** documenting the recalled drug preparation shall be kept by the pharmacy
- The defective drug preparation log shall be made available to the board within 7 days of the recall and shall be **kept on record for at least 10 years**
- A pharmacy shall not engage in **sterile compounding** nor shall a pharmacy prescribe, ship, mail, sell, transfer or dispense sterile drug preparations in the commonwealth **unless the pharmacy has obtained a license from the board**
- No pharmacy shall engage in **complex non-sterile compounding** nor shall a pharmacy prescribe, ship, mail, sell, transfer or dispense complex non-sterile drug preparations in the commonwealth **unless the pharmacy has obtained a license from the board**
- All retail **sterile compounding pharmacies** and retail **non-sterile compounding pharmacies shall report to the board, on an annual basis**, a list of prescriptions dispensed within and outside of the commonwealth, as well as the volume of these prescriptions
- All retail **sterile compounding pharmacy** and retail **non-sterile compounding pharmacies** licenses shall not be renewed until the licensee **certifies** that their **employees** have been **trained in lean concepts**
- Board shall establish a list of **procedural criteria** on which a retail **sterile compounding pharmacy** and retail **non-sterile compounding pharmacies** shall be **evaluated** at the time of **inspection**
- Board shall develop a **quality assurance procedure** for **sterile compounding pharmacies**
- Board shall establish **supplementary regulations for all retail sterile compounding pharmacies** and **retail non-sterile compounding pharmacies** intending to compound or dispense sterile drug preparations in the commonwealth
- Board shall establish a category of pharmacy **licensure for institutional pharmacies engaged in sterile compounding**
- All **institutional sterile compounding pharmacies shall report to the board, on an annual basis**, a list of prescriptions dispensed within and outside of the commonwealth, as well as the volume of these prescriptions
- All **institutional sterile compounding pharmacies** licenses shall not be renewed until the licensee **certifies** that their **employees** have been **trained in lean concepts**
- Board shall establish **supplementary regulations for all institutional sterile compounding pharmacies**

Be Familiar with these CT Web Resources:

- To open links right click and select open hyperlink
- **CT COMMISSION OF PHARMACY** (CT COP) http://www.ct.gov/dcp/cwp/view.asp?a=1620&Q=273844&PM=1
- **1ST Time Pharmacy Manager Overview**: http://www.ct.gov/dcp/lib/dcp/commission_-first_time_manager_questions_and_answers.pdf
- **Laws &Regulations (Drugs and Pharmacy)** http://www.ct.gov/dcp/cwp/view.asp?a=1618&q=275808&dcpNav=|#p
- **Commission Agendas & Meeting Minutes** http://www.ct.gov/dcp/cwp/view.asp?a=1620&q=275872
- **LICENSING & APPLICATIONS** http://www.ct.gov/dcp/cwp/view.asp?a=4332&q=273650
- **Pharmacist Licensing** http://www.ct.gov/dcp/cwp/view.asp?a=1620&q=514244

- **Non-Resident Pharmacy Reg.** http://www.ct.gov/dcp/cwp/view.asp?a=1620&q=512970
- **Verify a License**) http://www.ct.gov/dcp/cwp/view.asp?a=4308&q=507962
- **Fees & Renewal Dates** http://www.ct.gov/dcp/lib/dcp/pdf/forms/license_types,_prefix_&_fees14.pdf
- **News Releases** http://www.ct.gov/dcp/cwp/view.asp?a=1684&q=425186&dcpNav=|
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- **Check Application Status** https://www.elicense.ct.gov/
- **Renew On-line** **http://www.ct.gov/dcp/cwp/view.asp?a=1622&q=520536**

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Legislative/Regulatory Awareness

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- Board shall **establish a procedure to license non-resident pharmacies,** which prescribe, ship, mail, sell or dispense medications in the commonwealth, that pertains to the practice of pharmacy
- A **non-resident pharmacy** shall **designate a pharmacist in charge** who shall register with the board and shall be responsible for the pharmacy's compliance with this chapter
- Board shall **participate in any national data reporting system** which provides information on individual pharmacies, pharmacists and pharmacy technicians including, but not limited to, relevant databases maintained by the National Association of Boards of Pharmacy and the federal Food and Drug Administration.
- Board or board president may, without holding a hearing, **suspend or refuse to renew a pharmacy license** if the board or board president finds reasonable cause to believe that the health, safety or welfare of the public warrants the summary action; provided, however, that the board shall, within 7 days of such action, afford the licensee the opportunity of a hearing pursuant to chapter 30A
- Board shall **promulgate regulations** pertaining to the **issuance of cease and desist and quarantine notices**

*"The **Board may assess a pharmacy** ordered to correct a violation of regulations or administrative rules governing the practice of pharmacy, **a penalty of not more than $1,000 for each violation for each day the violation continues to exist beyond the date prescribed for correction**"*

- The commissioner of public health **shall develop and operate a searchable website**, which includes:
  (i) copies of all **enforcement action records** of any pharmacy or pharmacist licensed by the department whether they are located within or outside of the commonwealth;
  (ii) copies of any records of **serious adverse drug events**, as defined in section 51H of chapter 111, and data relative to such events collected and reported pursuant to section 39D, suffered by a patient or user of medications as a result of their use of medication prepared, made or constituted by a pharmacy or pharmacist licensed by the board whether within or outside of the commonwealth;
  (iii) the **names, locations and central points of contact for all licensed compounding pharmacies** based in the commonwealth as well as licensed non-resident pharmacies shipping compounded drugs into the commonwealth; and
  (iv) any other relevant information specified by the commissioner
- The **searchable website** shall include and **retain information** for not less than **10 years**
- Board shall require each RPH seeking renewal of a personal registration shall complete a minimum of **20 contact hours each calendar year of the 2 year renewal cycle**
- There shall be an **advisory committee to the board**. The committee **shall consist of** the commissioner of public health or a designee and 7 members who shall be appointed by the commissioner: 1 of whom shall be an expert in chapter 71 of the USP; 1 of whom shall be an expert in chapter 795 of the USP; 1 of whom shall be an expert in chapter 797 of the USP; 1 of whom shall be an expert in cGMP for aseptic processing; 1 of whom shall be an expert in pharmacoeconomics; 1 of whom shall be an expert in clinical pharmacology; and 1 of whom shall be a microbiologist
- Each member of the **advisory committee** appointed by the commissioner shall serve for a **term of 3 years**
- The **advisory committee shall** evaluate the practice of pharmacy across all settings and **recommend to the board any new or revised regulations and policies** necessary to improve the delivery of pharmacy services in the commonwealth

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- **Advisory committee shall advise the board**: on the establishment of **specialty pharmacy licensure** categories; on the development of **quality assurance**, **inspection** and **testing procedures** applicable to compounding; on the application of **accountability documentation** requirements in licensed sterile pharmacies and complex non-sterile pharmacies; the **development** of **regulations to supplement the USP**, all chapters; and any other area as requested by the board
- **Advisory committee** shall **evaluate the volume and revenue** of drug preparations generated by each licensed sterile compounding complex non-sterile compounding pharmacy and pharmacy in the commonwealth
- A**dvisory committee shall monitor** existing or potential **shortages** of medically necessary **drug products**
- **Board may assess a licensed pharmacy a penalty of not more than $25,000 for each violation of regulations or administrative rules** established pursuant to any general law that governs the practice of pharmacy
- **Board may assess a pharmacy**, licensed pursuant to this chapter and ordered to correct a violation of regulations or administrative rules established under any general law that governs the practice of pharmacy**, a penalty of not more than $1,000 for each violation for each day the violation continues to exist beyond the date prescribed for correction**
- **Assessments collected** related to these penalties shall be deposited in **the Quality in Health Professions Trust Fund** and shall be used to support particular initiatives
- **Board shall promulgate regulations for the administration of the fund,** in consultation with the division, including the establishment of eligibility criteria, program requirements and assessment and reporting processes
- Board may issue **a 1-time provisional license** for a period of not more than 1 year to an applicant for an initial pharmacy **specialty license**
- The department of public health (DPH), in consultation with the board of registration in pharmacy and the advisory committee shall conduct an **investigation of emerging models of coordinated, remote and shared pharmacy services**, including but not limited to: central fill pharmacies; central processing pharmacies; outsourcing facilities and telepharmacy
- The **department shall also issue a report indicating its support for or opposition to the adoption of certain pharmacy models in the commonwealth** and identifying those elements of said models that should be promoted in support of the commonwealth's efforts to promote efficient, cost-effective and patient-centered health care in community settings and within integrated care systems
- The **department shall file the report** on its investigation, including its recommendations and drafts of any legislation, if necessary, by filing the same with the clerks of the senate and house of representatives who shall forward a copy of the report to the joint committee on public health and the joint committee on health care financing **not later than December 31, 2015**
- The **board** of registration in pharmacy shall, in **consultation** with **DPH**, and **not later than December 31, 2014**, **promulgate regulations** establishing the requirements for **specialty licensure related to retail sterile and complex non-sterile compounding pharmacies and non-resident pharmacies**
- The **board** of registration in pharmacy shall, in **consultation** with **DPH**, and **not later than June 30, 2015**, **promulgate regulations** establishing the requirements for **specialty licensure related to institutional pharmacies engaged in sterile compounding**

Be Familiar with these NH Web Resources:

- To open links right click and select open hyperlink
- **NH BOARD OF PHARMACY** (NH BOP)
  http://www.nh.gov/pharmacy/index.htm
- **FAQs**:
  http://www.nh.gov/pharmacy/faq/index.htm
- **Laws, Regulations & Policies**
  http://www.nh.gov/pharmacy/laws/index.htm
- **DOCUMENTS & PUBLICATIONS**
  http://www.nh.gov/pharmacy/publications/index.htm
- **LICENSING & APPLICATIONS**
  http://www.nh.gov/pharmacy/licensing/index.htm
- **ABOUT THE BOARD**
  http://www.nh.gov/pharmacy/aboutus/index.htm
- **VERIFY A LICENSE**
  http://www.nh.gov/pharmacy/licensing/verification.htm

- **Report Changes to the Board**
  http://www.nh.gov/pharmacy/technicians/reporting_changes.htm
- **Prescription Drug Monitoring Program**
  http://www.nh.gov/pharmacy/prescription-monitoring/index.htm
- **Pharmacist Application to Administer Vaccines**
  http://www.nh.gov/pharmacy/documents/vaccines_app.pdf
- **Proposed Rules**
  http://www.nh.gov/pharmacy/laws/proposed-rules.htm
- **Board Meetings: Agendas & Minutes**
  http://www.nh.gov/pharmacy/aboutus/meetings.htm
- **Board Policy Re Changes to CII Rx**
  http://www.nh.gov/pharmacy/documents/cii-changes-nh-bop.pdf
- **Continuing Education**
  http://www.nh.gov/pharmacy/pharmacists/continuing_education.htm