I. REGULATIONS

Board of Pharmacy

Automated Pharmacy Systems in Institutional Pharmacies: The Board of Pharmacy approved proposed changes to 201 KAR 2:074 dealing with the use of automated pharmacy systems in hospitals and other health facilities. The changes were made based on input from hospital pharmacies and were approved by the Regulations Committee. The amended regulation was published February 1 and the public comment period ended February 28. The Board received several comments on the proposal and considered those changes at its March meeting. We expect a revised regulation to be considered at the May meeting of the Administrative Regulations Review Subcommittee.

Automated Pharmacy Systems in Long Term Care Facilities: The Kentucky Board of Pharmacy Regulations Committee is working on proposed regulatory changes dealing with the use of automated pharmacy systems in long term care facilities.

Department for Medicaid Services (DMS)

The Department for Medicaid Services has issued a series of new regulations establishing the guidelines for the new Medicaid managed care system in Region 3. The regulations outline the policies and procedures for recipients, providers and managed care organizations for the plans operating in Jefferson and surrounding counties. The regulations were filed as both emergency and ordinary regulations. The regulations essentially implement the contractual requirements between Medicaid and the four MCOs that began providing services in the region on January 1, 2013. The public comment ended on February 28, 2013 and we are awaiting a response from DMS.

II. 2013 LEGISLATIVE ISSUES

See 2013 KPhA Session Summary
Overview: KPhA gratefully acknowledges the engagement of pharmacist members throughout the Commonwealth who made legislative advocacy a personal priority during the 2013 legislative session. Pharmacists were united in your resolve to make a difference by conducting regular telephone calls and engaging in one-on-one conversations with your state senators and representatives. From the Government Affairs Committee, Chair Richard Slone, and the entire Board of Directors: Give yourself and your colleagues a well-deserved “pat on the back” for your due diligence and commitment. Your advocacy continues to make a difference! For the second year in a row, the top priority for YOUR KPhA advanced through the legislative process, this year without a dissenting vote! Be sure to thank your legislators and let them know what their support means to pharmacy in Kentucky.

KPhA acknowledges and thanks our advocacy partners for this session: American Pharmacy Cooperative, Inc., American Pharmacy Services Cooperative, EPIC Pharmacies, Inc., Kentucky Independent Pharmacy Alliance, Kentucky Retail Federation, National Association of Chain Drug Stores, and the National Community Pharmacists Association.

Lawmakers adjourned the 2013 General Assembly at midnight March 26, 2013. This year’s session was a busy and productive one for YOUR KPhA. The KPhA grassroots efforts led to passage of the association’s three key legislative priorities including PBM transparency legislation (SB 107), revisions to Kentucky’s controlled substance statutes (HB 217) and a clarification of the state’s pseudoephedrine law (HB 8). KPhA also was successful in stopping legislation restricting the substitution of opioids (HB 74), another legislative priority. The KPhA legislative team followed more than 30 pharmacy-related bills this session and the Association had significant input on many of these measures.

The following summary provides a narrative regarding the activity on some of the major issues affecting the pharmacy community that were considered during this year’s legislative session. This electronic version of the 2013 Summary of Pharmacy Issues includes links to the legislature’s official website so you can easily access the complete summaries prepared by legislative staff and all action on the measures, as well as review the full text of individual bills and resolutions. Bills enacted during the 2013 Session will take effect on June 25 unless a specific effective date was included in the legislation or the legislation contained an emergency clause which makes it effective as soon as it is signed by the Governor.

Pharmacy Benefit Managers (PBM): Governor Steve Beshear signed SB 107 on March 22. The bill represents a major victory for Kentucky’s pharmacies as it establishes a set of basic disclosures that PBMs must make in their dealings with contracted pharmacies. It requires that a PBM disclose in its contract with the pharmacy the pricing indices used to calculate the reimbursement paid to the
pharmacy for drug products. It also specifies that if the PBM uses maximum allowable cost (MAC) to determine reimbursement, it must disclose to the pharmacy what products are subject to MAC and what the MAC is for each of those drugs. **SB 107** requires PBMs to update MAC lists at least every 14 days and establishes parameters for price appeals by pharmacies. The bill was amended in the Senate to delay the requirement that PBMs provide retroactive reimbursement for successful MAC appeals. That language requires the PBM to include in their contracts with pharmacies a process for retroactive reimbursement for successful appeals no later than one year following the effective date of the act. The bill was sponsored by Senate Health and Welfare Committee Chairman Julie Denton (R-Louisville) and had broad bipartisan support in both chambers, passing without a single no vote in either chamber.

**Controlled Substances:** A bill revising the comprehensive anti-prescription drug abuse law enacted in 2012 quickly won legislative approval and was signed into law by the Governor on March 4. **HB 217**, sponsored by House Speaker Greg Stumbo (D-Prestonburg), incorporated many suggestions put forth by physicians, KPhA member pharmacists, Executive Director Robert McFalls and law enforcement officials brought up in hearings on the issue during the interim. It was designed to mitigate some of the unintended consequences caused by the passage of HB 1 during a 2012 special session. Two major changes of interest to pharmacies are included in the proposal. **HB 217** eliminates the requirement that hospitals and long term care facilities report drugs administered directly to patients to the state’s electronic controlled substances database (KASPER). Another provision eliminates the need for pharmacists to report the loss or theft of controlled substances to the state police. This requirement created unnecessary duplicate reporting requirements since pharmacists must already file reports with the DEA, Board of Pharmacy and local law enforcement officials. Both of these changes were requested by KPhA members and partners during the interim hearings. **HB 217** contained an emergency clause making it effective upon the Governor’s signature (March 4).

**REMINDER FROM 2012 Session:** As a result of HB 1 from 2012, pharmacies will be required to report to KASPER by the end of the next business day beginning on July 1, 2013.

**Pseudoephedrine Sales:** Unlike recent legislative sessions, the issue of pseudoephedrine (PSE) sales was not at the forefront. One measure relating to PSE sales, however, was acted upon by the legislature and is now law. **HB 8**, a bill dealing with synthetic drugs, contained a provision clarifying that pharmacies may continue to use a written signature to comply with the state’s PSE purchasing restrictions. The language was supported by Kentucky’s pharmacy community and the Kentucky Office of Drug Control Policy. A stand alone bill, **HB 146**, also addressed the issue but that measure stalled in the House. Since **HB 8** contained an “emergency clause”, it became effective on March 19.

**Medicaid Managed Care:** A number of proposals dealing with Medicaid managed care were filed this session but only one was approved by the legislature and that measure was vetoed by Governor Beshear. House Speaker Greg Stumbo (D-Prestonsburg) sponsored the legislation granting the Department of Insurance more authority over payments to providers by Medicaid Managed Care Organizations (MCOs). **HB 5** was a response to ongoing problems health care providers are experiencing with getting paid for services provided to Medicaid recipients enrolled in managed care. Currently, providers have to deal with both the state Medicaid agency and the Department of
Insurance to resolve payment delay issues. Oftentimes providers are frustrated with their inability to get final resolution. HB 5 seemed to stall in the Senate but ultimately received approval in the last days of the 2013 Kentucky General Assembly. Governor Beshear, however, vetoed the bill on April 5 and since the legislature adjourned in March, there was no opportunity to override the veto. Beshear issued a press release following the veto pledging to aggressively pursue a plan to ensure prompt payment to health care providers participating in Kentucky’s managed care Medicaid system.

Although Governor Beshear vetoed the bill, he announced a multi-pronged action plan to address the legislature's concerns, including:

- Prompt pay disputes to be reviewed by Ky. Dept. of Insurance: Keeping with the intent of HB5, the first action directed by the Governor is to move all responsibility for governmental review of provider complaints relating to prompt payment of medical claims from DMS to DOI. DOI has a well-established prompt payment dispute resolution process in place for use in the private health insurance market. This mechanism will allow for efficient review and resolution of claims. If improper payment practices are discovered, DOI can impose sanctions.

- Targeted audit of each statewide MCO by Ky. Dept. of Insurance: The Governor is directing DOI to conduct targeted audits of the three statewide MCOs. These reviews, called "Targeted Market Conduct Examinations," will seek out whether systemic changes are needed to address areas such as claim or complaint handling, prior authorization practices, or emergency medical service payments. MCOs will pay for the examinations, and reports are expected to be complete no later than August 15. Failure to comply with policies will result in sanctions.

- Education forums on best practices: The Governor is directing enhanced educational efforts to improve the managed care system. The Cabinet for Health and Family Services (CHFS) will sponsor educational forums in each of the eight Medicaid regions to allow medical providers, MCO representatives, and DOI representatives to meet face-to-face to discuss concerns about proper billing, appeals processes and any specific regional issues related to managed care. In addition, these forums are designed to foster conversations about how to improve the overall system of health care delivery.

The governor's full press release can be viewed at http://migration.kentucky.gov/Newsroom/governor/20130405hb5.htm

Representative Bob Damron (D-Nicholasville) and Senator Bob Leeper (I-Paducah) introduced similar proposals (HB 299 and SB 178) requiring Medicaid managed care organizations to abide by certain provisions of the insurance code regarding patient protection. Since the expansion of managed care in the state’s Medicaid program in 2011, patients as well as providers have voiced complaints about the provision of services, coverage and payment. Although the managed care organizations are licensed by the Department of Insurance, they are not subject to many of the rules that apply to other insurance companies. Last session, patient and provider groups joined forces to urge the legislature to compel MCOs to follow the same rules as commercial insurers. That effort fell short and no legislation was enacted. Damron’s bill, HB 299, died in the House while Leeper’s bill, SB 178, never received a hearing in the Senate committee to which it was assigned. Other proposals impacting Medicaid managed care also were filed but failed to pass, including one to require MCOs to establish
uniform copayments for drugs. **HB 449** easily cleared the House but died on the Senate floor after the state Medicaid officials voiced concerns over the measure.

**Restrictions on Generic Substitution:** Representative Addia Wuchner (R-Burlington) once again introduced legislation restricting the substitution of tamper-resistant opioid drugs. **HB 74** prohibited a pharmacist from substituting an opioid that does not have tamper-resistant qualities for one that does unless the pharmacist obtained written permission from the prescriber. The measure received a hearing in House Judiciary Committee but no vote was taken. The sponsor withdrew **HB 74** and made several attempts to revive the proposal as an amendment to other health-related bills. Those attempts were unsuccessful.

**Drug Wholesaling:** A measure to prohibit sales to wholesalers by retail pharmacies bogged down on the House floor after clearing the House Health and Welfare Committee. **HB 371** was sponsored by Representative David Watkins (D-Henderson) as a response to problems with “gray market” drugs entering the market through transactions involving the sale of drugs by pharmacies to wholesale distributors. It was pushed by the Kentucky Office of the Attorney General and the Kentucky Board of Pharmacy. Representative Watkins filed a floor amendment to make changes requested by the pharmacy community. The amendment clarified that the bill would not restrict returns of outdated or unsalable products or impact transfers between pharmacies. Two other proposals broadening the rules for inter-pharmacy transfers of drugs also failed to pass. **HB 322** and **HB 449** proposed to exempt inter-pharmacy transfers between unrelated pharmacies from the definition of “drug wholesaling.” Current law limits the amount of drugs that can be transferred between unrelated pharmacies before the activity is considered wholesaling.

**“Conscience Clause” Legislation:** After a lull of several years, the issue of a “conscience clause” again surfaced this session. Representative Joe Fischer (R-Ft. Thomas) filed **HB 143** allowing a health care provider, health care institution or payor to refuse to provide or pay for a medical service that violates his or her conscience. The issue was a hot topic shortly after the FDA approved the “morning after” pill several years ago but has since died down. **HB 143** was likely prompted by new federal rules on health insurance coverage for contraceptives contained in the Affordable Care Act. The bill died in the House Health and Welfare Committee without receiving a hearing.

**Naloxone:** The free conference committee on **HB 366**, a bill dealing with infant health, added language to the bill addressing the prescribing and dispensing of naloxone. The conferees included the provisions of **HB 79** that limit the liability of persons prescribing or dispensing naloxone for opioid overdoses in their free conference committee report and the report was passed by both chambers. Earlier in the session, **HB 79** stalled in the House after a number of unfriendly amendments were filed to the bill. **HB 366** contains an “emergency clause” making it effective upon the Governor’s signature on April 4.

**Advanced Practice Nurse Practitioners (APRNs):** Competing proposals affecting collaborative practice agreements between APRNs and physicians were filed this session but did not pass. **SB 51** proposed to eliminate the current requirement that APRNs must have a collaborative practice agreement with a physician in order to prescribe nonscheduled drugs. **SB 94**, on the other hand, would have set stricter standards for these agreements. Neither bill addressed the existing
requirements for the prescribing of scheduled drugs. **HB 8**, a bill that has been signed into law, will potentially have an impact on APRN prescribing of controlled substances. That measure contains a provision that preserves the prescribing privileges of provider groups, including APRNs and optometrists, if hydrocodone-containing drugs are rescheduled. Currently, the federal Drug Enforcement Administration is considering moving these drugs from Schedule III to Schedule II, a move opposed by the NCPA, among others.

**Physician Assistants (PAs):** Unlike past legislative sessions, PAs did not seek the authority to dispense prescription drugs. Physician assistants scored a victory, however, with the passage of **HB 104**. The bill eventually eliminates the requirements that a newly-licensed PA practice at the same location as the authorizing physician for a period of 18 months after licensure. The requirement is reduced to three months until May 31, 2014 and then is completely eliminated. The provision was added to the bill in the Senate after **SB 43**, a stand-alone bill making the change, stalled in the House.

**Dextromethorphan Sales:** A bill to prohibit the sale of products containing dextromethorphan as the sole active ingredient to anyone under the age of 18 died in the Senate after obtaining approval in the House. **HB 19** also would have made it illegal for those less than 18 years of age to falsify their age in order to purchase the product. Before passing the measure, the House adopted a floor amendment removing a provision banning a person from giving a product containing dextromethorphan to a person under 18 after concerns were raised that would make it illegal for a parent to give dextromethorphan to a child for a valid medical reason.

**Other Pharmacy Issues:**

- **HB 358**, a bill requiring that female children between the ages of nine and 16 and male children between the ages of 10 and 16 years be immunized against human papillomavirus (HPV) died in the Senate after narrowly passing the House. The bill contains an “opt out” provision for parents that did not want their child to receive the vaccine.
- Legislation to allow expedited partner therapy for the treatment of certain sexually transmitted diseases died in its original committee. **HB 429** would have allowed the prescribing and dispensing of drugs used to treat these diseases for a patient’s partner who does not have a patient-provider relationship.
- **HB 181**, a bill placing new limits on the amount of pharmacy school scholarships available under a program to encourage students from coal-producing counties to attend pharmacy school, was signed by the Governor on March 22.
- A bill to block the expansion of Medicaid eligibility (**SB 39**) died in the House. The bill would have prevented the state from implementing the Medicaid expansion provision of the federal health care reform act without express legislative approval.

**Therapeutic Shoe Fitting by pharmacy technicians and interns**
YOUR KPhA worked with the Kentucky Board of Pharmacy to clarify the issue of Therapeutic Shoe Fitting by Pharmacy Technicians in relationship to the KY Prosthetics, Orthotics and Pedorthics Practice Act of 2010. This issue was advanced as a legislative priority by the KPhA House of Delegates at the 2012 KPhA Mid-Year Conference. Pharmacists worried that legislation passed in
2010 would prevent pharmacy technicians and pharmacy interns from assisting in the fitting of therapeutic shoes for diabetic patients. The Board of Pharmacy, in a letter dated March 11, 2013, clarified that it had consulted with the Board of Prosthetics, Orthotics and Pedorthics and the two Boards were in agreement on this issue. Pharmacists are exempt from licensure under KRS Chapter 319B and may continue to provide therapeutic shoes to their patients pursuant to their pharmacist’s license, and that pharmacist technicians who meet the educational requirements of KRS 319B(8)(a),(b),or (c) along with pharmacy interns working under the supervision in a pharmacy can continue to assist pharmacists in the fitting of therapeutic shoes. KPhA worked with APSC and the Kentucky Retail Federation on this issue.

KPhA gratefully acknowledges our engagement with the Kentucky Retail Federation and the great work of our lobbyists, Jan Gould and Gay Dwyer.

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