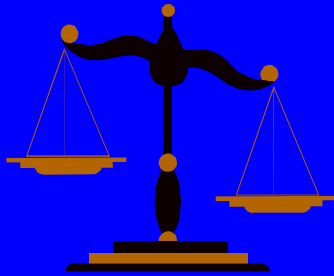


Pharmacy Law Update: Illinois Law – 2004 updates

UIC College of Pharmacy Alumni Weekend

Oak Brook Hills Resort

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Laws passed in last year

- Revisions to the Pharmacy Practice Act
- Prescription information
- Pharmacy technician training
- Sale of hypodermic syringes and needles
- Medicaid eligible prescriptions
- The Senior Citizens and Disabled Persons Prescription Drug Discount Act
- Multiple sclerosis and the Circuit Breaker Program
- The Illinois State Pharmacy Disciplinary Fund and the Illinois Department of Professional Regulation
- Medicare Drug Benefit Program

Revisions to the Pharmacy Practice Act

- 225 ILCS 85/3
 - (k-5) "Pharmacist" means an individual health care professional and provider currently licensed by this State to engage in the practice of pharmacy.
 - (s) "Patient profiles" or "patient drug therapy record" means the obtaining, recording, and maintenance of patient prescription information, including prescriptions for controlled substances, and personal information.

225 ILCS 85/15.5 (new) - Prescription information

- (a) Uncoordinated multiple controlled substances and drug seeking tendencies pose a significant threat to the health, safety, and welfare of patients. To address this threat, the General Assembly believes a physician who prescribes controlled substances should be provided with prescription information from pharmacies.
- (b) Upon request, a pharmacist shall provide a physician licensed to practice medicine in all its branches who is prepared to prescribe or has prescribed a controlled substance for a patient with information from the patient's most recent patient profile, including information about any prescriptions for controlled substances.

Sec. 17.1. Pharmacy technician training

- (a) Beginning January 1, 2004, it shall be the joint responsibility of a pharmacy and its pharmacist in charge to have trained all of its pharmacy technicians or obtain proof of prior training in all of the following topics as they relate to the practice site:
 - (1) The duties and responsibilities of the technicians and pharmacists.
 - (2) Tasks and technical skills, policies, and procedures.
 - (3) Compounding, packaging, labeling, and storage.
 - (4) Pharmaceutical and medical terminology.
 - (5) Record keeping requirements.
 - (6) The ability to perform and apply arithmetic calculations.

Sec. 17.1. Pharmacy technician training (cont)

- (b) Within 6 months after initial employment or changing the duties and responsibilities of a pharmacy technician, it shall be the joint responsibility of the pharmacy and the pharmacist in charge to train the pharmacy technician or obtain proof of prior training in the areas listed in subsection (a) of this Section as they relate to the practice site.
- (c) All divisions of pharmacies shall maintain an up-to-date training program describing the duties and responsibilities of a pharmacy technician.
- (d) All divisions of pharmacies shall create and maintain retrievable records of training or proof of training as required in this Section.

720 ILCS 635/2. Sale of hypodermic syringes and needles

- (a) A pharmacist may sell up to 20 sterile hypodermic syringes or needles to a person who is at least 18 years of age. A syringe or needle sold under this subsection
- (b) *must be stored at a pharmacy and in a manner that limits access to the syringes or needles to pharmacists employed at the pharmacy and any persons designated by the pharmacists.* A syringe or needle sold at a pharmacy under this subsection (b) may be sold only from the pharmacy department of the pharmacy.

Sale of hypodermic syringes and needles (cont)

- Amends the Hypodermic Needles and Syringes Act to allow anyone 18 years of age or older to purchase up to 20 hypodermic needles and syringes daily without a prescription.
- This bill now makes Illinois the 46th state that does not require a prescription for needles and syringes.
- There are no record-keeping requirements for this act and the Illinois Department of Public Health must provide materials for proper disposal of needles and syringes to the pharmacies that choose to sell them.
- This bill was introduced by the AIDS Foundation with the hope that this action will help reduce the spread of HIV and AIDS among intravenous drug users.

Medicaid eligible prescriptions

- SB 1109 - Revises the current co-pays required for Medicaid eligible prescriptions.
- The change leaves a \$3 co-pay for brand name prescription medications but reduces the \$1 co-pay to \$0 for generic products.
- Federal law prohibits mandatory fees for Medicaid recipients; however, pharmacies do not have to fill prescriptions for recipients who refuse to pay the co-pay fee.
- Some drugs including insulin, chemotherapy, dialysis, radiation therapy and other instances when medications are necessary to prevent life-threatening situations do not have co-pays regardless of brand or generic status.
- HB 703 - Prohibits any prior approval requirements for hemophilia medications for Medicaid patients.

The Senior Citizens and Disabled Persons Prescription Drug Discount Act

- SB 3 and HB 209 - Creates the Senior Citizens and Disabled Persons Prescription Drug Discount Act that significantly expands the current SeniorCare and Circuit Breaker Programs.
- Eligible seniors (any Illinois resident 65 years old or older) or disabled individuals will subscribe to a discount program for a \$25 annual fee. The prescription reimbursement to pharmacies will be based on AWP - 12% for brand name drugs and newly released generics (for the first 6 months post release) and AWP-35% for generic drugs plus fees of \$3.50 and \$4.25 for those two groups, respectively.

The Senior Citizens and Disabled Persons Prescription Drug Discount Act

- Seniors will pay less than the price the pharmacy is reimbursed at for each prescription. The discounts will be paid for by negotiated rebates from the pharmaceutical manufacturers.
- These rebates will also cover plan administration costs. The amount of savings for seniors is yet to be seen. This program went into effect July 1, 2003.

The Senior Citizens and Disabled Persons Prescription Drug Discount Act



- <http://www.illinoisrxbuyingclub.com/>
- Check out link to “Mail Order Price”:



- <http://savrx.pcpcorp.net/?link=qoute>

The Senior Citizens and Disabled Persons Prescription Drug Discount Act

- **Sav-Rx Canadian Mail Order** The Sav-Rx Canadian pharmacy offers an option for you to receive mail order prescriptions at incredibly low costs. Sav-Rx allows you the opportunity to save an additional 20%-30% on your mail order prescriptions through the use of our Canadian Mail Order Pharmacy. We currently have many popular higher priced prescriptions on our Canadian Pharmacy Drug List.
Sav-Rx guarantees the same quality product from Canada that you have come to expect from regular Sav-Rx mail order pharmacy.

Your prescription(s) will be mailed directly to your home! Please allow for an additional two weeks mailing time.

Mail Order Form: [Download here](#)

Medicare Prescription Drug, Improvement and Modernization Act (MMA)

Medicare Part D: Outpatient Rx Drug Benefit

- New Rx drug benefit beginning 2006
- Estimated cost of \$409.8 billion over 10 yrs with a net cost of \$394.3 billion.
- The country would be divided into several regions
 - In each region beneficiaries would have at least 2 plans from which to choose.

(MMA)
Medicare Part D:
Outpatient Rx Drug Benefit
(cont)

- Annual deductible of \$250
- Beneficiary to pay 25% of covered Rx drugs between \$251-\$2250, insurer to pay remaining 75%.
- Beneficiary to pay entire cost of Rx drugs above \$2250 until total out-of-pocket expenses (including \$250 deductible and the 25% cost sharing) reach \$3600. Then,
- Beneficiary to pay the greater of either a copay (\$2 generic/\$5 any other drug) or coinsurance that is equal to 5% of the cost of the drug. The insurer to pay the balance.
- Estimated initial 2006 premium would be \$35/month (\$420/yr)

Transitional Rx Drug Discount Card

- The law provides that discount drug cards be available in 2004 and 2005.
- Cards will be available no later than 6 months after enactment and will end when Rx benefits become available to beneficiaries in 2006
- Cards could be offered by:
 - PBMs
 - Wholesalers
 - Retail pharmacies
 - Insurers
 - or Medicare+Choice plans

Transitional Rx Drug Discount Card

- Card sponsors must obtain HHS approval.
- Hundreds applied, 25 approved.
- Could charge up to a \$30/yr enrollment fee.
- According to HHS, these cards could save seniors 15%-25% on Rx drugs at a pharmacy.

Transitional Rx Drug Discount Card

- April 8, 2004 OIG Guidance
 - Several discount card sponsors had planned to compensate pharmacists for time associated with helping patients enroll in programs.
 - OIG says providing pharmacies with compensation for assisting with enrollment process may constitute an illegal kick-back.
 - Subject to civil and criminal penalties under federal criminal anti-kickback statute.

Health Savings Account HSA

- The law establishes a tax-free savings account, HAS, for individuals under age 65 who have certain high deductible insurance policies.
- Individuals with health insurance policy with a deductible of at least \$1000 or families with a deductible of at least \$2000 or eligible.
- Contributions are tax-free, as would distributions from accounts if funds used for health care needs are not covered by the insurance policy.
- Could contribute an amount equal to the amount of their deductible, max annual contribution \$2600 for an individual, \$5150 for a family.

Medication Therapy Management (MTM) Programs

- Plans shall provide MTM program that is designed to assure, with respect to targeted beneficiaries, that covered Part D drugs are appropriately used. Services may be provided by pharmacists.
- Targeted beneficiaries are those individuals who:
 - have multiple chronic diseases (DM, asthma, HTN, hyperlipidemia, CHF)
 - are taking multiple covered Part D drugs
 - are identified as likely to incur annual costs for covered drugs that exceed a level specified by the Secretary

(MTM) Programs

(cont)

- Elements of the program may include:
 - Enhanced enrollee understanding to promote the appropriate use of medications and to reduce the risk of potential adverse events through education, counseling, etc.
 - Increased enrollee adherence with Rx medication regimens through medication refill reminders, special packaging, and other compliance programs.
 - Detection of adverse drug events and patterns of overuse and underuse of Rx drugs.
- Programs shall be developed in collaboration with licensed and practicing pharmacists and physicians.
- The PDP sponsor shall take into account in establishing fees for pharmacists and others providing services the resources used and time required to implement the MTM program.

Consumer Choice

- Any Willing Pharmacy
 - Plan shall permit the participation of “any willing pharmacy” that meets the terms and conditions under the plan.
 - Plans may reduce coinsurance or co-payments for drugs dispensed in in-network pharmacies

Consumer Choice (cont)

- Access
 - The PDP sponsor's network must include a sufficient number of pharmacies (other than mail order) to ensure convenient access.
 - The Secretary shall establish access rules for in-network pharmacies that are no less favorable than the DoD/TRICare standards.
- Level Playing Field
 - Sponsors **shall** permit enrollees to receive benefits through a non-mail-order pharmacy. Any non-mail-order pharmacy may provide the same services as a mail-order pharmacy.
 - Any differential in cost is paid by the enrollee.

Electronic prescribing

- Implementation no later than 4/1/08
- Provides for the electronic transmittal to the prescriber and to the dispensing pharmacy and pharmacist:
 - Information on eligibility and benefits (including drugs included in the formulary, and tiered formulary structure, and any prior authorization requirements)
 - Information on the drug being prescribed or dispensed and other drugs listed on the medical hx, including information on drug-drug interactions, warnings, or cautions, and when indicated, dosage adjustments
 - Information on the availability of lower cost therapeutically appropriate alternatives

Electronic prescribing (cont)

- The standards cannot impose an undue administrative burden on prescribers and dispensing pharmacies and pharmacists.
- The standards must permit electronic exchange of drug labeling and drug listing information maintained by the FDA and the National Library of Medicine.
- *Patient may designate a dispensing pharmacy.*
- Requires electronic transmittal of patient's medical history relevant to covered medication to pharmacist or other health professional.

Other Issues

- Dual Eligibles
 - Medicare will cover drug benefit for dual-eligibles (Medicare and Medicaid).
- DME
 - Payment frozen 2004-2006; phased-in competitive bidding process beginning in 2007 (includes blood glucose monitoring supplies).
 - Program is required to “protect” small suppliers by the Secretary developing procedures relating to bids and the awarding of contracts to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program.

Other Issues

(cont)

- Medicare Part B AWP Reform
 - 85% of AWP
 - Multiple source 106% of Average Sale Price (ASP); single source the lesser of 106% ASP or WAC.
 - Vaccines are exempt from reforms.
 - Physicians may choose to receive their drugs and biologics through competitive acquisition instead of the new ASP/WAC system.
 - The Secretary shall pay pharmacies a supplying fee for immunosuppressive drugs.

Other Issues

(cont)

- Transparency
 - A prescription drug plan (PDP) or Medicare Advantage (MA; managed care) plan sponsor shall disclose to the Secretary the aggregate negotiated price concessions made available to the sponsor or organization by a manufacturer, which are passed through in the form of lower subsidies, lower monthly premiums, and lower prices through pharmacies and other dispensers.
 - The Secretary may conduct periodic audits of the sponsors.

Other Issues

(cont)

- Importation
 - Authorizes pharmacy/wholesaler importation with safety protections
 - Expands importation to include wholesalers and pharmacists
 - Limited to Canada
 - Safeguards must be in place to ensure that each imported drug is safe and effective for the intended use of the drug and to protect the public health.
 - Canadian sellers must register with the Secretary.
 - The Secretary can suspend importation of a specific drug or by a specific importer upon the discovery of a pattern that are counterfeit or in violation of any requirement.

Other Issues

(cont)

- Authorizes personal importation with safety protections
 - Directs the Secretary to exercise discretion regarding enforcement to permit individual importation when the drug is clearly for personal use and does not appear to present an unreasonable risk to the patient; also directs the Secretary to focus on the cases that pose a significant threat to public health.
 - The program goes into effect only if the Secretary certifies that implementation of the program will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of covered products to the American consumer.

Other Issues

(cont)

- Chronic Care
 - Voluntary chronic care improvement program under the traditional fee-for-service and the Medicare Advantage programs.
 - Available for Part A and B beneficiaries with one or more of the targeted diseases such as CHF, DM, COPD, etc.
 - Pharmacists neither designated or excluded.
 - Provides care management.
 - A single point of contact to coordinate care across settings and providers.
 - Self-care education for the beneficiary, primary caregivers, family members, and health care providers.
 - Coordination between health services and Rx drug benefits.
 - Use of monitoring technologies to enable exchange of pertinent clinical information.
 - Education about and assistance obtaining hospice, pain management, palliative and end of life care.

Proposed Federal Laws

- Pharmacy Consumer Protection Act
- Medication Therapy Management Act of 2003
- Pharmacy Education Aid Act of 2003

Pharmacy Consumer Protection Act

- Amends the Federal Food, Drug, and Cosmetic Act by the following:
 - 1. Requires pharmacy websites to display information identifying the business, physician, and pharmacist associated with the website, and the states where the person is authorized by law to prescribe or dispense Rx drugs.
 - 2. Prohibits a website from referring a customer to a doctor who then writes a Rx without ever seeing the patient.
 - 3. Provides states with new enforcement authority modeled on the Federal Telemarketing Sales Act that will allow a state attorney general to shut down rogue sites across the country, rather than only in his/her state.

Medication Therapy Management Act of 2003

- Pharmacists providing medication therapy management for the treatment of asthma, diabetes, or chronic cardiovascular disease, including an individual on anticoagulation or lipid reducing medications; or such other chronic diseases as the Secretary may specify would be able to charge Medicare Part B.

Pharmacy Education Aid Act of 2003

- An act to amend the Public Health Service Act with respect to the practice of pharmacy.
- Loan Repayment Program for Pharmacists serving in critical shortage facilities.
 - Must have BA or PharmD, obtained educational loans for pharmacy education costs, and is licensed without restrictions in the state the designated health care facility is located

Pharmacy Education Aid Act of 2003 (cont)

- The Secretary may enter into an agreement with an individual to serve as a full-time pharmacist for a period of at least 2 yrs at a designated health care facility to make payments on the principle of and interest on any loan for tuition expenses, other educational expenses, living expenses.
- For each year of obligated service that an individual contracts the Secretary may pay up to \$35,000.

