

PHARMACY REGULATION IN CONNECTICUT

The purpose of pharmacy regulation is to provide government oversight in an area deemed in need of public health and safety assurances, as well as consumer protection. The legislature first recognized the need to regulate the practice of pharmacy in Connecticut in 1881 when it established an independent, three-member pharmacy commission authorized to license pharmacists. Over the years, the state has greatly expanded its regulatory role to encompass the manufacturing, distribution, prescribing, administration, and dispensing of prescription drugs. The authority for monitoring the distribution of prescription drugs is contained in the Pharmacy Practice Act, the State Food, Drug and Cosmetic Act, and the State Controlled Substance Act.¹ The Drug Control Division within the Department of Consumer Protection (DCP) is responsible for the enforcement of these acts.

Section I

Location of function within state government. Currently, DCP and the Department of Public Health (DPH) have an informal unwritten agreement that DCP investigates all reports of health professionals suspected of diverting drugs for either their own use or for sale. *The committee found a lack of clear policies and procedures for investigations performed by DCP that involve DPH licensees and believes more formal lines of communication need to be established.*

1. The Department of Consumer Protection and the Department of Public Health should establish a Memorandum of Understanding (MOU) in order to delineate their respective responsibilities with regard to the investigation of health care professionals licensed by the Department of Public Health. The MOU will assist each agency in protecting the public interest, ensuring maximum efficiency and benefit to the state of Connecticut, and minimizing any duplication of effort. The MOU should include, but not be limited to:

- **which agency has primary jurisdiction over prescription drug diversion investigations;**
- **the types of cases DPH should refer to DCP and the referral process to be used;**
- **the types of cases DCP should refer to DPH for investigation and the referral process to be used;**

¹ The Pharmacy Practice Act concerns the power and operations of the pharmacy commission, and the licensing and disciplining of individuals and businesses engaged in the practice of pharmacy. The Connecticut Food, Drug and Cosmetic Act is aimed at protecting the public from adulterated and/or misbranded products, and false advertising. The State Controlled Substances Act places certain drugs with the potential for abuse into categories, strictly regulates the prescribing, labeling, storing, record keeping, and dispensing of these drugs, and requires certain individuals and places who prescribe, administer, or dispense those drugs to register with DCP and the Drug Enforcement Agency within the U.S. Department of Justice.

- **how results of an investigation should be forwarded from one agency to another; and**
- **how action(s) taken by a health board concerning a case should be reported to the DCP.**

Automated systems. A major deficiency identified by this review is the lack of reliable automated information systems to capture the activities performed by the Drug Control Division. Currently, there are multiple systems operating -- a licensing system used departmentwide that identifies all licensees of the department, and a variety of systems used internally by the Drug Control Division. *The committee found that all of the systems are primarily used as rosters to track specific individuals or cases rather than as analytical and evaluation tools to manage programs.*

Although a departmentwide effort has been underway since the late 1990s to eliminate the need for multiple databases, to date, only licensing information has been brought online. *The department's plan is to use a single system to track licensing, enforcement, and revenue information, although the committee found no formal written document that describes this initiative or provides a time frame for the various phases to be undertaken.*

2. The Department of Consumer Protection should make improving its automated information systems a priority. It should establish a formal management team charged with: 1) identifying each division's management information needs; and 2) developing a plan and timetable for correcting and expanding its current systems by July 2005. For both inspection and investigation activities, the system should provide the Drug Control Division with the ability to identify:

- **significant case milestones;**
- **case outcome information; and**
- **final case action.**

The system should be capable of generating routine and customized reports on inspection history and information related to the division's investigation activities.

On January 1, 2006, January 1, 2007, and January 1, 2008, DCP shall submit to the legislature a report summarizing major activities of the division, including information on the number and type of pharmacy inspections and investigations conducted and the results.

With respect to enforcement activity, the report should include but not be limited to data on:

- **the number of investigations conducted;**
- **the reason for each investigation;**
- **the subject of each investigation;**
- **the outcome of each investigation;**

- **action taken by any DPH health board or the Commission of Pharmacy (if applicable);**
- **action taken by the DCP commissioner on a practitioner's controlled substance registration, if applicable; and**
- **investigatory timeframes from case opening to final board or commission action.**

Inspections

Although the law specifically requires the commissioner of DCP to inspect correctional facilities with respect to the handling of drugs, the committee found these facilities are no longer routinely inspected. The committee believes routine inspections of correctional facilities are an important function and should be performed as required by law. Therefore, the committee recommends:

- 3. the Department of Consumer Protection conduct inspections of correctional facilities as required under C.G.S. Sec. 20-577(b). On January 1, 2006, January 1, 2007, and January 1, 2008, the department should submit to the Legislative Program Review and Investigations Committee a report identifying the number of correctional facilities inspected within the previous calendar year.**

The Department of Public Health, as part of its biennial licensing process, inspects a variety of institutions including hospitals, long-term care facilities, and community health centers. As part of the inspection process, DPH examines prescription drug ordering, storage, security and recordkeeping, as well as the dispensing and administering of pharmaceuticals. The committee believes routine inspections of these facilities by DCP duplicate the inspections already performed by DPH as part of its licensing process, and statutory responsibility for conducting pharmacy inspections should be placed within the licensing agency. Therefore, the committee recommends:

- 4. state statutes shall be amended so that inspections of facilities licensed by the Department of Public Health related to the handling of prescription drugs be completed by DPH as part of its inspection process. Any deficiencies identified by DPH with respect to the handling of prescription drugs shall be forwarded to DCP for enforcement action.**

Retail pharmacies. Routine inspections of retail pharmacies typically last three to four hours and revolve around cleanliness of the pharmacy area, use of proper equipment, maintenance of appropriate prescription records, clearance of expired drugs from shelves, and other compliance issues. A standardized check-off inspection form is used along with a 13-page description that identifies in detail each requirement and a cover sheet that lists descriptive information about the pharmacy. The form has space for an agent to note any recommendations or deficiencies issued, and for signatures of the staff conducting the inspection and the pharmacist on duty. The completed form is given to the pharmacist on duty at the end of the inspection, and the agent conducts an exit interview explaining any violations found as well as information on how to correct them, and the pharmacist is asked to sign off on the inspection form. *The committee found:*

- *an outdated inspection form - the form itself needs to be updated because many of the items are no longer applicable;*
- *agent variation:*
 - *the face sheet of the inspection form and some of the items on the form itself were completed differently depending on the agent conducting the inspection; and*
 - *some agents will issue an “advisement” instead of a deficiency (which is considered more serious), although no criteria exists for when an advisement is sufficient;*
- *no methodology for sampling of pharmacy records - although the inspection involves a review of actual prescriptions for compliance with the law, no methodology is used to sample these records to control for differing numbers of prescriptions received by the pharmacy;*
- *no assurance by the pharmacy that deficiencies have been addressed - if deficiencies are issued, there is no requirement that the pharmacy manager submit a plan of correction or letter stating that all deficiencies have been corrected; and*
- *no criteria for mandatory re-inspections - the decision is up to the individual inspector.*

5. C.G.S. Sec. 20-577 shall be amended to require all retail pharmacies located in the community be inspected on a four-year cycle.

The Drug Control Division should revise the form used to inspect retail pharmacies to reflect current practices in the field. Such revisions should include provisions to ensure the use of automated dispensing devices and the use of electronic prescribing comply with any applicable laws or division protocols.

The division shall develop a methodology to sample a specific number of actual prescriptions for compliance with state laws based on the annual number of prescriptions received by the pharmacy.

The division should establish criteria, based on the number and/or severity of deficiencies issued, that will automatically trigger a re-inspection. Any pharmacy that has received a deficiency shall provide in writing, within 10 days of the deficiency being issued, a plan of correction or evidence that the deficiency has been corrected.

Division supervisors shall periodically review a random sample of inspection forms for completeness and consistency.

Investigations. Overall, the committee found the documentation of drug diversion investigations contained in the case files was excellent up to the conclusion of the investigation by the division.

*However, although case documentation was excellent up to the point of referral, the file usually contained no case outcome information **after it was referred** to either a DPH board or the pharmacy commission.*

- 6. The Memorandum of Understanding between the Department of Public Health and the Department of Consumer Protection recommended above, should contain a requirement that a summary of any investigation conducted by DPH or any action taken by a health board under DPH that involves allegations of prescription drug abuse be provided to the Drug Control Division for inclusion in its database.**

The Legal Office within DCP shall forward a copy of any action taken by the pharmacy commission or by the DCP commissioner, if the action is against the controlled substance registration of a licensed health professional with prescribing authority, to the Drug Control Division, for inclusion in its case files.

An agent in the Drug Control Division who currently serves almost full-time as the administrator to the pharmacy commission teaches the error prevention mandated by the pharmacy commission for pharmacists who have made prescription drug errors. The class is taught twice a year. No fee is charged to enroll in the class. The program review committee believes the error prevention class should be offered through organizations that provide other continuing education opportunities, given that staff resources in the Drug Control Division are limited.

- 7. The Department of Consumer Protection should outsource the class on prevention of prescription drug error class imposed by the Commission of Pharmacy on pharmacists who commit a medication error to an organization that is accredited by the commission.**

Destruction of controlled substances in nursing homes. Nursing homes call the Drug Control Division staff when they have excess stock of controlled substances and request the staff come to the facilities to destroy these drugs. In FY 03, division staff made 649 visits to nursing homes to destroy excess stock and 859 visits in FY 04. Based on the committee's calculations, if each drug destruction visit takes one hour (including driving time), over ten weeks of a full-time staff person's time per year is allocated to performing this activity. Given the limited staff resources, this activity could be performed directly by the nursing home, as it is in Massachusetts.

- 8. C.G.S. Sec. 21a-262 shall be amended so that two or more individuals licensed by either the Department of Public Health or the Department of Consumer Protection and affiliated with a long-term care facility may jointly dispose of excess stock of controlled substances. Only the following individuals can witness and perform the destruction: a nursing home administrator, a pharmacist consultant, a director of nursing services, or an assistant director of nursing services. The facility shall maintain documentation of each destruction performed, and such records shall be maintained in a separate log on a form developed by the Department of Consumer Protection. All records shall be maintained for a period of three years.**

- 9. The Department of Consumer Protection, in consultation with the Department of Social Services and the Commission of Pharmacy, shall study the possible use of automated dispensing machines at long-term care facilities and provide recommendations to the legislative committees of cognizance by January 1, 2006.**

Commission of Pharmacy

The committee found one commissioner, appointed as one of the four pharmacists to sit on the commission, is actually semi-retired. The statute requires that pharmacists on the commission be employed full-time as pharmacists.

The committee found that although the average length of service was 10 years, one commissioner has sat on the commission for more than 21 years and has served as commission chairperson for 15 of those years. A second commissioner has been on the commission for over 15 years.

Commission activities. No central database exists regarding commission actions, and no outcome information is routinely generated that aggregates the types of sanctions imposed by the commission. Although the committee believes that automating enforcement activity will begin to address this deficiency, a quarterly summary of actions taken by the commission, similar to the report published by DPH, should be published in the meantime.

- 10. The Department of Consumer Protection shall compile a quarterly regulatory action report and publish it on its website. The report should contain any disciplinary action imposed on individuals with controlled substance registrations by the DCP commissioner and on pharmacists and pharmacies sanctioned by the pharmacy commission and the reason for the action.**

Commission resources. Currently, one staff member from the Drug Control Division serves almost full-time as the pharmacy commission administrator. The administrator's job is largely paper driven and is focused on verifying that individuals and businesses seeking licensure meet the requirements, ensuring pharmacists' continuing education requirements have been met each year, attending commission meetings and recording any votes that occur, and tracking items pending before the commission. The committee believes that using an individual who is a licensed pharmacist as the commission's clerk is not the best use of resources. *The committee finds that an individual with much less education and experience could perform this position*

Section II

Collaborative practice. Collaborative Practice Agreements refer to arrangements under which prescribers (generally physicians) authorize pharmacists to engage in specified activities including adjusting and/or initiating drug therapy. Several states permit collaborative practice agreements in the community setting. Connecticut, however, restricts these agreements to inpatient hospital settings and long-term care facilities where they are governed by patient-specific written protocols by the physician treating the patient

Based on the widespread use of community pharmacists in other states as active participants in helping to increase immunization rates, the program review committee recommends a program similar to Massachusetts be established. Over 30 other states allow pharmacists to perform this function, and the committee could find no literature indicating any problems with this expansion in pharmacists' scope of practice. In addition, given the reports of shortages of health care workers trained in providing immunizations in case of a public health emergency, beginning to mobilize nontraditional providers to respond, such as pharmacists, would help the state meet its public health emergency preparedness goals.

11. A licensed pharmacist may administer adult influenza vaccinations provided that:

- **such administration is conducted pursuant to the order of a practitioner; and**
- **such activity is conducted in accordance with regulations adopted by the Department of Consumer Protection, in consultation with the Department of Public Health and the Commission of Pharmacy, which shall include, but not be limited to, requirements that:**
 - **all such courses must, at a minimum, meet U.S. Centers for Disease Control and Prevention guidelines, and be accredited by the Accreditation Council for Pharmacist Education, or a similar health authority or professional body; and**
 - **include courses in pre-administration education and screening, vaccine storage and handling, administration of medication, record keeping and reporting of adverse events.**