
LEGISLATIVE PROGRAM REVIEW
& INVESTIGATIONS COMMITTEE

Pharmacy Regulation in Connecticut

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PHARMACY REGULATION IN CONNECTICUT

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Introduction

The manufacturing and distribution of prescription drugs is regulated at both the federal and state levels of government. While the federal government has extensive control and recordkeeping requirements concerning the types of prescription drugs manufactured and dispensed, individual states have broad latitude over who may administer, prescribe, and dispense those drugs. In general, the focus of federal and state pharmacy laws is twofold:

- to protect the public from receiving unsafe, inappropriate, or incorrect medications by ensuring that individuals receive safe and quality pharmaceutical care. At the federal level, the Food and Drug Administration (FDA) is responsible for ensuring the purity, safety, effectiveness, and accurate labeling of certain drugs. States regulate the practice of pharmacy, the operation of pharmacies, and the distribution of prescription drugs.
- to reduce the abuse of drugs by imposing stricter requirements on the prescribing and dispensing of certain drugs that have the potential to be abused. These drugs are called controlled substances.¹ The Drug Enforcement Administration (DEA) is the federal agency that enforces laws pertaining to the manufacture, distribution, and dispensing of legally produced controlled substances. States share responsibility with DEA in preventing diversion of these types of prescription drugs by conducting investigations and taking both administrative and/or criminal action against certain individuals found to have diverted prescription drugs.

The Legislative Program Review and Investigations Committee voted to conduct a study in March 2004 of the operations of the Department of Consumer Protection (DCP) in implementing federal and state drug laws, and the Commission of Pharmacy and its authority to regulate the practice of pharmacy. The review focused on the management, activities, and resources of the Drug Control Division within DCP in carrying out its responsibilities. How the pharmacy commission acts to protect the public health and safety of Connecticut residents was also examined.

The program review committee reviewed the operations of the Drug Control Division to determine the effectiveness of its regulatory program. Overall, the committee found the division's operations to be largely paper driven with little automated information aggregated about various division functions. Specifically, the committee found an overreliance on managing on a case-by-case basis, with no automated information generated that could be used to measure the scope of program operations or program effectiveness. These deficiencies, the committee believes, are

¹Controlled substances are specified in federal and state regulation and are narcotics and other drugs that have the potential for abuse and misuse.

symptomatic of larger departmentwide weaknesses and are largely a result of inadequate management information systems.

Due to the lack of program data, committee staff conducted case file reviews of the inspection and investigation functions to assess regulatory effectiveness. The results of these reviews are presented in Chapter One. The question of whether DCP is the best location for the regulation of pharmacy is also considered in this chapter, and a committee recommendation to clarify the roles of DCP and the Department of Public Health (DPH) when investigating health professionals accused of diverting prescription drugs is also presented. Finally, Chapter One presents the committee's recommendations aimed at improving the Drug Control Division's regulatory program by strengthening the process used to inspect retail pharmacies, requiring outcome information on division activities be collected, aggregated, and reported, and mandating the development of a strategic plan to ensure scheduled automation initiatives meet the needs of division managers. The committee believes enactment of these recommendations will improve program accountability and facilitate the collection of reliable and comprehensive data.

Chapter Two of this report discusses the authority of the pharmacy commission and requires the department publish a quarterly summary of disciplinary actions taken by the commission. Chapter Three contains a recommendation that would allow pharmacists who receive additional training to administer influenza vaccinations in community settings, similar to programs operating in more than 30 other states. Finally, another area included in the study scope is how pharmacy benefit managers (PBMs) are regulated by the state. Chapter Four describes PBM activities and discusses the current status of pending litigation in two states that have adopted legislation to regulate PBMs.

Agency Responses

It is the policy of the Legislative Program Review and Investigations Committee to provide agencies subject to a study with an opportunity to review and comment on the recommendations prior to publication of the final report. Appendix A contains responses from the Department of Consumer Protection and the Department of Public Health.

Chapter One

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.² The Drug Control Division within DCP is responsible for the enforcement of these acts.

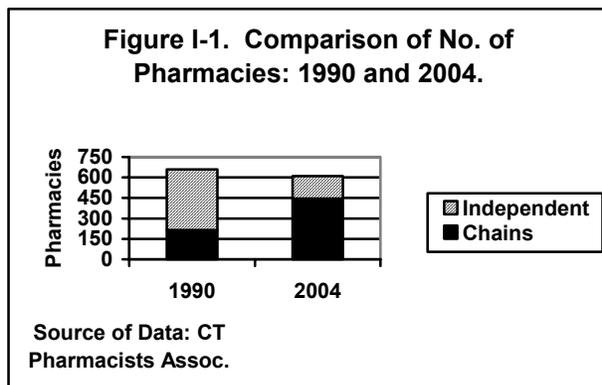
This chapter provides an overview of the pharmacy marketplace in Connecticut. It also describes the responsibilities of DCP in regulating the distribution of prescription drugs in Connecticut and makes recommendations on how the regulatory program operated by the department can be improved.

Connecticut Statistics

Pharmacies. Connecticut law requires pharmacies located in the state to be licensed by DCP. The number of pharmacies licensed in Connecticut has remained fairly stable since 1990. Figure 1-1 shows there were 658 *licensed* pharmacies in 1990 compared to 609 in 2004. The major difference between the two years is the shift from independent to chain pharmacies. As shown in the figure, there were 444 independent pharmacies in 1990 and 214 chains. By 2004, chains accounted for 73 percent of all pharmacies licensed in the state.

Out-of-state mail order pharmacies.

Connecticut law requires mail order pharmacies located out-of-state to *register* with the Department of Consumer Protection. No historical statistics are kept on the increase in the number of these types of pharmacies registering with DCP over the last decade. Currently, there are 322 out-of-state pharmacies registered in Connecticut.



² 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.

Pharmacists. Pharmacists prepare and dispense prescription drugs to consumers in hospitals, nursing homes, retail pharmacy stores, and home care settings. They consult directly with patients or their caregivers, explain proper use and storage of drug products, and provide information on contraindications for use. In terms of the number of licensed pharmacists, there are more in-state licensed pharmacists in 2004 (4,417) than there were in 1990 (3,661). However, the number of prescriptions written and dispensed as well as the number of new drugs available has increased over the last decade, which places greater demands on the workloads of pharmacists. This, in conjunction with additional academic requirements requiring students to obtain a Doctor of Pharmacy degree (Pharm. D.) before he or she may be eligible to sit for the licensing exam (instituted a few years ago) has contributed to a shortage in the field.

Pharmacy interns. Before a pharmacy license will be issued, an individual must obtain professional experience as a pharmacy intern. In order to serve as an intern, an individual must have completed two years of college, be enrolled in a professional program at an accredited pharmacy school, and be registered by the department upon the authorization of the pharmacy commission. As of August 2004, 350 interns were registered.

Pharmacy technicians. Pharmacy technicians work under the direct supervision of a licensed pharmacist and assist with everyday pharmacy functions. Public Act 98-31 required pharmacy technicians to register with the commissioner of the Department of Consumer Protection. The department has not maintained historical data on the number of pharmacy technicians registered by DCP since the law was enacted. As of August 2004, 4,433 technicians were registered.

Controlled substance registrants. Any health care practitioner licensed in Connecticut who writes prescriptions for controlled substances, as well as in-state hospitals and clinics where controlled substances are distributed or dispensed, must be registered with both the Department of Consumer Protection and the U.S. Drug Enforcement Agency (DEA). Practitioners who must be registered include physicians, dentists, podiatrists, veterinarians, osteopaths, advanced practice registered nurses, nurse-midwives, physician assistants, and optometrists. Currently 19,940 individuals hold controlled substance registrations.

Drug manufacturers and wholesalers. All drug wholesalers and in-state manufacturers must be registered in Connecticut and if they are located in Connecticut and manufacture or distribute controlled substances, the department also must license them. The department must also license about 240 laboratories that are located within the state and use controlled substances for the purpose of research, instruction, or analysis.

Regulation of Drugs at the State Level

As noted above, Connecticut has a long history of regulating the practice of pharmacy. Today, the Drug Control Division located in the Department of Consumer Protection is responsible for monitoring the distribution of all legal drugs and medical devices in Connecticut. The department issues licenses to in-state pharmaceutical manufacturers and wholesalers. Upon the authorization of the Commission of Pharmacy, the department also licenses pharmacies and

pharmacists involved in dispensing drugs, and it registers pharmacy technicians and out-of-state mail order pharmacy companies.

According to state law, the commissioner of DCP exercises general supervision over the Commission of Pharmacy. Housed within DCP since 1959, the pharmacy commission shares responsibility with the Drug Control Division for regulating the practice of pharmacy in Connecticut. In addition to authorizing the department to issue licenses, the commission administers exams for those seeking to be licensed in Connecticut, holds hearings on pharmacy practice issues, and makes final disciplinary decisions based on the outcome of those hearings. Connecticut statutes define the practice of pharmacy as:

The sum total of knowledge, understanding, judgments, procedures, securities, controls and ethics used by a pharmacist to assure optimal safety and accuracy in the distributing, dispensing and use of drugs and devices.

It is important to note the pharmacy commission only has disciplinary authority over individuals engaged in the practice of pharmacy (i.e., pharmacists and pharmacy technicians) and those facilities where they practice. Regarding controlled substances, DCP issues certificates of registration to qualified persons with prescribing authority to distribute, administer, or dispense those substances within the state. These persons include professionals licensed by the Department of Public Health (DPH). These registrations are in addition to any licenses to practice that must be issued by DPH. The commissioner of DCP may suspend or revoke controlled substance registrations, which means a practitioner would no longer be able to write prescriptions for those types of prescription drugs.

Location of function within state government. Other New England states house their pharmacy boards in various agencies. Both Massachusetts and Rhode Island house their pharmacy boards in their respective health departments. Maine's pharmacy board is in the Department of Professional and Financial Regulation, while New Hampshire's is under the auspices of that state's Health and Human Services Department, but it is considered independent for regulatory purposes. Vermont's pharmacy board is in the Office of Professional Regulation in the Office of the Secretary of the State.

Initially, the committee considered recommending the Connecticut Division of Drug Control and the Commission of Pharmacy be transferred from the Department of Consumer Protection to the Department of Public Health for several reasons. These included:

- DPH licenses all health professionals except for pharmacists;
- DPH has a unit dedicated to conducting investigations of health practitioners that it licenses, and it investigates all complaints against them except for those related to prescription drug diversion; and
- all state health boards except for the Commission of Pharmacy are located in DPH.

The committee conducted a legislative history of the regulation of prescription drugs in the state to determine why DCP and not DPH is responsible for: 1) regulating pharmacists and pharmacy technicians; 2) issuing controlled substance registrations that allow DPH licensed health professionals with prescribing authority to prescribe controlled substances; and 3) investigating all health care workers suspected of diverting prescription drugs.

The committee found that historically, three regulatory agencies - the pharmacy commission, the Department of Health, and the Commission of Food and Drugs -- exercised authority over different aspects of prescription (and nonprescription) drugs. One licensed retailers, one regulated the distribution of narcotics, and the other regulated all non-narcotic drugs. In 1959, the Commission of Food and Drugs was eliminated, and a new state agency entitled the Department of Consumer Protection was created. The new agency took over regulatory authority for non-narcotic drugs. In addition, the pharmacy commission was placed within the Department of Consumer Protection for “fiscal and budgetary purposes” although it still had its own staff. At the time, this was the only commission placed within the new agency. The health department retained the authority to regulate narcotic drugs.

In 1973, a significant shift in responsibility occurred concerning the regulation of narcotic drugs that resulted in the consolidation of all pharmacy activities within a single state agency. Public Act 73-681 established a drug division with DCP and transferred the authority to regulate controlled drugs and narcotics from the health department to DCP. Specifically, the bill took the narcotics control section within the health department and merged it into the newly created drug division within DCP.

At the time this was a controversial transfer of power and authority. The issue of whether a single agency should oversee controlled drugs had been before the legislature since 1967 without any resolution. The departments of health and consumer protection both had jurisdiction over controlled substances, depending upon if they were prescribed by doctors or dispensed by pharmacies. In addition, controlled substances that were seized by law enforcement personnel could end up in local police departments without any uniform procedures for disposal. In spite of many objections, the bill was passed and subsequently signed into law by the governor. As of July 1, 1973, all functions relating to drug regulation were consolidated within the Department of Consumer Protection where they remain today. The last major legislative change occurred in 1977 during government reorganization when the Commission on Pharmacy was placed within the Department of Consumer Protection.

After considering the legislative history, the program review committee rejected recommending the transfer of the Drug Control Division and the pharmacy commission from DCP to DPH for several reasons including:

- DCP’s oversight role involves regulating the retail business practices of pharmacies, a role that would be beyond DPH’s traditional regulatory scope;
- unlike DPH staff, DCP agents are extensively involved with law enforcement officials at the federal, state, and local level, have peace officer status (can obtain

and serve search warrants and make arrests), and conduct covert surveillance operations;

- a review of investigatory files by committee staff for FY 03 and FY 04 shows, on an individual case basis, drug diversion investigations conducted by DCP are thorough and comprehensive;
- DPH officials acknowledged that DCP does an “excellent job” in investigating DPH licensees; and
- on-site observations of division staff show an office atmosphere that has high morale, camaraderie, and cooperation among the staff.

Currently, DCP and 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.* For example, there are no written criteria or protocols for case referral from one agency to another, when investigations should be jointly conducted, or how actions taken by a DPH health board should be reported back to DCP. Therefore, the program review committee recommends:

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;**
- **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 DCP.**

A formal agreement will outline the responsibilities of each agency and ensure each agency is informed of any investigations opened or actions taken by a health board against an individual practitioner. Furthermore, a formal system for sharing information between the two agencies will protect against cases falling through the cracks by ensuring they are methodically tracked.

Department of Consumer Protection’s Automated Information Systems

As noted above, 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.*

Department system. Historically, the Department of Consumer Protection has operated three separate systems -- one for licensing, one for enforcement, and another for revenue -- and none had interface capabilities. Since the late 1990s, the department has been planning to upgrade its computer system. The first phase of the project was implemented in April 2004, when all licensing information was converted into the new system. The next phase of the conversion will occur in 2005 when compliance (i.e., inspections) and enforcement activity will be integrated into the new system.

Like any new system conversion, the first phase did not occur without problems. For example, one feature of the new system is that the internal licensing database accessible only to DCP staff is supposed to mirror the system available to the public on the department's website. However, the program review committee found discrepancies between the two systems for individuals under the jurisdiction of the Drug Control Division. Specifically, the number of controlled substance registrants listed in the internal database was 18,535; the public website listed 18,000. Although not a large discrepancy, the department was unable to explain the reasons for the difference. The DCP commissioner told program review staff that many issues have been identified regarding the system and already addressed, and the remainder should be resolved once the system has been operational for a full year.

The commissioner has acknowledged the system is evolving but notes that the most important accomplishment is that for the first time, consumers and private businesses can access and verify licensing information online without requesting DCP staff to do this. Once enforcement activity on licensees is also available, the public will have a powerful tool to obtain a variety of information about licensees before making decisions.

Another issue related to the rolling out of the new system is staff training. The drug control staff received training in using the new system in October 2003, six months prior to it being brought online. This lag time was problematic for staff that had to use the system once it was online and, in the opinion of the committee, the Drug Control Division staff need refresher training on the system.

Internal systems within the Drug Control Division. Although the licensing system is available departmentwide, the Drug Control Division maintains five systems to track its various activities.

- **Inspections** (three separate databases). One database is for retail pharmacies, another for hospitals and clinics, and a third for nursing homes. Each provides a roster of identifying information including name, address, and the date of last inspection. (None of the three captures information on the number and types of deficiencies issued or whether a re-inspection was necessary).
- **Investigations and consumer complaints.** Although this system is used departmentwide, the Drug Control Division accesses investigations and consumer complaints just for its division. Each division is responsible for inputting their own information, and the committee found not all of the drug control cases have been entered into the system. Furthermore, although there is a field for capturing case outcomes, it is rarely filled in. This database is used primarily as a mechanism to track individual cases, rather than as a management tool.
- **Staff assignments.** All staff assignments are entered into this system, along with case opening and closing dates and a description of the assignment. Although it could be used to measure individual agent workloads, including the amount of time spent on various office functions, it is used only to track individual staff assignments. The committee found this database may over-count assignments related to investigations since some cases were inputted before it was determined there was not enough information to investigate or that the division lacked jurisdiction.

The program review committee strongly commends the agency movement to a single departmentwide system that provides for data integration of different functions (i.e., licensing, inspection, enforcement, and revenue). However, the committee believes a more structured approach in preparing for the next project phase needs to be adopted. A strategic plan did exist during the early stages of the project, but it has not been updated for several years.

The committee believes prior to the implementation phase of any enforcement activity database, each division manager should conduct an internal assessment of his or her division's operations. This assessment should determine the type of management information that must be generated by the new system in order to present a clear and accurate picture about division operations. The goal of any reports that are generated from the new system will be to help to establish relevant and measurable objectives, and to monitor outcomes and performance. For the Drug Control Division, this means that specific case information should be available for all inspections and investigations it conduct, as well as aggregate program data. Therefore, the program review committee recommends:

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.**

The lack of an adequate management information system limits the department's ability to monitor performance, evaluate operations, and identify necessary improvements. Requiring basic program information be reported to the legislature will, at the very minimum, begin to orientate managers away from a case-by-case approach, to one based on program evaluation and management activities.

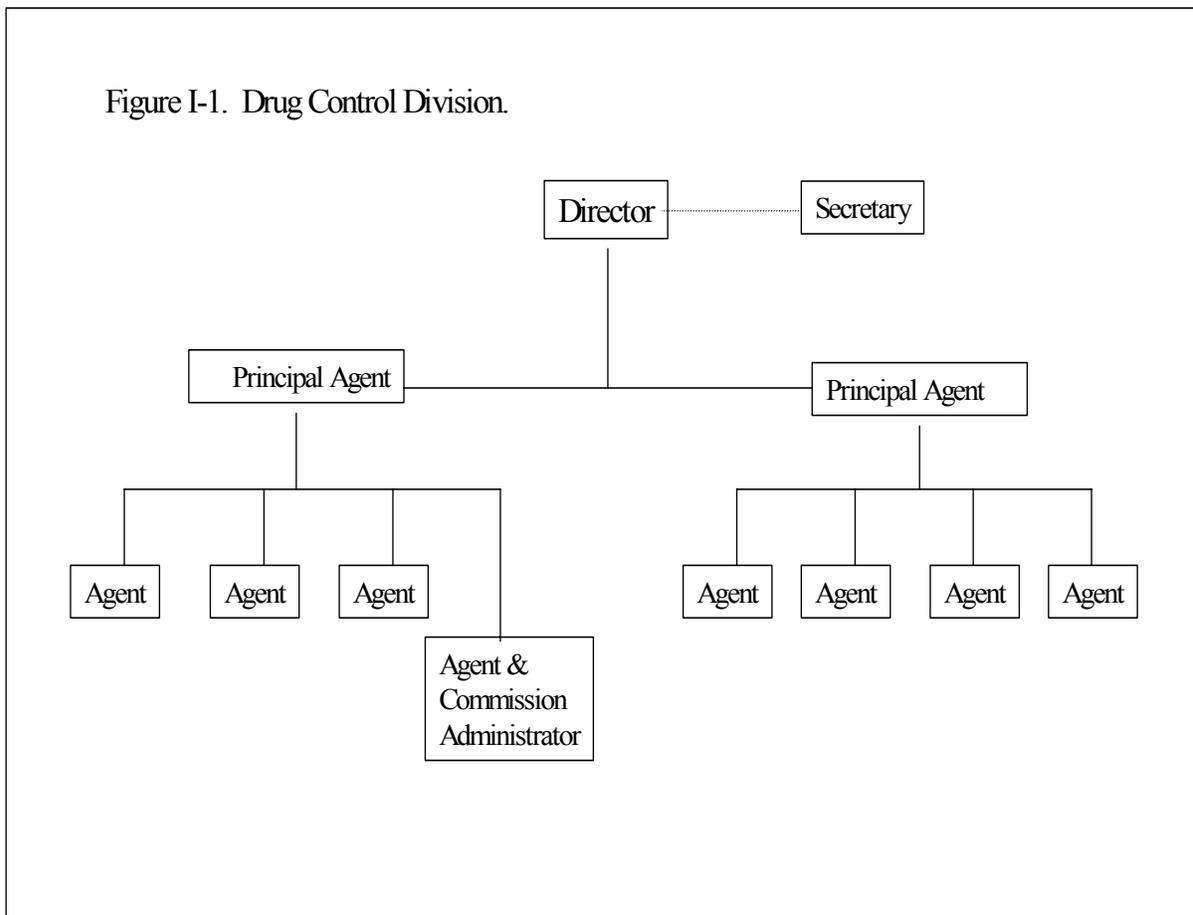
Division of Drug Control Resources and Responsibilities

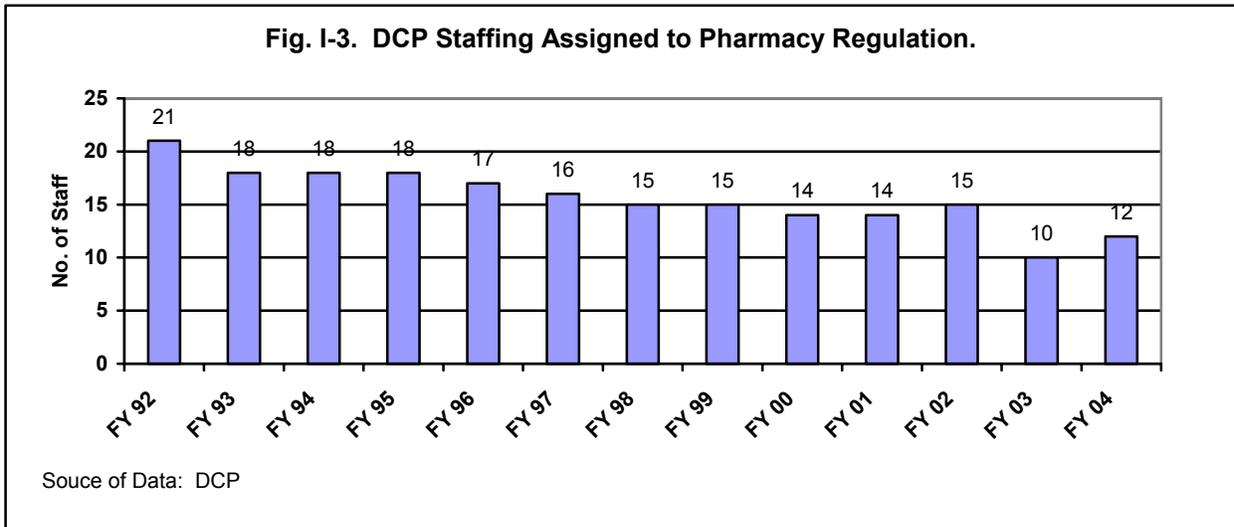
Organization and staff resources. Figure I-2 shows the organization of the Drug Control Division. The division is staffed by 11 agents, all licensed pharmacists including the director, and a secretary. The agents all have peace officer status under the Connecticut General Statutes, which empowers them to obtain and serve search warrants and arrest warrants, seize contraband controlled substances, and make arrests without warrant for certain offenses and under certain circumstances. All non-supervisory staff conduct both inspections and investigations. One agent serves almost full-time as administrator to the Commission of Pharmacy.

Figure I-3 shows staffing resources since FY 92. In FY 92, the department had 21 staff assigned to pharmacy regulation. By the end of FY 04, the division had only 12 staff—a 43 percent reduction in personnel resources. The largest reduction in staff occurred between FY 03 and FY 04 when the division lost five staff (at the end of FY 03). Although two new staff members were hired

in December 2003, the division still experienced a 25 percent reduction in staff between those two years.

It is important to note that although the division's resources have decreased significantly since 1990, the scope of its responsibilities has increased. The changes in the pharmacy environment over the last decade have been significant – the growth in the number and type of prescription drugs available, the number of prescriptions dispensed, the use of pharmacy technicians, and advances in technology have all contributed to the expansion of the division's oversight responsibilities.





Fiscal expenditures. Table I-1 shows the division’s expenditures since FY 99. The division’s expenditures grew by 13 percent over the six-year period examined. Expenditures grew about eight percent from FY 01 to FY 02, and three percent from FY 02 to FY 03, and then decreased 4 percent in FY 04. Personnel services account for about 93 percent of total expenditures.

<i>Fiscal Year</i>	<i>Personal Services</i>	<i>Operating Expenditures</i>	<i>Total GF Expenditures</i>
FY 99	\$850,464	\$71,935	\$922,399
FY 00	\$852,632	\$83,813	\$936,445
FY 01	\$865,749	\$95,719	\$961,468
FY 02	\$963,617	\$83,703	\$1,047,320
FY 03	\$993,678	\$87,910	\$1,081,588
FY 04*	\$970,929	\$69,327	\$1,040,256

*DCP could only provide estimates of personal service expenditures in FY 04 because of the conversion of budgetary data into the Core-CT system in November 2003. Due to system limitations, the department was only able to produce personal expenditure data for the Nov. 1, 2003 - June 30, 2004 period. Therefore, committee staff estimated July 1, 2003 – Oct. 31, 2003 expenditures by calculating average monthly expenditures for the Nov. through June period and multiplying by 12 months.

Source: Department of Consumer Protection

Scope of authority. The Drug Control Division performs several major activities in the monitoring of the prescription drug distribution system for compliance with state laws and regulations. Two major duties include:

- ensuring regulated persons and entities are in compliance with statutory and regulatory mandates by conducting inspections of establishments where drugs are located; and
- conducting investigations concerning:
 - pharmaceutical drug diversions by health care professionals, particularly with prescription drugs that are labeled as controlled substances; and
 - consumer complaints received primarily about medication errors.

In addition, division staff also:

- provide technical assistance to individuals located in a variety of pharmacy settings;
- destroy excess stock of controlled substance drugs for extended care facilities, some retail pharmacies, and the state police upon request;
- issue controlled substance registrations to health care practitioners who prescribe and/or administer controlled substances;
- provide training to law enforcement personnel, nurses, pharmacists, and pharmacy students, and speak to health care associations on a variety of drug enforcement issues; and
- ensure practitioner compliance with disciplinary sanctions imposed by the pharmacy commission.

Table 1-2 shows the frequency of the various staff assignments by activity performed for FY 03 and FY 04. Although the table is presented for general informational purposes, several caveats need to be made about the DCP staff activity database from which the information in Table I-2 comes, as well as another DCP database used to track DCP case referrals to the pharmacy commission and other health boards within DPH with respect to investigations. Program review staff noted different counts for investigations between the two databases that raise questions about the accuracy of the information captured in each. When asked about these discrepancies between the two databases, the division director stated that:

- the *staff activity database* may *over-count* investigations and complaints since some cases may have been inputted before it was determined there was not enough information to investigate or that the division lacked jurisdiction;
- prior to his tenure as director, some cases were never inputted into the *case referral database*, and thus any statistics would *undercount* the total number of investigations; and
- information is entered in the *staff activity database* at the beginning of an investigation, while the *case referral database* reflects the case status at the conclusion of the division's investigation, which may occur in another fiscal year so discrepancies would legitimately exist between the two.

Given this lack of reliability, committee staff conducted a manual file review for FY 03 and FY 04 to determine the actual number of cases investigated by the division. The results of the committee’s analysis are presented later in this chapter.

Table 1-2. Main Activities of Drug Control Division.		
Activity	FY 03	FY 04
Tech. Assistance	45	91
Drug Destruction	649	859
Investigation	377	535
Routine Inspection	225	34
Special Assignment	57	64
Special Inspection	260	191
Staff Seminars/Lectures	51	57
Source of Data: DCP staff activity database.		

Given these caveats, the table shows the most frequent activity conducted by staff is destroying controlled substance drugs. Most of the drug destructions occur at nursing homes, where staff also compare the drugs being destroyed to inventory records to ensure no diversion has occurred. The table also shows that the number of routine inspections decreased significantly between FY 03 and FY 04. This occurred, according to the division director, because of staffing reductions at the end of FY 03. However, the division director also noted that in addition to routine inspections, the division conducts special inspections, which are required for new pharmacies, and those that are closing, relocating, or have been remodeled.

According to division staff, the division also receives numerous calls from individuals with a variety of questions. These include inquiries about licensing requirements in the state, verification of licensing status, or consumer complaints that are not within its jurisdiction. Unfortunately, no log is kept on the number of calls received by the division so program review staff could not determine how the large volume of calls affects the division’s day-to-day workload. To respond to the high level of calls, however, on a rotating basis one staff person is assigned phone duty each day to answer and respond to calls.

Evaluation of Selected Drug Control Division Operations

As discussed above, the Drug Control Division performs several major activities in the monitoring of the prescription drug distribution system. The committee reviewed selected activities of the division including the:

- process used to inspect retail pharmacies and the results of those inspections;
- the types of investigations conducted in FY 03 and FY 04 and the outcomes of those investigations;
- use of division staff to provide continuing education training imposed by the Commission of Pharmacy for pharmacists found to have made medication errors; and

- use of division staff to destroy excess stock of controlled substances in long-term care facilities.

Findings and recommendations related to each of these activities are discussed separately below.

Inspections. Connecticut law requires the commissioner of DCP to hire staff to inspect all pharmacies and other places in which drugs and devices are or may be dispensed or retailed, and report any violations to the commissioner. *Although the law specifically requires the commissioner to inspect correctional facilities with respect to the handling of drugs, report on violations, and make recommendations for improvement to the authorities responsible for operating those institutions, the committee found these facilities are no longer routinely inspected.* The reason for this, according to the division director, is because these facilities no longer operate in-house pharmacies, and there are limited staff resources.

The committee believes routine inspections of correctional facilities are an important function and should be performed as required by law. Therefore, the committee recommends:

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 shall submit a report to the Legislative Program Review and Investigations Committee identifying the number of correctional facilities inspected within the previous calendar year.

The Drug Control Division also routinely inspects the pharmacy operations of the following entities:

- 609 pharmacies;
- 40 inpatient facilities (hospitals and state in-patient facilities); and
- 247 long-term care facilities.

The Department of Public Health, as part of its biennial licensing process, also inspects a variety of institutions including outpatient clinics, long-term care facilities, and certain hospitals. 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:

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.

The division also inspects research laboratories operating in the state (upon opening and closing) and has the authority to inspect the facilities of drug wholesalers and manufacturers licensed

in Connecticut, but usually defer these inspections to the U.S. Food and Drug Administration, which routinely inspect these types of facilities.

Inspection cycle. Connecticut law does not set a specific timetable in which routine inspections must be conducted. In interviews with program review staff, the division director stated that when the division was fully staffed, routine inspections were conducted on a four-year cycle. However, he acknowledged that only 34 inspections were performed in FY 04 because of staff reductions and the two new employees who were hired needed to be trained before they could conduct inspections on their own. The director also stated that his staff are frequently performing site visits at pharmacies providing technical assistance or conducting special inspections. If any violations are observed during these visits, the staff may advise the pharmacist or inform him or her that a violation will be issued.

Inspection purpose. The purpose of an inspection is to ensure compliance with state laws and regulations. In general, these laws concern:

- drug ordering;
- delivery;
- labeling;
- storage;
- security;
- recordkeeping; and
- dispensing.

Retail pharmacy inspections. 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. The pharmacist is asked to sign off on the inspection form.

A main focus of an inspection is ensuring proper documentation exists with respect to maintaining inventory and patient records. In particular, Drug Control Division staff conducting inspections will scrutinize controlled substance drug records to ensure compliance with the law, since these drugs are the most likely to be abused and, therefore, diverted. According to the division director, depending on the seriousness or extent of the violation, staff can either issue a deficiency or simply advise the pharmacist on duty (but not cite a deficiency) if violations of statute or regulation are found. Depending on the nature of the violation(s), division staff may or may not re-inspect the pharmacy at a later date.

Statistics. There were 632 licensed pharmacies in Connecticut as of December 3, 2004. Committee staff manually collected inspection data on 627 licensed community pharmacies in the state because none of the inspection data are automated, and no overall statistics are generated on the number or type of annual inspections performed or deficiencies issued. Specifically, committee staff compiled inspection information based on the last routine inspection performed by the division. Since some inspections involved new pharmacies as well as remodeled or relocating pharmacies, complete information on routine inspections existed for 552 pharmacies.

The analysis shows:

- over 30 pharmacies' most recent inspection report dated back to before 2000;
- 72 percent of the routine inspections conducted were of chain pharmacies, while 28 percent were of independents;
- 40 pharmacies (7 percent) had more than a four and one-half year span since their last routine inspections;
- 45 pharmacies (8 percent) required a re-inspection;
- the number of deficiencies issued ranged from zero to 13, with the majority (69 percent) of pharmacies being issued three deficiencies or less; and
- 87 pharmacies (16 percent) did not receive any deficiencies and, of these, the same agent inspected 56.

In addition to analyzing the inspection information, committee staff also accompanied a drug control agent on a three-hour inspection of a community pharmacy. Based on those observations, and examination and analysis of the inspection forms, 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.*

The program review committee believes that several modifications need to be made to the current retail pharmacy inspection process. One of the first initiatives should be to update the inspection form and automate the information contained on it. The committee also believes supervisors need to ensure staff conduct inspections in a consistent manner to ensure the integrity of the process.

Part of the inspection process involves an examination of actual prescriptions in order to detect whether possible forgeries exist or if there has been excessive prescribing activity, as well as ensuring that prescriptions are filled out properly and stored according to law. The committee believes a standard methodology needs to be developed to review these records. The methodology should be based on the number of prescriptions received by the pharmacy so it accounts for differing levels of dispensing activity among pharmacies.

Finally, although the law does not specify how often inspections must occur, the program review committee believes it is an important regulatory function of state government. Inspections serve as a deterrent to pharmacies and help ensure compliance with the law. Mandating a four-year inspection cycle seems reasonable given that there are about 625 retail pharmacies in the state and eight staff available to conduct inspections. A four-year cycle would require each agent to complete an average of 1.6 inspections per month.

As a result of the findings, the program review committee recommends the inspection process be modified as follows:

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.

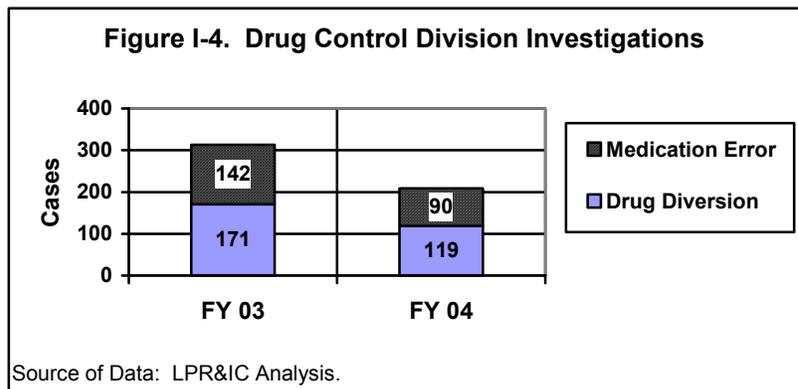
The division should establish criteria, based on the number and/or severity of deficiencies issued, that will automatically trigger a re-inspection. Any pharmacy that has received a deficiency shall provide in writing, within 10 days of the deficiency being issued, a plan of correction or evidence that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

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

Investigations. Although conducting inspections are an important part of the division’s work, the division director estimates that the majority of the staff’s time revolves around carrying out investigations. The division has broad authority to investigate any allegations involving misuse of prescription drugs and is also responsible for investigating all reports of complaints. Almost all of the investigations conducted by the division can be separated into two categories – those involving diversion of controlled substances by health care professionals and other workers with access to these types of drugs, and those concerning medication dispensing errors.

As noted above, although the division does maintain a database on its investigations, the program review committee found incomplete entries into it and no outcome information. Because the division does not produce any statistics on the number of investigations it conducts, committee staff collected information from the case files on all investigations opened by the division in FY 03 and FY 04.

Figure I-4 shows the total number of investigations conducted each year categorized by whether the investigations involved allegations of prescription drug diversion or medication error. Altogether the division conducted 313 investigations in FY 03, with 55 percent of them involving prescription drug diversion. In FY 04, there were only 209 investigations that committee staff identified in the case files. It is unclear how many more investigations were done, since individual agents may still have been working on some of the cases, and so those final reports would not have been filed at the time committee staff collected the data (September 2004). Each type of investigation is discussed separately below.



Drug diversion investigations.

Prescription drug abuse is a major problem in the United States. Federal and state law revolves around legitimate drug use and ensuring drugs are not diverted from their intended use. Drug abuse in most cases involves drugs that are called controlled substances.

Federal and state laws categorize all potentially abused drugs into one of five schedules. The restrictions on controlled substances vary according to the schedule in which the controlled substance has been placed. Controlled substances in Schedule I are the most restrictively controlled, and those in Schedule V are the least restrictively controlled. Schedule I includes illegal drugs like heroin and mescaline, while Schedule V includes many cough preparations that contain a limited amount of codeine.

People and places authorized to possess these drugs are then required to be registered with DEA. As noted above, under Connecticut law, practitioners who write prescriptions for controlled substances and inpatient and outpatient facilities that administer controlled substances must register with DCP as well as with DEA. This includes physicians, dentists, podiatrists, veterinarians,

osteopaths, advanced practice registered nurses, nurse-midwives, physician assistants, and optometrists.

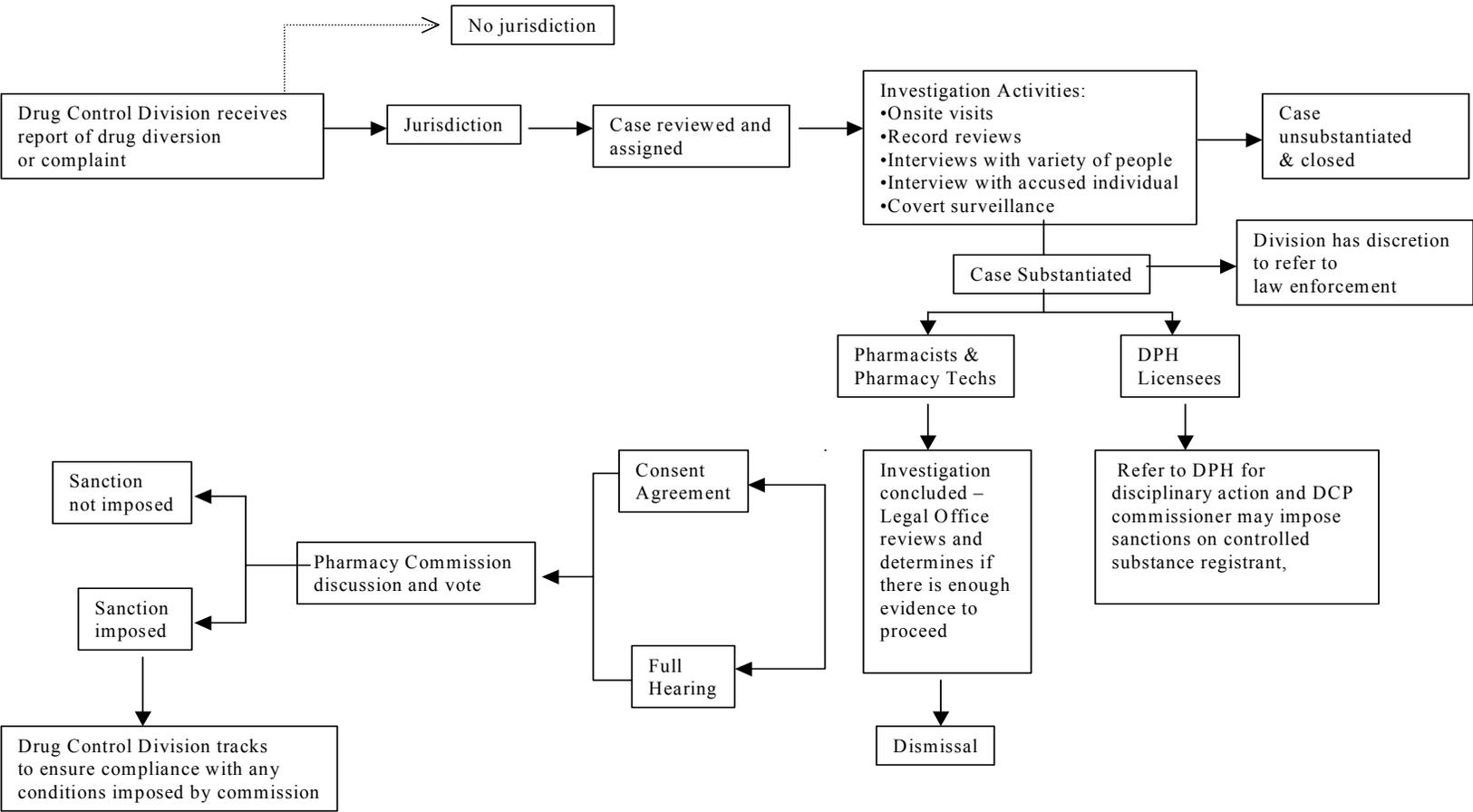
Federal and state laws also require specific records be kept so the whereabouts of any controlled substance can be followed along the entire distribution chain. Thus, every transaction in which controlled substances are received or dispensed must be recorded. Based on these records, it should be possible to identify, for any registrant, the controlled substances that are on hand, their source, and to whom they have been dispensed. This ensures these drugs can be tracked during the course of an investigation.

Figure I-5 outlines the process followed by the Drug Control Division when conducting an investigation involving allegations of drug diversion. The division investigates pharmacists and technicians as well as any health care practitioner who holds a controlled substance registration issued by the department. In addition to these practitioners who are authorized to prescribe drugs, the division also investigates nurses suspected of diverting controlled substances. The division has the discretion to refer investigations involving health care workers: to health boards or the pharmacy commission for administrative action; to local, state, or federal police for criminal action; or both.

Depending on the case, the division may or may not work with other law enforcement agencies when conducting the investigation. Whether or not this occurs depends on a variety of factors including who initiates the investigation, the volume of drugs allegedly diverted, whether it is a first-time offense, and whether the diversion was because of self-abuse or sale. During the course of an investigation, typical staff activities include interviews with a variety of sources, examination of prescription records for forgeries, review of pharmacy inventory records, and inventory audit of the drug suspected of being diverted.

Investigation sources. The division will open a drug diversion investigation based on information from a variety of sources. Figure I-6 identifies the type of individual who reported the suspected diversion to the division for cases reviewed by program review committee staff. In

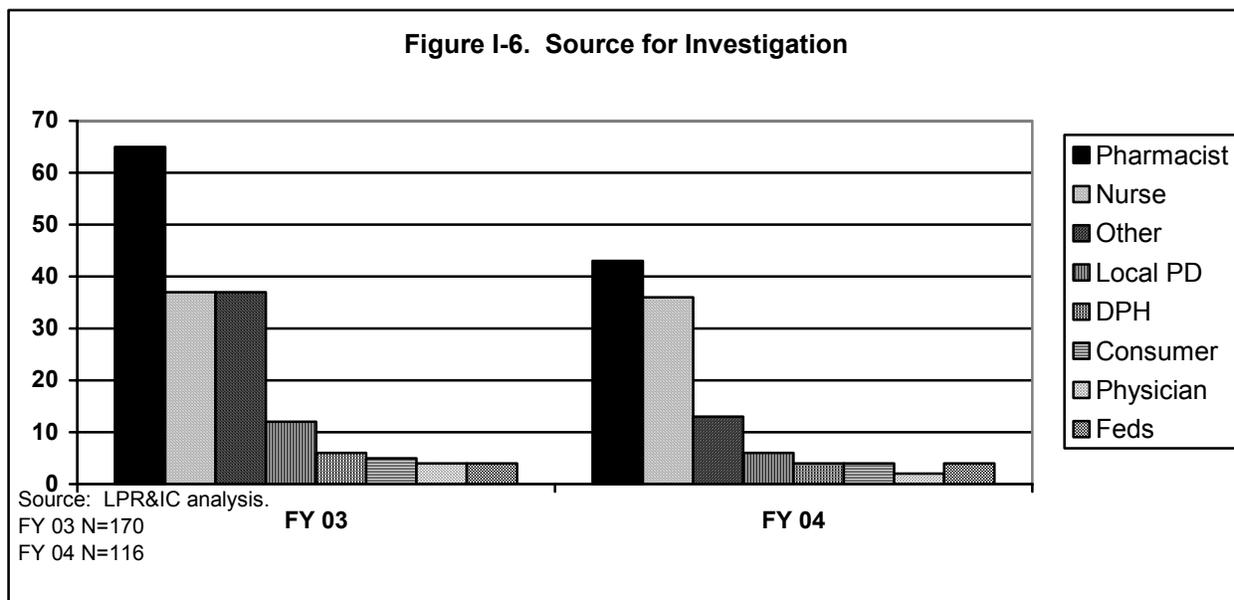
Figure I-5. DCP Investigation Process.



addition to nursing directors in nursing homes, pharmacists also frequently report suspected cases of diversion to the Drug Control Division. Typically, pharmacists will contact the division if they uncover unusual prescribing activity by one specific prescriber, if a prescription looks forged or altered, or if they suspect a co-worker is diverting drugs.

In FY 03, pharmacists accounted for 38 percent of all diversion reports and 37 percent in FY 04. Other sources include federal, state, and local law enforcement agencies, self-reported thefts or losses of controlled substances (by law, these must be reported to DEA and DCP), physicians, and consumers, counterpart offices in other states, state agencies such as the Department of Public Health and the Department of Social Services, and results of an inspection or audit by the division itself.

In addition to health professionals, the division will occasionally receive calls from local police departments to notify it of a non-health professional who is suspected of “doctor shopping” (i.e., visiting multiple doctors and fraudulently obtaining multiple prescriptions for the same drug). The Drug Control Division will canvass area pharmacies to review practitioner prescribing patterns, determine if multiple providers are prescribing controlled substances for one individual, and may even interview the individual suspected of doctor shopping. If the evidence suggests diversion is occurring, it is given to the local police department for arrest purposes. If it appears an individual is doctor shopping, the investigating agent notifies all health providers who had written any of the prescriptions.



Target of investigation. Table I-3 shows the number of investigations opened by the Drug Control Division for the two years in which data were collected and the investigation target. In both years, nurses were the most frequently investigated, accounting for about 40 percent of all investigations conducted. Physicians (FY 03) were also recurrent investigation targets. Investigations involving pharmacists and pharmacy technicians remained fairly consistent over the two-year period, with about 15 to 20 percent of all investigations performed focused on them.

<i>Health Professional</i>	<i>FY 03</i>	<i>FY 04</i>	<i>Total</i>
Nurse	64	51	115
Physician	36	13	49
Other	29	6	35
Pharmacy Technician	13	11	24
Pharmacist	12	13	25
Dentist	8	9	17
Nonspecific target	9	16	25
Total	171	119	290

Source of Data: LPR&IC analysis of DCP investigation files.

Typical investigations conducted by the Drug Control Division involving DPH licensed health professionals with prescribing authority concerned:

- inappropriate prescribing for self and/or family members;
- office staff calling in prescriptions without physician knowledge;
- over-prescribing for individuals; and
- prescribing outside an individual’s scope of practice (for non-physician prescribers).

Investigations of nurses almost always involved suspicion of drug diversion and usually were reported by a nursing services director at a nursing home. As part of the investigation, agents look for unusual medication administration patterns by the nurse suspected of diversion and compare those to patterns of other nurses in the home. This includes:

- reviewing medication administration records on several different dates to determine if larger doses are administered to a patient when the nurse suspected of the diversion is on duty;
- examining patient medical charts for physician medication orders and comparing them to medication administration records to determine if larger doses are used by the nurse under suspicion; and
- interviewing patients to make sure they obtained the correct medication.

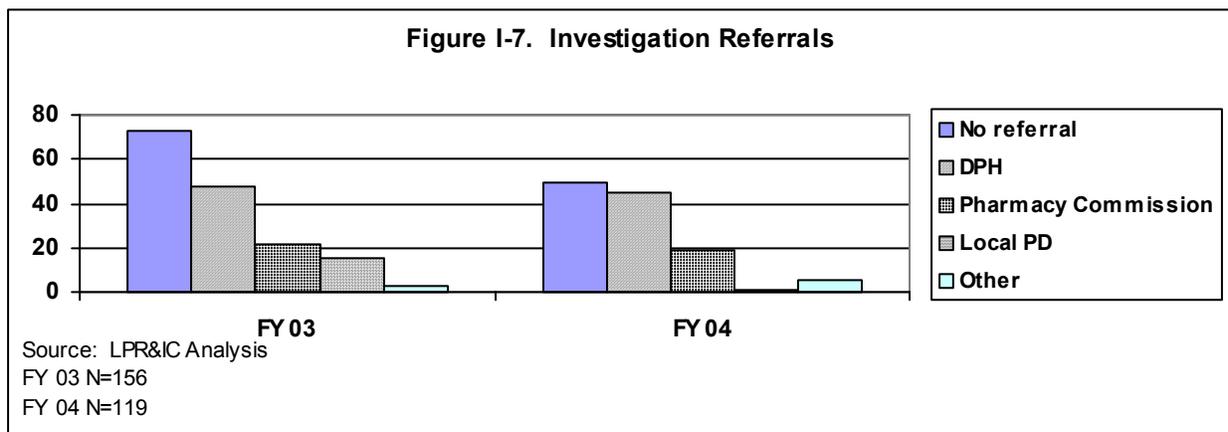
The “other” category shown in the table includes a variety of investigation targets including other practitioners with authority to prescribe controlled substances (such as optometrists, physician assistants, podiatrists, veterinarians, and osteopaths), individuals with access to prescription blanks or controlled drugs such as physician office staff or store clerks that go behind the pharmacy counter. The “non-specific” category shown in the table includes reports of lost prescription drugs that have been investigated by division staff because of the volume or circumstances related to the loss.

Average length of time to complete an investigation. The division does not compile statistics on the average time it takes to complete a drug diversion investigation. According to the division director each case is unique and may take anywhere from two days to one year. Based on program

review committee staff case file review for cases opened in FY 03, on average, it took 65 days for the Drug Control Division to complete 158 of the 171 total investigations conducted in FY 03. Data were not available on the remaining cases.

Investigation referrals. If evidence is collected that shows drug diversion occurred, the drug control agent will interview the individual and confront him or her with the evidence. If the individual is a health practitioner, the agent will explain that this information will be forwarded to the relevant board or commission and explain the types of disciplinary action that may be imposed. The agent will also try to obtain a confession, in writing, get the practitioner to immediately voluntarily surrender his or her license, and inform the practitioner of the addiction recovery group available for the applicable profession. If the individual holds a license through DCP or DPH, usually the division will not contact the police unless the diversion involved the trade or sale of the diverted drug.

Figure I-7 identifies whether or not the investigation resulted in a referral for further action. As the figure shows, almost half of the investigations conducted by the Drug Control Division are not substantiated and, therefore, are not referred. The largest numbers of referrals made are to the Department of Public Health, which then examines the investigation reports and determines whether or not to present them to the appropriate health boards for disciplinary action. Most of the investigations that are substantiated and referred to DPH involve nurses (40 cases in FY 03, compared to four cases that involved physicians and four that involved dentists).



Referrals to DPH. The DCP commissioner, not the pharmacy commission, has the authority to suspend, revoke, or refuse to renew an individual or facility controlled substance registration for a variety of reasons. In addition to any sanction imposed against a registrant by DCP, all investigations that have merit are referred to DPH for further disciplinary action by the appropriate licensing board.

Referrals to the pharmacy commission. Once an investigation is completed and the pharmacy commission has jurisdiction, the investigating staff will discuss the case with the department’s Legal Office. Based on the facts of the case, an attorney in the Legal Office will determine if there is a statutory violation and whether there is enough evidence to proceed with potential disciplinary action against a licensee. Outcomes at this stage include dismissal, settlement

through a negotiated consent order that is approved by the pharmacy commission, or a decision after a full hearing by the commission of pharmacy.

As part of the settlement process for cases that are under the jurisdiction of the pharmacy commission, one commissioner from the commission “steps down.” This means that the commissioner becomes familiar with all aspects of the case during the negotiation phase and agrees with the terms of any settlement that will be offered. The reason that one member “steps down” is that if a voluntary settlement is negotiated, the rest of the commissioners never learn the specifics of the case or the name of the violator, even though the commission must approve these settlements. These commissioners usually trust that the member who “stepped down” believes the proposed sanction is adequate. In addition, the commissioner cannot vote on the case when it comes before the commission and may respond to any questions that the other commissioners have.

If a voluntary settlement cannot be negotiated (either because the department does not want to offer one or the accused does not want to enter into one), the commission will hold a formal hearing. If a commission member “stepped down,” that member must abstain from discussing or voting on the case. The assistant attorney general assigned to the commission usually attends the hearings in case any legal administrative questions arise, and all proceedings are recorded to create a public record.

DPH board or pharmacy commission action. Outcome information on action taken by a DPH health board or the pharmacy commission is rarely contained in the investigation case file. To obtain information on actions taken by health boards, committee staff relied on the Regulatory Action Reports published quarterly by DPH. To gather data on disciplinary actions imposed by the pharmacy commission, committee staff reviewed the commission’s monthly meeting minutes since July 2002. Outcome information was collected only for investigations that were opened in FY 03 because it is likely the commission or DPH board has not yet acted on many cases opened in FY 04 and subsequently referred.

For cases opened by the Drug Control Division in FY 03, the program review committee identified 47 cases referred for further action to DPH.

- Of the 40 cases referred to the nursing board, the committee identified action taken by the board in 33 cases. Of these 33 cases, the nursing board imposed multi-year probation with conditions attached (e.g., random drug screens, therapy, employer reports, and no solo practice) on 24 nurses, revoked three licenses, suspended four licenses, and dismissed one case. In one case, the nurse voluntarily surrendered his or her license.
- There were four cases referred to the medical examining board. Of these, one license was suspended, one voluntarily surrendered, and one put on probation with conditions. An additional case concluded with an agreement to surrender the practitioner’s license on a specific date in the future.
- There were four cases referred to the dental board. Of these, the board imposed probation in two cases and accepted the voluntary surrender of the practitioner’s license in the other two cases.

Altogether, 22 out of 25 cases involving pharmacists and pharmacy technicians investigated by the Drug Control Division in FY 03 resulted in a referral to the pharmacy commission. Of the 22 cases, ten involved pharmacists accused of diverting prescription drugs and 12 involved pharmacy technicians. Sanctions imposed on pharmacists by the commission were similar to those imposed by the nursing board and included probation with various conditions attached. Action on pharmacist technician registrations were identified in only nine cases, with 86 percent involving a voluntary surrender and one case involving suspension of the technician's registration.

Length of time. The committee examined the average length of time it takes for the Drug Control Division staff to conduct an investigation and for board or commission action to occur. Data are only presented for cases opened in FY 03 because not all FY 04 investigations were completed by the end of the fiscal year. For cases that were opened in FY 03, it took on average:

- 239 days from case opening to DPH board action (based on 41 cases); and
- 126 days from case opening to pharmacy commission action (based on 18 cases).

Findings. 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. Each investigation case file was filed by the name of the health professional being investigated, and a summary sheet was included in the file. The summary sheet provided a chronology of a case and explained what and when actions occurred. This sheet provided a narrative of all the activities conducted by the agent related to the investigation and included:

- names of all individuals interviewed and their professional titles if applicable;
- names of any federal, state, or local officials who participated in the investigation;
- dates of significant meetings and a summary of any discussion that occurred;
- any evidence collected (if applicable);
- a summary of any interviews conducted with the accused, along with a written confession if applicable; and
- a recommendation on whether or not a case should be referred to either DPH or the pharmacy commission.

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. Automation of enforcement activity as recommended on page nine and ten of this report will assist in obtaining better information on the scope and outcome of investigations performed by the division and final action taken by the relevant health board or pharmacy commission. However, information about any action taken by a DPH health board or the pharmacy commission should be included in the case file. Therefore, the committee recommends:

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 should 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.

Ultimately, investigators in the Drug Control Division and those in the Department of Public Health should have online access to investigations conducted by either agency concerning DPH health professionals accused of diversion, regardless of which agency conducted the investigation. Likewise, if DPH investigates a health professional because of a practice issue, if the DPH investigation results indicate drug abuse was a contributing factor, the Drug Control Division should be made aware of this.

Medication error investigations. The other type of investigation conducted by the Drug Control Division are those involving medication errors. Almost all consumer complaints received by the Drug Control Division involve medication errors. The division accepts complaints received via telephone and in writing. According to the division director, most complaints are received over the phone from consumers regarding a medication error. The reason complaints are accepted over the phone is due to the potential serious harm that could result if a medication error was made. A small number of complaints relate to issues such as confidentiality of prescription information, improper substitution of a generic drug for a brand name drug, and pharmacy technicians performing duties outside their scope of practice or not having appropriate supervision.

During the 2002 session, the General Assembly recognized the potential harm caused by medication errors and passed legislation calling for the DCP commissioner to adopt regulations that require pharmacies to establish quality assurance programs designed to detect, identify, and prevent medication errors (P.A. 02-48). The law also requires each pharmacy to post a sign in a conspicuous location stating that if a consumer had a concern that an error occurred in the dispensing of his or her prescription, the consumer could contact DCP Drug Control division by calling a toll-free DCP number. This statement must also be included on each receipt or in each bag from a pharmacy containing a prescription drug. Finally, Public Act 02-48 requires records be kept ready for inspection for at least three years and available to DCP within 48 hours in cases in which the commissioner is investigating an error report.

Altogether, there were 142 medication error investigations conducted in FY 03 and 90 in FY04. Investigations involving medication errors are usually labor-intensive because division agents usually visit the pharmacy, as well as interview the individual making the complaint to collect evidence.

Process to investigate medication errors. When a complaint about a medication error is received, an agent will review the complaint to ensure the department has jurisdiction and, if so, open an investigation. Typically, medication error investigation activities include:

- interviews with the:
 - individual (or patient representative) making the complaint;

- health care practitioner who wrote the prescription (if applicable);
- drug wholesaler or manufacturer (if applicable).
- an onsite visit to the pharmacy where the error occurred, and a face-to-face interview with the pharmacist on duty at the time the error occurred;
- a review of the written prescription or fax to ascertain if the error was the result of poor handwriting; and/or
- identifying the location of the drug on the shelf to determine if similarly named drugs are next to each other.

According to the division director it can be difficult to verify whether or not an error has occurred, particularly when it involves a called-in prescription from a physician's office. If a complaint is substantiated, it means the director forwards the results of the investigation to the department's legal office for review for possible referral to the pharmacy commission.

The committee analyzed consumer complaints received in FY 03 and FY 04. The analysis shows:

- there were 142 complaints received in FY 03 and 90 in FY 04;
- the target of all investigations were pharmacists since the ultimate responsibility for the final check of each prescription rests with the pharmacist on duty;
- in FY 03, 86 percent of complaints investigated were referred to the pharmacy commission for action, and in FY 04, 76 percent were referred;
- over the two-year period, there were 19 pharmacists with multiple errors – 12 had two errors; three had three errors; three had four errors; and one had five errors; and
- the commission had not yet taken action in 78 percent of the cases reviewed involving pharmacists that had committed multiple errors.

Disciplinary action. Although no formal criteria exist, the pharmacy commission imposes similar disciplinary sanctions on pharmacists who have committed one or two prescription drug errors within a three-year period. These pharmacists must complete a continuing education class on the prevention of prescription drug errors. If it is a first error, the case will be dismissed upon completion of the class with a caution. If it is a second error, the pharmacist will receive a letter of reprimand. The type of sanction imposed by the commission becomes progressively more severe if more errors are committed within a three-year period. For the pharmacist who committed five errors (cited above), the commission imposed a two-week suspension, a one-year probation, a 90-day restriction on practicing without assistance, employer notification, \$1,000 fine, and required a risk management protocol be developed.

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

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.

Educational presentations. The Drug Control Division staff are also involved in training law enforcement personnel, hospital staff, and other medical and health professionals, in addition to speaking to health care associations, on a variety of drug enforcement issues including medication error prevention classes as noted above. Table I-4 shows there were 48 lectures given by division staff in FY 04. The table also summarizes the subject of the lectures, the target audience, and the number attending.

Table I-4. Educational Presentations in FY 04.			
<i>Subject</i>	<i>Audience</i>	<i>No. of Lectures</i>	<i>No. of Participants</i>
Narcotic Lecture	MPTC: Police recruits and officers, Judicial Marshals	13	558
Medication Errors	Pharmacists	4	734
Rave Party Drugs	East Hartford police	6	119
CT Pharmacy Law	pharmacists, hospital staff, pharmacy associations	16	1,225
Other	police recruits, physicians, LPNs, UCONN students, pharmacists and technicians	9	1,250
Total		48	3,886

Source: Department of Consumer Protection, Drug Control Division.

Tracking compliance. The division also monitors compliance of licensees who have been the subject of disciplinary orders imposed by the pharmacy commission. There are three primary areas that require monitoring by the division. They include individuals who have been sanctioned by the commission for:

- drug and/or alcohol abuse: typically consent agreements are negotiated and the practitioners voluntarily surrender their licenses for a period of time. If the practitioners meet the conditions of the agreements, their licenses are restored and they are placed on probation with various conditions imposed and drug screens required to be submitted to the division. Currently the department is monitoring 25 pharmacists.
- not meeting continuing education requirements: these individuals are tracked for a period of three years. At any given time the department is tracking approximately 10 to 20 pharmacists.
- Making medication errors: as noted above, pharmacists must take a mandatory class on how to prevent future errors. Their status is tracked until the class is completed.

Destruction of controlled substances in nursing homes. Long-term care facilities generally do not have pharmacies on site, so they typically receive controlled substances prescribed for specific patients in 30-day supplies. As patients leave or their medication needs change, the long-term care facilities accumulate stocks of excess controlled substances. The excess stocks can result in significant problems of waste and disposal.

Currently, 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. The staff activity database maintained by the department is the only aggregated source of information for the number of drug destructions performed each year. That database shows in FY 03, there were 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.

Committee staff contacted the state of Massachusetts to determine exactly how excess stocks of controlled substances are destroyed in nursing facilities. According to the Massachusetts Drug Control Division Director two nursing home staff, licensed by the public health department or the pharmacy board, are allowed jointly to dispose of controlled substances. The policy allows only four individuals employed by a facility to perform a destruction - a nursing home administrator, a director of nursing, an assistant director of nursing, and a pharmacist consultant. Each time controlled substances are destroyed it must be documented on a special form and maintained in a separate book. According to the director, there have been very few problems, and it is an efficient approach to dealing with this issue.

The committee believes a similar program would work well in Connecticut. Allowing responsible licensed employees of a long-term care facility to perform this function would free up division staff resources so that they can be used on other functions, such as conducting inspections. Therefore, the committee recommends:

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.

Automatic dispensing machines. The program review committee believes that destruction of controlled substances needs to be further studied to determine if a more cost effective approach to handling excess stocks of controlled substances in long-term care facilities could be developed. The majority of nursing home residents are recipients of Medicaid, a jointly funded state and federal program and therefore, many of the controlled substances being destroyed are paid for by public dollars.

One possible method would be to allow the use of automatic dispensing machines. These machines are similar to a vending machine – a pharmacy stores bulk drugs in the machine in separate bins, and it programs and controls the machine remotely. Only authorized staff have access to its contents, which are dispensed on a single-dose basis at the time of administration pursuant to a prescription. The machine electronically records each dispensing, thus maintaining dispensing records for the pharmacy. Because the drugs are not considered dispensed until the machine provides them, drugs in the machine are considered pharmacy stock, not waste. The state would need to authorize pharmacies to store stock in the automated dispensing machine and develop policies with respect to access and security. To explore this issue further, the program review committee recommends:

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.

Chapter Two

Commission of Pharmacy

The pharmacy commission is composed of six members appointed by the governor. Four members must be full-time pharmacists and two must be public members. At least two of the pharmacist members must be community retail pharmacists, and at least one must work full-time at a hospital pharmacy. The governor may select commission members from a list provided by the Connecticut Pharmacists Association or by other professional pharmacists' associations. Members' terms are coterminous with that of the governor. By statute, the commission is required to meet at least six times a year, although in practice, meetings are held about once a month.

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.

Authority and duties. The commission is responsible for overseeing the licensing of pharmacists and pharmacies, the registration of pharmacy interns and technicians, the dispensing of prescription and non-prescription drugs, and pharmacy practice in general. It has authority to discipline individuals engaged in the practice of pharmacy, has subpoena power, and can apply through the attorney general for temporary or permanent injunctions and temporary restraining orders to enforce the Pharmacy Practice Act.

The DCP commissioner supervises the commission's operations. The commissioner has, with the commission's advice, adopted regulations for licensing and disciplining pharmacists, licensing and operating a pharmacy, maintaining pharmacy records, and registering pharmacy interns and technicians.

Terms of commissioners. Connecticut law limits members of boards and commissions under DCP to two consecutive full terms of four years each, except that if no successor has been appointed or approved, such member shall continue to serve until a successor is appointed or approved. The committee examined the term lengths for each of the pharmacy commission commissioners (shown in Table II-1). *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 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.*

<i>Type of Member</i>	<i>Date Appointed</i>	<i>Length of Term</i>
Pharmacist ¹	1983	21 years
Public	1989	15 years
Pharmacist	1994	10 years
Pharmacist	1995	9 years
Public	2000	4 years
Pharmacist	2003	1 year
¹ Commission chairperson since 1989.		
Source: Connecticut State Register and Manual, Secretary of the State, 1983 – 2003.		

Licensing Pharmacists

The American Council on Pharmaceutical Education is the accrediting organization that sets standards for pharmacy schools and the standards for continuing pharmaceutical education. The University of Connecticut operates the only accredited pharmacy school in Connecticut.

The National Association of Boards of Pharmacy (NABP) is the nationally recognized entity for setting standards for testing and licensing pharmacists. The NABP administers the national examination for pharmacists. The association also operates a national clearinghouse for disciplinary actions and licensing transfers. Individuals applying to the commission in Connecticut for licensure by reciprocity are subject to a NABP search of disciplinary actions in other states, and that information is reported to the commission.

Pharmacist license. The department, upon the commission's authorization, issues licenses to practice pharmacy. In order to receive a license, an applicant must have:

- graduated from and received an entry-level professional pharmacy degree from a commission-approved college or school of pharmacy;
- served as a pharmacy intern as required by regulations;
- passed two exams administered by the National Association of Boards of Pharmacy (one is the North American Pharmacist Licensure Examination and the other is the Multi-State Pharmacy Jurisprudence Examination for Connecticut); and
- passed two state examinations administered by the Commission of Pharmacy on pharmaceutical mathematics and contemporary pharmacy practice.

In addition, all candidates must appear before the commission for a personal interview.

The national exams are computerized and can be taken at any time throughout the year. The commission administers the state exams twice annually (January and June), although exceptions can

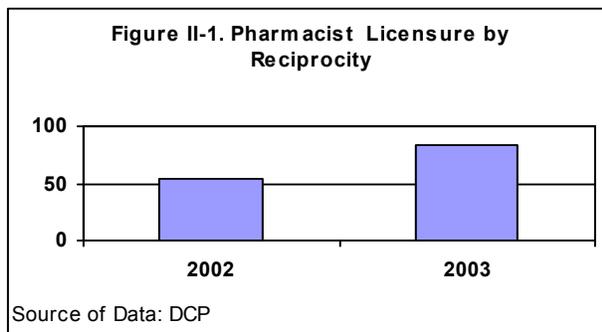
be made.³ The examination fees total \$850 -- \$600 for the national exams and \$250 (which includes the initial licensing fee) for the two administered by the commission.

Examination statistics. Although the commission does not routinely compile statistics on the number of candidates sitting for the examinations it administers, it did provide them for the most recent exams held (July 2004 exam). There were 103 individuals who applied for the July Pharmacy Calculations and Pharmacy Practice Examinations and 93 actually sat for the exams. The results show an 88 percent pass rate -- 82 individuals passed it, and 11 individuals failed it.

Licensure by reciprocity. The NABP administers the Electronic Licensure Transfer Program (ELTP) that allows pharmacists already licensed by examination in one state to obtain licensure in another state by reciprocity, other than those licensed in California or Florida. These states are excluded from reciprocity because they do not reciprocate if a Connecticut pharmacist wishes to be licensed. To obtain a license by reciprocity, a candidate must take the MPJE (CT version) national exam and, prior to licensure, appear for an interview before the Connecticut Commission of Pharmacy.

Figure II-1 shows the number of pharmacists licensed by reciprocity over a two-year period. Fifty-four pharmacists received licensure by reciprocity in 2002, and 83 in 2003, a 54 percent increase.

Continuing education requirement. A pharmacist's education does not end upon being licensed. Most states, including Connecticut, require licensed pharmacists to take continuing education courses annually or biennially in order to maintain their licenses to practice. Pharmacists obtain this additional education through correspondence courses, attending professional meetings and seminars presented by pharmacy associations, or participating in courses provided by pharmacy schools.



In Connecticut, the commission cannot authorize the department to renew a license (except for the first renewal) unless the applicant has satisfactorily completed at least 15 "contact hours" of continuing professional education in the calendar year immediately preceding the license's expiration. At least five of these hours must be earned by attending a live presentation of an accredited continuing education program. A pharmacist applying for renewal must submit a statement signed under the penalty of false statement that the pharmacist has satisfactorily completed no less than 15 contact hours of accredited continuing professional education in the previous calendar year.

According to the pharmacy commission administrator, about 10 percent (approximately 425) of renewal applications are subject to a random audit to ensure the continuing education requirement has been met. These applicants are asked to submit proof of continuing education classes taken. If an applicant has signed a renewal notice attesting to the completion of the continuing education

³ In 2004, a make-up exam was offered in September for candidates with valid reasons for not being able to take the July exam.

requirement and it is found the individual made a false statement, the individual is referred to the commission for disciplinary action. About 10 to 20 individuals annually are found not to have met the requirement based on the audit and are referred for disciplinary action.

Reasons for disciplinary action per the Pharmacy Practice Act. The commission may refuse to issue or renew a license, temporary permit or registration, may suspend or revoke a license or may assess a civil penalty of up to \$1,000 if it finds a license applicant or license holder has:

- 1) violated a drug law or laws relating to pharmacy practice;
- 2) been convicted of violating such a law;
- 3) been disciplined by a pharmacy disciplinary agency;
- 4) been refused a license elsewhere;
- 5) illegally possessed or sold drugs;
- 6) abused drugs;
- 7) made a false, misleading, or deceptive representation to the public or the commission;
- 8) maintained exclusive computer or phone lines to any practicing doctors, hospitals, or nursing homes;
- 9) substituted drugs, except as permitted by law;
- 10) returned to stock a drug possibly contaminated or substituted;
- 11) split fees for professional services with a prescribing doctor, administrator, or owner of a nursing home, hospital, or other health care facility;
- 12) entered into an agreement with a prescribing doctor, administrator, or owner of a nursing home, hospital, or other health care facility to dispense a secret formula or coded prescription;
- 13) committed or been a party to a fraudulent practice;
- 14) presented a fraudulent or illegally obtained diploma, or a diploma from a school which the commission does not approve;
- 15) been negligent or incompetent;
- 16) falsified a continuing education document;
- 17) permitted an unlicensed person to practice; or
- 18) failed to keep pharmacy premises orderly and sanitary.

The commission can also impose up to a \$5,000 fine for any person who violates any provision of the Pharmacy Practice Act for which no penalty has been provided. The commission may also refuse to issue or renew, or may suspend or revoke a license, if it finds that an applicant or license holder has a physical, emotional, mental, or other condition that would interfere with pharmacy practice or operation, subject to the Americans with Disabilities Act.

Pharmacy Technicians

The Pharmacy Practice Act also regulates the registration of pharmacy technicians who perform routine functions in the dispensing of drugs that do not require the use of professional judgment and are performed under a pharmacist's direct supervision. A person must be registered by DCP in order to act as a pharmacy technician.

Pharmacy technicians have to complete initial and continuing in-service training as determined by the pharmacist manager of each pharmacy. The pharmacist manager is responsible

for maintaining a written record documenting the initial and continuing training. Inspections conducted by the department typically review this information to make sure training has been documented.

Regulations recently adopted allow for a ratio of three technicians to one pharmacist, if the technicians have received certification by the National Pharmacy Technician Certification Board; otherwise the ratio is two to one. The pharmacist providing direct supervision of pharmacy technicians is responsible for their actions. License action may be taken against a supervising pharmacist for any violation relating using technicians for disallowed tasks.

Pharmacy technicians cannot:

- receive new prescription orders verbally from a prescribing practitioner;
- consult with a patient regarding medication;
- perform any identification, evaluation, interpretation, or needed clarification of a prescription;
- consult with the prescribing practitioner regarding a patient;
- interpret the clinical data in a patient medication record system;
- perform consultation with prescribing practitioners, nurses, etc;
- verify a prescription prior to its release for patient use; or
- determine generic and therapeutic equivalent drug products to be substituted for brand name products.

Pharmacy technicians must wear nametags that clearly identify them to the public as a technician. According to the Drug Control Division, consumer complaints are occasionally received regarding technicians operating in violation of the law.

Pharmacy License

A pharmacy must also be licensed to operate. The Department of Consumer Protection issues the license, upon the commission's authorization. A pharmacy license costs \$600, and \$150 to renew. Good for one year, the license must be prominently displayed within a pharmacy. With some exceptions, a doctor and his or her spouse or child may not own an interest in a pharmacy.

Every pharmacy license application must list a pharmacy manager who practices at the pharmacy on a full-time basis, and he or she may not manage more than one pharmacy at a time. The commission must be notified immediately of any change in pharmacy ownership, name, or pharmacy manager.

A pharmacy must be directly supervised by a pharmacist on the premises when it is open for business. The law authorizes the commissioner, with the advice of the commission, to adopt regulations specifying when a pharmacy may be open if a pharmacist is not present. The current regulations require that the prescription department be closed and secured when a pharmacist is not present. They also require a minimum of hours of operation for the prescription department, and provisions for the physical security of the department, prescription drugs, and controlled substances. The regulations require pharmacies be open a minimum of 35 hours per week.

Licensing and Registration Revenues

Table II-2 shows the fee schedule for licenses and registrations issued by the department for pharmacists, technicians, and pharmacies.

Table II-2. Fee Schedule			
<i>Type</i>	<i>New</i>	<i>Renewal</i>	<i>License or Registration</i>
Pharmacist	\$100*	\$30	License
Technician	\$50	\$25	Registration
Pharmacy (in-state)	\$600	\$150	License
Out-of-State Pharmacy	\$600	\$150	Registration

*Not including the \$150 examination fee.
Source: Connecticut General Statutes Sec. 20-601(1-17).

Table II-3 shows licensing and registration fees totaled almost \$600,000 in each of the three years examined. The department was unable to separate out fees paid by pharmacy technicians from those paid for a pharmacy license, even though two separate licenses are issued.

Table II-3. Licensing and Registration Revenues.			
<i>Fiscal Year</i>	<i>Pharmacist Technician/Pharmacy</i>	<i>Pharmacist</i>	<i>Total</i>
01	\$442,140	\$136,810	\$578,950
02	\$428,399	\$145,973	\$574,372
03	\$434,134	\$148,351	\$582,485

Source: Department of Consumer Protection

Disciplinary Actions

The department's legal office has compiled statistics on the number of cases brought before the pharmacy commission since calendar year 2000 (shown in Figure II-2). Since 2000, the number of cases has grown annually, with the greatest increase occurring in 2002. The spike in the number of cases that year was mostly because a large number of medication error cases were brought before the commission. Although the number of cases decreased in 2003, there still was a 44 percent increase from calendar year 2000.

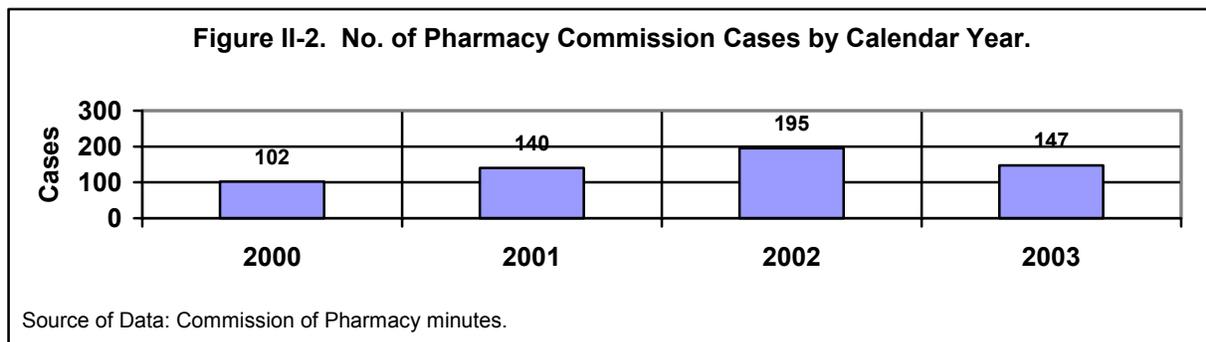
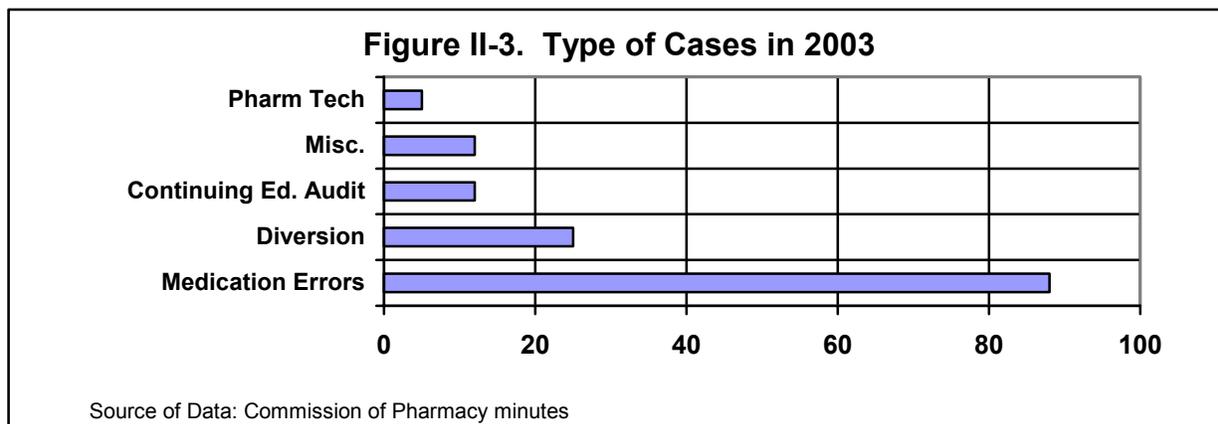


Figure II-3 shows the types of cases disposed by the commission in 2003. As the table shows, medication drug errors account for the vast majority of cases before the commission. Of the 147 total cases, fully 60 percent concerned medication errors. The next most common case type was drug diversion, which accounted for 17 percent of commission cases. Only 3 percent of the cases involved pharmacy technicians operating outside their scope of practice.



As noted throughout this report, no central database exists regarding commission actions, and no outcome information is routinely generated that aggregates the types of sanctions imposed by the commission. However, disciplinary action usually takes the form of one or more sanctions including:

- reprimand or censure;
- monetary penalty;
- remedial or corrective action;
- probation with requirements for the licensee to complete within a specified time;
- suspension of the license either indefinitely or for a specific period of time; and
- revocation of license.

Although the committee believes that automating enforcement activity will eventually allow the generation of commission activity statistics, a quarterly summary of actions taken by the commission, similar to the report published by DPH, should be published in the meantime. Therefore, the committee recommends:

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.

Chapter Three

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.

Some examples of situations these agreements are being used successfully include:

- flu/antiviral immunizations;
- immunizations;
- emergency contraception;
- asthma therapy management;
- warfarin anticoagulant therapy management;
- diabetic therapy management; and
- smoking cessation therapy.

Some collaborative practice agreements are designed to achieve larger public health goals and cover broad populations of patients. An example is a collaborative prescribing protocol that allows pharmacists to prescribe and administer vaccines. Committee staff found there are 31 states where pharmacists are actively administering immunizations (shown in Table III-1). Program review committee staff examined the Massachusetts program that allows certain pharmacists to administer adult influenza immunizations in the community setting and it is described below.

Table III-1. States Where Pharmacists are Actively Administering Immunizations

Alabama	Michigan	Oregon
Alaska	Minnesota	South Carolina
Arizona	Mississippi	South Dakota
Arkansas	Missouri	Tennessee
California	Nebraska	Texas
Delaware	Nevada	Utah
Georgia	New Mexico	Virginia
Iowa	North Carolina	Washington
Indiana	North Dakota	Wisconsin
Kentucky	Ohio	
Massachusetts	Oklahoma	

Source: American Pharmacists Association, September 2004.

Massachusetts

Pilot project. The Massachusetts Department of Public Health established a pilot project in September 2000 that established standards for pharmacist dispensing of certain medications by administration. The pilot on administration by pharmacists of influenza vaccine to adults was developed jointly with the health department, the Board of Registration in Pharmacy, and the Massachusetts Pharmacists Association. The program's pilot status was removed in the summer of 2004, and it is now a fully recognized program.

Massachusetts initiated a pilot project in order to demonstrate that pharmacists could collaborate with community health care providers in safely providing immunizations. The ultimate goal of the pilot was to increase access to vaccinations and thereby increase adult immunization rates. The DPH and the pharmacy board designated 14 pharmacies to participate in the project.

Training. Pharmacists were trained through the American Pharmacist's Association's Immunization Training Program in accordance with standards set by the federal Centers for Disease Control and Prevention (CDC). To receive certification for the course, pharmacists had to successfully complete a written exam, demonstrate ability to give intramuscular and subcutaneous injections, and have current CPR certification. In addition, the pharmacy board required pharmacies to have adequate staff to provide vaccination services.

Regulations and guidelines. Under regulations promulgated by the Massachusetts Department of Public Health, pharmacists who have completed an accredited training program may administer flu vaccines. The Board of Registration in Pharmacy and the Drug Control Program have adopted a Minimum Requirements Guideline outlining the requirements for pharmacist participation.

The joint guidelines require all courses, at a minimum, to meet CDC guidelines, and be accredited by the Accreditation Council for Pharmacist Education (ACPE) or a similar health authority or professional body, and include pre-administration education and screening, vaccine storage and handling, administration of medication, record-keeping and reporting of adverse events coursework.

Authority. In accordance with Massachusetts Controlled Substance Act, (M.G.L. Chapter 94C) and its Pharmacy Practice Act, (M.G.L Chapter. 112), pharmacists are authorized to dispense controlled substances. Unlike Connecticut, the statutory definition of "dispensing" in Massachusetts law includes administering a controlled substance pursuant to the order of a practitioner. However, up until the pilot was initiated, pharmacists were not administering any drugs and are currently limited to administering influenza vaccines.

Pharmacists can administer vaccinations only to adults upon the order of a practitioner. They also are required to collaborate with their patients' primary care providers and local health care providers to ensure continuity of care. The public health department and the pharmacy board jointly established a protocol for practitioner notification.

In addition, the director of the Drug Control Program told program review committee staff that there had been no adverse reactions to immunizations administered by pharmacists or any complaints filed by members of the public since the program was initiated.

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 committee staff 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.

Therefore, the committee recommends:

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.**

Chapter Four

Pharmacy Benefit Managers

While the primary focus of this study was on how the state regulates the practice of pharmacy, another area included in the study scope was how pharmacy benefit managers (PBMs) are regulated by the state. Pharmacy Benefit Managers are businesses that administer and manage prescription drug benefit plans for a variety of organizations. Current federal litigation challenges the legal ability of states to regulate PBMs making it uncertain whether Connecticut could impose similar regulation. This chapter describes PBM activities and discusses the current status of pending litigation in two states that adopted legislation to regulate PBMs.

Pharmacy benefit managers are private companies that administer and manage prescription drug programs for a variety of organizations, including the state of Connecticut's health insurance plan for state employees/retirees and certain recipients of DSS programs. A PBM can be an independent company or a subsidiary of a drug manufacturer, retail pharmacy chain, or health insurance company. The major functions of PBMs include:

- negotiating discounts with manufacturers, wholesalers, and pharmacies;
- managing drug formularies by overseeing the types of drugs that are prescribed and determining if there are less expensive alternatives that can be substituted;
- acting as financial intermediaries between pharmacies and health plan sponsors (e.g., verifying customer eligibility, handling disputes, and paying claims);
- operating drug utilization review programs, including the capacity to generate comparative profiles of physician prescribing patterns or pharmacy dispensing;
- purchasing and dispensing medications through mail-order companies they own; and
- creating and maintaining pharmacy networks to ensure adequate geographic access.

PBMs earn most of their revenues in three ways: 1) receiving a fee for the administrative tasks they perform; 2) negotiating discounts and rebates from drug manufacturers by including a company's drugs on a preferred drug list and obtaining a greater market share for the company's drug; and 3) through the operation of mail-order prescription drug companies.

Several concerns have been raised by a variety of legislators, state attorneys general, advocacy groups, and the media concerning the business practices of pharmacy benefit managers nationwide. Specifically, demands for greater transparency in the financial relationships between PBMs and drug manufacturers prompted several states to propose bills regulating PBM activities. During 2003, 22 states proposed bills concerning PBM regulation (Maine was the only state that passed comprehensive legislation), while in 2004, 12 states and the District of Columbia introduced legislation regulating PBMs (only legislation in South Dakota and D.C. was signed into law).

Proponents of PBM Regulation

The development and management of preferred drug lists by PBMs has become a central issue for those arguing for PBM regulation. The retention by PBMs of some or all of the rebates they obtain from manufacturers has become increasingly controversial, with the federal government as well as attorneys general in several states conducting investigations of this business practice. Other major PBM practices of concern are:

- establishing preferred drug lists that are based on the amount of manufacturer rebates received rather than clinical effectiveness;
- the propriety of the close relationships between many PBM companies and the pharmaceutical industry;
- lack of disclosure regarding contractual relationships with drug manufacturers; and
- marketing practices including collection and sale of patient information to help drug companies increase sales.

State actions. In recent years, a number of states (including Connecticut) considered legislation regulating the business practices of PBMs. Georgia was the first state to enact legislation regulating the practices of pharmacy benefit managers. The law, adopted in 2002, required every PBM providing services in Georgia be licensed as a pharmacy.

Maine. Maine was the first state to pass comprehensive legislation in 2003, which requires:

- payments to a PBM based on the volume of certain drugs dispensed or as a result of the savings from the substitution of drugs be passed on to the covered entity;⁴
- disclosure of financial terms between a PBM and a manufacturer to the covered entity; and
- consultation with and agreement by a prescriber before a PBM can switch the prescription drug to be dispensed to a covered individual.

The Maine law (An Act to Protect Against Unfair Prescriptive Drug Practices) also prohibits contractual terms inconsistent with a PBM's fiduciary duty and forbids agreements to waive provisions of the law. It creates an enforcement mechanism under the Maine Unfair Trade Practices Act for violations, with fines of not more than \$10,000.

Federal lawsuit. In September 2003, the Pharmaceutical Care Management Association (PCMA), a national association representing PBMs, filed a complaint in federal court in Maine seeking declaratory and injunctive relief from the Maine law as passed during 2003. The PCMA also filed a motion for preliminary injunction.

The complaint claims the Maine law:

⁴ Maine defines a covered entity as "a non-profit hospital or medical service organization, insurer, health coverage plan or health maintenance organization licensed pursuant to Title 24 or 24-A; a health program administered by the department or the State in the capacity of provider of health coverage; or an employer, labor union or other group of persons."

- violates the commerce clause of the U.S. Constitution;
- violates the takings clause of the U.S. Constitution by requiring trade secret disclosure; and
- seeks to regulate an area preempted by the federal Employment Retirement Income Security Act (ERISA).

Dismissing the commerce clause concern, the federal judge found the trade secrets and ERISA arguments persuasive enough to order a preliminary injunction on March 9, 2004. This summer, Maine sought to have the injunction lifted at least in terms of the trade secrets issue due to amendments made to its PBM regulation law in an April 2004 special legislative session, but was not successful. As of December 2004, the lawsuit is proceeding with the preliminary injunction in place.

The judge found that the Maine law “imposed new and broad regulations upon PBMs”, and generally concludes that the provisions of the Maine law “are virtually bound to collide with the ERISA goal of a “nationally uniform administration of employee benefit plans.” The judge elaborated on the ERISA concerns:

...this legislation presents a series of factors that make it problematic in light of ERISA preemption: 1) the national as opposed to state or even regional impact of the PBM industry; 2) the significant economic weight of the industry; 3) the centrality of the industry in the delivery and cost of health care benefits; 4) the vital nature of the health care benefits the PBM industry affects; 5) the breadth and detail of State regulation over the PBM industry; 6) the comprehensive scope of its enforcement provisions; and 7) the availability of private causes of action on benefit issues. In this context, for the Court to ignore ERISA would be to ignore the proverbial elephant in the room.⁵

Washington, D.C. The District of Columbia legislature adopted the *Access Rx Act of March 2004*. Title II of that act, entitled *Transparent Business Practices Among Benefit Managers*, is quite similar to the Maine law, and states that PBMs owe a fiduciary duty to a covered entity. Specifically, the act requires PBMs to pass on any payments received from drug manufacturers in connection with the utilization of prescription drugs by covered individuals. This is to include all payments that are based on volume of prescription drug sales or market share. Additionally, the act requires PBMs, upon written request from a covered entity, to disclose the quantity of drugs purchased and net cost of the drugs to the District including any rebates and discounts.

Federal lawsuit. In June 2004, the Pharmaceutical Care Management Association filed suit in the U.S. District Court for the District of Columbia (DC) to block enforcement of Title II of the legislation. The association is seeking an injunction on the grounds it would:

- result in higher prescription drug costs for D.C. residents because the act would require PBMs to divulge proprietary information they rely upon on behalf of purchasers to hold down consumers' drug costs;

⁵ Pharmaceutical Care Management Association v. Rowe, 307 F. Supp. 2d 164 (2004)

- violate current ERISA laws;
- limit federal workers' and retirees' access to affordable medicines; and
- expose PBMs and District employers to lawsuits because the act would allow confidential information to be accessed through court filings under the District of Columbia's Consumer Protection Procedures Act and expose PBMs and District employers to new lawsuits.

To date, no action has been taken by the D.C. federal district court.

South Dakota. Lawmakers in South Dakota enacted legislation in March 2004 that regulates the practice of pharmacy benefit management. The bill provides for the regulation of PBMs, including licensing as a third-party administrator, and "exercising good faith and fair dealing" toward covered entities. Entities contracting with a PBM may request the PBM disclose to the covered entity, the amount of all rebates and other revenues received from pharmaceutical manufacturers, and may obtain an audit of PBM records regarding such transactions. The bill also requires PBMs treat utilization information as confidential.

Opponents of PBM Regulation

Representatives of pharmacy benefit management companies maintain that current federal and state laws are sufficient to regulate PBM activities. In terms of regulation by state departments of insurance, the industry contends PBMs do not accept underwriting risk and, therefore, should not be licensed. Health insurers (or employers, if self-insured), not the PBM, are responsible for solvency risk.

Opponents of regulation believe PBMs should be governed in accordance with the functions performed (e.g., as drug utilization review companies or pharmacies) rather than as stand-alone entities. They believe regulating PBMs as separate entities rather than focusing on the individual services performed is duplicative. Specifically, they argue PBM functions such as drug utilization reviews and mail service pharmacies are already regulated at the state level. Finally, they charge that regulation would raise operating costs for PBMs and diminish their ability to pass on cost-savings to their customers.

According to the Connecticut Insurance Department, as of June 2004, of the four PBMs reported to have contracts with managed care organizations operating in the state, only one was licensed as a utilization review company.

Appendix A



STATE OF CONNECTICUT
DEPARTMENT OF CONSUMER PROTECTION
165 CAPITOL AVENUE, HARTFORD, CONNECTICUT 06106

EDWIN R. RODRIGUEZ
COMMISSIONER
BY HAND DELIVERY

February 3, 2005

Carrie E. Vibert, Director
Legislative Program Review and Investigations Committee
State Capitol Room 506
Hartford, CT 06106

This document will represent the response of the Department of Consumer Protection to the report issued by the Legislative Program Review (hereafter referred to as "LPR") and Investigations Committee of the State Legislature entitled "Pharmacy Regulation in Connecticut".

I want to take this opportunity to thank Mary Ellen Duffy for her professionalism and tremendous effort put forth in an attempt to understand and analyze very complex functions which are performed by the Drug Control Division.

LPR's findings, although enlightening, did not come as any great surprise insofar as an internal comprehensive review already underway had identified areas in need of process revision and targeted gain.

It should be noted that many of the changes that have already been initiated have involved both systems reanalysis and technical retooling. One example would be in the area of inspections. The Division has looked to streamline inspection processes by integrating a proprietary software database with onsite data entry. The inspection record generated onsite will capture pertinent data in a timely manner and eliminate the need for the agent to come into the office to hand in the assignment. The agent need only download the inspection to a Principal Agent in the office. It is anticipated that just this one change alone will increase the agents' efficiency regarding time management allotment.

The Drug Control Division

The Division's primary function is to protect the citizens of Connecticut in areas identified by the Pharmacy Practice Act, the Pure Food and Drug Act, the Uniform Food, Drug and Cosmetic Act,

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and the Controlled Substance Act. Within each of these acts, the Division, as regulatory entity, has a dual function: that of compliance and enforcement.

Location of Function within State Government:

We concur with the findings of the LPR that the Drug Control Division should be located within the Department of Consumer Protection.

MOUs - between the Department of Consumer Protection and the Department of Public Health

Topics that need to be addressed/included in MOUs:

- Primary jurisdiction over prescription drug diversion/street drugs use-DCP.
- Primary jurisdiction over practitioner/nursing practice issues-DPH.
- Any investigation that reveals information, the crux of which is substantively related to the core focus of the sister agency, should cause such information to be referred to said sister agency. The initial conference should be made via direct contact between the Division and DPH supervisors.

Note: A preliminary meeting was held with the Department of Public Health on February 2, 2005 regarding the aforementioned issues.

- The discussion of potential inspection duplication:
 - Extended Care Facilities-Changes could be realized with the implementation of new delivery systems or new disposal methods.
 - General Hospitals-Though this area does appear to contain duplication, a thorough review prior to any action would be appropriate and is overdue at this time. The history of the two Departments has identified duplication in the past (approximately 15 years ago). One explanation for the duplication is that, at the time, the DPH had on its inspection team one pharmacist that performed the pharmacy segment of the DPH inspection. Though the DPH inspection did not involve controlled substances, it did review various other pharmacy functions. This is where the duplication occurred. Since that time, the pharmacist position at DPH has been eliminated. Division inspections of these hospitals have also changed. In the past, inspections encompassed equal time on both nursing units and the pharmacy proper. Now, we spend most of our time within the pharmacy reviewing documentation. This is due in large part to automated systems, which most hospitals currently utilize. Additionally, review of the drug distribution process has become extremely complex with the advent of automation, robotics, out of state pharmaceutical patient review, off site pharmacy satellites, methadone programs, 340 b programs, strategic drug supplies from the CDC/Homeland Security, various other controlled substance protocols and the compliance with chapter 797 of the United States Pharmacopoeia Chapter. The Division currently employs two agents on the hospital inspection team: a former pharmacy supervisor from Massachusetts General Hospital with a Master's Degree in Hospital Administration and a former acting Director of Hospital Pharmacy who, coincidentally, was also the first pharmacy automation manager in the state. Their expertise in the field of institutional pharmacy oversight is peerless within the State of Connecticut, and their knowledge base is critical to the continued

success of the hospital team. As the Division begins to recover from the loss of staff, inspections will be increased.

We feel that it would be very positive to hold a meeting for the first time between the two departments to review each others' inspection functions in order to prevent any duplication of those functions. Also, new and innovative practice issues should be discussed by both departments to identify any changes or modifications to regulatory oversight.

Department /Division Automated Information Systems

Department system.

Internal assessments have already identified areas of concern regarding automated information systems and have begun to address these issues so as to maximize the Division's data collating abilities and retrospective analysis capabilities.

The above identified findings have been addressed in the new database and the system is active. Regarding the action taken by the various boards, all department action will be entered by the Division and access to the database will be provided to the Legal Division for their entry. Furthermore, a review of the Legal Division's accounting of the Division's cases will be conducted.

Analyzing the workflow process with advanced technology is an ongoing effort.

Internal systems within the Drug Control Division. Although the licensing system is available department wide, the Drug Control Division maintains five proprietary systems to track its various activities.

- **Inspections** Each type of inspection has its own table within the same database. The system reviewed by LPR was only for record purposes (Roster). The upgrade of the database has management-type reports that will be useful for determining trends and statistics.
 - Pharmacy Inspections will be conducted utilizing a newly designed computerized pharmacy inspection form. This automation will allow the inspections to be performed electronically in the field. The inspections will subsequently be downloaded and merged with other inspections to allow trend and statistical analysis. This new inspection form will enhance the Division's operating efficiencies by providing the following:
 1. The ability to statistically analyze data in a manner that will enable the Division to recognize trends in a more timely fashion;
 2. Predetermined data fields, such as "violations", can be flagged for automatic re-inspections;
 3. Violations that can be flagged would require written responses from the pharmacy regarding corrective action taken to address such issues;
 4. A standardization of the inspection process within the Division; and
 5. A decrease in the reliance on paper filing.

Note: The inspection form will not require additional software but may require additional hardware (Electronic Signature Pads).

- **Investigations and consumer complaints.**

- The investigations that are categorized as consumer complaints will be conducted utilizing a newly designed computerized complaint form. This will be computerized to allow the investigation to be performed electronically. The use of the new system will be merged with previous consumer complaint inspections to allow trend and statistical analysis.
- The use of this form will, in most instances, replace the current prose format report and allow the form to serve as the final report, which will be submitted to the legal division for consideration. This will substantially reduce the time required for an agent to prepare a written report and increase the efficiency of the Legal Division and Pharmacy Commission. In extremely complex consumer complaint investigations, a prose report will still be generated as well as the computerized form.
- In addition to the points noted above, the utilization of a computerized complaint form will aid the Division in the collection of pertinent data by requiring that all agents complete mandatory database fields before handing in the form.

Note: This system is currently active.

- **Staff assignments.** Though this table is primarily used for tracking staff assignments, it also can be used to track work flow and compare work flow between agents.
- The new database has capabilities to perform the appropriate data analysis along with enhanced managerial-level report queries.

Note: This system is current active and operational.

Evaluation of Selected Office Operations

Inspections.

The Division is empowered to regulate the various licensees that it registers. The area of compliance has been in need of review prior to the LPR. The number of compliance inspections performed on a yearly basis has been decreasing due to a corresponding decline in the number of agents. This decline has occurred over the past ten years but has recently accelerated with the last round of early retirements and layoffs. This year, the number of compliance inspections will be increased from last year but not to the level previously maintained prior to the staffing reductions of 2002. Mandating specific numbers of inspections, with the staff at its current level, would again cause some functions to be postponed, possibly reducing our ability to monitor the industry and thus impacting the public health.

Solution

The actual compliance reports utilized to conduct the inspections are in the process of being updated to more accurately reflect current practice standards. Unfortunately, due to declining staffing (early retirement), this upgrade has been behind schedule. The inspections are planned to be performed on laptops in the field. The information is intended to be compiled and used for various reports and analysis. In past years, during times of appropriate staffing levels, inspections were on a cyclical basis, which correlated to increased compliance at the industry level. With the proper staffing and technology, the level of inspections of retail pharmacies, for instance, could again be on a regular cycle.

- The Inspection Cycle as described in the LPR Findings, though attainable under current staffing, would most certainly result in shortcomings and inefficiencies in other equally important areas (i.e. investigations). Even if the positions are refilled, the hiring and training process takes approximately one year. During that time frame the number of investigations must be covered by the remaining staff.

- As part of its inspection process at the pharmacy level, the Division currently reviews controlled substance prescriptions as well as non controlled substance prescriptions for compliance purposes. There are pharmacies in the State of Connecticut that fill from 10 prescriptions to over one thousand prescriptions per day. Though the easiest remedy would be to apply an across the board formula for review of prescriptions, such as a percentage of prescriptions filled, this actually presents several problems:
 1. The actual number of prescriptions filled by a pharmacy is not required to be disclosed by the registrant;
 2. A flat percentage across the board could result in a large amount of time to review the 'required number', especially for high volume stores; and
 3. Variables that have to be considered, which could substantially increase the time required to inspect each store, include:
 - The volume of prescriptions (since numbers are not available);
 - The complexity of the prescriptions;
 - Cross checking the pharmacists' initials;
 - The presence of illegal prescriptions;
 - The presence of an error;
 - Inappropriate record keeping and/or misfiling; and
 - The need to randomize the prescription review to cover differences in staffing and policies over a period of time.

Note: All of the above variables could affect the number of prescriptions reviewed during the inspection process, which in turn could initiate a re-inspection.

The non inspections of some types of facilities (i.e. laboratories, wholesalers, etc.) was initiated several administrations ago. As new legislation was imposed, staff was not added and production gains were not sufficient to compensate for the additional burden. Division resources need to be allocated to complete this activity. This function requires human oversight.

Inspection of Correctional Medical Units wherein Pharmaceuticals are Stored

The preliminary meeting was held with the Correctional Pharmacy Department's Director on February 2, 2005. Discussions included internal automated systems, the types of medical units within correctional facilities, and the medication distribution systems.

Investigations

Findings

The Division has broken down the investigations into two separate categories: investigations and consumer complaints. Consumer complaints are investigations involving medication errors that are investigated by the Division (usually involving a pharmacist). Other investigations usually involve medical professionals and the diversion of controlled substances from their place of employment. The products produced by the Division, in the form of investigative reports, are regarded as the highest caliber by other municipal, state, and federal agencies who rely upon them to take criminal, administrative, and/or civil action against the licensee.

Solution

Consumer complaint investigations are now structured in order to increase Division efficiency. The information is entered directly into a designated database from the receipt of the complaint to the completion of the investigation. The completed record from the database can then be downloaded and used in place of the prose reports (in most cases). In addition to increasing the efficiency of both the Drug Control Division and Legal Division, this work flow change will capture gains in productivity and allow for comprehensive reporting capabilities and analysis.

This initiative is active in the trial phase.

The Legal Office within DCP.

The above identified findings have been addressed in the new database and the system is active. Regarding the action taken by the various boards, all Department action will be entered by the Division and access to the database will be provided to the Legal Division for their entry. Furthermore, a review of the Legal Division's accounting of the Division's cases will be conducted.

The Department of Consumer Protection's class on "Prevention of Prescription Drug Errors."

The outsourcing of this program has already been discussed with an interested professional group.

Destruction of Controlled Substances in Nursing Homes

Findings

The division is performing drug destructions of controlled substances for various registrants throughout the state. The majority of the drug destructions are performed in extended care facilities. The process of the destruction usually involves representatives of the facility and an agent. The destruction occurs at the facility. The function of performing these destructions is very time consuming and labor intensive. The medications are destroyed by flushing. During the process, a

review of the controlled substance records is performed and any patterns or signs of diversion are identified and investigated. This review is a public health and safety concern.

Solution

The solution is to eliminate the need for the Division to destroy these medications, yet continue to maintain control over the monitoring of the medication distribution process and controlled substance records.

Possible options include the following:

Some states have the controlled substances mailed to the state office of drug control for review and destruction. This is an unworkable solution in the State of Connecticut. The Division does not have the staff to receive, collect, document, store and destroy the controlled substances. It would require an increase in the current levels of staffing or require field personnel to be in the office. A substantial cost would also be incurred by the state in the form of disposal costs. This would only apply to controlled substances. Non controlled substances would still be destroyed by current methods by facility personnel.

Other states allow all the medications in the facility to be destroyed by the facility under specific guidelines. This is a system that would reduce the work load on the Division. It would shift the work load to the facility but not as much as would be expected because they are already involved in the process. The only missing person would be the Division representative. This system, though an option to help reduce the Division's burden, creates a more long term problem that could lead to widespread health care issues.* Furthermore, there is no cost savings to the state because the drugs are not being returned to the provider pharmacy for re-dispensing to other patients.

Other options must address the costs incurred at the state level by paying for the drugs "up front". Paying "up front" causes the drugs to be sent to the facility in various quantities. Whether all the medication is administered to the patient or only one tablet is administered and 60 are discarded, the state has paid for all of them and what is not used must be wasted. There is a small list of medications (non-controlled drugs) that may be returned to the provider pharmacy. Specific rules govern the drugs on this list as well as criteria for their return. The majority of items are discarded at the facility and the method of choice is to flush them.* In order for this system to be a viable option, changes must be made to expand both the non-controlled drugs on the list and to further include controlled substances.

A hybrid system of an expanded returnable list of medications, combined with a system where the controlled substances are not patient specific but are "unit stock", would all but eliminate the need for any waste of controlled substances. Placing controlled substances in a facility as "unit stock" (i.e. not designated for a particular patient) is nothing new. This system has existed in hospitals for at least 25 years. These unit stocks could be in the form of a manual system or a computerized automated system similar to currently utilized systems in hospitals today. The only waste would be the items that have passed their expiration dating. By not having to destroy controlled substances, the time savings to the division would be substantial. The cost savings to the state would also be substantial since the state would only be paying for the items that are administered to the patients instead of paying for what is dispensed to the patient. As Division oversight regarding the destruction process decreases, oversight can be compensated for by increasing the number of

facility inspections and/or increasing monitoring of controlled substances at the provider pharmacy location. The initiation of a hybrid system may require changes to occur over a period of time.

Automated storage and delivery systems would allow for:

- Increased quality assurance assessment;
- The use of bar code technology to decrease medication errors;
- Better statistical tracking of usage trends;
- Reduced cost for the payers; and
- Reduced waste into the environment.

Information on the feasibility of modifying the drug destruction process is currently being collected by the Division.

The above options, or any others that are being devised in the long term care industry, may not be appropriate for all situations, but legislation should be in place to allow the market place to experiment with different methods that may produce the desired results. The Division would retain the authority to perform drug destructions if deemed necessary.

All of the above options will require legislation or legislative changes.

*Any system that prevents the destruction of large numbers of medications would also serve another purpose. Several studies have been performed by the federal government, universities, and private organizations that indicate that destroying these medications in this manner (i.e. flushing) has a detrimental effect on our environment. Studies have indicated that several drugs such as antibiotics and hormones are finding their way into streams, soil, and ground water. Any system that reduces the waste of medications, reduces the cost to the state for medications, reduces the burden on the Division so that time could be used on higher priority functions, and protects the environment and therefore the citizens of the state, should be explored.

Pharmacy Commission

The Pharmacy Commission is not part of the Drug Control Division. Due to the fact that the Board Administrator is actually a Drug Control Agent, a process review was performed regarding the duties of the Board Administrator.

Commission of Pharmacy Activities

LPR has provided a reasonable assessment.

Collaborative Practice

Though under the purview of the Commission of Pharmacy, I agree with the findings of the LPR.

Sincerely,

A handwritten signature in blue ink, appearing to read "Edwin R. Rodriguez", with a long horizontal flourish extending to the right.

Edwin R. Rodriguez
Commissioner

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

J. Robert Galvin, M.D., M.P.H.
Commissioner



M. Jodi Rell
Governor

February 2, 2005

Carrie E. Vibert, Director
Legislative Program Review and Investigations Committee
State Capital
Room #506
Hartford, CT 06106

Dear Ms. Vibert:

Thank you for providing the Department with the opportunity to comment on the committee's findings and recommendations regarding the regulation of pharmacy services by the State.

I have taken your suggestion and submitted my comments under two sections. The first section is the Department's formal response to the committee's report. The second section contains comments relative to factual inconsistencies.

I would like to take this opportunity to commend the Legislative Program Review Staff regarding the content of the document. Additionally, you have my promise that the Department of Public Health will work with the Drug Control Division of the Department of Consumer Protection to formulate a Memorandum of Understanding regarding our collaborative efforts in the areas of investigations and the licensure of pharmacies within healthcare institutions. The DPH and DCP currently have a good working relationship and mutual respect for the functions of each agency, which will be enhanced in the future.

Please feel free to contact me should you have any questions or require additional information.

Sincerely,

A handwritten signature in blue ink that reads "J. Robert Galvin MD MPH".

J. Robert Galvin, M.D., M.P.H.
Commissioner

JRG:zsj

c. Karen Buckley-Bates, Director of Government Relations, DPH



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**STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
DIVISION OF HEALTH SYSTEMS REGULATIONS**

The Department of Public Health submits the following comments and recommendations regarding the Legislative Program Review and Investigations Committee report on Pharmacy Regulation in Connecticut.

- DPH recognizes and supports the functions performed by the Drug Control Division of the Department of Consumer Protection (DCP).
- DPH and DCP shall immediately begin the process of developing a Memorandum of Understanding (MOU) to delineate respective responsibilities inclusive of the recommendations made in the final report on Pharmacy Regulation in Connecticut.
- DPH will immediately begin providing DCP with copies of inspections/findings from licensed healthcare facilities that house institutional pharmacies, and will include in the MOU the sharing of complaints and adverse events reports regarding institutional pharmacies at receipt.
- DPH will immediately begin providing DCP with copies of disciplinary actions by Boards and consent agreements involving health care practitioners referred to DPH by DCP or those involving overlapping jurisdictional issues.
- DPH will work with DCP and the OAG to review the feasibility of online access to investigations of mutual concern.
- While both DPH and DCP inspect the pharmacies of fewer than 40 non-state inpatient facilities, the focus of these inspections is quite different. DPH nurses review the pharmacy for cleanliness, systems and supervision, timeliness of delivery to the nursing units, drug administration and other patient outcome-oriented parameters, while DCP pharmacists review drug accounting, reconciliation, diversion and other technical drug distribution parameters. Because of the very different skills sets and focus brought to these inspections, DPH would recommend continuing both the DPH and DCP inspections of this small number of pharmacies.
- DPH supports the recommendation that an alternative method to destroy controlled substances absent the presence of a DCP Drug Control Agent be researched. DPH will assist DCP with development of regulations for this process if such recommendation is enacted.
- DPH supports the recommendation that licensed pharmacists be allowed to administer adult influenza vaccinations, following appropriate training and demonstrated competence. This skill may also be useful during other public health emergencies.

First Section