REPORT OF THE
JOINT COMMISSION ON HEALTH CARE

STUDY OF LONG-TERM CARE PHARMACY OPERATIONS PURSUANT TO HJR 642 OF 1995

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

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Preface

House Joint Resolution (HJR) 642 of the 1995 Session requested the Joint Commission on Health Care to study long-term care pharmacy operations to determine whether existing Board of Pharmacy regulations unnecessarily prohibit sound pharmaceutical practices.

One of the trends that has developed in the practice of pharmacy over the past several years has been an increase in the number of long-term care pharmacies. Essentially, long-term care pharmacies provide prescription drug services to residents of long-term care facilities including nursing homes, assisted living centers and others. The distinguishing feature of long-term care pharmacies is that, rather than providing prescriptions to residents in the normal multiple day supply (e.g. a 30-day prescription), prescriptions are filled on a "unit dose" (e.g. morning, noon, and evening) basis. Once the prescription is filled, the long-term care pharmacy delivers the unit dose medications in a "unit dose cart" to the facility for distribution to the residents.

House Bill 2365, which was passed by the 1995 Session of the General Assembly, addressed several regulatory issues regarding long-term care pharmacies. The long-term care pharmacy community indicated that the only remaining issue to be addressed is whether pharmacy technicians should be allowed to conduct the final check of the prescriptions in the unit dose carts prior to their delivery to the long-term care residents. Current Board of Pharmacy regulations require a pharmacist to conduct this check. The long-term care pharmacies believe that technicians can conduct this final check as accurately as pharmacists. Several studies have concluded that technicians can perform this check as accurately as pharmacists.

The long-term care pharmacies argue that if technicians are allowed to conduct this final check, pharmacists would have more time for managing patients' drug therapy, counseling patients, and interacting with the patients' physician. However, many pharmacists believe that allowing a technician to conduct this check eliminates an opportunity for the pharmacist to check the prescription for potential drug interactions and review the patient's drug therapy.

The Board of Pharmacy has not reviewed the specific issue of technicians checking unit dose carts. However, in response to other issues regarding technicians, the Board has requested the Board of Health Professions to study the need for licensing and regulating pharmacy technicians. The Board of Health Professions is expected to complete its study in the Spring of 1996.

An issue that arose during the course of this study relates to hospitals providing pharmaceutical services to residents in affiliated long-term care facilities. Hospitals purchase prescription drugs from manufacturers at deeply discounted prices. Some hospitals that own or are affiliated with long-term care facilities want to take greater advantage of these drug discounts by providing prescription services to residents of affiliated long-term care facilities. Current Board of Pharmacy regulations allow hospital pharmacies to provide services to facilities located "on the premises" of the hospital, but prohibit the hospital pharmacy from providing services to facilities off the premises. Community pharmacists, who do not receive the same manufacturers' discounts, believe that allowing hospitals to service long-term care facilities located off of their premises gives the hospital an unfair competitive advantage.

Federal antitrust laws directly affect this issue. There are differing views as to whether these federal antitrust laws, and recent court cases which interpret these laws, allow hospital pharmacies to provide these services to affiliated health care facilities. Resolution of this issue appears to require a thorough legal analysis which is beyond the scope of this particular study.

The study offers three policy options for consideration.

* Option I would maintain status quo.

* Option II would introduce legislation amending the Code of Virginia to allow pharmacy technicians to check unit dose carts prior to delivery to patients.

* Option III would request the Board of Pharmacy, in cooperation with the Office of the Attorney General, to: (i) review current federal antitrust laws to determine their impact on the types of patients that can be serviced from hospital pharmacies; and (ii) re-evaluate current regulations governing hospital pharmacies in light of the legal review of federal antitrust laws.

Our review process on this topic included an initial staff briefing which you will find in the body of this report followed by a public comment period during which time interested parties forwarded written comments to us on the report. In many cases, the public comments, which are provided at the end of this report, provided additional insight into the various topics covered in this study.

Jane N. Kusiak
Executive Director

November 22, 1995

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Authority for Study

House Joint Resolution (HJR) 642, which was agreed to by the 1995 Session of the General Assembly, directs the Joint Commission on Health Care to study long-term care pharmacy operations in the Commonwealth to determine whether existing Board of Pharmacy regulations unnecessarily prohibit sound pharmaceutical practices.

Background

Numerous Changes Have Occurred in the Practice of Pharmacy Over the Past Several Years

Long-Term Care Pharmacies: One of the trends that has developed during the past several years has been an increase in the number of long-term care pharmacies. Essentially, long-term care pharmacies provide prescription drug services to residents of long-term care facilities, including nursing homes, assisted living centers and others. The distinguishing feature of long-term care pharmacies is that, instead of providing prescriptions to residents in the normal multiple day supply (e.g. a 30-day prescription), prescriptions are filled on a "unit dose" basis. Once the prescription is filled, the long-term care pharmacy delivers the unit dose medications to the facility for distribution to the residents.

As the long-term care population continues to grow, issues regarding the safe and efficient operation of long-term care pharmacies become increasingly important.

Use of Pharmacy Technicians: Another area in the field of pharmacy which has seen significant change has been the shifting of emphasis away from the distributive functions of the pharmacist (i.e. filling prescriptions) and toward the "cognitive" functions of pharmaceutical care (i.e. monitoring and managing drug treatments). A key point of debate in this trend has been the appropriate use of pharmacy technicians. More specifically, the issue is whether the practice of pharmacy has changed to the point where certain tasks no longer require the expertise of a pharmacist and could be performed

appropriately by a technician. To the degree that technicians can be used to perform these tasks, pharmacists can devote more time to other mandated functions which do require the educational background and pharmaceutical expertise of a pharmacist.

Much activity is ongoing across the nation to determine the appropriate role and functions of pharmacy technicians. The manner in which this issue is addressed here in Virginia can have a significant impact on the practice of pharmacy in the Commonwealth.

Long-Term Care Pharmacies Provide Pharmacy Services to the Majority of Long-Term Care Facilities in Virginia

The Virginia Coalition of Long-Term Care Institutional Pharmacy Providers represents seven of the long-term care pharmacies operating in Virginia. According to this coalition, long-term care pharmacies operating in Virginia provide daily "unit dose" pharmacy services to approximately 34,000 long-term care residents (including assisted living residents), which represents a substantial proportion of the total number of long-term care residents in Virginia. In addition to the pharmacies which operate exclusively as a "long-term care pharmacy," some retail pharmacies also provide "unit dose" prescription services to long-term care facilities as part of their overall operations.

Several Regulatory Issues Regarding Long-Term Care Pharmacies Were Addressed During the 1995 Session of the General Assembly

Several changes in the operation of long-term care pharmacies were enacted during the 1995 Session of the General Assembly through the passage of House Bill 2365.

House Bill 2365: The key provisions of House Bill (HB) 2365 include:

* the Board of Pharmacy, when promulgating regulations, shall consider the impact on costs to the public and within the health care industry;

* prescription orders entered on a patient's chart in long-term care facilities can include more than one prescription (formerly, only orders entered on patient charts in hospitals could include more than one prescription);

* prescription orders can be written as chart orders; and

* prescriptions for patients or residents of long-term care facilities served by a Virginia pharmacy from a remote location can be transmitted to the pharmacy by an electronic communications device over telephone lines (facsimile machine).

Few Regulatory Issues Regarding Long-Term Care Pharmacies Remain

HJR 642 requests the Joint Commission on Health Care to review Board of Pharmacy regulations to determine whether any of the regulations unnecessarily prohibit sound pharmaceutical practice in long-term care pharmacies. However, individuals in the long-term care pharmacy industry who requested that the resolution be introduced, indicated that HB 2365 addressed all but one of the regulatory issues that they believe need to be reviewed.

Use of Pharmacy Technicians to Check Unit Dose Prescriptions: The remaining regulatory issue identified by long-term care pharmacies pertains to the use of pharmacy technicians performing the final check of unit dose prescriptions prior to the medications being delivered to the long-term care facility.

In Addition to the Pharmacy Technician Issue Identified by Long-Term Care Pharmacies, Another Issue Arose During the Study Regarding Hospital Pharmacies Providing Pharmacy Services to Residents of Affiliated Long-Term Care Facilities

While not identified by the long-term care pharmacy community as a regulatory issue requiring review, an issue tangentially related to long-term care pharmacy identified by some nonprofit hospitals is the potential use of a hospital's inpatient pharmacy to provide pharmacy services to residents of long-term care facilities affiliated with the hospital.

The issue here is that hospital pharmacies can purchase drugs from manufacturers at significantly lower prices than other pharmacies. As will be discussed later in this issue brief, some nonprofit hospitals want to take further advantage of these price discounts and utilize their inpatient pharmacies to provide pharmacy services to residents of long-term care facilities that are owned by the same entity which owns the hospital. Currently, this practice is prohibited by Board of Pharmacy regulations.

Use of Pharmacy Technicians in Long-Term Care Pharmacies

Pharmacy Technicians are Not Recognized by the Virginia Board of Pharmacy

Currently, pharmacy technicians are not formally recognized by the Board of Pharmacy, nor are they mentioned in the Code of Virginia or any of the Board's regulations. As such, there currently is no state licensure, regulation, certification, or minimum training standards for pharmacy technicians.

The regulations (§ 6.1 (A)(6)(a)) require that only one person who is not a pharmacist be present in the prescription department at any given time with each pharmacist for the purpose of assisting the pharmacist in preparing and packaging prescriptions. While the term "pharmacy technician" is not used in the regulations, it is generally accepted that the "1 to 1" ratio of pharmacist to assistant in effect means one pharmacist to one technician.

While not officially recognized by the state, pharmacy technicians nonetheless perform a variety of important functions within almost every type of pharmacy, including long-term care pharmacies. Technicians often are used to perform "distributive" functions such as drug packaging, pill counting and prescription filling, and stocking. However, the "cognitive" functions of pharmacy such as monitoring and managing drug therapy (e.g. proper dosage, prescription strength, drug interaction, etc.) have been restricted to licensed pharmacists. Included in these cognitive functions has been the final checking and verification of a prescription prior to being delivered to the patient.

Virginia Board of Pharmacy Regulations Require That a Pharmacist Check and Certify Every Prescription Prior to Delivery to the Patient

As previously indicated, the primary regulatory issue identified for review by long-term care pharmacies is the use of pharmacy technicians to conduct a final check of unit dose prescriptions prior to their being delivered to the residents of a long-term care facility. Currently, Board of Pharmacy regulations require that a pharmacist check and verify each prescription prior to delivery of the order. Figure 1 identifies the pertinent Board of Pharmacy regulations which address this issue.

In a Unit Dose Dispensing Process, Prescriptions are Filled According to Each Dose to be Taken During the Day

As discussed earlier, in a unit dose dispensing system, prescriptions are filled according to the medications that a patient is instructed to take at specific times during the day as opposed to medications that are to be taken over an extended number of

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Figure 1

Board of Pharmacy Regulations:
Checking and Verifying Prescriptions

Part VI. Prescription Order and Dispensing Standards

§6.1. Dispensing of prescriptions; acts restricted to pharmacists

> **B.** After the prescription has been prepared and prior to the delivery of the order, the pharmacist shall inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of dispensing as a certification of the accuracy of, and the responsibility for, the entire transaction.

Part IX. Unit Dose Dispensing Systems

§9.1. Unit dose dispensing system.

> **A (8).** A record shall be made and maintained within the pharmacy for a period of one year showing:
> a. The date of filling the drug cart;
> b. The location of the drug cart;
> c. The initials of the person who filled the drug cart; and
> *d. The initials of the pharmacist checking and certifying the contents of the drug cart in accordance with the provisions in §6.1.B. (emphasis added)*

Source: Board of Pharmacy Regulations VR530-01-1

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days. In a unit dose system, each patient's medications are placed in a separate cassette tray which has individual compartments labeled for each dose to be taken during the day. For instance, the cassette tray may include

individual compartments labeled as: **Morning, Noon, Evening Meal, and Night**.

Pharmacist Performs Final Check: When the prescription order comes into the long-term care pharmacy, a pharmacist reviews the prescription. If approved by the pharmacist, the prescription then is entered into a computer to establish (or update) the patient's record, conduct various checks such as drug to drug interactions, etc. Based on the computer entry, medications are pulled from stock and placed in the individual compartments of the patient's cassette tray according to the prescription(s) ordered by the patient's physician. The cassette trays then are placed into a drug cart. A pharmacist conducts a final check of each unit dose prescription to make certain that each compartment contains the proper drug, drug strength, and dosage for the patient.

After the final check has been completed, the drug carts are delivered to the appropriate long-term care facility. Facility staff, typically nurses, administer the medications to the residents. The carts which were left at the facility for the previous day's unit dose prescriptions are picked up and taken back to the long-term care pharmacy for filling the next day's prescriptions.

Long-Term Care Pharmacies Believe Pharmacy Technicians Should Be Able to Check Unit Dose Carts Prior to Delivery

The final check of each unit dose prescription performed by a pharmacist in a long-term care pharmacy requires the pharmacist to verify that the drug placed in the cart for each unit dose conforms exactly to the information contained in the computer record for the patient. The pharmacist reads information from the computer screen for each unit dose and compares it with information on the medication contained in the individual unit dose compartments. The specific task of checking the prescription with the information on the computer screen is straightforward and does not require the "checker" to make any drug therapy decisions. The "checker" only verifies that the medication in the tray is the same as the prescription information in the computer.

Because of the routine nature of the "checking" function, the long-term care pharmacies believe this task could be performed with equal, if not better, accuracy with pharmacy technicians. Specifically, the long-term care pharmacies suggest that technicians conduct the final check and that pharmacists conduct random "quality assurance" reviews of between 5 and 10 percent of the unit dose medications as an additional quality check. In this

proposed arrangement, pharmacists would continue to have overall responsibility for the accuracy and quality of each prescription.

Long-term care pharmacies argue that by allowing technicians to conduct the final check of the unit dose medications, and reducing the amount of time pharmacists spend on routine tasks, pharmacists will be able to spend additional time on the more "cognitive" functions of pharmacy such as monitoring drug therapy, interacting with physicians, counseling patients, and responding to inquiries from patients' families.

Six Studies Have Found That Pharmacy Technicians Are As Accurate as Pharmacists in Checking Unit Dose Carts

The issue of whether pharmacy technicians can accurately check the prescription medications dispensed in unit dose carts has been studied by several different researchers since 1978. The studies were conducted primarily by hospital pharmacists. Each of the studies found that technicians could check unit dose carts as accurately as a pharmacist.

Study Limitations: While the results of each of the six studies are consistent, it is important to realize that in several of the studies the technicians were specially trained, and in at least one study, the technicians had to achieve a minimum level of accuracy prior to being included in the study. Thus, it is arguable that the results can be generalized to only trained technicians with certain minimum skill levels. Also, in some of the studies, the number of technicians used in the study was quite small (three researchers used only two technicians) which may limit the degree to which the results can be generalized to other technicians.

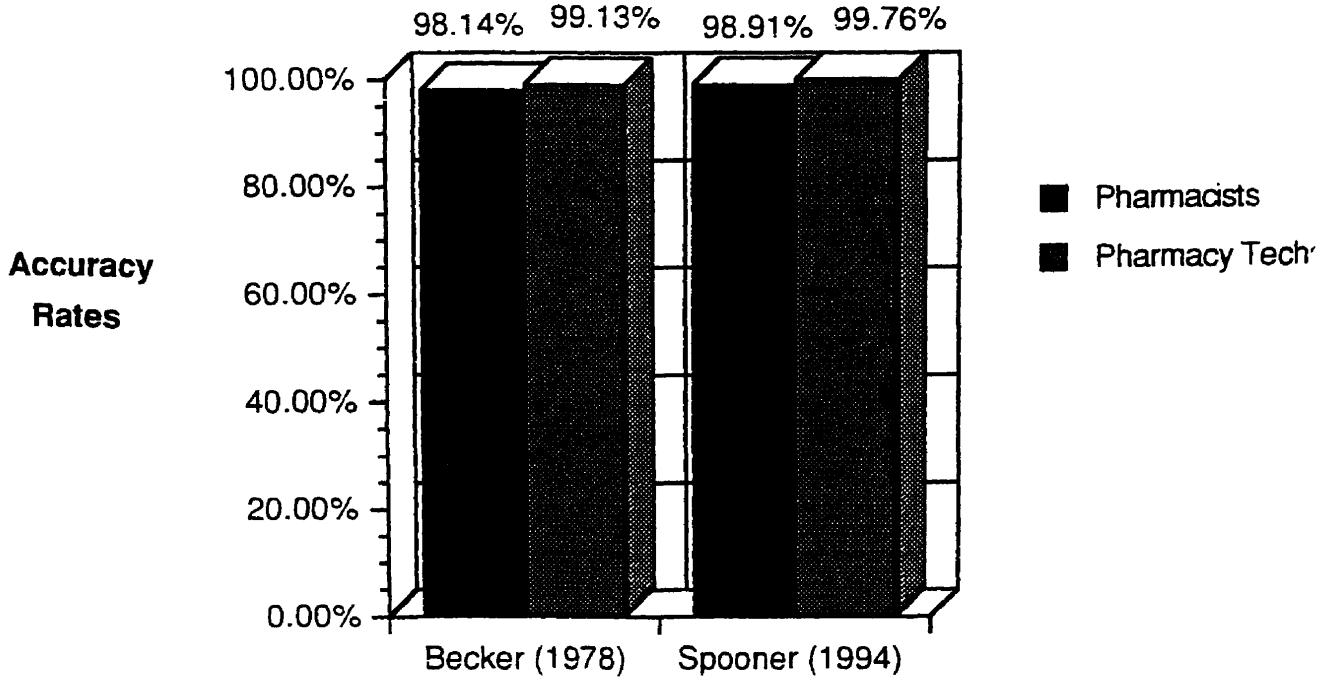
Study Results: While the specifics of each study varied somewhat, the basic methodology was the same for all but one study. In five of the six studies, separate groups of pharmacy technicians and pharmacists were used to conduct the final "check" of the prescription medications placed in unit dose carts. After the cart was checked, a licensed pharmacist (other than those used in the "checking phase") conducted a follow-up review of the unit dose carts to determine the accuracy of the "checker." All of the studies found that pharmacy technicians were as accurate, or more accurate, than the pharmacists who performed the same "checking" task. Figures 2 and 3 illustrate the results of four of these studies.

In the sixth study, the researchers did not compare technicians to pharmacists. Instead, the study looked at whether technicians could maintain a minimum level of accuracy in checking the carts.

As seen in Figure 2, both Becker (1978) and Spooner (1994) found that pharmacy technicians had a slightly higher accuracy rate than pharmacists when checking prescriptions in unit dose carts. In both studies, the researchers concluded that pharmacy technicians can check unit dose carts as accurately as pharmacists.

Figure 2

Analysis of the Accuracy Rates of Pharmacy Technicians and Pharmacists Conducting Final Checks of Unit Dose Prescriptions

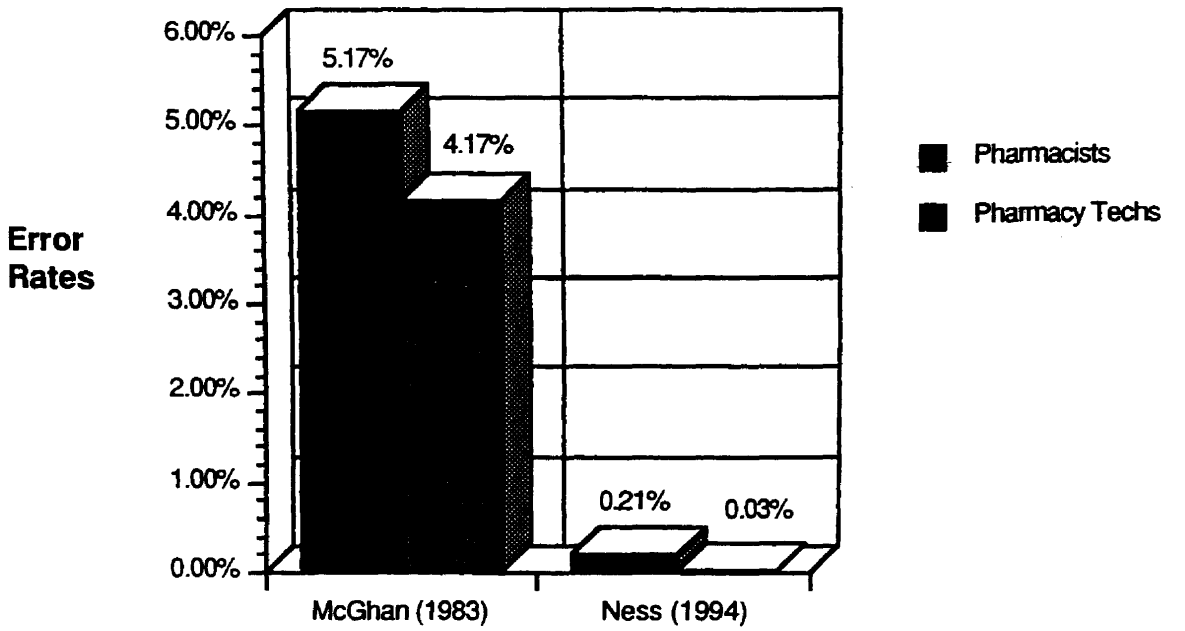


Source: American Journal of Hospital Pharmacy 35:432-434 (Apr) 1978; Hospital Pharmacy, Vol. 29, No. 5, 433-437

In Figure 3, the results of two studies that measured the error rates of technicians and pharmacists are presented. While the methodology of these two studies is different than the Becker and Spooner studies, the results are similar in that they found essentially no differences between technicians and pharmacists in checking unit dose carts.

Figure 3

Analysis of the Error Rates of Pharmacy Technicians and Pharmacists Conducting Final Checks of Unit Dose Prescriptions



Source: American Journal of Hospital Pharmacy, Vol. 51, 354-357 (Feb) 1994; Medical Care, Vol. 21, No. 4, 445-453

McGhan Study (1983): In the McGhan study, the researchers concluded that, while pharmacists had a higher error rate than pharmacy technicians, there is no significant difference in the error rates for the two groups. McGhan also reported that during the phase of the study when technicians were checking the unit dose carts, pharmacists reported spending significantly more time counseling patients. This finding supports the argument of the long-term care pharmacies that allowing technicians to check the carts would result in additional time for the pharmacist to spend on the "cognitive" aspects of pharmacy.

Ness Study (1994): The error rates calculated in the Ness study are substantially lower than the McGhan study due to different methods used in calculating the rates. Another reason for the lower error rates in the Ness study is that, in order for a technician to be included in the study, he/she had

to undergo special training and pass an examination with a minimum accuracy rate of 99.98%. The number of prescriptions checked in the Ness study also was substantially greater than that in the McGhan study. Nonetheless, the results of the Ness study corroborate those of McGhan in that pharmacists were found to have a somewhat higher error rate than technicians when checking unit dose carts.

Grogan Study (1978): While the four studies identified above calculated and compared error and accuracy rates of pharmacists and pharmacy technicians, Grogan compared the actual number of errors committed by pharmacists and pharmacy technicians. He found that in 38 trials, pharmacists committed 11 checking errors whereas pharmacy technicians committed 10. While there was only a very slight difference in the number of errors, and the sample size was relatively small, he concluded that technicians could check unit dose prescriptions as safely and efficiently as pharmacists.

Woller Study (1991): The Woller study did not attempt to compare the accuracy rates of pharmacists and technicians, rather the study sought to determine if a system of quality control could be developed that would yield a predetermined minimum level of accuracy (99.8%) for the process of checking unit dose carts.

In this study, three Minnesota hospitals conducted a nine-month project in which 27 specially trained technicians checked unit dose carts for errors that were purposely introduced into the cart. The results of the study indicated that with strict quality control measures, specially selected and trained technicians can perform unit dose prescription checking with an accuracy rate of at least 99.94%.

Like the McGhan study, Woller also concluded that pharmacists were able to increase the amount of time spent in direct communication with other health care professionals. Increased participation by pharmacists in drug-use evaluation and other therapeutic drug monitoring activities also was reported.

Some Pharmacists Have Expressed Concern About Technicians Checking Prescriptions

By law, pharmacists are ultimately responsible for the accuracy of the prescription that is delivered to the patient. A number of pharmacists have expressed concern that having a technician conduct the final check will have an adverse impact on patient safety. While the specific task of "checking"

prescriptions may be routine, some pharmacists view the checking task as an opportunity to conduct a final review of potential adverse drug interactions and the appropriateness of the patient's drug therapy. If technicians check the prescriptions, this opportunity for a final review is lost. This issue was addressed in the Spooner study discussed above.

The Board of Pharmacy Has Not Reviewed the Specific Issue of Technicians Checking Unit Dose Carts; the Training, Certification, Regulation and Licensure of Pharmacy Technicians is a Key Issue

The appropriate role and function of pharmacy technicians goes far beyond the specific issue of whether pharmacy technicians should be allowed to check unit dose prescriptions in long-term care pharmacies. The appropriate use of pharmacy technicians is part of a broader issue of whether pharmacy technicians should be regulated and licensed by the Commonwealth, and whether there should be mandatory certification and training standards.

As previously noted, pharmacy technicians are not recognized by the Board of Health Professions or the Board of Pharmacy. Consequently, there are no state licensure requirements, no regulations or minimum training standards. The training and qualifications of technicians are determined by the individual pharmacists and pharmacies that employ these individuals.

Board of Pharmacy Concerns: With respect to the issue of technicians performing checks of unit dose carts in long-term care pharmacies, the Board of Pharmacy has not conducted any study or review of this issue. However, the Board's primary concern is that, if technicians are going to be performing new duties, there needs to be some assurance that the technicians are properly trained. Inasmuch as there are no required training or performance standards, the Board is concerned that improperly trained technicians could be assigned to performing critical tasks, such as checking unit dose carts.

The Board of Pharmacy Has Requested the Board of Health Professions to Study the Issue of Regulating and Licensing Pharmacy Technicians

Because of the significant changes that have occurred in the practice of pharmacy over the past several years, the Board of Pharmacy has received numerous requests and comments concerning the delegation of certain tasks, currently restricted to pharmacists, to pharmacy technicians. In response to these requests, the Board of Pharmacy has requested the Board of Health Professions to conduct a study to determine if there is a need for some level of

regulation of pharmacy technicians. Specifically, the Board of Pharmacy has asked the Board of Health Professions to determine:

* if the practice of pharmacy has changed to the point where certain tasks no longer need the educational and experiential level of a pharmacist to safely perform;

* if the performance of these tasks prevents the pharmacist from adequately performing other mandated tasks;

* if there is a need for a pharmacist's knowledge and skills to be used in performing other functions in order to assure safe drug therapy; and

* if there is a need to establish standards and minimum competencies for those persons who may be performing tasks delegated by the pharmacist.

The Board of Health Professions held a public hearing on this issue on August 15, 1995. Comments will be accepted through March 30, 1996. Following its study, the Board of Health Professions will make recommendations to the Board of Pharmacy regarding the need for regulation and licensure of pharmacy technicians.

After receiving the recommendations of the Board of Health Professions, the Board of Pharmacy will address the many issues regarding pharmacy technicians (e.g. regulation, licensure, training, appropriate roles and functions). Through this process, the issue of pharmacy technicians checking unit dose carts likely will be addressed.

Long-Term Care Pharmacies and Most Pharmacists Believe There is No Need to Regulate or License Pharmacy Technicians; Rather There Should Be Voluntary Certification

The long-term care pharmacies, as well as the Virginia Pharmacists' Association and the American Pharmaceutical Association all oppose licensure and regulation of pharmacy technicians. Instead, these groups support training for technicians and voluntary certification, such as a national certification program. (The Pharmacy Technician Certification Board, an autonomous nonprofit corporation, recently began administering a national certification exam.) Each of the groups also believes that pharmacists should retain the ultimate responsibility for the accuracy and quality of each prescription.

Delegation of Technician Duties: These groups believe that, instead of regulation and/or licensure, pharmacists should be given authority to determine what tasks can be delegated to a technician. In this manner, pharmacists can determine, on an individual basis, the tasks they are comfortable in delegating to their respective technician. The long-term care pharmacies indicate that they would use this authority to allow technicians to check the unit dose carts in their pharmacies. Moreover, the long-term care pharmacies would continue to have the pharmacist: (i) conduct random quality assurance checks; (ii) certify the contents of the unit dose carts; and (iii) be responsible for the accuracy and quality of the tasks performed.

While the Virginia Pharmacists' Association supports allowing pharmacists to determine what tasks should be performed by technicians, it is concerned that in a long-term care pharmacy, there may be limited opportunity for pharmacists to monitor the technician performing the final check of the unit dose carts. Moreover, the Association also is concerned that having a technician perform the final check and holding the pharmacist responsible for the accuracy and quality of the prescription places the pharmacist in a difficult position.

Based on Available Information, it Appears that Few, if Any, States Permit Technicians to Check Unit Dose Carts in Other States

The National Association of Boards of Pharmacy (NABP) conducted a survey of all 50 states' pharmacy laws and regulations. The 1994-95 survey includes various information on the tasks that technicians are permitted to perform in each state. However, information on whether technicians are permitted to perform the final check prior to the delivery of the prescription was not included in the survey. However, the Executive Director of the NABP indicated that, other than pilot studies in three states, no state currently allows technicians to perform the final check.

Also, the Executive Director of the Pharmacy Technician Certification Board, which administers the national certification exam, indicated that she is not aware of any state which allows technicians to conduct the final check.

Hospital Pharmacies Providing Services to Residents of Affiliated Long-Term Care Facilities

Some Nonprofit Hospitals Seek Regulatory Approval to Use Their Inpatient Pharmacies to Provide Pharmacy Services to Residents in Affiliated Long-Term Care Facilities

As previously noted, an issue was raised during the course of this study which, while not directly related to the operation of a long-term care pharmacy, is related to pharmacy services for residents of long-term care facilities. The specific issue is whether inpatient hospital pharmacies should be permitted to provide pharmacy services to residents of long-term care facilities that are owned by or affiliated with the hospital.

Hospital Inpatient Pharmacies Purchase Prescription Drugs from Manufacturers at Substantial Discounts

Drug manufacturers sell their prescription drugs to hospitals at substantially discounted prices; prices that generally are not available elsewhere in the marketplace. To maximize the cost-effectiveness of their drug purchasing arrangements, some nonprofit hospitals which are affiliated with long-term care facilities want to provide pharmacy services to residents of these long-term care facilities through their inpatient pharmacy. In so doing, the hospitals argue they could reduce substantially the cost of providing prescription services to these residents.

Board of Pharmacy Regulations Restrict the Types of Patients Who Can Receive Prescription Drugs from Hospitals' Pharmacies

Board of Pharmacy regulations limit the types of patients for whom hospitals can provide pharmacy services. Figure 4 identifies the pertinent Board of Pharmacy regulation which addresses this issue.

Section 10.6.B. of the regulations states that if a pharmacy in a hospital dispenses drugs to persons other than those listed in §10.6.A., the pharmacy must obtain a separate pharmacy permit and operate in a space apart from the hospital pharmacy. At least one hospital, Maryview Hospital, has established a separate pharmacy within the hospital to service the residents of an

Figure 4

Board of Pharmacy Regulations: Types of Patients Serviced by Hospital Pharmacies

Part X. Pharmacy Services to Hospitals

§10.6. Pharmacy Services.

A. In addition to service to inpatients, a hospital pharmacy may dispense drugs to the following:

1. *Patients* who receive treatments or consultations *on the premises;* (emphasis added)

2. Outpatients, or emergency patients upon discharge for their personal use away from the hospital; and

3. The hospital employees, medical staff members, or students for personal use or for the use of their dependents.

Source: Board of Pharmacy Regulations VR530-01-1

affiliated long-term care facility, Maryview Nursing Home. While this arrangement enables the hospital to provide services to the nursing home, it is expensive and staff-intensive for the hospital to operate two separate pharmacies.

The Board of Pharmacy Has Reviewed The Issue of Hospitals Providing Pharmacy Services to Affiliated Long-Term Care Facilities, and Has Ruled That The Regulations Prohibit This Activity

In August, 1994, Chesapeake General Hospital requested that the Board of Pharmacy review this issue with specific reference to their desire to provide pharmacy services to Georgian Manor residents under its inpatient pharmacy permit. Georgian Manor is located two miles from the hospital, and, thus, is not located "on the premises" of the hospital.

The Board voted unanimously at its October, 1994 meeting that the residents of Georgian Manor do not meet the criteria for hospital pharmacy services as set forth in §10.6. of Board Regulations, and, as such, the hospital may not provide regular pharmacy services to them. The Board's published ruling was silent on the issue of whether services could be provided to long-term care facilities located on the hospital's premises or whether hospitals were not permitted to provide services to any affiliated long-term care facility. Chesapeake General Hospital requested an additional hearing before a Conference Committee of the Board. The Conference Committee heard the appeal, and voted not to make any further recommendation to the full Board.

The Purchase and Sale of Prescription Drugs is Governed by Federal Antitrust Laws

In addition to Board of Pharmacy regulations which govern the purchase and sale of prescription drugs, federal antitrust laws also have a significant and direct bearing on this matter.

Robinson-Patman Anti-Discrimination Act: Of the various federal antitrust laws, the act that is most relevant to hospital prescription drug purchasing is the Robinson-Patman Anti-Discrimination Act. This act was added to the antitrust laws of the United States in 1936, and it prohibits any price discrimination among different purchasers of goods of like grade and quality if the effect of such discrimination is likely to injure competition among the sellers. (Greenberg, 1986.)

Nonprofit Institutions Act: Because many nonprofit institutions expressed fear that they would be adversely affected by the prohibition against price discrimination, Congress passed the Nonprofit Institutions Act in 1938 to exempt the purchase of goods by a nonprofit institution *for its own use* (emphasis added) from the Robinson-Patman Act. (The Nonprofit Institutions Act also is known as the Section 13C Exemption to the Robinson-Patman Act.) As a result of the Nonprofit Institutions Act, nonprofit hospitals can purchase drugs "for their own use" at special hospital prices. Drugs purchased at special prices and used for other purposes would be a violation of antitrust laws. The Nonprofit Institutions Act has remained essentially unchanged since its passage.

Two Court Cases Provide Guidance on What Constitutes a Hospital's "Own Use" of Drugs Purchased at Special Prices

Abbott Laboratories et al. v. Portland Retail Druggists Association: In this 1976 case, the Portland Retail Druggists Association sued Abbott

Laboratories and twelve other drug manufacturers claiming that the manufacturers were discriminating in price between sales to nonprofit hospitals and those to community pharmacies. The druggists claimed this activity violated the Section 13C Exemption of the Robinson-Patman Act. The case eventually was reviewed by the U.S. Supreme Court.

In its ruling, the Supreme Court identified various "dispensing categories" (i.e. different types of patients) that fell within and outside the Section 13C Exemption. Residents of long-term care facilities affiliated with a hospital were not one of the dispensing categories addressed in the ruling. However, the Supreme Court did state that drugs for inpatient, emergency room, and outpatient use *on hospital premises* (emphasis added) were found to be clearly for a hospital's own use. (Greenberg, 1986.) The reference to "on hospital premises" is consistent with the current language in the Board of Pharmacy regulations.

De Modena v. Kaiser Foundation Health Plan: In this 1977 case, retail pharmacists in California and Oregon sued Kaiser-Permanente Medical Care Program claiming that sales of drugs to its members violated Section 13C of the Robinson-Patman Act as interpreted in the *Portland* case.

The U.S. Court of Appeals ruled that drugs purchased at special prices by a not-for-profit health maintenance organization (HMO), such as Kaiser, are purchased for the HMO's own use within the meaning of the Nonprofit Institutions Act, and, thus, qualify for protection under the Act. (Greenberg, 1986.) The U.S. Supreme Court denied a request to review this case.

The De Modena case is seen by some as a major clarification of the original *Portland* case in that the court ruled the HMO could purchase drugs for its members without regard to any of the permissible "dispensing categories" of hospital patients articulated in the *Portland* case. More importantly, the case seems to indicate: (i) a more flexible approach to determining what constitutes "own use," and (ii) favorable treatment for complex hospital structures (e.g. hospitals and affiliated health care facilities owned by the same nonprofit entity) that wish to purchase drugs for various categories of patients.

Some Nonprofit Hospital Pharmacies Believe Federal Law Permits the Hospital Pharmacies to Provide Services to Residents in Affiliated Long-Term Care Facilities and That Virginia Regulations Should Be Revised to Permit This Activity

In light of the DeModena case, some nonprofit hospitals which own or are affiliated with long-term care facilities believe federal law permits them to use their hospital pharmacy to provide pharmacy services to residents in these long-term care facilities, and that Virginia regulations should be revised to permit this activity. These hospitals argue that the current regulations permit hospitals to provide services to residents of long-term care facilities if the facility is located "on the premises" of the hospital. So that they can provide these services to facilities not located on the premises, they believe the words "on the premises" contained in §10.6 (A.1) of the regulations should be deleted.

However, as previously noted, in its 1994 ruling on the Chesapeake General Hospital case, the Board of Pharmacy did not officially state its specific reason for interpreting the regulations to mean that hospitals cannot provide services to residents of long-term care facilities. Thus, it is not clear whether such a change in the regulations necessarily would resolve this matter.

Policy Considerations: In addition to the legal issues involved (i.e. do federal antitrust laws permit hospitals to provide services to affiliated long-term care facilities, and do Virginia regulations parallel federal antitrust laws), there also is a policy consideration as to whether an expansion of hospital pharmacy services is appropriate given the competitive advantage that hospital pharmacies enjoy by virtue of the discounted pricing from manufacturers. Thus, the issue of whether hospital pharmacies should be able to provide services to long-term care facilities involves legal and health care policy analyses.

Legislation Introduced During the 1995 General Assembly Session to Allow Hospitals To Provide Pharmacy Services to Long-Term Care Facilities Was Not Enacted; Antitrust Concerns Still Remain

Senate Bill (SB) 1112, which was introduced during the 1995 Session of the General Assembly, would have amended §54.1-3434 of the Code of Virginia such that hospitals which own and operate a nursing home or certified nursing facility may provide pharmacy services and drugs for the residents of such homes or facilities under the hospital's inpatient pharmacy

permit. However, antitrust concerns raised by long-term care pharmacies and retail pharmacists resulted in the bill not being passed.

The Virginia Pharmacists' Association and the long-term care pharmacies continue to have antitrust concerns regarding any expansion of the types of patients that can receive pharmacy services from hospital pharmacies.

Summary

Functions of Pharmacy Technicians

The only regulatory issue identified by long-term care pharmacies relates to amending the regulations such that pharmacy technicians can perform the final check of unit dose prescription carts prior to their being delivered to a long-term care facility. Current Board of Pharmacy regulations require that a pharmacist conduct this final check.

Long-term care pharmacies argue that technicians can perform this function as accurately and safely as a pharmacist, and that if performed by a technician, pharmacists will have more time to perform "cognitive" functions such as drug therapy review, patient counseling, and physician consulting. Several studies support the contention that technicians can check unit dose carts as accurately as pharmacists. Long-term care pharmacies believe that pharmacists should be given authority to delegate tasks to their technicians according to the skill level and expertise of the technician. If the regulations permitted such delegation of duties, long-term care pharmacies would delegate the task of checking unit dose carts to technicians.

The Boards of Pharmacy and Health Professions currently are reviewing the need to regulate and/or license pharmacy technicians. While the issue of technicians checking unit dose carts has not been identified as a specific task of the Boards' study, this issue likely will be affected by the results of their deliberations.

Hospital Pharmacy Services

The second issue, which is related tangentially to long-term care pharmacy operations, is the desire of some nonprofit hospital pharmacies to provide pharmacy services to residents of long-term care facilities affiliated with the hospital. These hospitals want to maximize the favorable drug prices

they receive from drug manufacturers. Long-term care pharmacies and retail pharmacists are opposed to an expansion of the types of patients that can be served by a hospital pharmacy.

Current Board of Pharmacy regulations prohibit hospital pharmacies from providing services to affiliated long-term care facilities. There is some question as to whether the regulations preclude hospitals from providing services only to long-term care facilities not located on the hospital's premises, or whether the prohibition also applies to facilities located on the hospital's premises.

Federal antitrust laws directly affect this issue. There are differing views as to whether these federal antitrust laws, and the recent court cases which interpret these laws, allow hospital pharmacies to provide these services to affiliated health care facilities. Resolution of this issue appears to require a thorough legal analysis which is beyond the scope of this particular study.

Policy Options

Option I: Maintain Status Quo

Under Option I, the Joint Commission would take no legislative action to address the issue of whether pharmacy technicians should be allowed to check unit dose prescription carts prior to delivery to long-term care facilities. In Option I, this issue would be left to the regulatory powers of the Board of Pharmacy to determine the appropriate course of action, based on the Board of Health Professions' study of the need for regulation and licensure of pharmacy technicians.

Also, no action would be taken with respect to whether hospital pharmacies should be permitted to provide pharmacy services to residents of affiliated long-term care facilities. This issue has been reviewed previously by the Board of Pharmacy. Option I assumes that the Board of Pharmacy will revise its regulations regarding this issue if it believes that recent court decisions or other developments warrant such action.

Option II: Introduce Legislation Amending the Code of Virginia to Allow Pharmacy Technicians to Check Unit Dose Carts Prior to Delivery to Patients

In Option II, legislation would be introduced to amend the Code of Virginia to allow pharmacy technicians to conduct checks of unit dose carts prior to delivering the medications to the patient. Inasmuch as technicians currently are not recognized in the Code or in the Board of Pharmacy's regulations, this Option would require careful legislative drafting. Also, this Option would not take into account the regulatory process and the current study that the Board of Pharmacy has requested the Board of Health Professions to conduct regarding the need for regulation, licensure and training standards for pharmacy technicians. The Board of Health Professions' study will not be completed until after the 1996 Session of the General Assembly.

Option III: Request the Board of Pharmacy, in cooperation with the Office of the Attorney General, to: (i) Review Current Federal Antitrust Laws to Determine Their Impact on the Types of Patients That Can Be Serviced from Hospital Pharmacies; and (ii) Re-Evaluate Current Regulations Governing Hospital Pharmacies in Light of the Legal Review of Federal Antitrust Laws

As discussed in this issue brief, while recent court cases seem to indicate a broadening definition of the types of patients that can be serviced from a hospital pharmacy, there still are differing views as to whether federal antitrust laws permit hospital pharmacies to provide these services to certain patients, such as residents of affiliated long-term care facilities. It appears that a thorough legal analysis of these issues is needed prior to changing existing regulations. Under Option III, the Board of Pharmacy, in cooperation with the Office of the Attorney General, would be requested to: (i) review federal antitrust laws to determine their impact on the types of patients that can be serviced from hospital pharmacies; and (ii) re-evaluate its regulations governing hospital pharmacies in light of the findings of the legal review.

APPENDIX A

GENERAL ASSEMBLY OF VIRGINIA -- 1995 SESSION

HOUSE JOINT RESOLUTION NO. 642

Directing the Joint Commission on Health Care to study long-term care pharmacy operations.

Agreed to by the House of Delegates, February 4, 1995
Agreed to by the Senate, February 21, 1995

WHEREAS, the Commonwealth's long-term care pharmacies provide daily, safe, reliable, cost-effective pharmaceutical services to tens of thousands of inpatients and residents of long-term care facilities, including nursing home, retirement care, mental care, and adult care facilities; and

WHEREAS, long-term care pharmacies use state-of-the-art, unit-dose or blister-pack card technology to reduce the operating costs and increase the reliability of drug administration services at the facilities of long-term care providers; and

WHEREAS, quality control practices of long-term care pharmacies have, for many years, been under the continual, direct supervision of licensed pharmacists, thereby ensuring a record of safe, reliable dispensing services; and

WHEREAS, long-term care pharmacies provide on-site, drug therapy utilization reviews, consulting and training services to long-term care providers at minimal or no additional costs to the providers, patients or residents; and

WHEREAS, pharmacies serving long-term care facilities have implemented standards of practice for quality control procedures using properly trained ancillary personnel acting under the personal supervision of a pharmacist to ensure the accuracy of the prescriptions filled; and

WHEREAS, the Board of Pharmacy's regulation requiring a pharmacist's certification of a completed prescription prior to its delivery does not contribute any incremental measure of reliability to existing, long-standing quality control procedures of long-term care pharmacies; and

WHEREAS, the Board of Pharmacy's regulation requiring a pharmacist's certification of a completed prescription prior to its delivery adds significant cost to the dispensing process without contributing any concomitant increase in reliability; and

WHEREAS, both hospital pharmacies and long-term care pharmacies are permitted by Board of Pharmacy regulations to dispense drugs for administration to a hospital inpatient, based upon the facsimile transmission of a physician's chart order exempt from meeting all normal prescription elements set forth in §§ 54.1-3408 and 54.1-3410 of the Code of Virginia; and

WHEREAS, a long-term care pharmacy is prohibited by Board of Pharmacy regulations from dispensing a drug on the basis of the facsimile transmission of a physician's chart order entered at a long-term care facility unless such order is accompanied by a separate, written prescription signed by the physician; and

WHEREAS, the U.S. Drug Enforcement Administration has authorized the facsimile transmission of a prescription written for a Schedule II controlled drug to be administered to a resident of a long-term care facility, and further, has authorized the facsimile copy to serve as the original written prescription; and

WHEREAS, over the years, the practice of long-term care facilities has progressed to more closely resemble that of hospitals, and pharmacy practice statutes written years ago no longer reflect the significant technical advances in modern long-term care pharmacy practice; and

WHEREAS, there is no reasonable basis for requiring a separate, written prescription in addition to the physician's chart order in the case of a patient or resident of a long-term care facility where none is required for a hospital patient whose stay is transitory; and

WHEREAS, long-term care pharmacies are not accessible to walk-in customers from the general public and are considered and regulated as institutional pharmacies; and

WHEREAS, increasingly, long-term care pharmacies, in a manner similar to acute care pharmacies, provide comprehensive pharmacy services to the growing population of acute care patients residing in nursing facilities; and

WHEREAS, on the basis of these and other pharmaceutical practices and procedures, long-term care pharmacies operate more like hospital pharmacies than independent pharmacies; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Joint Commission on

Health Care be directed to study long-term care pharmacy operations in the Commonwealth to determine whether existing Board regulations unnecessarily prohibit sound pharmaceutical practices that (i) promote compliance with the prescriber's instructions; (ii) include controls and safeguards against diversion of drugs or devices; (iii) maintain quality, quantity, integrity, safety and efficacy of drugs or devices dispensed; (iv) support maintenance of complete records; (v) promote technical advances in the practice of pharmacy and the distribution of controlled drugs, devices or substances; and (vi) improve the quality of pharmaceutical services to the citizens of Virginia in a cost-effective manner.

The Joint Commission on Health Care shall complete its work in time to submit its findings and recommendations to the Governor and the 1996 Session of the General Assembly as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents.

APPENDIX B

Joint Commission on Health Care

Summary of Public Comments on Draft Issue Brief 6:
Long-Term Care Pharmacy Operations

Comments regarding the "Long-Term Care Pharmacy Operations" Issue Brief were received from the following six interested parties:

The Medical Society of Virginia
Virginia Society of Hospital Pharmacists
Virginia Pharmacists Association
R. Michael Berryman (R.Ph.)
B.L. Dunlavey (R.Ph.)
Community Pharmacy Coalition

Policy Options Presented in Issue Brief

Three policy options were presented in the Issue Brief for consideration by the Joint Commission on Health Care.

Option I: Maintain status quo.

Option II: Introduce Legislation Amending the Code of Virginia to Allow Pharmacy Technicians to Check Unit Dose Carts Prior to Delivery to Patients

Option III: Request the Board of Pharmacy, in cooperation with the Office of the Attorney General, to: (i) Review Current Federal Antitrust Laws to Determine Their Impact on the Types of Patients That Can Be Serviced from Hospital Pharmacies; and (ii) Re-Evaluate Current Regulations Governing Hospital Pharmacies in Light of the Legal Review of Federal Antitrust Laws

Summary of Comments

Most commenters supported Option I. There was general agreement that no action on the pharmacy technician issues should be taken until after the Boards of Pharmacy and Health Professions have completed their current study. No one submitted comments in favor of allowing technicians to check unit dose carts.

Regarding the issue of hospitals using their inpatient pharmacy to provide prescription services to residents of affiliated long-term care pharmacies, one commenter supported Option III; another stated that off-site long-term care facilities should not be serviced by an inpatient pharmacy.

Summary of Individual Public Comments

The Medical Society of Virginia (MSV)

Madeline I. Wade, Director of Legislative Affairs, indicated that the MSV feels the current policy for pharmacy technicians is in the best interest of health care and that Option III should be pursued. Ms. Wade also recommended the Board of Pharmacy review its regulations governing hospital pharmacies servicing residents of affiliated long-term care facilities.

The Virginia Society of Hospital Pharmacists (VSHP)

Fred Chatelain, R.Ph., M.S., Legislative and Regulatory Committee Chairman, recommended that the Joint Commission on Health Care adopt Option I. Mr. Chatelain recommended that the technician issues be addressed by the current Board of Health Professions study. Regarding hospital pharmacies providing services to residents of affiliated long-term care facilities, he noted that the Board of Pharmacy regularly reviews its regulations, and that it will make changes should legal developments call for such revisions.

The Virginia Pharmacists Association (VPA)

Ms. Rebecca P. Caudhill, R. Ph., Interim Executive Director, indicated that the VPA strongly recommends Option I for both the technician and hospital pharmacy issues. She noted that the Boards of Pharmacy and Health Professions should be allowed to address these issues.

R. Michael Berryman (R.Ph.)

R. Michael Berryman (R.Ph.) did not recommend a specific Option, but noted that having pharmacists conduct the final check of prescriptions in unit dose carts provides one additional check on drug interactions and the appropriateness of the patient's drug therapy. Mr. Berryman also commented that a "reasonable" technician to pharmacist supervisory ratio should be maintained.

B. L. Dunlavey (R.Ph.)

B. L. Dunlavey (R.Ph.) did not recommend a specific Option, but commented that some long-term care pharmacies fill and deliver prescriptions without a pharmacist's review and evaluation. He stated that technicians should not be allowed to conduct the final check of prescriptions in unit dose carts, and that pharmacists should conduct the final check of all medications.

Community Pharmacy Coalition

Cynthia L. W. Warriner commented on behalf of the Community Pharmacy Coalition. Ms. Warriner stated that the Coalition strongly recommends Option I. She noted that it would be prudent to wait for the results of the study being conducted by the Boards of Pharmacy and Health Professions prior to taking any action on the pharmacy technician issues.

Regarding hospitals providing pharmacy services to affiliated long-term care facilities, Ms. Warriner commented that hospitals should be able to provide services to long-term care facilities located on-site, but that affiliated facilities located off-site are part of the free marketplace; and, therefore, should not be served by a hospital pharmacy.

JOINT COMMISSION ON HEALTH CARE

Director

Jane Norwood Kusiak

Senior Health Policy Analysts

Patrick W. Finnerty

Stephen A. Horan

Office Manager

Mamie V. White