UNITED STATES GENERAL ACCOUNTING OFFICE

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HUMAN RESOURCES DIVISION

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B-133044 December 21, 1978

The Honorable Jesse Helms
United States Senate

Dear Senator Helms:

You requested by letter dated April 3, 1978, that we evaluate the Veterans Administration's (VA's) outpatient pharmacy program. Specifically, you were interested in whether (1) addictive and habit-forming drugs are properly controlled, (2) maintenance drugs are received by patients in a timely manner and in adequate quantity, and (3) the authenticity of physicians' prescriptions is ascertained.

As agreed with your office, we visited VA medical centers in Asheville, Durham, and Fayetteville, North Carolina. The enclosure to this letter describes the results of our review in detail. On September 13, 1978, we briefed a member of your office on the general contents of this report.

VA established extensive controls over drugs and other medications dispensed by its pharmacies. However, because of the discrepancies we found at the medical centers visited, which may also exist at other VA medical centers, additional controls are needed and improvements can be made in existing procedures. We are making several recommendations to the Administrator of Veterans Affairs to improve the outpatient pharmacy program.

At your request, we did not obtain written comments from VA on this report. We did, however, discuss a draft of the report with program officials in VA's Department of Medicine and Surgery, who expressed general agreement with it.

HRD-79-29
(40171)

As agreed with your office, we are sending copies of this report to the Administrator of Veterans Affairs. Unless you publicly announce its contents earlier, no further distribution will be made until 10 days from the date of the report. At that time we will send copies to interested parties and make copies available to others upon request.

Sincerely yours,

Gregory J. Ahart
Director

Enclosure

ENCLOSURE I

VETERANS ADMINISTRATION'S OUTPATIENT PHARMACY PROGRAM AT SELECTED MEDICAL CENTERS

INTRODUCTION

By letter dated April 3, 1978, Senator Jesse Helms requested that we evaluate the Veterans Administration's (VA's) outpatient pharmacy program. He was concerned whether (1) addictive and habit-forming drugs are properly controlled, (2) maintenance drugs are received by the patients in a timely manner and in adequate quantity, and (3) the authenticity of physicians' prescriptions is ascertained.

As subsequently agreed with Senator Helms' office, we conducted our review at three VA medical centers--Asheville, Durham, and Fayetteville, North Carolina. We also interviewed officials and professional staff responsible for and involved in outpatient pharmacy operations at VA's central office and the three centers. We reviewed VA internal audit reports, regulations, patient medication folders, and drug receipt and dispensement records. We also observed pharmacy operations in filling prescriptions and maintaining physical security over drugs and supplies.

Background

VA's Department of Medicine and Surgery administers VA's health care delivery system by providing care in 172 hospitals, 219 outpatient clinics, 89 nursing care units, and 16 domiciliaries. About 1.2 million veterans were treated in VA facilities during fiscal year 1977. VA medical staff also handled about 15 million outpatient visits. VA spent $4.2 billion to treat patients in VA facilities during fiscal year 1977. Total expenditures for drugs and related supplies at all VA pharmacies during the same year were $176 million.

VA's medical services include treatment of acute and chronic illnesses in hospital and ambulatory care settings. At one time most veterans had to be hospitalized to receive care. Escalating hospital costs and the recognition that many cases could be more effectively cared for on an ambulatory basis prompted the Congress in 1973 to enact Public Law 93-82, which allowed VA hospitals to treat eligible veterans on an outpatient basis if such treatment would obviate the need for hospitalization.

The demand for ambulatory care, which resulted from the 1973 law, placed a great deal of pressure on VA medical centers--especially for pharmacy services. For example, the number of prescriptions filled increased from 16,580,000 in fiscal year 1973 to 29,923,000 in fiscal year 1977--an 80-percent increase. Veterans may receive prescriptions at the pharmacy or by mail.

Drug classification

VA is required to order, receive, store, and dispense all drugs in accordance with regulations governing drugs and pharmaceuticals of the Drug Enforcement Administration (DEA) and the Food and Drug Administration. DEA identifies drugs which have potential for abuse and/or addiction and classifies them as controlled substances. These drugs are subject to more stringent controls against unauthorized use than are other drugs. Controlled substances are categorized under schedules I through V, depending on (1) the degree of each drug's potential for abuse, (2) its level of acceptance in medical treatment, and (3) its potential to produce psychological or physical dependency. Schedule I drugs which are currently not accepted for medical use--such as heroin and marihuana--have the highest potential for abuse; schedule V drugs have the least potential.

The VA Pharmacy Service Manual states that each health care facility is to have available appropriate pharmacy services to provide quality and timely patient care. The pharmacy services are to promote optimal patient care in the most therapeutically efficient manner, and are to economically administer the total pharmacy program.

ADEQUACY OF DRUG CONTROLS

VA has extensive controls over controlled substances and other drugs to assure adequate provisions for the receipt, distribution, control, accountability, and administration of medications. However, some improvements can be made in their implementation, and some additional controls are needed.

Improvements needed in executing existing controls

VA can improve its control over drugs by clarifying an existing policy, by enforcing some existing procedures, and, in other cases, by maintaining complete and accurate records.

Existing policy needs clarification

Until April 1978 VA policy on prescriptions for schedule II substances and schedule III narcotics prevented prescriptions for these substances from being refilled. To conform to DEA regulations, VA removed the constraint on refilling prescriptions for schedule III narcotics in April 1978. This change did not eliminate the existing requirement to maintain a register of schedule II substances, schedule III narcotics, and alcohol. The register is required to show the quantities of these substances received and dispensed by the pharmacy.

VA policy allows a maximum of a 30-day supply of schedule III narcotics to be dispensed and up to five refills to be issued. Asheville and Fayetteville pharmacy officials stated that they retain the original controls over schedule III narcotics; they do not allow these substances to be refilled and continue to maintain registers. The Durham medical center implemented the April 1978 change and interpreted it to also eliminate the requirement to maintain the receipt and dispensement register for schedule III narcotics while retaining registers for schedule II substances and alcohol.

The chief pharmacist at the Durham medical center stated that the policy needs to be clarified before any register is maintained for schedule III narcotics. He also stated that the requirement would again burden pharmacy operations due to the additional time required to record the numerous daily transactions of such narcotics. The Director of the Pharmacy Service, VA Central Office, stated that the pharmacies are still required to maintain the register, and he plans to clarify the misunderstanding.

Existing procedures for narcotic inspections need to be enforced

VA policy requires monthly inspections of schedule II substances and schedule III narcotics in the pharmacy, wards, and clinics. The medical center inspectors are required to count or measure the quantities on hand and verify the quantities with the amounts shown in pharmacy registers.

Drug inspectors at the Asheville medical center were not making an actual count of schedule II substances and schedule III narcotics. A physical count was not being taken of some drugs which were maintained in large bulk containers holding 500 or 1,000 pills. If a bottle had recently been opened, the inspectors would not take the time to count

the pills. The Asheville medical center director stated that during future inspections a physical count will be made with automatic pill counters.

A similar situation was found with a schedule II liquid narcotic compound which was maintained in a gallon container and dispensed as needed at the Durham medical center. Inspectors were not actually measuring the remaining balance in the gallon container, but were merely certifying the balance, as stated on the narcotic register. After reviewing the register, we identified an apparent shortage of approximately a quart of the narcotic compound which had been dispensed but not recorded on the narcotic register. This error, as well as mathematical mistakes in the register, went undetected. If an actual measurement had been made, the inspectors would have observed the discrepancy from the narcotic register and would have identified prior errors. The pharmacy now maintains the compound in premeasured bottles and/or a graduated container.

Complete and accurate records should be maintained

As discussed earlier, VA policy requires monthly inspections of drugs on medical center wards and clinics. To accomplish this the pharmacy is to provide the inspector with a complete list, by ward and clinic, of the schedule II substances and schedule III narcotics dispensed to each ward since the last inspection. By comparing this list with individual ward records, the inspector can verify the ward's receipt of the substances and subsequent ward dispensement.

The drug inspectors at the Durham medical center were consistently finding narcotics on the wards for which the pharmacy had not provided records showing that drugs had been dispensed. This problem occurred because of recordkeeping errors in the pharmacy. There is potential for misuse without detection by the inspector or pharmacy officials without proper records of drugs dispensed to the wards.

Accountability could be improved

VA can improve its accountability for some substances by instituting additional procedures for substances shipped by registered mail and for substances that are to be destroyed or returned to manufacturers because they are outdated or contaminated. Some VA medical centers may also desire to establish special controls over potentially abusive substances.

Additional controls needed

To minimize loss, theft, or abuse, VA requires that all schedule II substances and schedule III narcotics mailed to patients be sent by registered mail; the return receipt is requested by VA.

The Asheville medical center had implemented its own policy and procedures over registered mail items. The pharmacy maintained a separate record for each item sent by registered mail. When the pharmacy received the return receipt from the post office, a pharmacy official would attach this receipt to the initial record. This procedure enabled the pharmacy to (1) be assured the medication had been delivered and (2) initiate a tracer if the return receipt had not been received in a reasonable time.

The other two medical centers visited did not have procedures similar to those that the Asheville medical center used to assure that medications had been delivered. These pharmacies would place the return receipt in the patient's medication folder or a separate file without assuring that a receipt had been received for each medication sent by registered mail.

Another VA policy requires that excess or unusable schedule II substances and schedule III narcotics accumulated in the pharmacy be turned over to the medical center supply service after a certain period of time for destruction or return to the manufacturer. Extensive procedures exist for returning such items from wards or clinics to the pharmacy. The procedures require that duplicate turn-in slips identifying the substance be dated and signed by ward and pharmacy officials. All three medical centers were storing returned items in the pharmacies' safes for destruction or return to the manufacturer.

Similar procedures did not exist for recording substances which were (1) removed from pharmacy stock, (2) returned by the Postal Service as undeliverable, or (3) returned by patients or family members. The Asheville and Fayetteville medical centers did not maintain turn-in slips for these three situations. The Durham medical center was maintaining the slips for substances taken from pharmacy stock or returned by patients or family members, but not for items returned by the Postal Service.

The Asheville pharmacy was maintaining a register of each item that was returned to the pharmacy by wards or patients or that was removed from pharmacy stock. Each substance was individually sealed in an envelope and numbered in accordance with the register. This practice enabled the pharmacy to maintain good control over items to be destroyed and made it possible to detect the pilferage of any returned item. The other two medical centers did not maintain such controls.

Special treatment for potentially abusive substances

Each of the three medical centers visited had taken various measures to provide greater control over certain substances. For example, the Fayetteville medical center had decided to restrict outpatient prescriptions for valium (a schedule IV tranquilizer) to 120 tablets; no refills were allowed. A pharmacy official stated that the additional controls were placed on this substance because medical center officials were concerned that the potential for abuse of this drug might be higher than that indicated by its current DEA classification. The Asheville medical center has also limited the quantity of valium dispensed at any one time in two wards. The chief pharmacist stated that ward personnel wanted additional controls over valium, and they therefore limited ward inventory to 25 tablets.

A ward official at the Asheville medical center stated that the drug doriden (a schedule III tranquilizer) had also been placed under tighter control. One ward required that a specific order be obtained from a physician each time the drug is administered.

Additional physical security has been established in the supply warehouse at the Asheville and Fayetteville medical centers. These medical centers store all controlled substances--except for one substance, which is maintained in a locked refrigeration unit--in the warehouse vaults until they are dispensed to pharmacy service. Access to the warehouse vaults is limited to three officials at each medical center.

Durham supply officials decided to adopt similar controls over controlled substances. Supply officials stated that they had taken a physical inventory of controlled substances several days before our visit, and they had accounted for 20 bottles of valium tablets. A shortage of one bottle

containing 500 tablets was discovered during our physical inventory. Supply officials could not account for the shortage, and this was a major factor in the decision to place all controlled substances in the warehouse vault.

DISPENSING MEDICATIONS IS GENERALLY TIMELY

VA required mail-out prescription requests to be processed and dispatched within 2 working days; however, no time frame has been established for prescriptions received at the pharmacy window. Each medical center requires mail-out prescriptions for refills to be held if the prior dispensement was less than 20 days earlier. The quantity of drugs in a patient's possession is limited in this way. Except for problems with mailout prescriptions at the Durham medical centers, all three medical center pharmacies were generally providing patients their medication in a timely manner.

Durham pharmacy officials were making a concerted effort to complete mail-out requests in a timely manner. However, the pharmacy was generally taking from 5 to 7 working days to fill prescription refill requests. Pharmacy officials attributed the delay to an excessive workload and a shortage of one pharmacist. Medical center officials stated that the pharmacy encourages patients to request refill prescriptions 10 days before their current supply is depleted. This 10-day period allows enough time for the prescriptions to reach the patients so that their medication can be maintained. The acting medical center director stated that, considering this 10-day period, he did not believe a timeliness problem existed or that patients were being inconvenienced. He stated that patients would complain if a problem existed, and he was not aware of any complaints.

The other two medical centers averaged less than 2 days to process mail-out prescriptions. The Fayetteville pharmacy encouraged patients to allow the medical center to mail their medication rather than wait at the pharmacy for the prescriptions to be processed. The chief pharmacist stated that this practice was adopted because patient waiting space was limited.

Pharmacy records show that since January 1978 the average time patients had to wait at the Fayetteville pharmacy window was less than 30 minutes. Similar data was not available at the other two medical centers. Based on our observations of pharmacy activities and discussions with pharmacy

officials, the average time patients at these medical centers waited at the pharmacies varied from less than 1 to about 3 hours.

DISPENSING MEDICATIONS APPEARS ADEQUATE

VA has stringent restrictions on the quantity of drugs dispensed for any given prescription. These restrictions include

--no more than a 30-day supply should be filled at one time,

--no refills are allowed for schedule II substances,

--no more than five refills are filled for lesser controlled substances and other medications, and

--no presriptions over 6 months old are refilled regardless of the number of refills authorized and remaining.

In addition, each medical center had established and implemented more stringent controls. For example, Asheville and Fayetteville pharmacy officials stated that they will not refill prescriptions for schedule III narcotics, and the Fayetteville pharmacy, as discussed earlier, will not refill prescriptions for valium. The Durham pharmacy will approve up to five refills of schedule III narcotics if a physician indicates on the prescription that the medication is needed for a chronic condition.

A Durham pharmacy official stated that the medical center has restricted the quantity of schedule II substances and schedule III narcotics to 100 doses at a time. This restriction may limit the patient's medication to less than a 30-day supply; however, medical center officials believed that a patient receiving such large quantities of medication should be returning to the medical center more frequently.

We identified several cases where patients appeared to be receiving excessive quantities of narcotic drugs. Medical center officials investigated these cases and stated that most of the patients had terminal illnesses. For example, one terminal cancer patient was receiving 400 dilaudid tablets (a pain reliever), a schedule II narcotic, for a 2-week period. The chief pharmacist for the outpatient pharmacy stated that the large quantity of medication was considered necessary since the patient had been receiving narcotics for a long time and had built up a resistance to the medication.

PROCEDURES APPEAR
ADEQUATE FOR DETERMINING
IF PRESCRIPTIONS ARE AUTHENTIC

VA policy requires that physician signature cards be maintained. Signature cards were not generally maintained for the prescriptions we reviewed at the Durham pharmacy; the other two pharmacies maintained signature cards. Pharmacy officials from these hospitals stated that the cards are used to verify the prescriptions written by newly assigned doctors.

Pharmacy officials stated that signature cards have limited value for ascertaining the authenticity of prescriptions. These officials stated that the signatures as written on the cards seldom resemble the signatures as they appear on individual prescriptions because doctors take greater care in signing the cards than the prescriptions.

Because signature cards may not be very helpful, pharmacies use other means to discourage and detect forgeries. Based on our observations and discussions with pharmacy officials, we learned that

--pharmacy officials can readily become familiar with and recognize doctors' signatures, as the pharmacy will accept only prescriptions written by medical center staff physicians;

--blank prescription pads are controlled and stored in the pharmacy's vault;

--patients must present documentary evidence of eligibility before prescriptions are processed; and

--pharmacists can identify errors and changes which indicate that a prescription might be forged.

CONCLUSIONS

VA has established extensive controls over drugs and other medication dispensed by its pharmacies. However, because discrepancies were found at the three medical centers--which may also exist at other medical centers--additional action should be taken to strengthen and improve these controls to (1) assure that prescriptions are properly filled and delivered to patients and (2) reduce the potential for theft, loss, and abuse.

(1) (2)

ENCLOSURE I

RECOMMENDATIONS TO THE VA ADMINISTRATOR

We recommend that the Administrator direct the Chief Medical Director to:

--Clarify its policy on schedule III narcotics so that each medical center pharmacy understands the need to maintain the register of receipt and dispensement of these drugs.

--Restate the policy for narcotic inspections of medical center pharmacies and wards, emphasizing the requirement of making actual counts and measures of drugs during these inspections.

--Reemphasize the importance of maintaining proper administrative records, especially on highly controlled substances.

--Direct medical center pharmacies to establish and maintain records or logs of drugs sent to patients via registered, return receipt requested mail, and to initiate followup action when these records do not show receipt by the patient.

--Direct medical center pharmacies to establish and maintain records or logs of all drugs held by the pharmacy pending destruction or return to the manufacturer.

--Encourage VA medical center officials to initiate necessary controls in addition to those established by VA to better control substances which they believe have a high potential for theft, loss, or abuse.