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VA HEALTH CARE

Efforts to Improve Pharmacies' Controls Over Addictive Drugs

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SUMMARY

The more than 200 Department of Veterans Affairs (VA) pharmacies routinely handle large quantities of prescription drugs--narcotics, depressants, and stimulants--that the Drug Enforcement Administration has classified as controlled substances, based on their potential for abuse or addiction. In June 1991, GAO found that VA's pharmacies had inadequate controls over many addictive drugs, resulting in thefts of large quantities of these drugs in recent years. GAO recommended that VA tighten its security procedures to minimize losses and develop a more systematic approach for detecting thefts. The Chairman, Subcommittee on Oversight and Investigations, House Committee on Veterans' Affairs, asked GAO to monitor VA's efforts to improve controls over addictive drugs.

VA has greatly improved controls over bulk supplies of addictive drugs stored in its pharmacies and made improvements in dispensing areas. New security procedures should make it difficult to divert drugs from bulk supplies without detection. However, VA's efforts to strengthen controls over addictive drugs in dispensing areas have been less effective. Progress was slowed, in part, by pharmacy managers' varying interpretations of VA's new policies, as well as some reluctance to spend resources to improve drug security practices. Although VA is working to improve controls over these supplies, it will take many months before dispensing supplies are adequately controlled in all pharmacies. VA's inclusion of its addictive drug controls as material weakness in the 1991 Federal Managers' Financial Integrity Act Report should help ensure that VA's corrective actions will be accomplished and, more importantly, help eliminate weaknesses in those controls.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss the Department of Veterans Affairs' (VA's) controls over addictive prescription drugs. At a hearing last June, you released our report which disclosed that (1) inadequate controls had resulted in thefts of large quantities of addictive drugs from VA pharmacies and (2) pharmacy managers generally became aware of the thefts only after law enforcement agencies notified them about criminal activities involving the use of VA drugs.[1] The report recommended that VA tighten its security procedures to minimize drug losses and develop a more systematic approach for detecting thefts. At the conclusion of the hearing, you asked us to monitor VA's efforts to improve controls over addictive drugs.

In a July 1991 letter, the Deputy Chief Medical Director for Administration and Operations told you that VA planned to implement several management initiatives in response to our report and members' concerns. To assess these initiatives, we reviewed newly developed policies and procedures for safeguarding addictive drugs and discussed them with a wide range of VA staff, including pharmacists in headquarters and regional offices. In addition, we visited 6 pharmacies and surveyed 16 others by telephone to see how the new policies and procedures had been implemented. We also analyzed all pharmacies' responses to two questionnaire surveys that VA used to assess compliance with new policies and procedures.

In summary, we found that VA has greatly improved controls over bulk supplies of addictive drugs stored in its pharmacies. New security procedures should make it difficult to divert these drugs without detection. However, VA's efforts to strengthen controls over addictive drugs in dispensing areas have been less effective. Progress was slowed, in part, by pharmacy managers' varying interpretations of VA's new policies, as well as some reluctance to spend resources to improve drug security practices. Although VA is working to improve controls over these supplies, it will take many months before dispensing supplies are adequately controlled in all pharmacies.

I would like now to describe how addictive prescription drugs are classified, highlight VA's management initiatives, and provide a general assessment of the major initiatives.

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[1]VA Health Care: Inadequate Controls Over Addictive Drugs (GAO/HRD-91-101, June 6, 1991) and Controls Over Addictive Drugs in VA Pharmacies (GAO/T-HRD-91-36, June 19, 1991).

VA PHARMACIES HANDLE PRESCRIPTION DRUGS WITH ABUSE POTENTIAL

The more than 200 VA pharmacies stock a variety of prescription drugs that are regulated under the Controlled Substances Act. The act authorizes the Drug Enforcement Administration to categorize prescription drugs, as well as other substances, into one of five groups, called schedules, based on their potential for abuse or addiction. Schedule I and II drugs have the highest potential for abuse, and schedule V the lowest. Schedule I drugs do not have approved medical uses in the United States. VA's pharmacies stock, on average, 79 drugs[2] that are included on schedules II, III, IV, and V; few stock more than 120 scheduled drugs.

At the time of last year's hearing, VA policy was to divide scheduled drugs into two groups for security and record-keeping purposes. One group included all schedule II drugs and those schedule III drugs containing narcotics, hereafter referred to as higher scheduled drugs. The other group, referred to as lower scheduled drugs, contained the nonnarcotic schedule III drugs, as well as schedule IV and V drugs. VA's pharmacies handle, on average, slightly more lower (56 percent) than higher (44 percent) scheduled drugs.

As I previously testified, VA's controls over higher scheduled drugs appeared adequate to detect and facilitate investigations of drug losses and made it difficult to divert drugs without detection. VA required that each pharmacy maintain an internal audit system that included monthly unannounced inspections of higher scheduled drugs. Under this system, pharmacies were to maintain a separate record showing all receipts and disbursements from stock, thereby maintaining a perpetual inventory of the drugs on hand. A comparable control system for lower scheduled drugs was not required, and few pharmacies were using one.

VA'S MANAGEMENT INITIATIVES FOR IMPROVING DRUG CONTROLS OVER LOWER SCHEDULED DRUGS

In a February 1992 letter, the Deputy Chief Medical Director for Administration and Operations informed you of VA's progress in strengthening controls over lower scheduled drugs. He provided information on revised security procedures for storing and dispensing lower scheduled drugs and on new procedures for

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[2]Individual dosage forms and strengths of the same drug type are considered separately. For example, 5 mg injectable and tablet forms of the same drug are counted as two drugs, as are 5 mg and 10 mg tablets of the same drug.

detecting thefts, including perpetual inventory procedures for bulk stocks. He also reported that VA had developed an action plan, which contained a goal of providing pharmacies with resources to maintain perpetual inventories of working stocks of all lower scheduled drugs, including development of a computerized drug accountability system.

Before discussing VA's major initiatives, I would like to briefly describe, for context purposes, VA's overall management strategy.

VA's Management Strategy for Implementing Drug Control Initiatives

The Pharmacy Service, regional offices, and local pharmacies shared responsibility for developing and implementing VA's drug control initiatives. The Pharmacy Service was responsible for the overall development and coordination of the drug control improvement policies and procedures. Local pharmacies were responsible for implementation. The Pharmacy Service and regional offices shared responsibility for monitoring local pharmacy compliance.

Pharmacy Service officials faced several challenges as they tried to implement drug control improvement initiatives. These included (1) educating local pharmacy managers about the need for policy changes, (2) operating within existing budgets, and (3) developing policies that were flexible enough to accommodate differences in the pharmacies' operating practices.

Soon after the June 1991 hearing, pharmacy officials started to alert local pharmacy managers about the need for change and to provide them with new policy guidance. Between July and September they held conference calls and individual discussions. In September, they issued written policy requirements, and since then, they have continued to hold monthly conference calls, as well as individual discussions, to help pharmacies understand the new requirements.

To help monitor implementation of the drug control initiatives, Pharmacy Service officials developed a questionnaire, which they distributed to all local pharmacy managers in December 1991. Pharmacists in VA's regional offices reviewed the managers' responses and identified pharmacies that were having trouble complying with the new requirements. Regional pharmacists then discussed with local pharmacy managers ways to improve performance. They generally followed the same procedures for a subsequent survey distributed in February 1992. In late May 1992, VA sent a third survey to pharmacy managers.

VA Has Greatly Improved Controls Over Bulk Supplies of Addictive Drugs

After visiting 6 pharmacies and speaking with managers of 16 others, we believe that the new controls over bulk supplies should permit managers to detect losses when they occur. VA's September 1991 policy requires managers to store bulk supplies of lower scheduled drugs in locked areas accessible to only a few authorized employees. Managers are also to maintain perpetual inventory records on these supplies, reconcile inventory records to physical counts every 72 hours, and have independent inspectors reconcile inventory records to physical counts every month.

Most pharmacies reported on VA's surveys that they had implemented the new loss detection procedures for bulk supplies. Our review of drug losses that pharmacy managers reported between October 1991 and March 1992 showed that managers have used the new procedures to detect drug losses. Four pharmacies reported losses from bulk supplies of 500 doses. In addition, the new procedures act as an effective deterrent because employees should be less likely to try diverting drugs when they know managers have systems in place that could uncover their activities.

VA Continues to Improve Controls Over Working Stocks of Addictive Drugs

VA's goal is to establish a perpetual inventory system for working stocks of all lower scheduled drugs comparable to the one used for bulk supplies. As I testified last year, VA's computer system did not have the capability to do this. Therefore, VA officials developed a plan to modify its system by December 1992 and obtain additional funding by October 1993. In the interim, they required pharmacy managers to develop and use alternative measures to deter theft and detect losses.

VA's Birmingham Information Systems Center is developing the software needed to modify VA's computer system so that pharmacies can maintain perpetual inventory records of all scheduled drugs. When the software is available, VA expects pharmacy managers to use it to determine the "book balance" of each addictive drug that their pharmacies dispense. This will enable pharmacy managers to periodically conduct unannounced inspections during which they (1) physically count the stocks of each line item, (2) reconcile the physical counts to the book balances, and (3) investigate any significant variances.[3]

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[3] Managers will also be able to maintain perpetual inventories on any other items, such as high value non-scheduled drugs, that they select.

Until the software is operational, VA requires pharmacy managers to develop a system which uses pharmacy receipt and dispensing records to reconcile the inventory balances of selected drugs each month. Pharmacy managers are expected to (1) count the quantities on hand at the beginning of the month, (2) make adjustments for receipt and dispensing activities during the month, (3) compare the results to the counts at the end of the month, and (4) investigate any significant variances. In its September 1991 policy, Pharmacy Service referred to this system as "risk management indicators."

Initially, some managers had difficulty implementing the new requirement. Upon visiting three pharmacies during the first 3 months after VA's new policy guidance was issued, we found that two of the pharmacy managers had not implemented systems because they were confused about how to establish risk management indicators. Pharmacy Service officials recognized similar problems through their discussions with other managers. They have taken steps to educate pharmacy managers, primarily through monthly conference calls and individual discussions.

Based on pharmacies' responses to its questionnaire survey, VA now believes that most pharmacies have established appropriate interim systems. While some maintain perpetual inventories on all working stocks of lower scheduled drugs, the majority of pharmacies reconcile inventory balances for one or two drugs each month. For those reconciling selected drugs, the Pharmacy Service has established a tolerance of 500 doses as a threshold for assessing the adequacy of pharmacies' systems: that is, if a pharmacy can detect the loss of a 500-count bottle of a drug, that pharmacy has a sufficiently sensitive system.

Based on our later visits to 3 additional pharmacies and discussions with 16 other pharmacy managers, we believe that pharmacies have improved controls over addictive drugs but some are still struggling to implement risk management systems. Six pharmacies had established perpetual inventories of some or all lower scheduled drugs and 13 established risk management systems. Of the latter 13, 10 pharmacy systems appear to meet VA's requirements, but 3 pharmacies were reviewing pharmacy records for selected drugs without physically counting working stocks.

Our review of the 13 pharmacies' risk management systems raised concerns about whether they were sufficiently sensitive to adequately detect losses. Pharmacy managers have had difficulty implementing this requirement because inadequacies in their computer software forced them to rely on estimates of the quantities dispensed. The pharmacies' systems frequently found variances between estimated inventory balances and existing supplies, but most of these variances were fewer than 500 doses. The pharmacies generally attributed the variances to software inadequacies. These systems provide opportunities for some

quantities of these drugs to be diverted without detection.

VA REPORTED CONTROL WEAKNESSES INVOLVING SCHEDULED DRUGS IN PHARMACIES

As we recommended, the Secretary of Veterans Affairs has reported VA's controls over lower scheduled drugs as a material weakness in his fiscal year 1991 Federal Managers' Financial Integrity Act Report. This requires VA managers to use a formal process for tracking the implementation of drug control improvement initiatives. For example, top managers are to meet semiannually to review progress of planned actions to correct control weaknesses. Ultimately, the Pharmacy Service is responsible for providing evidence that corrective actions have been taken, including explanations of processes used to ensure the effectiveness of such actions. In addition, the Pharmacy Service must conduct a post-implementation evaluation 6 to 12 months after the last corrective action has been completed.

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Mr. Chairman, in conclusion, VA has made progress in strengthening its controls over addictive drugs stored and dispensed in its pharmacies. This progress has been aided by the concern that you and this Subcommittee expressed about this issue and by the leadership and the commitment exhibited by VA's top management to improve this situation. VA's inclusion of its addictive drug controls as a material weakness in the 1991 Federal Managers' Financial Integrity Act Report should help ensure that VA's corrective actions will be accomplished and, more importantly, help eliminate weaknesses in those controls.

This concludes my prepared statement. I will be happy to answer any questions that you or other members of the Subcommittee may have.