

REPORT BY THE STATE AUDITOR OF CALIFORNIA

**The Department of Health Services'
Information on Drug Treatment
Authorization Requests**

93012

October 1993

October 5, 1993

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The Governor of California
President pro Tempore of the Senate
Speaker of the Assembly
State Capitol
Sacramento, California 95814

Dear Governor and Legislative Leaders:

SUMMARY

The Bureau of State Audits and its contractor, The Thornton Group, present the fifth in a series of semiannual reports concerning the way the Department of Health Services (department) processes reimbursement requests for certain prescribed drugs under the California Medical Assistance Program (Medi-Cal). These requests are known as drug treatment authorization requests (TARs).

In response to Chapter 716, Statutes of 1992, we obtained from the department statistical information, compiled each month, concerning the number of TARs received and processed from June 1990 through May 1993. This report focuses on the drug TARs processed during the 12 months from June 1992 through May 1993. The past four reports on this subject have been prepared by the Office of the Auditor General (OAG). However, the OAG closed in December 1992 because of budget reductions, but in May 1993, the Bureau of State Audits began operation and assumed responsibility for this audit pursuant to Government Code Section 8546.8.

The department received approximately 211,400 drug TARs from June 1992 through May 1993. This represents an increase of more than 47,300 (29 percent) drug TARs since June 1990 through May 1991, the first year of the OAG's review. The increase in the number of drug TARs received, as stated in the OAG's last report, may have occurred

partly because of the addition of approximately 1,423,000 (a 39 percent increase since June 1990) Medi-Cal beneficiaries eligible to obtain drugs through Medi-Cal.

Furthermore, from June 1992 through May 1993, the department processed approximately 53,000 (33 percent) more drug TARs than it did during the first year of our review. In addition, the department's monthly backlog of drug TARs received by mail had risen to approximately 5,000 in May 1993. In comparison, at the end of May 1991, the department's backlog of drug TARs received through the mail was approximately 2,900.

From June 1992 through May 1993, the department reported that its average time for processing mailed drug TARs exceeded the 5 working days state law requires. More specifically, the department reported that, in May 1993, it took an average of 16 days to process mailed-in drug TARs. In the OAG's first report on drug TARs, it reported that in December 1990 the department took an average of 15 days to process mailed-in drug TARs. Five of the six pharmacists we contacted stated the delays in obtaining a response to their mailed-in drug TARs had not caused lapses in medication or problems for patients.

The department processes drug TARs in drug units located in Stockton, Los Angeles, and San Bernardino. According to the chief of the department's Medi-Cal Operations Division Northern Field Operations Branch, the department contracted with nine pharmacist consultants in April 1993 to enable the drug units to process drug TARs more effectively and promptly. The department entered into 18-month contracts with three pharmacist consultants in the Stockton drug unit and six pharmacist consultants in the Los Angeles drug unit. In addition, the department hired two full-time pharmacist consultants to staff a newly created satellite drug unit in San Bernardino.¹ Before the increase in staff, the Los Angeles drug unit included two pharmacist consultants and the Stockton drug unit included seven pharmacist consultants. The role of the pharmacist consultants, who are licensed pharmacists, is to process drug TARs by either approving, denying, modifying, or returning the TARs to the providers (to request additional information).

We sampled drug TARs to determine if TARs received by FAX and by the department's audio response telephone system -- Voice Drug TAR System (VDTS) -- were processed within 24 hours of receipt, as federal law requires. From June through November 1992, we found the department was not processing these drug TARs within 24 hours. However, based on another sample we selected from drug TARs received during May 1993 (after

¹ Although the San Bernardino unit was established during our review, TAR workload statistics for the San Bernardino unit were not reported until June 1993, which is beyond our study period. Staff in the San Bernardino satellite unit report to the Los Angeles drug unit administrator and have been assigned to process drug TARs submitted through the mail.

the department contracted with nine pharmacist consultants), we found the department met the 24-hour requirement.

Finally, in response to Section 14105.42 of the Welfare and Institutions Code, the department provided us with information regarding the number of fair hearing requests beneficiaries made to appeal a denied drug TAR and the number of complaints received from providers. Nineteen fair hearing requests were submitted to the Department of Social Services from June 1992 through May 1993. Of those, 7 were withdrawn before the cases were heard. Two of the remaining 12 fair hearing requests were approved, 2 were denied, 2 were dismissed, and the decisions on the remaining 6 were still pending at the time of our review. The department reported that it did not receive any complaints about its processing of drug TARs from June 1992 through May 1993.

BACKGROUND

Authorized in 1965 under Title XIX of the Social Security Act, Medi-Cal provides a wide array of health care services including payment for prescription drugs to public assistance recipients and low-income families. Under the provisions of Title 22 of the California Code of Regulations, the department administers Medi-Cal; the state and federal governments jointly fund it.

Under Medi-Cal, beneficiaries may receive prescription drugs from a list the department has established. This list is known as the Medi-Cal list of contract drugs and, according to the chief of the department's field services branch, includes drugs from most therapeutic categories. Therapeutic categories are classifications of drugs addressing specific medical problems. For example, the contract drugs are classified into such therapeutic categories as antibiotics, cardiac drugs, and gastrointestinal drugs. According to the chief of the field services branch, when a doctor prescribes a drug that is not on the list of contract drugs, the provider, generally a pharmacist, must receive authorization to seek reimbursement for the cost of the drug. The provider's request for authorization is known as a treatment authorization request (TAR).

Currently, the department has two Medi-Cal drug units that process drug TARs. These drug units are located in Los Angeles (with a satellite drug unit in San Bernardino) and Stockton. Drug TARs can be submitted via FAX, the department's Voice Drug TAR System (VDTS), or mail. Drug TARs submitted by FAX and VDTS are restricted to initial supplies of prescribed drugs and drugs that are urgently needed. Drug TARs submitted by mail generally cover renewals or retroactive approvals of prescribed drugs. In both renewals and retroactive approvals, the beneficiary, or patient, may have already received the drug.

Although the Stockton drug unit once processed VDTS drug TARs statewide, most of the VDTS drug TARs were reassigned to the Los Angeles drug unit as of April 1992. The Los Angeles drug unit employs more medical transcribers than the Stockton drug unit and is therefore better able to handle drug TARs received by VDTS. At the same time, the Stockton drug unit assumed responsibility for processing most of the mailed-in TARs.

Drug TARs received by FAX or mail are first reviewed by medical transcribers for completeness. Mailed-in TARs are date stamped on the day they are received in the drug unit. The drug TARs are then forwarded to pharmaceutical consultants, who are licensed pharmacists. The consultants process a drug TAR by either approving it, denying it, approving it with modifications, or returning it to request further information from the provider. After a decision is made on a drug TAR, the medical transcriber returns the TAR to the provider.

Drug TAR information received by VDTS is retrieved by medical transcribers. The medical transcribers type the information onto a TAR form and forward the form to the pharmaceutical consultants. The pharmaceutical consultants process the drug TAR by either approving it, denying it, approving it with modifications, or returning to request further information from the provider. The decision is recorded on the VDTS, and the provider can determine the status of the request by accessing the system. An office assistant also returns a copy of the TAR to the provider by mail.

SCOPE AND METHODOLOGY

Chapter 716, Statutes of 1992, requires the OAG to prepare an analysis and summary of the department's data on drug TARs. Further, Section 14105.42 of the Welfare and Institutions Code mandates that the OAG submit a report on this data to the Legislature beginning February 1, 1991, and every six months thereafter until January 1, 1999. Chapter 12, Statutes of 1993 (Government Code Section 8546.8) directs the Bureau of State Audits to assume these responsibilities.

To fulfill these requirements, we obtained statistical data from the department regarding drug TARs received by telephone, VDTS, FAX, and mail. We also obtained data on the number of drug TARs approved, modified, denied, and returned. These data cover the 12 months from June 1992 through May 1993. We visited the Los Angeles and Stockton drug units that processed drug TARs to observe how they did so and to determine how they counted the drug TARs they received and processed each month.

We also reviewed the methods the drug units used for measuring the time it takes them to respond to a drug TAR from the time it is received at the drug unit to the time the drug unit returns the completed drug TAR to the provider. In addition, we conducted tests to determine if the Los Angeles and Stockton drug units are processing initial and urgent drug TARs submitted via FAX and VDTS within 24 hours as required by federal law effective July 1, 1991. We also conducted a test in the Stockton drug unit to determine if mailed-in TARs are processed within five days as state law requires. We contacted six pharmacists who had submitted drug TARs through the mail and had received the approved drug TAR from the drug unit in more than five days to determine if Medi-Cal beneficiaries were experiencing any lapses in medication because of processing delays.

To determine the accuracy and reliability of the monthly statistical reports, we analyzed a judgmental sample of the drug unit records covering two months. We did not do enough testing of the department's counting of the drug TARs and compiling of the drug TAR data to assess the overall impact of any errors on the numbers reported. However, we made adjustments for slight errors identified in our sample in this report. Specifically, we identified and adjusted for slight computation errors for September 1992 for drug TAR statistics reported by the Stockton drug unit and for May 1993 for drug TAR statistics reported by the Los Angeles drug unit.

To obtain data on the number of denied drug TARs that have been appealed to the Department of Social Services, we interviewed staff and collected data for June 1992 through May 1993. Similarly, to obtain data on the number of complaints the department has received about its processing of drug TARs, we interviewed staff and collected data for June 1992 through May 1993.

DRUG TARs RECEIVED

The number of drug TARs received fluctuated from month to month from June 1990 through May 1993. More specifically, the number of drug TARs received varied from a low of 11,521 in September 1990 to a high of 19,965 in March 1993 (see Attachment A).

Figure 1

Figure 1 shows that number of drug TARs received is steadily increasing. During the first year of the OAG's review, from June 1990 through May 1991, the drug units received approximately 164,100 drug TARs. From June 1992 through May 1993, the drug units received approximately 211,400 drug TARs, representing an increase of more than 47,300 (29 percent) drug TARs since the first review.

As mentioned in the OAG's July 1992 report, the increase in the number of drug TARs received may have occurred because of the increase in the number of Medi-Cal beneficiaries. In June 1990, the department reported 3,675,000 Medi-Cal beneficiaries. According to the department, by May 1993 the number of Medi-Cal beneficiaries had increased to 5,098,069, resulting in 1,423,069 (39 percent) more Medi-Cal beneficiaries eligible to obtain drugs through Medi-Cal than in June 1990. Attachment A provides more detailed information on the number of drug TARs received each month.

DRUG TARs RECEIVED ACCORDING TO METHODS OF DELIVERY

As Figure 2 shows, the most common method of submitting drug TARs is through the mail, followed by drug TARs submitted by FAX and VDTS. Providers submitted 985 drug TARs via FAX during July 1990, the first month that drug TARs could be submitted by FAX. As Attachment A shows, during May 1993, providers submitted 8,149 drug TARs via FAX, an increase of more than 7,164 (727 percent). In the past year, from June 1992 through May 1993, the number of drug TARs submitted by FAX increased to 85,907, representing an increase of approximately 256 percent over the first year.

Figure 2

While the number of drug TARs submitted by FAX has risen, the number of drug TARs submitted by VDTS and mail has leveled off. Figure 2 shows that the volume of drug TARs received via VDTS at the department has been relatively constant since December 1991. Figure 2 also shows that not only are providers most likely to submit drug TARs through the mail, but drug TARs submitted through the mail represent the department's most stable workload among drug TARs.

DRUG TARs PROCESSED

Figure 3 shows the number of drug TARs processed at the drug units from June 1990 through May 1993.

Figure 3

During the first year of the OAG's review, from June 1990 through May 1991, the drug units processed 162,200 drug TARs. In comparison, from June 1992 through May 1993, the drug units processed 215,287 drug TARs, an increase of more than 53,000 (33 percent) drug TARs.

Attachment C provides details on the number of drug TARs approved, modified, denied, and returned by the drug units from June 1990 through May 1993. From June 1990 through May 1993, the drug units processed a total of 546,671 drug TARs. Of those, 70 percent were approved, 15 percent were modified, 11 percent were denied, and 4 percent were returned.

BACKLOG OF UNPROCESSED DRUG TARs

As Figure 4 shows, the department's monthly backlog of drug TARs submitted through the mail has fluctuated from June 1990 through May 1993.

Figure 4

From June through December 1992, the number of unprocessed drug TARs dropped from 8,794 to 2,307. However, in February and April of 1993, the number of unprocessed drug TARs rose again. Finally, in May 1993, the number of unprocessed drug TARs decreased to 5,051 (see Attachment B for monthly totals).

Because the drug units prioritize and process drug TARs submitted by FAX and VDTs within 24 hours, the backlog of drug TARs consists only of those submitted through the mail. In April 1992, the department assigned the primary responsibility for processing all mail-in drug TARs to the Stockton drug unit. For drug TARs submitted through the mail, Figure 5 provides a comparison of those that were processed and unprocessed from June 1990 through May 1993. According to staff in the Stockton drug unit, the fluctuations in unprocessed drug TARs were primarily because of changes in staffing. From August through December 1992, unprocessed drug TARs gradually decreased because the pharmacist consultants in the Stockton drug unit were allowed to work overtime during that period. In addition, to reduce the backlog of unprocessed drug TARs, unprocessed drug TARs were sent to the department's headquarters and processed by the pharmacist consultants there. In January 1993, the number of unprocessed TARs increased because one full-time pharmacist consultant was on leave. Similarly, other drug unit staff took time off during April 1993. The number of unprocessed drug TARs rose to approximately 5,000 in May 1993. However, in April 1993 the department added three pharmacist consultants to the Stockton drug unit. Because the department has established 18-month contracts for these positions, the department expects the backlog of unprocessed drug TARs to decrease further in future months.

Figure 5

DISAGREEMENTS OVER PROCESSING TIME FOR DRUG TARs

Section 14103.6 of the Welfare and Institutions Code requires that pharmaceutical consultants process drug TARs in an average of five working days. Additionally, this section states that, if the pharmaceutical consultant does not make a decision on a drug TAR within 30 days of receiving it, the request shall be considered approved. Additionally, Section 1927 (d)(5) of the federal Social Security Act of 1990 requires states to respond to all drug TARs within 24 hours of receipt. The federal Department of Health and Human Services' Health Care Financing Administration (HCFA) upholds this position, regardless of whether the TAR is for an initial or urgent prescription or for reauthorization of an existing prescription. It also upholds this position regardless of how the drug TARs are delivered to the department. In interpreting those regulations, the department expects the drug units to process initial or urgent drug TARs (that is, drug TARs typically submitted via FAX or VDTS) within 24 hours and to process reauthorization drug TARs (that is, drug TARs typically submitted through the mail) within five working days.

Although the Welfare and Institutions Code and the Social Security Act seem to conflict in their requirements, the OAG's last report stated that the federal government was expected to issue regulations in April 1992 to resolve the difference. However, according to our discussions with HCFA, as of August 25, 1993, these regulations have not yet been issued. The HCFA did not provide an estimated date of issuance.

Previous OAG reports stated that the drug units were processing initial and urgent drug TARs submitted by VDTS and FAX within 24 hours as required by law. During this audit, we selected at random and reviewed a sample of 417 drug TARs submitted by FAX to the Stockton drug unit on two days within the review period. We also reviewed a sample of 75 drug TARs submitted via VDTS to the Stockton drug unit. In eight instances, we were unable to determine the date drug TARs submitted by FAX were received. However, of the remaining 409 drug TARs in the sample, 408 drug TARs were processed within 24 hours as required. Further, we found that all of the drug TARs submitted via VDTS in our sample had been processed within 24 hours.

Additionally, we reviewed a sample of 206 drug TARs submitted by FAX to the Los Angeles drug unit in March 1993 and 66 drug TARs submitted via VDTS in August 1992. We found that only 75 of the 206 drug TARs submitted by FAX were processed within 24 hours, but 65 of the 66 drug TARs submitted by VDTS were processed within 24 hours. According to the Los Angeles drug unit manager, the reason drug TARs submitted by FAX were not processed within 24 hours was because the drug unit was

staffed with only two pharmacist consultants who were unable to keep up with the drug TARs workload. Now, however, the Los Angeles drug unit has increased its staff by six pharmacist consultants. This should allow the Los Angeles drug unit to process drug TARs within the 24-hour requirement.

As mentioned previously, the department contracted with six pharmacist consultants in the Los Angeles drug unit in April 1993. To determine the effect of the staff increase on the unit's ability to meet its workload demands, we selected another sample of drug TARs that providers submitted by FAX and VDTS on May 28, 1993. Specifically, of the 220 drug TARs submitted by FAX, 217 were processed within 24 hours as required. In addition, we found that all of the 70 drug TARs submitted by VDTS were processed within 24 hours.

PROCESSING TIME FOR MAILED-IN DRUG TARs

According to the OAG's last report, the drug units reported processing their mail-in drug TARs in an average of more than the five working days required by state law. The following table shows the average time each unit took to process mailed-in drug TARs from December 1990 through May 1993.

**Average Time of Processing Mailed Drug TARs
By Drug Unit, in Days
December 1990 Through May 1993**

		Los Angeles	Stockton
1990	December	15	-
1991	May	9	6*
	December	28	12
1992	May	-	25
	December	-	6
1993	May	-	16

Source: Los Angeles and Stockton drug units

* Before December 1991, the Stockton drug unit reported only the average time for processing mailed drug TARs originally submitted to the Los Angeles drug unit and subsequently sent to the Stockton drug unit for processing. These numbers do not include the average processing time for mailed drug TARs the Stockton drug unit received and processed directly.

The Los Angeles drug unit discontinued accepting drug TARs submitted by mail in April 1992. As a result, the Stockton drug unit was the only drug unit reporting a turnaround time for mailed-in drug TARs during our review period. In May 1993, the Stockton drug unit reported that it took an average of 16 working days to process mailed-in drug TARs, up from 6 working days reported in May 1991 and December 1992. The increase in the Stockton drug unit's processing time is a result of the increase in the backlog of unprocessed mailed-in drug TARs, which, as we discussed previously in this report, was caused by staffing changes. Also, according to the department, drug TARs submitted by mail (generally renewals or retroactive approvals) are not as urgent as drug TARs submitted through VDTS and FAX. However, the department hopes that through its addition of three pharmacist consultants to the Stockton drug unit, it has addressed this delay in processing mailed-in drug TARs.

To determine if beneficiaries suffer a lapse in medication as a result of delays in the drug TAR approval process, we contacted six pharmacies during our review. The six pharmacies included in our sample had submitted drug TARs to the Stockton drug unit that were not processed within the five-day requirement. Of the six pharmacists included in our sample, only one pharmacist indicated that processing delays have resulted in lapses in medication for patients. According to the pharmacist, however, of those mail-in TARs that are delayed, less than 5 percent could present a problem for his patients in terms of lapses in medication. However, in all instances, pharmacists indicated a willingness to dispense the medication (either for a limited supply or for the fully prescribed amount) to the patient in advance of receiving the approved drug TAR to avoid any lapses.

INFORMATION ON DRUG TAR FAIR HEARINGS AND COMPLAINTS

For all denied drug TARs, Section 14105.42 of the Welfare and Institutions Code requires the department to report to the Legislature the number of fair hearings requested,

approved, denied, and pending. This code section also requires the department to report to the Legislature the number of complaints from beneficiaries and providers regarding the difficulty or inability of obtaining a response to a drug TAR.

Beneficiaries request fair hearings through the Department of Social Services to appeal denials of drug TARs. From December 1990 through May 1991, the department received only 2 requests for fair hearings. From June 1991 through May 1992, the department received 10 requests for fair hearings, 3 of which were withdrawn before the cases were heard. According to information the drug units provided, from June 1992 through May 1993, 19 requests for fair hearings were received. Seven of those requests were withdrawn before the cases were heard. The remaining cases were heard before an administrative law judge. Two of the cases were approved, 2 cases were denied, 2 were dismissed, and the remaining 6 cases are pending decision.

The 7 of 19 fair hearing requests that were withdrawn appeared to be the result of misunderstandings about the TAR process. Both of the fair hearings that resulted in approvals were only approved in part. For example, one TAR was only approved in part because the denial of payment was related to a billing problem. This billing problems was handled by the department's fiscal intermediary, and the fair hearing process has no jurisdiction over this. Thus the judge could only approve the drug TAR in terms of medical necessity. Fair hearing requests that resulted in denials were related to unlabeled or unauthorized usage. For example, a drug TAR for the drug Prozac was denied because it was being requested for an unlabeled use, obsessive compulsive behavior. Prozac is typically a drug that is prescribed for severe depression, not obsessive compulsive behavior.

During the same period, June 1992 through May 1993, the drug units reported that they did not receive any complaints from beneficiaries or providers regarding the difficulty or inability of obtaining a response to a drug TAR.

The Thornton Group conducted this review under contract with the Bureau of State Audits, whose authority is vested by Section 8543 of the California Government Code. This review was conducted according to generally accepted governmental auditing standards and was limited to areas specified in the audit scope section of this report.

Sincerely,

KURT R. SJOBERG
State Auditor

ATTACHMENTS

- A** Drug Treatment Authorization Requests Received by Means of Delivery
June 1990 Through May 1993
- B** Drug Treatment Authorization Requests Processed
June 1990 Through May 1993
- C** Drug Treatment Authorization Requests
Approved, Modified, Denied, and Returned
June 1990 Through May 1993

RESPONSE TO THE AUDIT

Health and Welfare Agency
Department of Health Services