Administrative Closure
Alleged Inappropriate Prescribing of
Controlled Substances and Alleged Abuse of Authority
Tomah VA Medical Center
Tomah, WI
MCI# 2011-04212-HI-0267

Background

The VA Office of Inspector General (OIG) Office of Healthcare Inspections (OHI) conducted a review to assess the validity of multiple allegations made by a series of complainants. Common elements among the concerns included alleged misprescribing and diversion of opioid drugs by a high ranking physician at the facility (Dr. Z) and by a (b)(6) (b) Y), as well as abuse of administrative and clinical authority by Dr. Z. The various allegations were compiled from:

- A complaint made in March, 2011 by a facility (b)(6) (with a corresponding VISN response in June, 2011 and a September, 2011 report from the VISN Chief Medical Officer (CMO) on remedial actions taken).
- Anonymous complaints made in August, 2011, via a letter sent to the OIG and Congressman Ron Kind of the U.S. House of Representatives.
- A physician at the facility in March, 2012, while the inspection was actively ongoing.

By several anonymous respondents to an EAR survey in May, 2012, that was conducted prior to a regularly scheduled CAP inspection. A total of 32 specific allegations were made by these sources, several of which came to light at various points while the inspection was underway.

The scope of our review included the assessment of the practice patterns and controlled substance prescribing habits of Dr. Z and (b) Y, as well as the administrative interactions of Dr. Z with subordinates and his approach to clinical leadership, specifically as these related to issues around the prescribing of controlled substances. We also looked for any concerns by Federal and municipal law enforcement authorities or other signals of drug diversion related to the practices of Dr. Z and (b) Y. Because of the potential seriousness of the allegations and their origination from multiple sources, we performed an

exhaustive review of the individual practitioners named. Because of the allegations of criminal activity, our efforts throughout this inspection were closely coordinated with the OIG's Criminal Investigation Division (51).

We reviewed documents from VA and non-VA sources as follows:

1. Statement of Charges, Settlement Agreement and Final Order from a state Medical Board concerning charges brought against Dr. Z shortly after his date of appointment to the VA.
2. Letters from the Veterans Integrated Service Network (VISN) 12 Director and the VISN 12 CMO.
3. Five peer reviews, and correspondence from Dr. Z to the Peer Review Oversight Committee and the VISN 12 regarding allegations made in March, 2011, and subsequent actions by VA management.
4. Scope of practice documents and routine peer reviews for (b)(6) Y.
5. OIG Master Case Index records of 19 cases at Tomah VAMC since 2009.
6. Ten peer reviews of Dr. Z's practice performed in November, 2009, along with minutes of a subsequent special session of the Peer Review Committee, and related correspondence between Dr. Z and the Committee.
7. Tomah VAMC police reports of overdoses/suspected overdoses for a three-year period.
8. Reports on adverse drug reactions in patients treated by Dr. Z and (b)(6) Y compiled by the Tomah VAMC pharmacy.
9. Documents related to the suicide of a Tomah VAMC (b)(6) professional immediately following termination of employment (memoranda, e-mail messages, Sheriff's Department reports, union representation records and related internal union correspondence).
10. Documents related to the appeal of a terminated Tomah VAMC (b)(6) to the Merit Systems Protection Board (MSPB) (appellant's brief for MSPB jurisdiction, narrative of (b)(6) experiences, supporting materials for decisions).
11. Relevant Medical Center Memoranda on pain management, chronic opioid use, and adverse drug event surveillance.
12. VA/DoD Clinical Practice Guideline on Management of Opioid Therapy for Chronic Pain (May, 2010).

We also requested Tomah VAMC police reports on sales of prescribed or illegal drugs on the Tomah VAMC campus in the preceding three years, but were told there have been no Uniform Offense Reports of such activities.

We conducted general chart reviews as follows:

1. Patients who were specifically identified in complainants' allegations.
2. Patients who were included in June, 2011, peer reviews of Dr. Z's practice.
3. A patient of (b)(6) Y who was identified by an informant to Tomah municipal police as being involved in drug diversion.
4. Selected individuals from a list of the 100 patients at Tomah VAMC receiving the highest doses of opioids

We also performed structured chart reviews and compiled the results using a SharePoint®-based data entry tool and Microsoft Excel® spreadsheet as follows:

1. All patients in the care of Dr. Z and/or (b)(6) Y who were among the 100 patients at Tomah having the highest doses of opioids (32 cases).
2. Patients on a list provided by the Tomah municipal police department of individuals suspected of drug crimes, who were receiving prescriptions for controlled substances from any provider at Tomah (24 cases; 15 were patients of Dr. Z and/or (b) Y).

We collected an e-mail dataset for review consisting of 227,532 unique e-mail messages and 859 associated files originating from 17 individuals. This review was performed using Clearwell software. We searched terms that could signal potential drug seeking behavior, such as those related to early refills and urine drug screens, in order to assess what was being communicated about these topics, as well as what advice or instructions were being given. We also reviewed messages pertaining to specific individuals in cases where administrative/supervisory conflicts were reported to exist.

We reviewed several extensive Microsoft Excel®-based datasets derived from pharmacy records with assistance from the VISN 12 Pharmacy Executive as follows:

1. Early refills of controlled substances and antidepressants (for comparison) at Tomah VAMC over the period of January 1, 2011 to September 12, 2012.
2. Total morphine equivalent amounts of opioids dispensed during FY 2012 in all VISN 12 facilities by site, provider, and patient.

We conducted telephone interviews prior to a site visit, including:

1. The complainant in the case where he/she was not anonymous.
2. Tomah and Milwaukee municipal police officials; a Diversion Investigator from the Drug Enforcement Administration (DEA), United States Department of Justice.
3. Current and former Tomah VAMC staff who were identified by complainants as having key information, including a (b)(6), a physician, and four pharmacists.
4. The newly appointed Director of Tomah VAMC.

We also engaged the assistance of three pharmacist consultants to assist us in evaluating the clinical and administrative aspects of Dr. Z's interactions with pharmacy staff and the staff's roles in facilitating patient safety and appropriately dispensing controlled substances. We provided the consultants with access to recordings of the interviews with the four pharmacists who had previously left Tomah VAMC.

We conducted a site visit at the facility on from August 22-23, 2012 -12. We interviewed the Associate Director (the Director was on sick leave), the Chief of Staff, the Mental Health Associate Chief of Staff, the Chair of the Pharmacy and Therapeutics Committee, the Director of the facility's Opioid Workgroup, the facility's Police Chief, the Pharmacy Director, the Outpatient Pharmacy Supervisor, two clinical pharmacists, six outpatient staff pharmacists, one contract dispensing pharmacist, three psychiatrists, two primary care physicians, a physician's assistant, a (b)(6) specialist, Dr. Z, and (b) Y,

During the site visit, we toured the outpatient pharmacy to assess security issues that had been raised in interviews. We also met with the Acting Chief Information Officer to discuss obtaining e-mail files that we were unable to retrieve remotely.

Following the site visit, we conducted several additional interviews by telephone as follows: the Medical Center Director, the Director of Human Resources, and the VISN Pharmacy Executive.

Findings

We did not substantiate allegations that the Tomah municipal and Milwaukee police departments made complaints about drug trafficking at the Tomah VAMC. However, the Tomah police department reported suspicions that certain Tomah VAMC patients were

misusing their prescribed controlled substances in various ways including drug diversion.[1]

We substantiated the allegation that at least five outpatient pharmacy staff left the facility in recent years. Pharmacists reported various reasons for leaving. The four pharmacists whom we interviewed expressed concerns regarding the facility's (and ultimately Dr. Z's) expectations for dispensing opioids and other controlled substances. One pharmacist, a new employee, was not retained by the facility at the conclusion of his/her initial employment period. This individual reported that on three occasions he/she had refused to fill prescriptions for controlled substances due to concerns about patient safety and/or drug diversion. A second clinical pharmacist who left the Tomah VAMC reported feeling inappropriately blamed by Dr. Z for the suicide of a patient. A dispensing pharmacist, relatively new to the facility, reported that he believed there were 40-50 patients who were regularly presenting to the outpatient pharmacy for early refills of opioids, and that pharmacists were told by Dr. Z they had to fill the prescriptions. He feared this would place his license at risk. A clinical pharmacist who had been hired in a supervisory capacity reported that when some of the pharmacists expressed discomfort with dispensing high doses of opioids to patients, Dr. Z would become angry and would insist that this pharmacist discipline the other pharmacists under his supervision.

We did not substantiate the allegation that Dr. Z was mismanaging a patient with complex regional pain syndrome by attempting to arrange an inappropriate above the knee amputation.

In the context of having obtained multiple contradictory facts and statements during the course of this inspection, often based on second or third hand accounts, we did not substantiate allegations of abuse of authority, intimidation and retaliation when staff question controlled substance prescription practices.

While we did not substantiate the allegations of abuse of authority, intimidation and retaliation when staff question controlled substance prescription practices, we did find that these are widely held beliefs and concerns among most pharmacy staff and among some other staff.

[1] Additionally, during the course of their investigations of a few deceased veterans they had noted large quantities of prescribed controlled substances in their (the veterans') residences. However, no law enforcement actions were being taken. Early in this inspection we became aware that the DEA was actively investigating complaints of inappropriate prescribing and drug diversion at the Tomah VAMC.

We found that the Chief of Pharmacy reports to Dr. Z by virtue of his (Dr. Z's) administrative leadership position.

We found that some patients at Tomah VAMC had a pattern of early refill requests, which can be a potential risk behavior for substance abuse. Pharmacists expressed a reluctance to question such early refills. Review of a VISN 12 pharmacy leadership data analysis indicated that Dr. Z, (b) Y, and other clinicians at the Tomah VAMC provided more than 7 days early controlled substance refills. A pre-April 12, 2012, local facility policy did not allow exceptions to the "no early refill" rule. A newer policy does not prohibit exceptions but does not provide practical guidance, parameters, or processes by which to approach early refills or navigate the clinical complexity of such exceptions.

We substantiated the allegation that negative urine drug screens (UDS) are not acted on and that controlled substances are still prescribed in the face of a negative UDS. In the course of our review of selected case histories and from the structured medical record review, we found that for some patients, when a UDS was performed and showed absence of prescribed medication, documentation in progress notes did not always acknowledge this or indicate what, if any, clinical intervention or change in treatment was initiated with the patient. For example, we found in a general chart review of a selected case treated by (b)(6) Y that multiple negative UDS (i.e., UDS that did not show presence of prescribed medications) were not acted on. In our structured medical record review, 52 of 56 patients had UDS performed at least one time between January, 2009, and April, 2012. The remaining four patients had no UDS performed during this time interval spanning more than three years, although all were treated chronically with opioids during this period. Of the 52 patients who had UDS performed at least one time between January, 2009, and April, 2012, there were five patients who were being prescribed opioids at the time of the negative test, i.e., the test failed to confirm that they were actually taking their prescribed medication.

We did not substantiate the allegation that opioid contracts are not being "encouraged" by Dr. Z. We found that 48 of 56 patients in the structured medical record review had an opioid contract. Of the patients lacking opioid contracts, Dr. Z was a primary prescriber of opioids for none, and (b) Y was a primary prescriber of opioids for two.

Several allegations dealt with general over prescription of narcotics at the facility, and specifically alleged over prescription by Dr. Z and (b)(6) Y. The appropriateness of prescribing opioids to a particular patient or the appropriateness of a particular dose utilized is a complex matter that must take into account the patient's history, current

medical and psychiatric status, social situation, and other factors. The clinical decision making underlying this process is based on the practitioner's clinical judgment and other factors that vary from patient to patient. In this context, we did not substantiate the allegations that opioids were prescribed inappropriately to specific individuals or in inappropriate doses.

However, based on the analysis depicted in Tables 1 and 2 below, we determined that the amounts of opioids prescribed by Dr. Z and (b)(6) Y in aggregate and to individual patients were at considerable variance compared with most opioid prescribers in VISN 12. Table 1 below shows prescription drug data prepared by VISN 12.

Table 1. Morphine Equivalents Prescribed by each VISN 12 VAMC Station in FY 12.

Station	Total Morphine Equivalents	Unique Patients with Opioid Prescriptions	Total Morphine Equivalents/Unique Patients with Opioid Prescriptions	Average Daily Morphine Equivalents Dispensed (Total Morphine Equivalents/365 days)
676[2]	36,845,093	3171	11,619	100,945
585	28,974,019	3570	8,116	79,381
578	66,814,245	9144	7,307	183,053
607	42,341,117	5893	7,185	116,003
556	21,668,793	3390	6,392	59,367
695	51,990,679	9888	5,258	142,440
537	42,127,193	8662	4,863	115,417

As shown in Column 1 for FY 12, the range among VISN 12 facilities for total morphine equivalents was 21,668,793 to 66,814,245. Tomah was ranked 5th (highest to lowest) of the seven facilities in VISN 12. Column 2 indicates that the facility has the smallest number of patients treated with opioids, which in part may reflect the smaller size of the overall patient population at the facility relative to larger facilities in VISN 12. Column 3 indicates the total morphine equivalents per unique patients treated with opioids. Tomah VAMC ranks highest in this category.[3]

VISN 12 provided similar data on a provider level for providers throughout VISN 12. For total morphine equivalents prescribed in FY 12, (b)(6) Y was highest in the VISN

[2] Tomah VAMC

[3] It is possible that these numbers may not be directly comparable since larger facilities with more extensive surgical and emergency treatment services likely have more patients that are treated acutely for short time frames with smaller opioid doses. However, data presented suggest this may not be the entire explanation. It can be conclusively stated from Table 1 is that the total amount of opioids prescribed in aggregate at the Tomah VAMC is in the middle range compared with other VISN 12 facilities.

among 3206 providers who wrote prescriptions for opioids. Dr. Z was the seventh highest opioid prescriber in VISN 12, and a (b)(6) at Tomah VAMC was the fifth highest prescriber. These three providers accounted for 33.3% of all morphine equivalents prescribed at Tomah VAMC in FY 12.

Table 2. Ten highest individual VISN 12 clinician prescribers (by morphine equivalents) in FY 12

Equivalence Determined by Total Quantity Dispensed in FY12				
Station	TotalMorphEquiv	UniquePats	TotalMorphineEquiv	AveDailyMeqDispensed
			Total Morph Eq/Unique Rx Pts	Total Morph Eq/365 Days
676 (b)(6) Y)	5,326,011	182	29,264	14,592
585	4,213,089	366	11,511	11,543
578	4,162,684	271	15,360	11,405
537	3,810,090	311	12,251	10,439
676 (b)(6))	3,734,272	332	11,248	10,231
585	3,489,265	340	10,263	9,560
676 (Dr. Z)	3,218,188	128	25,142	8,817
578	3,159,204	50	63,184	8,655
556	2,721,641	107	25,436	7,457
695	2,427,161	270	8,989	6,650

Data for the ten highest individual prescribers in the VISN are shown in Table 2. Considering these ten highest prescribers, three were from Tomah VAMC, while two other facilities had two providers each, and the remainder had one or none. Among these ten highest prescribers in the VISN, the total morphine equivalents prescribed for the one year period ranged from 2,427,161 to 5,326,011 morphine equivalents, and morphine equivalents per unique patient ranged from 8,989 to 63,184.[4] Thus, even among these ten highest individual prescribers, there was considerable variation in amounts prescribed; the total morphine equivalents prescribed by (b)(6) Y was more than double that prescribed by the tenth highest prescriber in the VISN, and morphine equivalents per unique patient was more than threefold higher.

On a per patient basis, (b)(6) Y prescribed 29,264 morphine equivalents per patient (second highest among VISN 12 clinicians) during FY 12; for Dr. Z, the number was comparable (25,142; fourth highest among VISN 12 clinicians). Patient populations can vary from facility to facility, complexity of patient case mix can vary from provider to provider, and individual patient characteristics and needs vary from patient to patient. Nevertheless, it seems clear that the total amount of opioid and opioid per patient prescribed by (b)(6) Y and

[4] Because of continuing public interest, the OIG decided to publish this report in February 2015. In preparing the report for publication, we identified an error in this sentence; we originally reported the range as 8,989 to 29,264. We corrected the report for publication.

Dr. Z are at considerable variance compared with most opioid prescribers in VISN 12, and the data support that total opioid prescribing for one additional individual prescriber at the facility is likewise unusually high.

We did not substantiate the allegation that "Opioids are contraindicated for PTSD, but this is part of [Dr. Z's] treatment plan." In review of patient medical records, emails, and during the course of our interviews we did not find documentation that opioids were being used to treat PTSD. In each case, medical record review indicated a history of a pain related condition and use of opioids for treatment of pain.

At the time of our site visit, Tomah VAMC leadership reported that a Pain Management Committee met on a monthly basis. The Committee was co-chaired by (b)(6) Y and a primary care physician with a background in pain management. Other members included another physician with a background in pain management, Dr. Z as an adjunct member, a (b)(6) One co-chair told us that the Committee addresses mainly administrative issues but that individual clinical cases were addressed by a smaller group of clinicians. This smaller group consisted of (b)(6) Y, the (b)(6) and possibly a member of nursing staff not affiliated with the committee. An opioid work group was in the process of being formed. The focus of the work group was to establish surveillance of clinician prescribing patterns. The planned work group included the members of the Pain Management Committee with the addition of the Director of Pharmacy.

Summary and Conclusions

We did not substantiate the majority of allegations made in the various complaints that OIG received. Although the allegations dealing with general overuse of narcotics at the facility may have had some merit, they do not constitute proof of wrongdoing. We did not find any conclusive evidence affirming criminal activity, gross clinical incompetence or negligence, or administrative practices that were illegal or violated personnel policies.

Nevertheless, our inspection raised potentially serious concerns that should be brought to the attention of VISN 12 management for further review. In particular, we noted that the amounts of opioid equivalents prescribed by Dr. Z and (b)(6) Y, both in aggregate and per individual patient, were at considerable variance compared with most opioid prescribers in the VISN, and that a Tomah VAMC (b)(6) was likewise prescribing an unusually high total opioid amount. Additionally, while it is true that certain clinicians may be treating patients with unusual conditions that require unconventional treatments,

it would seem more clinically appropriate for such complex patients to be treated by a specialist or subspecialist in their particular condition, rather than a (b)(6) or (b)(6)

Also of concern was the dysfunction of multidisciplinary collaboration in patient care that we observed, particularly between the pharmacy staff and Dr. Z. Perceptions of abuse of authority, intimidation and retaliation are problematic in themselves because they diminish or even preclude the willingness to communicate concerns about potential safety issues or aberrant patient behaviors. From a systems perspective, facility leadership, staff, and ultimately patients and their safety, benefit when there is an environment of communication, collaborative care, approachability, and functional checks and balances. When effective, such collaboration provides a system of checks and balances that reduces medication errors and enhances general patient safety, and is especially important in this setting given the quantities and dosage of opioids that are being utilized in seriously ill patients. The facility appeared to be at a functional impasse with respect to such collaboration. The pharmacy staff uniformly indicated that they were reluctant to question any prescription ordered by Dr. Z or any aberrant behavior by his patients (for example, frequent requests for early refills) because they feared reprisal, even though most of them could not give a first-hand account of negative actions toward them by Dr. Z. For his part, Dr. Z complained that pharmacists (except for one) were unwilling to approach him with problems or concerns and were uninterested in learning more about his treatment approach and rationale

The Chief of Pharmacy reporting to Dr. Z by virtue of Dr. Z's administrative leadership position may complicate the perception that Dr. Z misuses his authority to compel acquiescence with his clinical decisions.

For patients with complex oncology problems, hospitals often have committees known as tumor boards, comprised of clinicians from multiple disciplines (oncology, surgery, radiation oncology, nursing, nutrition among others) that convene periodically to discuss and recommend an integrated plan for patients with complex cases of cancer.

There are several suggestions that should be brought to the attention of the facility Director and VISN management, as follows:

- The facility Director should implement a vehicle by which clinicians and staff can openly and constructively communicate concerns and rationale when disagreements arise concerning dispensing of opioid prescriptions.

- The facility Director should review the reporting structure in the context of safeguarding bi-directional clinical discourse from actual or perceived administrative constraint.
- The facility Director should ensure development of guidance, parameters, processes, or a specialty clinic based mechanism to assist clinicians and staff with managing complex patients requesting early opioid refills.
- The facility Director should consider some variant of the tumor board model as one potential avenue by which to foster collaborative interdisciplinary management when presented with very complex clinical pain cases.
- The VISN should conduct further evaluation and monitoring of relative and case-specific opioid prescribing at Tomah VAMC on both a facility and individual clinician level.

I concur with the recommendation for administrative closure of this inspection. The material in this report will be briefed to VISN 12 Senior Staff including the VISN 12 Director and CMO, and to Tomah VAMC's Director. A report of contact from that briefing will be appended to this administrative closure.

Based on our review, I am administratively closing this case.

JOHN D. DAIGH, JR, M.D.
Assistant Inspector General for
Healthcare Inspections

3/12/14