

ASSESSING VA'S RISKS FOR DRUG DIVERSION

HEARING
BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND
INVESTIGATIONS
OF THE
COMMITTEE ON VETERANS' AFFAIRS
U.S. HOUSE OF REPRESENTATIVES
ONE HUNDRED FIFTEENTH CONGRESS
FIRST SESSION

MONDAY, FEBRUARY 27, 2017

Serial No. 115-4

Printed for the use of the Committee on Veterans' Affairs



Available via the World Wide Web: <http://www.fdsys.gov>

U.S. GOVERNMENT PUBLISHING OFFICE

29-370

WASHINGTON : 2018

For sale by the Superintendent of Documents, U.S. Government Publishing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512-1800; DC area (202) 512-1800
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ASSESSING VA'S RISKS FOR DRUG DIVERSION

Monday, February 27, 2017

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON VETERANS' AFFAIRS,
SUBCOMMITTEE ON DISABILITY ASSISTANCE
AND MEMORIAL AFFAIRS,
Washington, D.C.

The Subcommittee met, pursuant to notice, at 3:30 p.m., in Room 334, Cannon House Office Building, Hon. Jack Bergman [Chairman of the Subcommittee] presiding.

Present: Representatives Bergman, Bost, Poliquin, Dunn, Arrington, and Kuster.

Also Present: Representatives Roe and Walz.

OPENING STATEMENT OF JACK BERGMAN, CHAIRMAN

Mr. BERGMAN. Good afternoon. This hearing will come to order. I want to welcome everyone who has joined us today.

Today, we will address the lack of oversight and internal controls regarding controlled substances within the Veterans Health Administration that leave facilities open to drug diversion and veteran harm.

The diversion of drugs from VA health care facilities is an incredible patient safety issue that puts veterans, VA employees, and the public at tremendous risk. Unfortunately, the news has recently been filled with story after story of drug diversions within VA.

In Little Rock, Arkansas, a VA pharmacy technician reportedly used his access to medical supplies Web sites to order and divert 4,000 oxycodone pills, over 3,000 hydrocodone pills, and more than 14,000 Viagra and Cialis pills, at the cost to the VA of more than \$70,000. This technician was allegedly selling these drugs on the street, where they had a value of more than \$160,000.

At a VA facility in Florida, a registered nurse was apparently stealing oxycodone and hydromorphone from the hospital to feed her addiction. Keep in mind, these are medications that should have been going to veterans for their care.

These issues are, in part, a result of VA having inadequate procedures in place to safeguard against theft and diversion of controlled substances. A recent Government Accountability Office audit requested by this Committee found that one VA medical center missed 43 percent of the required monthly inspections, mostly in critical care areas such as the operating room and the intensive care unit. In addition, three other facilities did not follow all of VHA's requirements for inspections of controlled substances.

This is not the first instance where weaknesses were identified in VA's controlled substance inspection program. In 2009 and 2014, the VA Office of Inspector General found that some medical facilities were not conducting monthly inspections and some inspections were incomplete. VA has been given multiple opportunities to address these concerns. This leaves me wondering what VA is doing to repair the lax oversight and apparent absence of accountability regarding these issues within VHA.

To make matters worse, there are also issues with drug testing employees to ensure that they are suitable to provide care to our veterans. A 2015 Office of Inspector General report found that VA Medical Centers were not conducting preemployment and random drug tests for testing-designated positions in many instances across VHA, which amounted to tens of thousands of employees not receiving drug tests required by the Drug-Free Workplace Program.

Most recently, in January 2017, the OIG found high backlogs in background checks, to include drug testing, for high-risk positions at the Atlanta VA Medical Center.

It is precisely these tools that have been put into place to help protect patients and health care organizations from drug diversions and harm. However, VA does not seem to be taking them as seriously as it should.

Based on the oversight reports and numerous diversion incidents we will discuss today, I am concerned that VA's controlled substance oversight program is not working and that staff who fail to follow proper procedures are not being held accountable for violations.

In case after case, what we see are examples of drugs being diverted for personal use or personal gain, yet there does not seem to be much progress made by the VA to correct the glaring problems that allow it to happen.

What is even more concerning is that the programs to help deter diversion or identify illegal employee drug use are not being implemented consistently within the VA health system. We are in the midst of an opioid epidemic, and it's time for VA to start making effective changes to avoid putting veterans and the employees who serve them at risk.

With that, I recognize Ranking Member Kuster for her opening statement.

OPENING STATEMENT OF ANN KUSTER, RANKING MEMBER

Ms. KUSTER. Thank you, Mr. Chairman.

And thank you for choosing this topic. I am particularly interested, as the cochair, the founding cochair, of our congressional Task Force to Combat the Heroin Epidemic. I appreciate this testimony.

This afternoon, we are again examining VA's role in ensuring that prescription drugs are safely controlled in VA medical facilities.

Less than a year ago, former Chairman Kaufman and I held a hearing of the O&I Subcommittee on this very issue in Colorado because the Drug Enforcement Agency, DEA, found several violations in the Denver VAMC. We continue to hear disturbing reports in hospitals and clinics, in our communities, that some health care

employees are stealing controlled substances for their own personal use or personal gain. We know that these cases are on the rise throughout the country.

One health care employee diverting controlled substances can be a serious public health risk and can cause significant harm to many patients. We learned this lesson the hard way in New Hampshire with the technician who was injecting himself with fentanyl at a hospital in Exeter, New Hampshire. But it turned out this had started at the Baltimore VA Medical Center and continued in more than a dozen hospitals in other States, infecting up to 50 patients in our community with Hepatitis C, and some of these patients were veterans.

From this example, it is clear that the nationwide trend of opiate diversion also impacts our VA. The VA health system is one of the Nation's leading prescribers of opioid medication. Diversion in the VA threatens the safety of veterans and hampers efforts to address the opioid epidemic in our communities. Preventing diversion of these substances should be a paramount concern.

That's why I find the GAO and IG's findings particularly troublesome. It's unacceptable that some VA medical facilities are not conducting routine inspections to prevent and identify drug diversion. Background investigations that could potentially identify employees who have diverted drugs or who may have a drug/substance-use problem were backlogged in Atlanta. Healthcare employees at the Atlanta Medical Center were not subject to drug testing for 6 months, which could identify diversion of prescription drugs.

We need to get to the bottom of why these safeguards and processes are not being followed. I want to know if the procedures when followed would work to prevent drug diversion. I want to know if VA has the resources it needs to conduct the inspections, the background checks, and to administer its Drug-Free Workplace Program.

I am also concerned about the VA hiring freeze that is currently in place and that VA HR employees are not exempt. The GAO and IG identified that staff need more personnel and more training to properly conduct these inspections. They also identified the need for more HR personnel to address the background-check backlog in Atlanta. Without adequate support staff in place, VA medical facilities will continue to struggle to comply with the procedures and programs that they must follow to ensure that our veterans receive safe care.

Finally, I look forward to learning about progress at the VA with regard to the Opioid Safety Initiative that we passed within CARA, the Comprehensive Addiction and Recovery program, just last year to bring down the rate of opioid prescriptions for all of our veterans. We must do everything we can to help veterans suffering from chronic pain and to help veterans struggling with substance abuse and addiction.

The opioid epidemic is destroying the lives of veterans and their families in communities across New Hampshire and all across the country, and we need to work together to find innovative solutions to end this epidemic. As I say to my colleagues, heroin does not choose R's and D's. We can work together. We are proud champions

of the Comprehensive Addiction Recovery Act that we passed last Congress, and I look forward to hearing about VA compliance.

Thank you, Chairman Bergman, and I yield back.

Mr. BERGMAN. Thank you, Ranking Member Kuster.

I ask that all Members waive their opening remarks, as per this Committee's custom.

With that, I welcome our first and only panel, who is now seated at the witness table.

On the panel, we have Dr. Carolyn Clancy, Deputy Under Secretary for Health for Organizational Excellence. She is accompanied by Dr. Michael Valentino, Chief Consultant for the Pharmacy Benefits Management Services of the Veterans Health Administration.

We also have Mr. Nick Dahl, Deputy Assistant Inspector General for Audits and Evaluations. He is accompanied by Ms. Emorfia Valkanos, Health Systems Specialist for the Office of Healthcare Inspections in the Office of the Inspector General.

Finally, we have Mr. Randall Williamson, the Director of the Healthcare Team for the Government Accountability Office; and Dr. Keith Berge, Consultant in Anesthesiology and Chairman of the Mayo Clinic Enterprise-Wide Medication Diversion Prevention Committee.

I ask that the witnesses please stand and raise your right hand.

Do you solemnly swear, under penalty of perjury, that the testimony you are about to provide is the truth, the whole truth, and nothing but the truth?

Please be seated.

Let the record reflect that all witnesses have answered in the affirmative.

Dr. Clancy, you are now recognized for 5 minutes.

STATEMENT OF CAROLYN CLANCY, M.D.

Dr. CLANCY. Good afternoon, Chairman Bergman, Ranking Member Kuster, and Members of the Subcommittee. Thank you for the opportunity to discuss oversight of controlled substances and the Drug-Free Workplace Program at VA facilities. I will address inspections to minimize diversion, drug testing for selected employees, and our commitment to accountability for employees who do not live up to our core values.

I am accompanied today, as you mentioned, by Mike Valentino from Pharmacy Benefits.

GAO's recently released report on medical facility controlled substance inspection programs in four of our facilities has prompted a swift response. We concurred with GAO's six recommendations and are now implementing them. Expect them to be fully implemented by October of this year. We conducted a conference call last week with over 450 field-based staff to launch the action plans and to provide tools that support that effort, followed by distribution of written instructions. Additional dissemination efforts are planned over the next 2 weeks.

Although GAO and VA Inspector General identified selected instances of noncompliance with these robust controls, I believe the system is working as designed to make it difficult for VA staff to

divert drugs and, most importantly, to give us the tools to be able to detect diversion rapidly and take action when it does occur.

VHA implemented robust controlled substance internal controls in the early 1980s. In many cases, these measures exceed those required by the Controlled Substances Act, and we believe they align closely with Mayo Clinic's recommended best practices.

Data from January 2nd of 2014 through March 11th of 2016 show that VA's reported controlled substances loss rate is 0.008 percent, or 8 per 100,000. And it is VA's very own internal controls that lead to the vast majority of diversion cases being identified.

The use of illegal drugs by VA employees is inconsistent with the special trust placed in those who care for veterans.

The Inspector General recently reviewed allegations at the Atlanta VA Medical Center of a backlog of unadjudicated backgrounds investigations and found that mandatory drug testing of new hires did not occur over a 6-month period, resulting in a backlog of about 200 background investigations. It was also found that the Drug-Free Workplace Program was not administered from November of 2014 to May of 2015.

Atlanta VA leadership implemented a number of changes in 2016 in response to these recommendations, such as moving the human resources department under the direct supervision of the Medical Center director and developing a secondary database for staffing and tracking all background investigations.

We expect that that backlog will be cleared by the end of this March, and, if not, we'll keep you informed.

In addition, VA has made great strides towards improving the Drug-Free Workplace Program. In October 2015, drug program coordinators began certifying on a monthly basis that employees selected for random drug testing were tested, when they were tested, or why they were not tested.

The VA is also developing procedures to ensure the drug-testing coding of employees in approximately 180,000 testing-designated positions is accurate and complete. On March 1st of 2016, the Assistant Secretary For Human Resources and Administration published a memorandum stating that 100 percent of all applicants tentatively selected for appointment to a testing-designated position be drug tested prior to appointment.

VA works closely with local, State, and Federal law enforcement entities to identify specific geographic areas with reported mail losses, and VA's identification of loss clusters has led to successful arrests, prosecutions, and convictions. VA has developed a culture of controlled substance loss reporting and has adopted a practice of over- rather than underreporting suspected cases of diversion.

Mr. Chairman, I am proud of the health care our facilities provide to our veterans, including prescription drug services. The issues we're discussing here today are closely related to our Nation's overarching struggle with opioid use. As a whole, our Nation needs to come up with a better alternative to pain management than opioids.

VA is at the forefront of this challenge with our Opioid Safety Initiative, which we pioneered in August of 2013. We are actively reducing the number of opioids we prescribe and the number of veterans receiving these prescriptions. Instead, we're offering a va-

riety of complementary and integrative medicine treatments for chronic pain, such as chiropractic and acupuncture, among many other options. Initiatives like these will reduce the number of controlled substances VA prescribes, making it easier to maintain their oversight.

With support from Congress, we look forward to continuing to improve our oversight of controlled substances and Drug-Free Workplace Programs, which will further improve the care of our veterans and the care that they deserve.

Thank you for the opportunity to testify, and I look forward to your questions.

[THE PREPARED STATEMENT OF CAROLYN CLANCY APPEARS IN THE APPENDIX]

Mr. BERGMAN. Thank you, Dr. Clancy.

Mr. Dahl, you are now recognized for 5 minutes.

STATEMENT OF NICK DAHL

Mr. Dahl. Mr. Chairman, Ranking Member Kuster, and Members of the Subcommittee, thank you for the opportunity to testify today on the Office of Inspector General's work related to the Drug-Free Workplace Program and the oversight of controlled substances at VA facilities.

I am accompanied by Emorfia Valkanos, who is a member of the OIG's Healthcare Inspection staff in Manchester, New Hampshire, and is also a former VA pharmacist.

The Federal Drug-Free Workplace Program was initiated with the goal of establishing a drug-free Federal workplace. The program made it a condition of employment for all Federal employees to refrain from using illegal drugs on or off duty. VA has designated safety-sensitive occupational series as testing-designated positions, including positions such as physicians, nurses, police officers, and motor vehicle operators.

In recent years, the OIG has completed two projects that assessed aspects of the Drug-Free Workplace Program. In March 2015, the OIG issued a report detailing the results of an audit of VA's program. We identified program weaknesses in three areas.

First, preemployment applicant drug testing. If a tested applicant has a verified positive test result, VA should decline extending a final offer of employment. However, we reported that VA did not ensure compliance with policy to drug test all applicants selected for a testing-designated position prior to appointment. Instead, VA selected only about 3 of every 10 applicants for testing.

Second, employee random drug testing. We estimated VA achieved a national drug-testing rate of 68 percent of employees selected for random drug testing in fiscal year 2013. In our review of 22 randomly selected facilities, we found 4 facilities did not test any randomly selected employees, 10 had compliance rates ranging from 31 to 89 percent, while the remaining 8 facilities tested at least 90 percent of their randomly selected employees.

We also estimated at least 9 percent of about 206,000 employees in testing-designated positions were not subject to the possibility of random drug testing because they were not properly coded with a drug test code in VA's personnel system. Those not subjected to

random drug testing included physicians, nurses, and addiction therapists.

Finally, reasonable-suspicion drug testing. We reported VA lacked sufficient oversight practices to monitor whether facilities referred all employees with a positive drug test result to the Employee Assistance Program.

Based on our work, we determined VA's program was not accomplishing its primary goal of ensuring illegal drug use was eliminated and VA's workplace was safe. We made five recommendations, and, as of today, one recommendation remains open.

A more recent report focused on human resources issues at the Atlanta VA Medical Center. During this review, we substantiated an allegation that there was no drug testing of employees in testing-designated positions for at least 6 months in 2014 and 2015. Despite the lack of drug testing for 6 months, we found no indications VA management at either the local or the national level was aware of the lapse.

Because no drug testing occurred, the Atlanta VA Medical Center lacked assurance that employees who should have been subject to drug testing during this period remained suitable for employment. We made two recommendations focused on the Drug-Free Workplace Program, and VA reported they have taken action on these recommendations.

VA also requires that managers at VHA facilities ensure that a controlled substances inspection program is implemented and maintained. The OIG has reviewed VA's management of controlled substances during our combined assessment program reviews. We rolled up the results of our work in June 2014, and GAO references that work in their recent report.

The OIG also has a vigorous investigative program related to drug diversion. We primarily focus on three categories: first, the diversion of controlled and noncontrolled substances by VHA employees. The diversion of drugs by health care providers for personal use is a serious issue that the OIG diligently pursues.

Next, the diversion of controlled substances and noncontrolled substances for illegal distribution, which involve cases where VA pharmaceuticals are diverted or stolen for the purpose of illegal sale.

Also, the diversion of controlled substances by a theft of mailed pharmaceuticals. Our investigations have revealed mailed pharmaceuticals are vulnerable to theft at any point in the process, with the most common occurrence being theft by employees of the mail carrier.

In conclusion, the OIG has provided crosscutting oversight of the Drug-Free Workplace Program and controlled substances inspections through our audits and inspections. This oversight is necessary to ensure VA takes the steps necessary to reduce risks to the safety and well-being of veterans and VA employees by having and following proper program controls. We also actively investigate drug diversion and seek prosecution for those engaged in drug diversion.

Based on our work in recent years, we have concluded VA lacked reasonable assurance that it is achieving a drug-free workplace and adequately securing controlled substances.

Mr. Chairman, this concludes my statement. We would be happy to answer any questions that you or other Subcommittee Members may have.

[THE PREPARED STATEMENT OF NICK DAHL APPEARS IN THE APPENDIX]

Mr. BERGMAN. Thank you, Mr. Dahl.

Mr. Williamson, you are now recognized for 5 minutes.

STATEMENT OF RANDALL B. WILLIAMSON

Mr. WILLIAMSON. Thank you, Chairman Bergman and Ranking Member Kuster and Members of the Subcommittee.

The increase in the prescribing and use of opioids over the last two decades, sometimes referred to as the opioid explosion, has brought with it the need for medical facilities to undertake efforts to prevent diversion of opioids and other controlled substances by facility employees for their own personal use.

Diversion of controlled substances can compromise patient treatment, can be costly to the facility, and can cause harm in our communities for those that are the recipients of illegally obtained controlled substances.

I am here today to discuss our recent report on VHA's efforts to prevent diversion of opioids and other controlled substances through its controlled substance inspection programs.

All VA medical facilities that store and dispense controlled substances are required to undertake monthly inspections of all areas within the facilities that are authorized to have controlled substances.

Each facility director is responsible for overseeing the inspection program and appointing a coordinator to manage the program and inspectors who conduct the inspections. Usually, both the coordinators and the inspectors have other responsibilities within each facility and work part-time on the inspection program. The coordinator is responsible for ensuring that monthly inspections are conducted and for submitting reports to the facility director summarizing inspections and any trends.

We found that the program was not being managed according to VHA policy and needed improvement in certain areas.

First, monthly inspections are not always being conducted as required. We visited four VA medical facilities across the country and found that, over a 14-month period, one facility missed 43 percent of the required inspections while another missed 17 percent. The operating rooms in one facility, for example, were not inspected at all because we were told that the inspectors needed to arrive before or after normal operating room hours and could not do so because of their conflicting work schedules.

Second, when conducting the inspections, facility inspectors did not always follow VHA policy requirements, as was the case for three of the four facilities we visited. For example, inspectors don't always verify that controlled substances have been properly transferred from pharmacies to automated dispensing machines in patient care areas; or inspectors didn't always count all of the controlled substances stored in patient care areas.

Third, we found that local written inspection procedures were not fully consistent with VHA policy requirements. We found this problem at three of the four hospitals we visited.

These three weaknesses increased the risk of diversion at VA facilities.

We found that many of these problems were allowed to happen, in part, due to poor oversight at the facility and network levels. Facility directors at two of the four facilities we visited did not consistently perform their oversight responsibilities for the inspection program, which include reviewing monthly inspection reports and implementing corrective actions if missed inspections or other problems are identified.

Also, we found that two of the four network managers who had oversight responsibilities for the medical centers we visited did not review facilities' quarterly trend reports, as required. The controlled substance inspection coordinator is required to prepare and submit these quarterly reports based on trends identified in the monthly inspections.

Further, one of the two networks that actually did review the quarterly trend reports took no action to ensure that one of the facilities in our review that had not prepared quarterly trend reports had a corrective action plan to do so in the future.

Aside from the oversight weaknesses, we found that there is limited training for coordinators to better ensure that they have a complete and detailed understanding of VHA's inspection procedures.

Finally, two of the facilities we visited had backup coordinators to help manage the inspection process and complete inspections when the primary coordinator or inspectors could not carry out their responsibilities because of pressing job duties or unforeseen circumstances. We recommended that VA adopt this type of practice systemwide, and VA concurred. VA also concurred with our five other recommendations to improve the process and provide better oversight.

This concludes my opening remarks.

[THE PREPARED STATEMENT OF RANDALL B. WILLIAMSON APPEARS IN THE APPENDIX]

Mr. BERGMAN. Thank you, Mr. Williamson.

Dr. Berge, you are now recognized for 5 minutes.

STATEMENT OF KEITH BERGE, M.D.

Dr. BERGE. Chairman Bergman, Ranking Member Kuster, and Members of the Subcommittee, thank you for the opportunity to speak with you today about drug diversion from the health care workplace. Such diversion is a crime that endangers all patients, health care employers, coworkers, and even endangers the diverters themselves.

While we have long known of these hazards of patients being deprived of pain medication by diversion, only fairly recently has the grave risk to extremely vulnerable patients been revealed by outbreaks of disease, such as blood poisoning by bacteria or viruses that have been transmitted by drug diverters swapping syringes in

the commission of their crimes. In the process, many patients have been infected with potentially fatal illnesses.

I have attached for your review a paper authored by the CDC investigators outlining six such outbreaks over a 10-year period that resulted in illness and death in patients.

One of these diversion infection scenarios included Veterans Affairs patients being exposed to a diverter that communicated his hepatitis C infection to approximately 50 patients. This individual was referred to earlier in the introduction comments. This diverter was a radiation technologist who traveled the country, working for multiple employment agencies. He had been fired from multiple jobs for diverting fentanyl for his own use, but by simply lying about previous terminations on job applications and in the absence of a national registry of radiation technologists, he had no trouble finding employment.

In the darkened invasive radiology suites, he would swap fentanyl syringes on the anesthesia cart with ones he had previously used to inject himself. He would then excuse himself to a restroom, inject himself with the stolen fentanyl, draw up tap water, and repeat the process with the next patient's fentanyl. In this manner, he conveyed his potentially lethal illness to many innocent victims.

The patients described in these eight outbreaks were all extremely vulnerable positions, either undergoing an invasive procedure while under anesthesia or while in an intensive care unit.

Clearly, such behavior is unacceptable. In recognition of these dangers posed by diversion, the Drug Enforcement Administration requires stringent drug control policies and procedures to be put in place to protect controlled substances from attack across all points of the manufacturing, distribution, dispensing, administration, and disposal spectrum.

The drugs used in the health care setting are highly sought-after drugs of abuse, both by addicts and by those who would profit richly from the sale of stolen drugs. Experience at the Mayo Clinic and elsewhere has shown the necessity of having robust surveillance, detection, investigation, and intervention programs in place in order to minimize the risk to all involved.

While it will impossible to completely eliminate drug diversion from the health care workplace, it is imperative that robust systems rapidly detect and halt such activity. I have attached for your review an article from the Mayo Clinic authors, myself included, which outlines our program from its inception through its very successful implementation.

While we continue to try to improve our system, it has proven quite effective in identifying a host of drug diverters since implementation 7 years ago. Diverters come from diverse backgrounds and include physicians, pharmacists, pharmacy techs, nurses, nursing students, nursing assistants, janitors, patients, patient family members, nursing home attendants, hospice workers, and strangers off the street.

These stories are incredible, but they all point to the powerful draw that these drugs have over addicts. As such, it is not good enough to merely have effective policies and procedures on the books; they must actually be rigorously followed.

Diverters are generally clever and desperate, and they will gravitate into areas of a system where they perceive the drugs to be most vulnerable to attack. It therefore behooves any health care facility to have a reputation for being effective at rapidly identifying, terminating, and prosecuting drug diversion and drug diverters. Only by doing so can we protect the most vulnerable of our patients from preventable harm.

As I've stated, this problem will never go away, so we must become very good at rapid intervention. Only by instituting and following effective antidiversion policies and procedures will this be possible.

I thank the Committee for its attention to this very important issue and stand ready to answer any questions you may have. Thank you.

[THE PREPARED STATEMENT OF KEITH BERGE APPEARS IN THE APPENDIX]

Mr. BERGMAN. Thank you, Dr. Berge.

The written statements of those who have just provided oral testimony will be entered into the hearing record.

Mr. BERGMAN. We will now proceed to questioning.

Dr. Clancy, in your testimony, you state that the VA performs an actual count of all controlled substances every 72 hours. Who performs these counts, and who oversees that these counts actually occur at each facility?

Dr. CLANCY. So what I saw when I made a more or less unannounced visit to the D.C. VA last week is that pharmacy techs who are working in the vault are doing that, and they are double counting as they're doing it. So, in other words, there are two assistants who are each verifying, because counting a lot of pills is prone to missing one and so forth. And that is further verified by a supervisor.

Mr. BERGMAN. Given the weaknesses identified by the OIG and more recently by GAO, how can VA central office be sure that these counts are taking place and that they are accurate? You observed one.

Dr. CLANCY. Yes. Well, I think that Dr. Berge just said it well. We have very good policies in place, but it's very important that they are rigorously followed. So we are exploring right now how we might do some backup audit to make sure that those policies are followed.

As I mentioned in my opening, we actually have already disseminated written statements to the field. I would be happy to make a copy of that memo available for the record or just for your interest.

But, again, it's very, very important to know that this actually happens, that our aspirations are as good as what we're delivering on.

Mr. BERGMAN. Thank you.

Dr. Clancy, how many cases of drug diversion has the Controlled Substance Inspection Program identified in the last 2 years?

Dr. CLANCY. So what I have here is a poster, which we could make available to the Committee—Mike, if you could just turn that around—of controlled substance losses by type.

So the data that we looked at specifically goes from January 2nd of 2014 to March 11th, I believe, of 2016. What you see is that 91.4 percent of these losses occur outside our facility in the mail system. And that leaves about 1.5 percent, I believe, from employees internally.

But, again, this is something that we're checking all the time. And if there's any question whatsoever, VA police are engaged, as well as the Inspector General's Office, and they've been most helpful.

Mr. BERGMAN. And of those losses that occurred at VA facilities outside of the loss in the postal, will you be able to provide the Subcommittee a list of those facilities where the drugs have been reported missing or stolen in the last 2 years?

Dr. CLANCY. We would be happy to do that.

Mr. BERGMAN. Okay.

Mr. Williams, what is the role of the medical center directors in terms of ensuring inspections and proper oversight?

Mr. WILLIAMSON. Well, they are key at the facility level for reviewing the monthly inspection reports, identifying any issues that arise, such as missed inspections, inspections that are not done correctly and other things that the coordinator reports to them. And they then are responsible for holding staff accountable and developing corrective action plans.

Mr. BERGMAN. I see I've got about a minute left here.

Dr. Berge, VA's Office of Human Resources Management reported to the OIG that they interpreted language in the VA's Drug-Free Workplace Handbook to require only some job finalists for testing-designated positions to be drug tested before being appointed.

Would this be an acceptable practice in your health care organization?

Dr. BERGE. I believe in our health care organization we do post-offer-of-employment testing on all applicants.

Mr. BERGMAN. And what are the consequences for hiring health care workers prior to drug testing or completing background checks?

Dr. BERGE. Well, you might be letting the fox in the henhouse. You might be letting somebody who would test positive and is, in fact, an addict into an area where they can get their hands on drugs.

There's an example of that in the Denver area within about 3 years ago. Kristen Parker, she is now spending 30 years in Federal prison for infecting about 36 patients with her hepatitis C. But, in retrospect, she was a heroin addict that took a job in a facility and started diverting fentanyl.

Mr. BERGMAN. Thank you.

Ranking Member Kuster, you are recognized for 5 minutes.

Ms. KUSTER. Thank you, Mr. Chair.

Thank you to our panel. I particularly want to thank the GAO and the IG for their helpful reports.

I want to focus in on evidence demonstrating we know what a successful drug diversion deterrence program would look like, and yet we continue to have this problem at various VISNs.

My question is: Currently, the VA gives authority to the individual facilities to implement these inspection procedures. Is there any reason—and I guess this is for Dr. Clancy—why the VA could not streamline this process and apply one standard to all facilities and, in fact, have an inspection team based out of the central office that would go out to the VISNs?

It seems what I'm hearing is that this is often just an added task. In fact, in one case, it was somebody who was a food services worker, that this was just an add-on. It doesn't seem as though we're taking it sufficiently seriously.

And wouldn't it make more sense if we had an office of inspection that would then go out to the VISNs perhaps, as you did yourself, without advance warning and do these checks?

Dr. CLANCY. Thank you, Congresswoman. That's exactly what we're going to be looking into. And I think what we need to look at is how much of this could be done remotely, how much of it requires on-site presence, and, frankly, how much can we identify ahead of time which facilities are likely to have the most challenges.

I suspect that in some instances—but we need to test this—we will know which facilities are more likely to be compliant. I guessed correctly which one was the facility in the GAO report based on many, many other things I knew about that particular facility. And I wasn't incredibly surprised by the distribution of the others.

But we need to actually up our game and make sure that great policies are implemented consistently. There's no question about that.

Ms. KUSTER. And at least have consistency. What I'm curious about is having a system that would be consistent throughout.

So I have got a couple minutes. I want to return to the issue of reducing the amount of opiate medication generally in the VA population. We had testimony from a medical researcher that, out of the 60,000 surgeries a year, 99 percent of people get opiate medication, and 1 in 15 will become a chronic user of opiates. That's what is feeding this epidemic.

Can you talk to me more about both the program within CARA, encouraging VAs to reduce the use of opiate medication, or any other examples that you might have in the system?

Dr. CLANCY. Of course. And thank you for the question.

I'm happy to report that we are on track for all the provisions in CARA. Incredibly enough, VA's portion of that is named for a veteran who died under our care. And I was literally speaking with his father yesterday, and I have been most impressed by the family honoring the experience of their son by working with us to make sure that we provide better care.

VA has really been on the forefront of reducing the use of opioids. So, beginning in August of 2013, we've seen a 31-percent reduction in the number of patients receiving opioids. We've seen a 56-percent reduction in the number of veterans who are receiving an opioid and another type of drug which has a particularly high risk for adverse reactions.

We are doing much more frequent urine testing, because we're trying to minimize diversion from patients, veterans actually sell-

ing the drugs that they got at VA to elsewhere. So the right answer on a urine drug screen is positive, that you're actually taking the medications you received.

We're seeing the overall dosage of opioids has decreased quite significantly for—and we've also seen—we have seen these results at a time when we've seen an overall growth in the number of veterans we are serving.

I want to be clear: We're not done, and we will continue to monitor this. And I'm very proud of the work that we are doing to offer veterans alternatives to chronic pain management.

Ms. KUSTER. My time is up, but I would just say to the chair that, as we continue, I would love to have further testimony about the chronic pain programs and how we can bring down the use of opiate medication.

Thank you.

Mr. BERGMAN. Mr. Bost, you are recognized for 5 minutes.

Mr. BOST. Thank you, Mr. Chairman.

And, Dr. Clancy, I'd like to continue down that same path. The Ranking Member actually asked the first part of the question I was going to ask, but I still want to go down that. And that was, okay, the report from 2009 and then again in 2014 on the weakness that the VA Controlled Substance Program had, now, you kind of explained what the VA central office was doing, but what about the VISN and at the faculty level? What are we doing there?

Dr. CLANCY. So every one of our networks that's a Veterans Integrated Service Network has a pharmacy lead there. I will say that it's my understanding that there's some variability in terms of how many other members of the team that they have. Many of them are quite strong in terms of reviewing facility reports and providing that kind of oversight. Others, it's my understanding, are less so. I'd be happy to provide more detail for the record.

But I think that we need a very consistent approach: here's the facility's responsibility; here is the second line, which should be the network; and then central office providing what is sometimes referred to as the third line of defense. I'm quoting from, sort of, accepted practices in internal audit, which is an area that we have just started up within my group.

Mr. BOST. Okay. And I know that you've been trying to do that since the 2014 report, but why do you suppose that when all of a sudden the GAO came back, many of those same weaknesses showed up again? What are we not doing correctly to move quick enough to try to deal with this?

And it is getting to a point of epidemic, and not just in the VA. It's nationwide, the epidemic that we're dealing with. But we have to set the example.

Dr. CLANCY. I would agree. And that's precisely how we think of it, as setting an example.

I think, to some extent—I believe it was Mr. Williamson referred to the fact that some of these coordinators have collateral duties. I do note that, for many of our facilities, anesthesia and the operating rooms tend to be areas, probably because of the hours, where there have been problems conducting inspections.

Every facility in our system has been directed, redirected quite recently, to have a backup coordinator.

My colleague from pharmacy who's here today—not Mr. Valentino, one of his top lieutenants—came with me the other day, and he noticed that maybe there was a little problem with not randomly conducting the inspections throughout the month. If you let it go till the end of the month, which is understandable—but, nonetheless, if, you know, stuff happens that week, that means you will have slipped a month and so forth.

So that is the kind of thing that I think we can and will improve on.

Mr. BOST. My next question is for Mr. Dahl.

In your investigation related to the 2015 and 2017 reports, how many positions identified as no background check completed were the high-risk or the testing-designated positions? Do you know that?

Mr. DAHL. Well, the 2015 report did not get into the background investigations. Our 2017 report, which was focused only on the Atlanta VA Medical Center, I wouldn't have that information at hand, but I'd be happy to look into that.

Mr. BOST. Can we get a copy of that to try to figure that out? Because we want everyone tested, because, as you described, somebody at the panel did, that everyone is at risk with this, anyone we hire. That being said, if we're going to drop them into those high-risk positions, we've definitely got to do some backing up and making sure.

And I'm kind of short on time here, but, Dr. Berge—and this is a question that I'm sure my constituents and people throughout this Nation are going to ask, would your health care organization hire a clinic professional prior to completing a background check?

Dr. BERGE. No.

Mr. BOST. That's what I thought.

Okay. What risks are associated with hiring a clinical staff prior to a background check?

Dr. BERGE. Well, one source of frustration is, like, when we are interviewing an applicant for, say, our nurse anesthesia school, that employment law forbids us to ask, have you been through treatment for chemical dependency before? Well, we have had such people come in that developed fentanyl addiction and then, in retrospect, well, they've gone through treatment for cocaine abuse in the past.

So, in some ways, we're barred from asking some of those questions. But we would complete the post-offer-of-employment drug testing.

Mr. BOST. And if I can just add, first off, let me say this—and I know I'm running short on time, Mr. Chairman—but this is an issue I've dealt with on a State level and then here at this level as well. The one thing we want to remember is how vitally important those tests are, because this disease—and it is a disease to be an addict.

I had a friend that, one time, when we begged him to talk to us, he gave us an information, it wasn't correct, and he came back and said to us, what part of I'm an addict, I lie, don't you understand? That's why it's so vitally important to not only do the question but make sure that we do the followup checks.

And the concern I see is the holes that are existing in the system. We can't have it—we want to do everything we can to empower you to try to stop this epidemic that is affecting—and it doesn't matter what your race is, what your gender is, what your socioeconomic status is. We've got to continue to work on this.

So thank you very much.

Mr. CHAIRMAN, I yield back.

Mr. BERGMAN. Thank you.

Mr. Walz, you are recognized for 5 minutes.

Mr. WALZ. Thank you, Mr. Chairman.

And thank you all for being here.

Dr. Clancy, you and I have a long history in this too. Just for the Committee's sake, for the new members, the first piece of legislation that we authored in 2008 was the pain directive that went to the VA to set up the step pain management. That was with a lot of work that came in from the folks from the Mayo Clinic, from Boston Scientific, and all of the best practices, working in conjunction with the VA. This is one of those issues that the seamlessness between the private sector and the VA is pretty strong. We all have the same issues.

But my colleagues were getting at it, and the Ranking Member knows this, the fundamental issue here is pain management. It's in the beginning, and our Nation goes through these cyclical issues of issuing opioids, pulling them back, which creates its own problem.

The diligence on the control side, we can always do better on that. And I think there's been some great suggestions there. But I would suggest to all of us—that program, am I right, Dr. Clancy, was never fully implemented? We had this discussion out in Tomah, Wisconsin, here about 18 months ago. Did we ever fully implement it before it expired?

Dr. CLANCY. I'm not sure, but I could get back to you on that.

What I do know is, thanks to the new legislation that Representative Kuster was asking about, the CARA bill, we are now making sure that there is pain management expertise and teams accessible by all our facilities. For some of our facilities, that's going to be partly virtual, but, you know, as an integrated system, we can do that—

Mr. WALZ. But it builds on that same principle—

Dr. CLANCY. Absolutely.

Mr. WALZ [continued].—and fully implemented the same thing that's happening in the private sector. Because most of us know, as the VA goes, so goes the rest of the system in a lot of ways, just because of the sheer volume of this.

How much collaboration, Dr. Clancy, do you have with, like Dr. Berge, experts that are out there?

Dr. CLANCY. Well, I am just meeting Dr. Berge today, although we have a mutual colleague friend. But we consult with others pretty broadly. And, in fact, when the CDC published their guidelines on opioids last year, they drew on expertise from a number of folks in the VA, including from your district. Because, as you said, this is all about a common health challenge shared by the country.

Mr. WALZ. Dr. Berge, again, thank you for being here. And you and your colleagues over the years have—I think the thing about this is to not think everything is reactive, and this recent opioid epidemic and the overdoses and everything else that come with it, that that was not a surprise to many folks like yourself.

But when you said Mayo Clinic saw that you had maybe some holes in there, you decided to turn around, and now recognized as one of the best, how long did it take you to implement that before you saw or expected to see change?

Dr. BERGE. We were probably about a year and a half in creating our system. And that was in response to a tampering diversion that ended up on the front page of the newspaper and embarrassed us. We tried to work through every spot in the supply chain where we were vulnerable and figure out a plan to address that. And it takes some time to go through that process.

Mr. WALZ. And you have facilities—how many facilities?

Dr. BERGE. Well, we have the Midwest, the Minnesota facility and surrounding area. We also have Jacksonville, Florida, and some small surrounding area; and Scottsdale, Arizona, and some surrounding area.

Mr. WALZ. So the numbers, you have 50,000-plus employees, roughly?

Dr. BERGE. About 70,000 employees.

Mr. WALZ. About 70,000 for the entire system on that, so this is a big health care system that's been able to—I think one of the maybe frustrations—and I know it frustrates you too, Dr. Clancy—is sometimes the slowness of the reacting to these situations as the bureaucracy takes time.

You're feeling comfortable now, Dr. Clancy, that there is, with the new legislation, with the emphasis on this, with the situations that come up that are unacceptable—and the thing is, as I think for many of us, we know that what's happened in these situations that have been brought to light are happening in the private sector. Our responsibility is the VA. Our responsibility, both from an oversight and a legal responsibility but also from an ethical responsibility, is to those veterans.

Do you feel like it's moving quickly enough for you?

Dr. CLANCY. I'm excited by how enthusiastic our employees are about this. I mean, this is a national problem. I'm excited by the progress we've made. But we will be tracking this very, very closely.

Mr. WALZ. Because I get it too. They're embarrassed by this. We recognize that when it's not done right—the issue in—the surrounding areas impacted it. This is a tragic situation.

I guess the news for all of us in here is we can do something about it and do something quickly, because we have that ability in the VA. And I guess I'm just looking to see these things maybe be implemented as quickly as we can, and I know you are too.

And I thank you all for your testimony.

Mr. BERGMAN. Thank you.

Mr. Poliquin, you are recognized for 5 minutes.

Mr. POLIQUIN. Thank you, Mr. Chairman, very much.

Mr. Dahl, you're with the Inspector General's Office, correct, sir?

Mr. DAHL. Yes, sir.

Mr. POLIQUIN. And, Mr. Williamson, you're with the Government Accountability Office?

Mr. WILLIAMSON. Correct.

Mr. POLIQUIN. Okay. Great.

You two gentlemen, please, the last 8 years or so, you've repeatedly reported that there's a problem with keeping track of the drugs at the VA facilities, making sure they're not stolen and sold and so forth and so on. Is that correct?

[Nonverbal response.]

Mr. POLIQUIN. Okay. So would you both conclude that we still have a problem?

Mr. DAHL. I'm sorry, I missed that.

Mr. POLIQUIN. Would you conclude that we still have a problem?

Mr. DAHL. I would think that, based on GAO's recent work, that there is still an issue.

Mr. POLIQUIN. Thank you.

Dr. Clancy, you are the Deputy Under Secretary for Health for Organizational Excellence. What does that mean? Does that mean, in part, keeping track of who's got these harmful drugs and make sure they're not put in the wrong hands?

Dr. CLANCY. What it means is providing oversight for quality, for safety of care, and for integrity.

Mr. POLIQUIN. Okay.

Dr. CLANCY. And integrity is about compliance with the stated policies.

Mr. POLIQUIN. Okay. What person at the VA, Dr. Clancy, what one person is responsible for this problem? Who's the head banana?

Dr. CLANCY. That would be the Under Secretary for Health.

Mr. POLIQUIN. Who's that?

Dr. CLANCY. Right now, that is someone in an acting position, Dr. Poonam Alaigh. You know that our Under Secretary was recently confirmed as Secretary.

Mr. POLIQUIN. Could you spell that name for me, please?

Dr. CLANCY. A-l-a-i-g-h.

Mr. POLIQUIN. Okay. And you report to that person, that individual?

Dr. CLANCY. What?

Mr. POLIQUIN. You report to that individual. Is that correct?

Dr. CLANCY. Yes.

Mr. POLIQUIN. Okay.

When someone is caught, Dr. Clancy, stealing drugs and selling them or making them available to folks that shouldn't have them, like our veterans that we're working so hard to help, what action is taken?

Dr. CLANCY. It depends on the specifics of the circumstances—

Mr. POLIQUIN. Do you call the cops?

Dr. CLANCY. Yes.

Mr. POLIQUIN. You do. Good. Okay.

And what sort of actions recently have taken place in the system that you can share with us about people being held responsible for this abuse?

Dr. CLANCY. I think you have probably seen from newspaper articles that a fair number of people that we have brought to the attention of law enforcement have, in fact, been convicted and are

serving time. They're paying their debt to society. And we would be happy to get you a whole list for the record.

Mr. POLIQUIN. That would be great. We will make sure we get that list. Thank you very much.

Integrated services networks, who are they and what do they do? And how are they involved in this?

Dr. CLANCY. So we have facilities—that is hospitals, clinics, and so forth—all over the country, including Alaska and Hawaii and Guam and even a clinic in Manila and so forth. So a big, big span of reach. And so the system is organized into these networks. This is sort of a submanagement model.

Mr. POLIQUIN. Okay. And what does the integrated service networks do?

Dr. CLANCY. They manage and provide oversight for the facilities and clinics in that particular area.

Mr. POLIQUIN. Okay. So they'd be responsible also for making sure that we have a good headcount, so to speak, on where the drugs are and where they're being dispensed, correct?

Dr. CLANCY. Yes.

Mr. POLIQUIN. Okay. Good. And who's the head person over there?

Dr. CLANCY. There are 18 of these networks. So, in your area, that would be Dr. Michael Mayo-Smith for New England.

Mr. POLIQUIN. Okay. We'll make sure we get a list of these people also.

Mr. Williamson, have you found in traveling around the country and dealing with separate VA facilities that there is inconsistency—and I think Congresswoman Kuster asked this question earlier; I want to make sure I get it straight—there is inconsistency in which organizations, which medical facilities actually do a better job than not in following these protocols?

Mr. WILLIAMSON. Absolutely.

Mr. POLIQUIN. Okay. How do you fix that problem?

Mr. WILLIAMSON. There was one facility that we looked at that did everything right, and what was going on there was commitment and leadership from the medical director right down to the inspectors. And that's what you need. It's a culture—

Mr. POLIQUIN. So there is an example at the VA that this can be done correctly.

Mr. WILLIAMSON. Yes.

Mr. POLIQUIN. Okay. And what would you guess, what percentage of the VA facilities around the country are doing this well?

Mr. WILLIAMSON. Ten, 15 percent.

Mr. POLIQUIN. Ten or 15 percent.

So, Mr. Chairman, there are 85 percent of the VA facilities around the country who are dispensing drugs illegally or at least in a hurtful way, correct?

Mr. WILLIAMSON. I wouldn't say dispensing drugs illegally. They're not following the tenets of the inspection process.

Mr. POLIQUIN. Okay. And, as a result, these drugs get in the wrong hands.

Mr. WILLIAMSON. Correct.

Mr. POLIQUIN. Okay. Good.

Dr. Berge, you're in the private sector over at Mayo, correct?

Dr. BERGE. Correct.

Mr. POLIQUIN. Okay. At least you're outside the government sector.

Dr. BERGE. Correct.

Mr. POLIQUIN. Good. Have you found that with an effective drug control program that you can save money?

Dr. BERGE. I believe we can. I believe if you were to ask the executives of the Exeter, New Hampshire, hospital that's being, you know, sued, you know, multiple lawsuits, that they wish they had a more effective system in place.

Mr. POLIQUIN. Besides avoiding litigation, is there a way to save money when you have an effective program like this?

Dr. BERGE. That's extremely hard to quantify, I think. I mean, to have an effective system in place is not an inexpensive endeavor in itself. But it allows you to—we have heard that the word on the street is don't go to work for Mayo, because if you're going to steal drugs, they'll catch you.

Mr. POLIQUIN. Gotcha. Thank you.

Thank you very much for being here.

Mr. Chairman, thank you very much.

Mr. BERGMAN. Thank you.

Dr. Dunn, you are recognized for 5 minutes.

Mr. DUNN. Thank you, Mr. Chairman.

Dr. Clancy, I serve a constituency that actually has a veterans hospital, the Lake City facility. And there was testimony here that we did not read aloud but I think you're familiar with that they had a problem in the Lake City facility recently with a nurse misappropriating drugs.

Can you discuss the corrective actions and protocols that have been established at that Lake City facility in the wake of this incident to restore the quality of care and the level of workplace safety for the community?

And, also, tell me if your current controlled substance coordinator in that facility is properly certified and educated on the management of controlled substances and the supply chain and the management policies.

Dr. CLANCY. I would be happy to take that for the record. Our first focus was on protecting patients and then holding the individual accountable. But I will get the rest of the information—

Mr. DUNN. Okay. So you're not familiar with that particular incident in the Lake City facility?

Dr. CLANCY. I am familiar with the incident. I'm not familiar with all of the details of the followup. But we will find that for you.

Mr. DUNN. All right.

Let me depart for a second. Dr. Berge, you're an expert in substance abuse, I think, and how it comes to pass. I'm a surgeon, and I've managed operating rooms, I've directed hospitals and, you know, large clinics. And this is a problem we all have to address. It's just part of the job that we have to do when we do health care.

Mr. DUNN. And I've seen this studied at the State level as well. I'm looking at this particular pie chart here that suggests that 90 percent of the problem with diversion with controlled substances is occurring not in the health care facilities, but in the United States Postal Service and in UPS. Now, I want to tell you that I've looked

at a lot of drug diversion, a lot of problems with this in my 35-year career as a surgeon, I have never seen anything like this reported. This is perilously close to the old excuse, the dog ate my homework. Do you believe that 90 percent of the problem of drug diversion in this country occurs in the United States Postal Service?

Mr. BERGE. I'm not really qualified to comment on that because that's not where we see it. I'm basically assigned to within the walls of our healthcare facility, so what happens without, I don't know. That's not what we see at Mayo, we see other forms of diversion.

Mr. DUNN. Perhaps I should redirect that question, Dr. Clancy, and say, do you mean by this that the 90 percent of the problem occurs in the Veterans Administration facility mail rooms? Or are you actually saying that employees of the United States Postal Service, and the United Parcel Service, or people who victimize them are getting 90 percent of the diverted drugs?

Dr. CLANCY. What I am saying, and I'll ask my colleague to elaborate, is that between the time the prescriptions are put in an envelope, and understand that we have a central mail order pharmacy which, for most prescriptions, works extraordinarily well, it does a high order of business, very large volumes. Somewhere between there and the veterans home where it was supposed to go is where it is diverted. On occasion, we've heard from veterans that that's actually diverted by a family member and so forth. But it could be any one of those points and that's where working with the inspector general, VA police, and outside law enforcement has been very helpful.

Mr. DUNN. Okay. So let's drill down on this a little bit farther, because this looked like they were laying it off on the Postal Service. What's happening is the VA is taking—getting receipt of the drugs from who they purchased from, and then they are distributing it in their system. Now they may be using UPS or USPS, and somewhere between once the VA has the drug and the VA passes it off to another part of the VA, the drugs are being diverted. Is that the system?

Dr. CLANCY. No, this is outside the VHA system.

Mr. DUNN. So I have to tell you, 35 years, I've never heard this kind of accusation, 90 percent of the problems in the postal system, I'm flabbergasted, Mr. Chairman. And let the record reflect my incredulity.

Mr. WILLIAMSON. Dr. Dunn, we looked at this. One of the first things that we tried to obtain was good data. I would be very suspicious of the VA data because drug losses are not always synonymous with diversion, so one has to be careful of that. But the reporting system, VA doesn't have a good reporting system for drug diversion cases, so I would be very suspicious of this VA data.

Mr. DUNN. I am too. Thank you.

Mr. BERGMAN. Thank you.

Dr. Roe, you're recognized for 5 minutes.

Mr. ROE. Thank you, Mr. Chairman. I want to go along with a little bit of what Dr. Dunn was doing. Obviously, we know that there's a drug epidemic, and certainly in the State of Tennessee I live in, it is. Is there any data on how many veterans die of drug overdose deaths by both with Diazepines and with opioids? Dr.

Clancy, do you have any information on that? How many of our veterans?

Dr. CLANCY. We do track that very closely, and we would be happy to get that for you for the record.

Mr. ROE. The other thing I have, as I looked at this graph more, I couldn't figure out you determined 90 percent. I mean, if somebody is home and just said I didn't get my drugs. Look, one good thing, if there is any good thing about an electronic health record, what used to happen to us when we would close our office at 5 o'clock, people would start calling in and ask about, Well, I just had surgery—we had a big practice—2 weeks ago, and Dr. So-and-so didn't leave me enough medicine, I need you to call me a prescription in. The EMR, I'd just pull it up and say, well, you don't seem to be a patient in our practice. People are very clever at being able to get drugs. How many—when you say 90 percent, how in the world could you ever figure that number out, because you say here that the Post Office doesn't deliver it. How do you know that?

Mr. VALENTINO. I can help with that. This is based on a sample of reports from January 2014 through March of 2016. So whenever we have a loss, we have a template that the individual facility fills out. What happened? Who did you report it to? DEA, OIG, VA police and security and so on and so forth. In those reports, we're able to glean information and identify if it was a situation where a VA staff member diverted a drug, or whether it was a patient calling and saying, I didn't get my package. And our packages are sent with tracking information.

So we can tell where it is in the delivery stream. And at some point, if the patient says they don't get it, we have one of two situations: either they did get it, or a family member got it, or it went missing somewhere. So these are—I agree, these may not be diversions, but these are indeed lost reports that are generated—

Mr. ROE. I'm sorry to interrupt you, because my time is short. But it looked to me like, if we can know how many died, if there is a real problem, looks like there may be a better way to deliver these medications to people, than sending them out in the mail. I mean, if that's where nine out of 10 of these problems are, and we're losing a lot of people, it looks to me like that's a sloppy system, if that's the case.

Anyway, Dr. Clancy, in your written testimony, you said 92 percent of—get lost by mail, and you sort of answered about how you got at that information. And in viewing the DEA forms 106 submitted to the Committee, we learned of instances where VA mailed controlled substances to the wrong address, and worse, to the wrong veteran. How many cases from the 92 percent that were missing in the mail were those delivered to the wrong address or to the wrong person? That's really sloppy.

Dr. CLANCY. We would be happy to get that for the record.

Mr. ROE. Well, just—and we appreciate that. And please take that for the record and note that the numbers—and bring those numbers to the Committee. And for now, what's the VA doing to ensure that they get the right prescription? That's just sloppy work when you mail it to the wrong address, or to the wrong person, for goodness sakes.

Dr. CLANCY. There's a big part of the effort initiated by Secretary McDonald and my VA transformation that includes making sure that veterans data is integrated from multiple sources, because after all, many veterans get multiple services from us, so that when they move, change phone numbers or whatever, we've got accurate information. Everything that is mailed out is bar-coded so that it can be tracked. So if a veteran calls up a facility and says, My medications didn't come, they can actually track it, there's a tracking number, whether it's Postal Service or UPS. And ultimately, that's helpful in law enforcement in figuring out what happened.

Mr. ROE. But is that a system we want to continue at the VA? Because the VA is a huge system, and treating millions of people, and not thousands, but millions.

Mr. VALENTINO. So you're right, absolutely right that this is an area where it's not working as well as it should. If we required every veteran to come in to pick up their controlled substances, we could certainly do that, I think it could create some unintended consequences, some of our veterans live very far away. So we may have to look at other options for them to get their controlled substances.

Mr. ROE. Now I agree with that, it would do that. I'm not saying that you should do that. We have a situation now where there's 30-something thousand people, these are all deaths that are preventable. It is really disturbing to me, that when you have probably as many people die of drug overdose deaths as car wrecks now, so it is a huge problem for the entire country.

Mr. Chairman, I yield back.

Mr. BERGMAN. Mr. Poliquin is recognized for one follow-on question.

Mr. POLIQUIN. Thank you very much, Mr. Chairman. I appreciate it. I would like to follow up on what Chairman Roe was just talking about. It's clear to me and I think everybody in this room that the VA, and God bless them, they are doing a horrible job when it comes to this issue. Why in the heck do we have to dispense the pills from the VA? How many pharmacies do we have in this country? I don't know, Doctor, I mean we have a bunch of them, right? Why in the heck can't we have pharmacies around the country closer to where our population is, where our veterans are, why don't they dispense the pills, if you guys are doing such a horrible job? Dr. Clancy?

Dr. CLANCY. I'm sure, as my colleague noted, first of all, mail order works extraordinarily well for other types of medications, and as we work through how to reduce this area of vulnerability, there may be a lot of other options that we could consider.

Mr. POLIQUIN. Good. So, in other words, what you are saying if you're getting an aspirin or something like that, it will probably make sense, but a controlled substance. Maybe it's better if it's closer to home, right, where folks come in and they are known by the folks at the pharmacy, and you know, we've got a problem here, so forth and so on. Why not? I think we ought to consider that. I don't know what the protocol is, Mr. Chairman, I bet these nice folks can come back to us at some time and report back to us. I would like to follow up, if I can, along the same vein, is that Mr.

Dahl and Mr. Williamson, my eyes are bad, it's Mr. Williamson, right? Great. You two fellows said that roughly 10 or 15 percent of the medical facilities in the VA are doing this right. That means there are 80, or 85 percent, or 90 percent—

Ms. WILLIAMSON. That's what I would—we only looked at four, and the IG looked at 58, but that's based on, you know, some—

Mr. POLIQUIN. There are a bunch of them that are doing it wrong?

Ms. WILLIAMSON. Excuse me?

Mr. POLIQUIN. There are a bunch of them that are doing it wrong?

Ms. WILLIAMSON. Correct.

Mr. POLIQUIN. I have an idea, Mr. Chairman, why don't we get you nice folks to talk to our great staff here, and find out who's doing it right? And we'll have our staff, Mr. Chairman, call up the folks that are doing it right, and let's find out why they are doing it right, and then maybe we can have this nice person, Mr. Alaigh, who, I believe, Dr. Clancy report to, who would be the Under Secretary for Health Organizational Excellence, have him come before the Committee, and then we can see, okay, we've had these folks that are doing it right, now we're having a problem at the VA doing it wrong. Maybe you can tell us why 80 percent are doing it wrong. It's just an idea. What do you think about that, Mr. Dahl, do you think that would work?

Mr. DAHL. I missed that last part, sir.

Mr. POLIQUIN. Do you think that would work? Would that give us a little bit of help to the folks that are doing it wrong?

Mr. DAHL. Best practices, it wouldn't hurt to share them.

Mr. POLIQUIN. There you go. We are all trying to get this right, because we have a lot of veterans who are in pain, and we got a lot of folks that are having problems with opioids and heroin, including the Second District of Maine that I'm very concerned about. So anything that we can do to help you folks, we'll do that. And I know our great staffer, Kate, will be in touch with you folks to get the names that we talked about.

Yes, Doctor.

Dr. CLANCY. I just wanted to make the point that we often do do sharing of best practices and have a big initiative on that now, and I think it is a splendid idea to—

Mr. POLIQUIN. Have you been doing that for the last 8 years?

Dr. CLANCY. Not in this particular area. We have focused a lot on reducing opioid use.

Mr. POLIQUIN. The last year, the last 2, or the last 3?

Dr. CLANCY. The last couple of years.

Mr. POLIQUIN. The last couple of years. But you still have about 80 percent not doing it right?

Dr. CLANCY. I am not quite as confident. I think that may be a slightly pessimistic projection, but I will tell you when we look, I will let you know.

Mr. POLIQUIN. Thank you. Even more, Mr. Chairman, more reason for us to get the folks who are doing it right to come and report to us and maybe have the person who is in charge of everybody tell us why the other folks are doing it right.

Dr. CLANCY. If I might, Dr. Alaigh is a woman.

Mr. POLIQUIN. Wonderful. Thank you very much. I appreciate it. Thank you, Mr. Chairman. I yield back my time.

Mr. BERGMAN. Thank you. Thanks to everyone. Thanks to the witnesses. This has been a great next first step as we move forward with a very serious issue here. You are now excused.

It is clear from the testimony that has been provided today, as well as the numerous cases we here about in the news that drug diversion is a major problem at VA facilities. The lack of oversight over VA's controlled substances and the apparent lack of accountability for failing to monitor proper distribution, storage and destruction is troubling. We hope that by bringing this issue to light, it will encourage the VA to take steps necessary to impose better oversight and control.

I look forward to hearing back on the progress and changes the VA is making. I ask unanimous consent that all Members have 5 legislative days to revise and extend their remarks and include extraneous material. Without objection, so ordered.

I would like to, once again, thank all our witnesses and the audience members for joining in today's conversation. With that, this hearing is adjourned.

[Whereupon, at 4:44 p.m., the Subcommittee was adjourned.]

A P P E N D I X

Prepared Statement of Carolyn Clancy, M.D.

Good morning, Chairman Bergman, Ranking Member Kuster, and Members of the Subcommittee. Thank you for the opportunity to discuss oversight of controlled substances and Drug Free Workplace programs at Department of Veterans Affairs (VA) facilities. I am accompanied today by Michael A. Valentino, Chief Consultant for the Veterans Health Administration's (VHA) Pharmacy Benefits Management Service (PBM).

Introduction

VHA is the Nation's largest integrated health care system, and pharmacy services are a vital part of delivering the high-quality health care our Veterans deserve. Our pharmacy program is widely regarded as the professional benchmark for clinical pharmacy practice, drug formulary management, prescription fulfillment services, and 1A¹medication 1A²safety.³

VHA's PBM is responsible for providing a broad range of pharmacy services via 260 VA medical center and community-based outpatient clinic pharmacies and 7 Consolidated Mail Outpatient Pharmacies (CMOP). In fiscal year (FY) 2016, VHA dispensed more than 147 million prescriptions to over 5 million unique Veterans. Of these, 30 million were provided by medical facility pharmacies, and 117 million by CMOPs.

Oversight of controlled substances is multi-faceted and involves: 1) ensuring VA lists controlled substances on its National Formulary that have evidence of safety and effectiveness; 2) providing evidence-based prescribing criteria for controlled substances; 3) developing internal controls for physical drug security; 4) using electronic prescribing to prevent forgery; 5) monitoring suspected cases of theft or diversion and taking appropriate follow-up action; 6) addressing any controlled substances prescribing that does not align with evidence-based criteria; 7) implementing patient-focused initiatives such as medication take-back programs; 8) overdose education and naloxone distribution; and 9) ensuring the availability of complementary and integrative medicine therapies in place of controlled substances.

As part of its long-standing focus on medication safety, VHA implemented robust controlled substance security measures in the early 1980s. In many cases, these security measures far exceed the requirements of the Controlled Substances Act (CSA). For example, CSA requires that an actual count of scheduled II controlled substances and an estimated count of most of Schedule III through V controlled substances be performed every two years. However, VA performs an actual count of all Schedules of controlled substances every 72 hours. In addition CSA allows Schedule III through V controlled substances to be dispersed among non-controlled substances in the pharmacy. However, VA requires all Schedules of controlled substances to be stored under lock and key, with electronic access controls requiring two-factor authentication.

Individuals who are determined to divert controlled substances may find a way to do so despite the existence of robust controls. This is true within and outside of VA. Data from January 2, 2014, through March 11, 2016, show that VA had 2,405 reports of internal and external losses, some of which were due to diversion. The data also show that approximately 92 percent of controlled substances losses occur

¹Gellad, W.F., Good, C.B., & Shulkin D.: Addressing the opioid epidemic: Lessons from the Veterans Affairs. *JAMA Int. Med.* (in press).

²Aspinall, S.L., Sales, M.M., Good, C.B., Canzolino, J.J., Calabrese, V., Glassman, P.A., Burk, M., Moore, V., Neuhauser, M.M., Golterman, L., Ourth, H., Morreale, A., Valentino, M., & Cunningham, F.E. Pharmacy benefits management in the Veterans Health Administration revisited: 2004–2014: A decade of advancements. *J. Manag. Care. Pharm.* 2016; 22(9):1058–1063.

³United States Senate Committee on Veterans' Affairs, Hearing on Overmedication: Problems and Solutions, Apr. 30, 2014. 113th Cong. 2nd sess. Washington: GPO, 2015 (statement of Mark Edlund, Health Services Researcher, RTI International).

in the mailing system during shipping to the Veteran, 1.5 percent of losses are due to diversion by VA staff, 1.2 percent are due to external theft outside of the mailing system, 0.3 percent are due to dispensing errors and 5.6 percent are unknown but likely due to manufacturer shortages in stock bottles, miscounts, or similar issues.

During this same time period, VA dispensed approximately 29 million prescriptions for controlled substances, as well as a very large number of individual doses of controlled substances for hospitalized patients. Using only the number of controlled substance prescriptions, which overestimates reports of loss by not including inpatient doses, the 2,405 reports filed indicate a controlled substance loss rate of 0.008 percent.

Opioid Safety Initiative (OSI)

The OSI was chartered by the Under Secretary for Health in August 2012 and piloted in several Veterans Integrated Service Networks (VISN). Based on the results of these pilot programs, OSI was implemented nationwide in August 2013. The OSI objective is to make the totality of opioid use visible at all levels in the organization. This includes key clinical indicators such as the number of unique pharmacy patients dispensed an opioid, unique patients on long-term opioids who receive a urine drug screen, patients receiving an opioid and a benzodiazepine (which puts them at a higher risk of adverse events), as well as the average morphine equivalent daily dose (MEDD) of opioids.

OSI has demonstrated achievement by multiple metrics, including by: a reduction in the number of patients receiving opiate analgesics; 2) a reduction in the number of patients receiving them for longer than 90 days; 3) a reduction in the concurrent prescription of opiate analgesics with other controlled substances that have potential for drug interactions; 4) a reduction in their average daily dose; and 5) an increase in the number of patients who are receiving opiate analgesics with completed drug screens.

Results of key clinical metrics for the OSI from the fourth quarter 4 of FY 2012 (beginning in July 2012) to the first quarter of FY 2017 (ending in December 2016) are:

- 208,036 fewer patients receiving opioids (679,376 patients to 471,340 patients, a 31 percent reduction);
- 69,148 fewer patients receiving opioids and benzodiazepines together (122,633 to 53,485 patients, a 56 percent reduction);
- 157,300 fewer patients on long-term opioid therapy (438,329 to 281,029, a 36 percent reduction).
- The percentage of patients on long-term opioid therapy who have had a urine drug screen to help guide treatment decisions has increased from 37 percent to 86 percent (a 49 percent increase)
- The overall dosage of opioids is decreasing in the VA system as 26,350 fewer patients (59,499 to 33,149, a 44 percent reduction) are receiving greater than or equal to a 100 MEDD.

Additionally, the desired results of OSI have been achieved despite an overall growth of 119,766 patients who are receiving prescriptions from VA at the same time. While these changes may appear to be modest, given the size of the VA patient population, they signal an important trend in VA's use of opioids. VA expects this trend to continue as it renews its efforts to promote safe and effective pharmacologic and non-pharmacologic pain management therapies.

GAO Report

The Government Accountability Office (GAO) provided VHA a draft report on December 16, 2016, titled VA HEALTH CARE: Actions Needed to Ensure Medical Facility Controlled Substance Inspection Programs Meet Agency Requirements. In the report, GAO found that diversion of opioid pain relievers and other controlled substances by health care providers has occurred at several VA medical facilities. VA concurred with GAO's six recommendations from this report:

1. The Under Secretary for Health should ensure that VA medical facilities have established an additional control procedure, such as an alternate controlled substance coordinator or a pool of extra inspectors, to help coordinators meet their responsibilities and prevent missed inspections.

2. The Under Secretary for Health should ensure that VA medical facilities have established a process where coordinators, in conjunction with appropriate stakeholders (e.g., pharmacy officials), periodically compare facility inspection procedures to VHA's policy requirements and modify facility inspection procedures as appropriate.

3. The Under Secretary for Health should improve the training of VA medical facility controlled substance coordinators by ensuring the training includes the inspection procedures that VHA requires.

4. The Under Secretary for Health should ensure that medical facility directors have designed and implemented a process to address nonadherence with program requirements, including documenting the nonadherence and the corrective actions taken to remediate nonadherence or the actions that demonstrate why no remediation is necessary.

5. The Under Secretary for Health should ensure that networks review their facilities' quarterly trend reports and assure facilities take corrective actions when nonadherence is identified.

6. The Under Secretary for Health should ensure that networks monitor their medical facilities' efforts to establish and implement a review process to periodically compare facility inspection procedures to VHA's policy requirements.

The final GAO report was published on February 15, 2017, and VA is in the process of implementing the recommendations:

1. VHA's Directive 1108.02, Inspection of Controlled Substances, provides guidance to Facility Directors to ensure the Controlled Substances Programs develop and remain compliant with the requirements. The PBM will develop a memorandum that outlines the expectations of Directive 1108.02 and specifically the requirements to: 1) have mandatory training; 2) appoint an alternate Controlled Substance Coordinator; and if one is not already appointed, to provide back-up support; and 3) adding inspectors to the program to ensure inspections are not missed. Each Facility Director will then be provided this memorandum, and Facility Quality Managers (QM) will report compliance to the VISN QM Officer.

2. Each Medical Facility Director will be required to compare the current inspection program policy and procedures with VHA Directive 1108.02 using the Self-Assessment guide. The self-assessment will be completed by a multidisciplinary group including the Controlled Substance Coordinator, Chief of Pharmacy or designee, Nurse Executive or designee, and Facility QM or designee. The results of the self-assessment will be reviewed by the facility QM Committee. An action plan must be developed for identified deficiencies and progress tracked until completion through the QM committee.

3. The Deputy Under Secretary for Health for Operations and Management (DUSHOM) will provide the memorandum developed in response to Recommendation 1 that outlines the requirements that all current and future Controlled Substance Coordinators complete the Talent Management System web-based Controlled Substance Inspector Certification training program in addition to the Controlled Substance Coordinator Orientation Training Course. The certification course contains detailed information on conducting inspections. VHA Directive 1108.02, Inspection of Controlled Substances, will be updated with this requirement.

4. PBM will develop guidance to be distributed by the DUSHOM directing Medical Facility Directors to assess adherence with program requirements at least quarterly. The facility QM Committee will review and evaluate monthly and quarterly reports for adherence with requirements and corrective actions taken or required to ensure compliance with program requirements in VHA Directive 1108.02. All corrective actions will be documented and followed through to completion by the QM Committee and reported to the Medical Facility Director.

5. PBM will develop a memorandum that outlines the expectations of Directive 1108.02 and specifically the requirements that Networks will: 1) review their facilities' quarterly trend reports and ensure facilities take corrective actions when nonadherence is identified, and 2) monitor their medical facilities' efforts to establish and implement a review process to periodically compare facility inspection procedures to VHA's policy requirements. The DUSHOM will provide this memorandum to each Network Director, who will disseminate it to the Facility Directors, thereby ensuring appropriate actions have been taken to ensure the actions listed in the memorandum are completed.

At completion of each of these actions, the VISN QM Officer will monitor compliance and provide an action plan for any non-compliant facilities within that VISN to PBM and the DUSHOM. The two offices will meet and decide whether any further actions are needed. The status of each response is in process, and the target completion date is October 2017.

VA's Drug Free Workplace Program

VA, as an employer, understands that well-being of its employees is essential to the successful accomplishment of the agency's mission, and is dedicated to maintaining high employee productivity. As such we are committed to implementing Executive Order (EO) 12564, signed by President Ronald Reagan on September 15, 1986, requiring all Federal agencies to develop a plan to combat drugs in the workplace.

VA takes very seriously our mission to provide top quality care and services to our Veterans. In doing so, our human resources offices play a very vital role in implementing our Drug Free Workplace Program (DFWP). As the second largest employer in the Federal Government, VA can and should continue to show the way towards achieving drug-free workplaces through programs designed to offer drug users a helping hand and, at the same time demonstrating that drugs will not be tolerated in the workplace. The use of illegal drugs by VA employees is inconsistent with the special trust placed in such employees who care for Veterans. VA has recently made great strides towards improving the Drug Free Workplace Program.

Beginning in October 2015, Drug Program Coordinators began certifying on a monthly basis that employees selected for random drug testing were tested, when they were tested, or why they were not tested. In November 2015, the Office of Human Resource Management began reviewing the data entered in the notification site for compliance and has continued in the ensuing months to conduct this review. Those Coordinators not in compliance with the certification process are reported to their chain of command until compliance is achieved.

VA is developing procedures to ensure the drug testing coding of employees in Testing Designated Positions (TDP) is accurate and complete. We are working with our HR Smart (VA's recently implemented human resources information system) business partner to implement a monthly process ensuring that all employees occupying Testing Designated Positions identified in VA Directive 5383 are included in the pool of random selectees each month. The update process will run prior to the random selection of employees to be tested that month. In addition, queries are now available to human resource (HR) offices to assist them in ensuring all testing designated positions are appropriately coded.

VA is committed to 100 percent testing of all final selectees for Testing Designated Positions prior to appointment. On March 1, 2016, the Assistant Secretary for Human Resources and Administration published a memorandum stating that 100 percent of all applicants tentatively selected for appointment to a TDP be drug tested prior to appointment.

VA has implemented a process to monitor local compliance with VA's DFWP requirements. Beginning in March 2016, the DFWP website was modified to reflect that Coordinators were to certify that all applicants selected for all TDPs were tested in accordance with VA Handbook 5383. Those Coordinators not in compliance with the certification process are reported to their chain of command until compliance is achieved.

OIG Review of Drug Testing at Atlanta VA Medical Center

In April 2015, the VA Office of Inspector General (OIG) opened an investigation at the Atlanta VA Medical Center (VAMC) to review allegations of a backlog of over 300 unadjudicated background investigations and that mandatory drug testing of new hires did not occur over a 6-month period. It is important to note that this inspection happened before many of the institutional changes described above were implemented.

The investigation substantiated both allegations and found that, as of July 2015, the Atlanta VAMC had a backlog of about 200 unadjudicated background investigations; Atlanta VAMC human resources personnel acknowledged a backlog dating as far back as 2012. It was also found that the DFWP was not administered from November 2014 to May 2015.

VA appreciates OIG's work in making recommendations to improve our hiring processes. Atlanta VAMC leadership implemented a number of changes in 2016 including:

- realigning the human resources department under the direct supervision of the Medical Center Director;
- hiring a new human resources officer;
- dedicating a senior staff member to the personnel security section to oversee personnel assigned to that function; and
- developing a secondary database to work in tandem with the current system for staffing and tracking all background investigations, expiration, status, open and closed dates.

Atlanta VAMC identified 220 employees who require drug testing, and began notifications to these employees in December 2016. A phased approach is necessary to take into account workload, the number of people tested, and staffing levels. The Atlanta VAMC expects to complete testing by March 2017.

CONCLUSION

Mr. Chairman, I am proud of the health care our facilities provide to our Veterans, including prescription drug services. With support from Congress, we look forward to continuing to improve our oversight of controlled substances and drug free workplace programs, which will further improve the care our Veterans deserve. Thank you for the opportunity to testify before this subcommittee. I look forward to your questions.

Prepared Statement of Nicholas Dahl

Mr. Chairman, Ranking Member Kuster, and Members of the Subcommittee, thank you for the opportunity to testify today on the Office of Inspector General's (OIG) work related to oversight of controlled substances and drug free workplace programs at VA facilities. I am accompanied by Emorfia Valkanos, a member of the OIG's Office of Healthcare Inspections staff in Manchester, New Hampshire, who is also a pharmacist.

BACKGROUND

The Federal Drug-Free Workplace Program was initiated by Executive Order 12564 in 1986. The Executive Order established the goal of a drug-free Federal workplace and made it a condition of employment for all Federal employees to refrain from using illegal drugs on or off duty. The following year, Congress passed legislation (P.L. 100-71, Supplemental Appropriations 1987) designed to establish uniformity among Federal agencies' drug testing, confidentiality of drug test results, and centralized oversight of the drug testing program.

Within VA, the Deputy Assistant Secretary for Human Resources Management is responsible for the implementation of the Department's Drug-Free Workplace Program. Drug Program Coordinators at each Veterans Health Administration (VHA) facility are responsible for scheduling drug tests each month for randomly selected employees. Department-wide, VA randomly selects 285 employees each month across its facilities for drug testing for an annual total of 3,420 employees.

VA Directive and Handbook 5383, VA Drug-Free Workplace Program, establishes policies and procedures for VA's Drug-Free Workplace Program. The Handbook designates safety-sensitive occupational series as Testing Designated Positions (TDPs), such as physicians, nurses, police officers, motor vehicle operators, and Senior Executive Service employees.

There are several components to VA's Drug-Free Workplace Program, including:

- Pre-employment applicant testing of final selectees for TDPs.
- Random monthly drug testing of employees in TDPs. (Human Resources officials are responsible for properly coding employees in TDPs with the drug test code in VA's personnel information system.)
- Drug testing of employees when there is reasonable suspicion of on-the-job drug use or where drug use is suspected following a workplace accident or injury.

VA also requires that managers at VHA facilities ensure that a controlled substance inspection program is implemented and maintained. VHA Handbook 1108.02, Inspection of Controlled Substances, details requirements for facility controlled substances inspections.

OIG WORK

In recent years, the OIG has conducted an audit and a review where we assessed aspects of the Drug-Free Workplace Program. The audit included a comprehensive assessment of the effectiveness of VA's Drug-Free Workplace Program. We identified program weaknesses and made recommendations to improve the effectiveness of the program. The review revealed one medical center did not conduct drug testing for a 6 month period. The review also revealed a lack of oversight of the Drug-Free Workplace Program, both at a local and national level, in that the 6 month lapse in testing was not timely identified.

Drug-Free Workplace Program

In March 2015, we reported VA needed to improve the management of its Drug-Free Workplace Program to ensure the program was effective in maintaining a workplace that is free from illegal drug use.¹ We identified program weaknesses and determined VA's Program was not accomplishing its primary goal of ensuring illegal drug use was eliminated and VA's workplace was safe.

Pre-Employment Applicant Drug Test

We reported that VA's Office of Human Resources Management (OHRM) did not ensure facility Human Resource Management Officers complied with VA's policy to drug test all applicants selected for a TDP prior to appointment. Instead, VA selected about 3 of every 10 applicants selected for a TDP for pre-employment drug testing. If a tested applicant has a verified positive test result, VA should decline extending a final offer of employment. While VA's Drug-Free Workplace Program Handbook states every individual tentatively selected for employment in a TDP is subject to a drug test before appointment, OHRM officials interpreted this language as meaning only some finalists for TDPs needed to be drug tested before being appointed. Because of this interpretation, we estimated approximately 15,800 (70 percent) of the nearly 22,600 individuals VA reported appointing into TDPs during fiscal year (FY) 2013 were not drug tested before being hired.

Employee Random Drug Testing

We estimated VA achieved a national employee random drug testing rate of 68 percent of the 3,420 employees selected for random drug testing in FY 2013. Of 22 randomly selected facilities, we found 4 did not test any randomly selected employees, 10 had compliance rates ranging from 31 to 89 percent, and 8 tested at least 90 percent of their randomly selected employees. Facility Coordinators could not explain why the majority of the 32 percent of employees were not tested.

We also estimated at least 19,100 (9 percent) of about 206,000 employees in TDPs were not subject to the possibility of random drug testing because they were not coded with a Drug Test code, as required, in VA's personnel information system. Those not subjected to random drug testing included physicians, nurses, and addiction therapists. In addition, VA may have incorrectly identified as many as 13,200 employees with the Drug Test code-meaning, employees in positions that do not usually require random drug testing were subject to testing. We found VA did test non-TDP employees, which reduced the probability that employees in high-risk, safety sensitive TDPs were selected for drug testing.

Reasonable Suspicion Drug Testing

OHRM lacked sufficient oversight practices to monitor whether facilities referred all employees with a positive drug test result to the Employee Assistance Program (EAP). VA's Drug-Free Workplace Program Handbook requires facilities to refer all employees with a positive drug test result to its EAP for assessment, counseling, and referral for treatment or rehabilitation. However, facility Coordinators reported that only 17 of 51 employees who tested positive for drugs as a result of reasonable suspicion or after a workplace accident or injury were referred to their facility's EAP.

We made five recommendations to the Deputy Assistant Secretary for Human Resources Management. These recommendations included:

- Ensuring all final selectees for TDPs complete pre-employment drug testing prior to appointment
- Increasing accountability to ensure all employees selected for random drug testing are tested
- Improving the accuracy of Drug Test coding in VA's personnel information system
- Implementing procedures to ensure Custody and Control forms are accurately completed
- Ensuring compliance with Program requirements, such as referring employees who test positive to the EAP.

The then Acting Deputy Assistant Secretary concurred with our recommendations and provided action plans that were responsive to our recommendations. This included a plan to require mandatory pre-employment drug testing of all candidates selected for a TDP. Action in response to four of the five recommendations has been completed. VA continues to work on actions to ensure the accuracy of Drug Test coding in its personnel information system. Recently, VA notified us that they continue

¹ Audit of VA's Drug-Free Workplace Program, March 30, 2015.

to work with their personnel information system business partner to implement this recommendation. We will continue to track their progress until we receive documentation that action is complete.

Human Resources Delays

In January 2017, we reported on delays in the processing of certain human resources functions at the Atlanta VA Medical Center (VAMC).² We conducted our work to assess allegations that there was a backlog of unadjudicated background investigations³ and mandatory drug testing for new hires in TDPs⁴ did not occur for a period of at least 6 months between 2014 and 2015. We substantiated both allegations. Regarding the allegation that the Atlanta VAMC did not administer the Drug-Free Workplace Program for 6 months, we found no drug testing was completed at the VAMC from November 2014 through May 2015. This lapse occurred because the facility Coordinator left the position in September 2014 and the alternate Coordinator did not assume the collateral duties required of this position. Further, other VAMC Human Resources personnel were unaware of the Drug-Free Workplace Program responsibilities. Despite the lack of drug testing for 6 months, we found no indications VA management was aware of the lapse. Because no drug testing occurred, the Atlanta VAMC lacked assurance that employees who should have been subject to drug testing remained suitable for employment. We made five recommendations in the report:

- Develop an action plan to ensure staff have appropriate background investigations and determinations are accurately recorded
- Ensure all suitability adjudicators receive the mandatory training and background investigation required for the position
- Provide training to all human resources staff on the requirements of the personnel suitability program
- Ensure human resources staff are trained on the requirements of the Drug-Free Workplace Program and the responsibilities of their positions
- Review the Drug-Free Workplace Program on a regular basis to ensure compliance with regulations and that employees hired during gaps are subject to corrective testing.

The Atlanta VAMC Director concurred with our recommendations and reported that action has been taken with regards to the Drug-Free Workplace Program. When we receive documentation of action related to those recommendations, we anticipate closing them.

Evaluation of the Controlled Substances Inspection Program

During our past inspections of VHA medical centers through our Combined Assessment Program reviews (CAP Reviews), we analyzed pharmacy operations including environment of care, management of controlled substances, and pharmacy security. In 2008, we reported facility managers needed to reinforce compliance with VHA policy regarding controlled substances inspections. We conducted another review during our fiscal year 2013 CAP Reviews to include 58 facilities and issued a summary of the results in June 2014.⁵ The summary report contained 10 recommendations focused on opportunities for improvements:

- Conducting annual physical security surveys and correcting identified deficiencies
- Completing controlled substances quarterly trend reports and providing them to facility Directors
- Conducting monthly controlled substances inspections of non-pharmacy areas
- Completing non-pharmacy controlled substances inspection activities
- Performing emergency drug cache quarterly controlled substances physical counts and monthly verification of seals
- Validating completion of required drug destruction activities
- Verifying 10 percent of outpatient pharmacy written prescriptions for Schedule II drugs
- Validating accountability of prescription pads stored in the pharmacy
- Defining policy for acceptable reasons for missed controlled substances area inspections

²Review of Alleged Human Resources Delays at the Atlanta VAMC, January 30, 2017.

³An adjudication is considered backlogged after 90 days without a determination.

⁴There was also no monthly random drug tests for current employees in TDPs.

⁵Combined Assessment Program Summary Report - Evaluation of the Controlled Substances Inspection Program at Veterans Health Administration Facilities, June 10, 2014.

- Providing annual controlled substances inspectors training.

VA concurred with the recommendations and reported in December 2014 that action had been taken to address these recommendations.

Investigative Work

The OIG conducts criminal investigations regarding drug diversion classified in three categories.

Diversion of Controlled and Non-controlled Substances by VHA Employees

Diversion by healthcare providers is a serious issue that OIG diligently pursues. Not only is it an issue of theft, it is potentially an issue of patient safety if the provider is ingesting controlled substances while on duty, if false entries are placed in patient files to cover up the diversion, or if patients are given another substance in place of the diverted drug. OIG recently concluded an investigation of drug diversion that resulted in a former Albany, New York, VAMC hospice nurse being sentenced to 82 months' incarceration and 3 years' supervised release after pleading guilty to tampering with a consumer product and obtaining controlled substances by deception and subterfuge. The investigation by the OIG and the Food and Drug Administration, Office of Criminal Investigation, revealed the defendant stole oxycodone hydrochloride from syringes and replaced the contents with Haldol, an anti-psychotic medication. The investigation further revealed the defendant may have inflicted pain and suffering on dying hospice patients by diverting their pain medications for his own use and replacing it with a drug that was subsequently administered by other nurses.

Diversion of Controlled and Non-controlled Substances for Illegal Distribution

VA pharmaceuticals are also diverted or stolen for the purpose of illegal sale. An ongoing investigation at the Little Rock, Arkansas, VAMC has led to two pharmacy technicians and a pharmacy technician student trainee being indicted for charges to include conspiracy, theft, and possession with intent to distribute. The OIG investigation resulted in the defendants being charged with diverting and distributing 4,000 oxycodone tablets, 3,300 hydrocodone tablets, 308 oz. of promethazine with codeine syrup, and over 14,000 Viagra and Cialis tablets. Three additional VA employees were identified as part of the drug diversion, resulting in a resignation and reassignments. The monetary loss to VA is over \$77,000.

Diversion of Controlled Substances via Theft of Mailed Pharmaceuticals

Mailed pharmaceuticals are vulnerable to theft at any point in the process. The most common occurrence is theft by employees of the mail carrier, either Government or private. This type of diversion results in veterans experiencing delays in receiving their medication. A recent VA OIG and UPS Security investigation revealed a defendant stole several VA packages containing oxycodone and morphine that were intended for veterans residing in Memphis, Tennessee. During the investigation, the defendant was caught attempting to steal an additional package and confessed to the thefts. The (now) former UPS driver was sentenced to time served and 3 years' probation after pleading guilty to theft.

CONCLUSION

The OIG has provided cross cutting oversight of the Drug-Free Workplace Program through our audits, inspections, and investigations. This oversight is necessary to ensure that VA takes the necessary steps to reduce risks to the safety and well-being of veterans and VA employees by having and following the proper program controls. We also have an active program investigating and having those engaged in drug diversion prosecuted. Without appropriate actions, we concluded VA lacked reasonable assurance that it is achieving a drug-free workplace and adequately securing controlled substances.

Mr. Chairman, this concludes our statement. We would be happy to answer any questions that you or other Subcommittee Members may have.

Prepared Statement of Randall B. Williamson

Actions Needed to Ensure Medical Facilities' Controlled Substance Programs Meet Requirements

Chairman Bergman, Ranking Member Kuster, and Members of the Subcommittee:

I am pleased to be here today to discuss our recent report on the controlled substance inspection programs at medical facilities run by the Department of Veterans Affairs (VA).¹ The Veterans Health Administration (VHA), which operates VA's health care system, requires that each of its medical facilities with stocks of controlled substances implement an inspection program to help reduce the risk of employees diverting for their own personal use controlled substances intended for veterans. Diversion of controlled substances such as opioid pain relievers can occur anywhere in a facility where employees have access to controlled substances, and this diversion can pose a risk to veterans—for example, by depriving them of needed medications. Without effective practices to reduce the risk of diversion by employees and to quickly identify it, diversion can remain undetected.

Under its controlled substance inspection program, VHA requires medical facilities to conduct monthly inspections following specified procedures outlined in VHA's inspection program policy. These inspections must be performed in all facility areas that are authorized to have controlled substances—including pharmacies and patient care areas such as operating and emergency rooms.² At each medical facility, the facility's director is primarily responsible for overseeing the inspection program and ensuring that the facility's program adheres to VHA's requirements. The facility director must appoint a coordinator to manage the controlled substance inspection program and the inspectors who conduct the inspections. The coordinator is responsible for ensuring that the inspections are conducted each month and submitting reports summarizing the results from the monthly inspections and trends to the facility director. The Veterans Integrated Service Network (network) that oversees the facility is responsible for reviewing the inspection program trend reports annually.

My testimony today summarizes the findings from our report analyzing the implementation and oversight of controlled substance inspection programs at select VA medical facilities. Accordingly, this testimony addresses:

1. the extent to which selected VA medical facilities have implemented controlled substance inspection programs as required by VHA policies, and

2. VHA's oversight of these programs at selected VA medical facilities.

In our report, we recommend several key actions that VA should take to ensure that the facilities' inspection programs meet VHA's requirements, and my testimony summarizes these recommendations and VA's response to them.

To conduct our work, we reviewed VHA policies and interviewed officials from 1) VHA Central Office, 2) a nongeneralizable selection of four VA medical facilities, and 3) the four networks that oversee these facilities. We selected the four facilities to achieve variation in geography and in the number of prescriptions for opioid pain relievers dispensed in the states in which the facilities operate. The four VA medical facilities we selected are located in Washington, D.C.; Milwaukee, Wisconsin; Memphis, Tennessee; and Seattle, Washington. We compared the number of controlled substance inspections that officials from each of the four VA medical facilities reported to us as having been completed from January 2015 through February 2016 to the number of inspections that should have been conducted, based on VHA's policy requirements. We reviewed the inspection procedures in place at each of the four facilities as described in the facilities' inspection program policies and other guidance documents, and we compared these procedures to VHA's policy requirements. We also reviewed the monthly and quarterly inspection reports for each of the four selected facilities during our review period and analyzed the contents of VHA's online training courses for coordinators and inspectors. We compared the implementation and oversight of the facilities' controlled substance inspection programs to VHA's policy requirements and to federal standards for internal control related to control activities, monitoring, and oversight.³ Further details on our scope and

¹GAO, VA Health Care: Actions Needed to Ensure Medical Facility Controlled Substance Inspection Programs Meet Agency Requirements, GAO 17 242 (Washington, D.C.: Feb. 15, 2017).

²As described in our report, we reviewed VHA's controlled substance inspection program policy issued in 2010, which was the most current policy at the time our review. See Department of Veterans Affairs, Veterans Health Administration Handbook 1108.02, Inspection of Controlled Substances (Washington, D.C., Mar. 31, 2010). VHA issued an update to its policy in November 2016. See Department of Veterans Affairs, Veterans Health Administration Directive 1108.02, Inspection of Controlled Substances (Washington, D.C., Nov. 28, 2016).

³GAO, Standards for Internal Control in the Federal Government, GAO 14 704G (Washington, D.C.: Sept. 10, 2014). GAO, Standards for Internal Control in the Federal Government, GAO/AIMD-00-21.3.1 (Washington, D.C.: Nov. 1, 1999). Internal control is a process effected by an entity's management, oversight body, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved.

methodology are included in our report.⁴ The work this statement is based on was performed in accordance with generally accepted government auditing standards.

Selected VA Medical Facilities Did Not Conduct All Monthly Inspections or Follow All Required VHA Inspection Procedures

We found that from January 2015 through February 2016, one of the four selected facilities we reviewed missed 43 percent of the required monthly inspections, and another facility missed 17 percent of these inspections. Further, at both facilities, most of the missed inspections were for patient care areas such as the operating rooms.⁵ At one of the two facilities, inspectors had missed all 14 inspections of the facility's operating rooms during our 14-month review period. The facility's coordinator told us that the operating rooms were not inspected during this time because the assigned inspectors needed to arrive before or after normal operating room hours to obtain access to the controlled substances and were unable to conduct the inspections due to their conflicting work schedules.⁶ As a result of missed inspections in the operating rooms and other patient care areas, these medical facilities lack reasonable assurance that their physical inventory of controlled substances matches the recorded inventory, thereby increasing the risk that controlled substances could be stolen. Further, their ability to protect veterans from the harm that can result from diversion, such as depriving them of needed pain medications, is limited. The other two VA medical facilities we reviewed fully adhered to VHA's requirement to conduct monthly inspections in their patient care areas and pharmacies.

We also found that three of the four selected VA medical facilities, when conducting inspections, did not include, or correctly follow, three or more of the nine VHA inspection requirements we reviewed. The fourth facility we reviewed had implemented inspection procedures that followed these nine requirements. For example, inspectors at two facilities did not verify that controlled substances had been properly transferred from their facility pharmacies to the automated dispensing machines in patient care areas.⁷ VHA requires inspectors to verify that all controlled substances transferred by a pharmacy on a selected day were received in patient care areas such as the operating room. However, at one facility, inspectors told us that they did not conduct this required procedure in one of the facility's two pharmacies. At another facility, inspectors verified only a sample of controlled substances dispensed by the pharmacy to confirm that the substances were actually transferred. Without checking that all controlled substances were properly transferred, inspectors may not identify controlled substances that are dispensed by the pharmacy and subsequently diverted rather than stocked in the automated dispensing machines located in patient care areas.⁸

We found that several factors contributed to the missed inspections and incorrect implementation of inspection procedures that we identified.

First, the two VA medical facilities that missed inspections lacked an additional control procedure, such as designating an alternate coordinator or appointing additional inspectors, to help prevent missed inspections when the assigned inspectors could not conduct them. Both of the facilities that conducted all of the required monthly inspections had an alternate coordinator to assist the coordinator in managing the inspection program, including scheduling the inspections and following up with inspectors to ensure inspections are completed. In addition, the alternate coordinator at one of these facilities conducted inspections when inspectors had unforeseen circumstances that prevented them from completing the assigned inspections. In contrast, the two medical facilities that missed inspections did not have an additional control procedure, such as the use of an alternate coordinator. Without coordinators ensuring that the monthly inspections are conducted, VA medical facilities lack assurance that the inspection programs are meeting the objective to reduce the risk of diversion of controlled substances.

Second, three of the four VA medical facilities in our review did not have written inspection procedures that were fully consistent with VHA's policy requirements.

⁴See GAO 17 242.

⁵VHA's inspection program policy requires that facilities inspect patient care areas and pharmacies on a monthly basis using specific procedures.

⁶A team of inspectors is assigned from various areas of the medical facility.

⁷Automated dispensing machines are computerized drug storage and dispensing medication cabinets.

⁸The VA Office of the Inspector General also found in 2009-and again in 2014-that VA medical facilities did not always conduct required inspections or follow VHA's required procedures. For example, see VA Office of the Inspector General, Combined Assessment Program Summary Report: Evaluation of the Controlled Substances Inspection Program at Veterans Health Administration Facilities (Washington, D.C.: June 10, 2014).

This likely contributed to their inspections not following certain VHA policy requirements. (See figure 1.)

Figure 1: Comparison of Written Inspection Procedures at Four VA Medical Facilities with Selected VHA Inspection Requirements, as of February 2016

Controlled substance inspection procedure required by VHA	VA medical facility A	VA medical facility B	VA medical facility C*	VA medical facility D
Required pharmacy inspection procedures				
1. Ensure that all ordered controlled substances have been placed in inventory.	●	●	○	○
2. Perform a physical count of controlled substances in the pharmacy.	●	○	○	●
3. Perform a physical count of the emergency cache.	●	○	○	●
4. Verify the 72-hour inventory counts by pharmacy.	●	●	○	○
5. Reconcile one day of pharmacy dispensing.	●	●	○	●
6. Verify hard-copy prescriptions.	●	○	○	○
7. Verify documentation of controlled substances on hold for destruction.	●	●	○	○
Required patient care area inspection procedures				
8. Perform a physical count of controlled substances in patient care areas.	●	●	○	●
9. Validate dispensing of controlled substances.	●	●	●	●

● Written procedure is consistent with VHA requirement

○ Written procedure is absent or inconsistent with VHA requirement

Source: GAO | GAO-17-442T

Note: At the four selected Department of Veterans Affairs (VA) medical facilities, we reviewed written inspection procedures that were included in the local inspection program policies, training manuals and other guidance documents and compared them to the Veterans Health Administration's (VHA) inspection program requirements included in VHA's 2010 policy. See Department of Veterans Affairs, Veterans Health Administration Handbook 1108.02, Inspection of Controlled Substances (Washington, D.C.: Mar. 31, 2010).

aVA medical facility C had no written procedures for its pharmacy inspections. Although this VA medical facility's inspection program policy stated that inspections must follow the required procedures included in VHA's Handbook 1108.02, this handbook was not included in the guidance that inspectors told us they used in performing and implementing the inspection procedures.

The one VA medical facility that had written inspection procedures that were consistent with VHA's policy requirements has an ongoing process to conduct comprehensive reviews of its procedures. At this facility, the coordinators had conducted separate reviews of the facility's procedures in coordination with two pharmacy managers, according to a facility official. In contrast, at the other three selected VA medical facilities, the coordinators' reviews of the facilities' procedures were not as comprehensive. For example, the coordinator at one facility told us he had compared the facility's procedures to the VHA requirements but did not involve other facility officials to verify the accuracy of his review.

Third, while VHA relies on coordinators to ensure that the inspections are conducted correctly, we found that VHA's training course for coordinators lacks substantive information about VHA's required inspection procedures. VHA's training course for inspectors, in comparison, includes substantive information about the required inspection procedures. While two of the four coordinators we interviewed told us they were provided helpful on-the-job training at their medical facilities, which included shadowing the prior coordinator, three of them told us that additional coordinator training was needed.

In our report we noted that missed inspections and gaps in facilities' local inspection procedures and coordinator training are inconsistent with federal internal control standards, which state that management should periodically review their procedures for effectiveness and provide proper training to achieve results. We concluded that missed inspections and gaps in inspection procedures and training could significantly limit VHA's ability to reduce the risk of diversion of controlled substances. To address these shortcomings, we recommended that VA ensure that VA medical facilities establish an additional control procedure, such as an alternate coordinator, to help prevent missed inspections as well as a process in which coordinators and other stakeholders compare facility inspection procedures to VHA's policy requirements and modify facility procedures, as appropriate. We also recommended that VA improve its coordinator training by ensuring that the training includes the inspec-

tion procedures that VHA requires. VA agreed with these recommendations and said it plans to take steps to implement them by October 2017.

Oversight of Controlled Substance Inspection Programs by Selected VA Medical Facilities and Networks Is Inconsistent

We found inconsistent oversight of the controlled substance inspection programs at selected VA medical facilities by facility directors and by the networks to which the facilities report. Directors at two of the four facilities had not implemented corrective actions to address missed inspections identified by coordinators in the monthly inspection reports that the directors had reviewed. In addition, one of four facility directors did not receive quarterly trend reports during our review period as required by VHA policy and did not implement a corrective action to ensure that he receives future reports. Further, we found that two of the four networks did not review their facilities' quarterly trend reports as required by VHA policy. Officials at one of these two networks told us that they were unaware of the requirement, while an official in the other network told us the officials responsible for reviewing the reports did not realize it was a requirement.⁹ One network that had reviewed the quarterly trend reports did not follow up with a facility in our review to ensure that the coordinator had submitted missed trend reports to the facility's director. We also found that this coordinator had not completed other quarterly trend reports, and the facility's director did not develop a corrective action plan to ensure the completion of these reports in the future.

In our report, we pointed out that the inconsistent oversight by the directors and networks is contrary to federal internal control standards, which call for oversight to be ongoing to assess performance, promptly remediate deficiencies, and hold individuals accountable for their responsibilities. We concluded in our report that without ongoing monitoring by facility directors and networks—including holding facilities accountable for correcting nonadherence to program requirements—VHA lacks reasonable assurance that facilities will correct deficiencies on a timely basis. To address these oversight problems, we recommended that VA ensure that medical facility directors have a process in place to document and correct nonadherence with program requirements. We also recommended that VA ensure that the networks review their facilities' quarterly trend reports and ensure that facilities take corrective actions when program nonadherence is identified. VA agreed with our recommendations and said it plans to take steps to implement them by October 2017.

Chairman Bergman, Ranking Member Kuster, and Members of the Subcommittee, this concludes my statement. I would be pleased to respond to any questions that you may have at this time.

GAO Contacts & Staff Acknowledgments

If you or your staff members have any questions concerning this testimony, please contact me at (202) 512-7114 (williamsonr@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Other individuals who made key contributions to this testimony include Marcia A. Mann, Assistant Director; Pamela Dooley (Analyst-in-Charge); Krister Friday; and Carmen Rivera-Lowitt.

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⁹VHA included this network requirement in a 2014 memo that it issued in response to the VA Office of the Inspector General findings on weaknesses in the inspection programs. See VA, Memorandum on Controlled Substance Inspection Program Requirement, VA Office of Inspector General-Combined Assessment Program Findings (Washington, D.C.: July 9, 2014).

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Prepared Statement of Keith H. Berge, M.D.

Chairman Bergman, Ranking Member Kuster, and Members of the Committee,
Thank you for the opportunity to speak with you today about drug diversion from the health care workplace. Such diversion is a crime that endangers all patients, health care employers, coworkers, and even endangers the diverters themselves. While we have long known of these hazards of patients being deprived of pain medicine by diversion, only fairly recently has the grave risk to extremely vulnerable patients been revealed by outbreaks of diseases such as blood poisoning by bacteria or viruses that have been transmitted by drug diverters swapping syringes in the commission of their crimes. In the process, many patients have been infected with potentially fatal illnesses. I have attached for your review a paper authored by CDC investigators outlining 6 such outbreaks over a 10 year period that resulted in illness and death in patients. One of the diversion/infection scenarios included Veteran's Affairs patients being exposed to a diverter that communicated his Hepatitis C infection to approximately 50 patients. This diverter was radiation technologist who traveled the country working for multiple employment agencies. He had been fired from multiple jobs for diverting fentanyl for his own use, but by simply lying about previous terminations on job applications, and in the absence of a national registry of radiation technologists, he had no trouble finding employment. In the darkened invasive radiology suites he would swap the fentanyl syringe on the anesthesia cart with one he has previously used to inject himself. He would then excuse himself to a restroom, inject himself with the stolen fentanyl, draw up tap-water, and repeat the process with the next patient's fentanyl. In this manner, he conveyed his potentially lethal illness to many innocent victims. The 8 patients described in these outbreaks were all in extremely vulnerable positions, either undergoing an

invasive procedure while under anesthesia, or in an Intensive Care Unit. Clearly, such behavior is unacceptable, and in recognition of these dangers posed by diversion the Drug Enforcement Administration requires stringent drug control policies and procedures to be put in place to protect controlled substances from attack across all points of the manufacturing, distribution, dispensing, administration and disposal spectrum. The drugs used in the healthcare setting are highly sought after drugs of abuse, both by addicts and by those who would profit richly by the sale of stolen drugs.

Experience at the Mayo Clinic and elsewhere has shown the necessity of having robust surveillance, detection, investigation, and intervention programs in place in order to minimize the risk to all involved. While it will be impossible to completely eliminate drug diversion from the healthcare workplace, it is imperative that robust systems rapidly detect and halt such activity. I have attached for your review an article from Mayo Clinic authors, myself included, which outlines our program from its inception to very successful implementation. While we continue to try to improve our system, it has proven quite effective in identifying a host of drug diverters since implementation 7 years ago. Diverters come from diverse backgrounds, and include physicians, pharmacists, pharmacy techs, nurses, nursing students, nursing assistants, janitors, patients, patient's family members, nursing home attendants, hospice workers, and strangers off the street. The stories are incredible, but they all point to the powerful draw that these drugs have over addicts. As such, it is not good enough to merely have effective policies and procedures on the books; they must actually be rigorously followed. Diverters are generally clever and desperate, and they will gravitate into the area of a system where they perceive the drugs to be most vulnerable to attack. It therefore behooves any healthcare facility to have a reputation for being effective at rapidly identifying, terminating, and prosecuting drug diversion and drug diverters. Only by doing so can we protect the most vulnerable of our patients from preventable harm. As I've stated, this problem will never go away, so we must become very good at rapid intervention. Only by instituting and following effective anti-diversion policies and procedures will this be possible.

I thank the Committee for its attention to this important issue, and stand ready to answer any questions you may have.

Keith H. Berge, M.D.
Consultant, Anesthesia & Perioperative Medicine
Chair, Medication Diversion Prevention Subcommittee

Statements For The Record

AMERICAN SOCIETY OF ANESTHESIOLOGISTS

Jeffrey Plagenhoef, M.D., President, American Society of Anesthesiologists

On behalf of more than 52,000 members, the American Society of Anesthesiologists (ASA) would like to thank Chairman Bergman, Ranking Member Kuster and members of the Subcommittee for holding the hearing, "Assessing VA's Risks for Drug Diversion," and providing ASA the opportunity to submit a Statement for the Record. We greatly appreciate your willingness to discuss this important topic and how it impacts our nation's Veterans. Physician anesthesiologists are health care professionals who manage and administer a large number of controlled substances in their roles as perioperative physicians, and are pain medicine specialists, diagnosing and treating patients with complex pain conditions. As leaders in patient safety, anesthesiologists thereby are uniquely positioned to address this issue. ASA believes prevention of, and education about, drug diversion activities are critical. We look forward to working with the Committee and others on a multidisciplinary approach to minimize the potential for drug diversion and ensure patients in the Department of Veteran Affairs continue to receive high-quality care.

It is no secret that the potential for drug diversion by clinicians, staff, patients, family members and others is a real threat at any hospital, surgery center, nursing home, pharmacy or other care organizations. News media and internal reviews, such as the February 2017 GAO report on controlled substance inspection programs,¹ have played an important role in revealing some of these instances where health care professionals have diverted drugs for their own use, and in some cases, the pa-

¹United States Government Accountability Office, Actions Needed to Ensure Medical Facility Controlled Substance Inspection Programs Meet Agency Requirements, February 2017, Available at: <http://www.gao.gov/assets/690/682804.pdf>

tient fatalities that have been the result. Moreover, a report by the Substance Abuse and Mental Health Services Administration (SAMHSA) illustrates that drug diversion contributed to a fourfold increase in substance abuse treatment admissions between 1998 and 2008 among individuals aged 12 and older.² It is also widely known that certain healthcare specialties, such as anesthesiology, are associated with increased risk for abuse of and dependency on certain classes of drugs. For this reason, ASA feels strongly about identifying and adopting strategies that lead to successful drug diversion deterrence programs. As a result, ASA's Committee on Occupational Health has created a model curriculum on substance use and disorder. This curriculum identifies the problem of drug diversion and addiction, specifically in the occupation of anesthesiology, detection, re-entry into the occupation, as well as prevention.³

As the Committee is aware, there are institutions that already implement successful drug diversion deterrence programs. In fact, some of these programs have been highlighted in testimony for this hearing. In addition, the Centers for Medicare & Medicaid Services (CMS) has resources describing the role of practitioners in preventing drug diversion.

Furthermore, Congress and Federal agencies have taken important steps to curb opioid abuse and misuse. For example, during the 114th session, Congress passed the Comprehensive Addiction and Recovery Act (CARA), which included ASA-supported provisions to expand access to naloxone; allow patients to partially fill prescriptions for controlled substances; reauthorize NASPER, a public health grant program for prescription drug monitoring programs; and enable National Institutes for Health (NIH) to intensify pain research. Additionally, the Centers for Disease Control and Prevention (CDC) issued the Guideline for Prescribing Opioids for Chronic Pain, which ASA collaborated with the agency to develop.

There has been a heightened focus by regulators to tighten prescription requirements and work to change prescribing practices in response to the opioid epidemic. ASA is a long-time proponent of the use of multimodal, multidisciplinary pain management strategies including interventional techniques that will decrease reliance on opioids for chronic pain. While efforts to address the opioid epidemic are underway, there is a growing need to address drug diversion. ASA believes it is important to consider these alternative treatments as not only a method of decreasing patient reliance on opioids, but to also reduce the incidence of drug diversion.

The Drug Enforcement Agency (DEA) is heightening its scrutiny of healthcare organizations. As evidenced DEA's FY 2016 Performance Budget, there was a 9% increase in the budget devoted to Diversion Control.⁴ It is no surprise that hospitals, surgery centers, nursing homes, pharmacies and other organizations will be held accountable for a lack of oversight and diligence when diversion occurs. Therefore, it would be prudent for health care providers, including anesthesiologists, to take preemptive steps to mitigate risks.

As previously mentioned, there are already institutions implementing successful drug diversion deterrence programs and a lot to be learned from the information that already exists. ASA believes that training and education are integral to successful drug diversion deterrence programs. ASA recommends that all employees be educated on how to identify, detect and report potential drug diversion. It is also important that they are able to do this anonymously, either through a telephone hotline or other immediate method. A limited number of health care professionals should also be properly trained on the use of automated dispensing units, with the caution that overreliance on these units can create a false sense of security. Multimodal pain management techniques should be considered and employed whenever possible in order to reduce reliance on opioids. Additionally, policies and procedures should be developed with respect to waste/destruction of controlled substances and segregation of duties, including the ordering, receipt, inventory, storage, and stocking of controlled substances in different locations. It is also advisable to frequently review drug management data, including investigating and reviewing discrepancies on a timely basis and conducting 'unscheduled' reviews.

²The TEDS Report, Substance Abuse Treatment Admissions Involving Abuse of Pain Relievers: 1998 and 2008, July 15, 2001. Available at: https://www.dea.gov/divisions/dal/2010/dallas071610.pdf?utm_source=ABCeAlert&utm_campaign=Hospital%20Drug%20Diversion%20Prevention&utm_content=2-20-17

³SUD Curriculum, ASA Committee on Occupational Health, Tetzlaff, John, November 12, 2015, Available here: <https://www.asahq.org/media/sites/asahq/files/public/resources/asa%20committees/substance-use-disorder-model-curriculum-42216.pdf?la=en>

⁴Drug Enforcement Agency, FY 2016 Budget and Performance Summary, Available here: <https://www.justice.gov/sites/default/files/jmd/pages/attachments/2015/01/30/28-bs-section-ii-chapter-dea.pdf>

ASA believes it is important to proactively take steps to mitigate the risk of drug diversion. Having procedures in place that inform every employee of the importance of preventing drug diversion, including disciplinary actions, can reduce risks. Even with certain safeguards in place, institutions are vulnerable. Therefore, it is important to work closely with and in cooperation with law enforcement, including local police and the DEA.

ASA thanks the Committee for the opportunity to submit this Statement for the Record and would like to offer our members as a resource to the Committee, and also to emphasize our willingness to work with you and the Department of Veterans Affairs to address the issue of drug diversion.

Sincerely,

Jeffrey S. Plagenhoef, M.D.
President
American Society of Anesthesiologists

VA OIG QFR RESPONSE

March 24, 2017

The Honorable Jack Bergman
Chairman
Subcommittee on Oversight and Investigations
Committee on Veterans' Affairs
U.S. House of Representatives Washington, DC 20511

Dear Mr. Chairman:

At the February 27, 2017 hearing before the Subcommittee, Mr. Nick Dahl, Deputy Assistant Inspector General for Audits and Evaluations, was asked a question regarding a recent Office of Inspector General (OIG) report, Review of Alleged Human Resources Delays at the Atlanta VA Medical Center, that he replied to that he would provide the information for the record.

The question was from Congressman Mike Bost dealing with the number of background checks that were not completed at the Atlanta VA Medical Center (VAMC) for positions that were high-risk or testing designated positions. The Atlanta VA Medical Center did not maintain adequate records for us to identify the number individuals who had not completed the background investigation process during our audit work. On February 3, 2017, we requested additional information on the status of the reviews. In a response dated February 22, 2017, the Atlanta VAMC Director advised that they determined that 863 background investigations needed to be adjudicated. This number varies from the original reported backlog of 200 due to a severe lack of documentation and subsequent discovery that Human Resource personnel performing the background adjudication checks during this timeframe did not have the necessary training or the minimal background level.

We request that this letter be included in the hearing record. Thank you for your interest in the OIG.

Sincerely,

/s/

MICHAEL J. MISSAL

Copy to: The Honorable Mike Bost

