Ameritox℠
Medication Monitoring Solutions

Fighting Opioid Dependency

For Those Who Fought for Us.



Ameritox and Valor Healthcare

Over the last 20 years, Ameritox has delivered data-driven medication monitoring solutions for the prescription narcotic and behavioral health markets, serving over 9,500 physicians across 4,900 practices. Ameritox stands on the front line of medication detection testing technology through partnerships with leading health systems, academic research institutions and government agencies.

Valor Healthcare is the largest provider of contract CBOC services to the VA, and is the only CBOC contractor with independent TJC blanket accreditation for Ambulatory Care and PCMH (PACT) certification. In total, Valor Healthcare provides medical care to 122,000 veterans within 33 CBOC facilities.

In 2015, Ameritox and Valor partnered to introduce RxGuardian, a new medication monitoring system, to CBOCs and other clinics across the country.

Ameritox℠ Medication Monitoring Solutions | Valor HEALTHCARE

Executive Summary

Pressure from the media and the populace is mounting for legislators, local leaders and the military and civilian health care community to take decisive action to stem the opioid epidemic. Ameritox and Valor Healthcare have been working in partnership toward that end, by addressing the absence of a comprehensive urine screening. Only with a highly sensitive testing system and user-friendly reports can physicians effectively manage an opioid prescription regimen for veterans with chronic pain.

When a patient suffers from chronic pain, clinic physicians typically initiate Chronic Opioid Therapy (COT) and perform urine drug screening to monitor adherence to their prescription regimen. The common method for drug testing has major limitations: while it detects the presence or absence of opioids, it does not distinguish between classes of drugs, nor does it detect quantities. This leaves physicians with few tools for determining if the patient has duplicate prescriptions, or is consuming dangerous levels of a drug or combination of drugs. It can turn opioid regimen decisions into guesswork -- not a comfortable position for a physician with concern and liability for patient outcomes.

Ameritox tackled this deficit in adherence monitoring by developing a sensitive medication monitoring technology that provides that all-important differentiation and quantification of substances in the urine sample. Our algorithms can detect minute quantities of 12 classes of opioid drugs, including heroin,

codeine, morphine, hydrocodone and others. This data is processed by our patented software program, which generates clear, concise reports.

We named this medical monitoring system RxGuardian. With its greater sensitivity, and the breadth of reporting features, this system represents a vast improvement in urine screening technology.

In 2015, we joined with Valor Healthcare to launch a quality improvement initiative, providing veteran clinic physicians with this tool for accurately evaluating COT adherence and establishing safer opioid prescribing practices. We sought to provide them with a high visibility into individual and group dosing patterns as well. This information, over time, constitutes the essential "evidence" in evidence-based practices.

With its greater sensitivity, and the breadth of reporting features, this system is a vast improvement in urine screening technology.

This paper introduces RxGuardian and recounts the results of our testing in two beta sites, both of them Valor Healthcare veteran treatment facilities. Based on the successes of our initiative, Ameritox and Valor Healthcare are poised to extend RxGuardian use to the other 31 Community Based Outpatient Clinics (CBOCs), as well as civilian laboratories and clinics.

The RxGuardian medication monitoring system enhances physicians' abilities to ensure patient compliance to prescription regimens. Imbedding RxGuardian into your clinical protocol is a proactive step to improve opioid adherence levels of chronic pain patients.

It is a powerful ally in the fight against opioid abuse within the veteran population.

> ***"The Ameritox drug screen provides objective data in an arena where important prescribing decisions are being made with limited, subjective information."***
>
> *– Valor Healthcare Physician*

Background

The Scale of the Epidemic

We don't need to look far down the newspaper page or beyond our circle of acquaintances to know that opioid abuse is epidemic in America today. Opioid dependency is devastating to users and their families, and strains our national resources to the tune of $78.5 billion a year. This particular drug problem elicits a special sympathy from us, and rightly so, because most often the cascade of abuse is triggered by *legitimately prescribed opioids...*for *real pain.* Most of those who wind up in trouble don't set out on a joy ride or to break any laws. They just want relief. This is true in both the civilian and veteran populations. Misusers, abusers -- however we label them -- deserve the best solutions we can find in

pain management and healing, including quality monitoring of their prescription medication use and compassionate counseling.

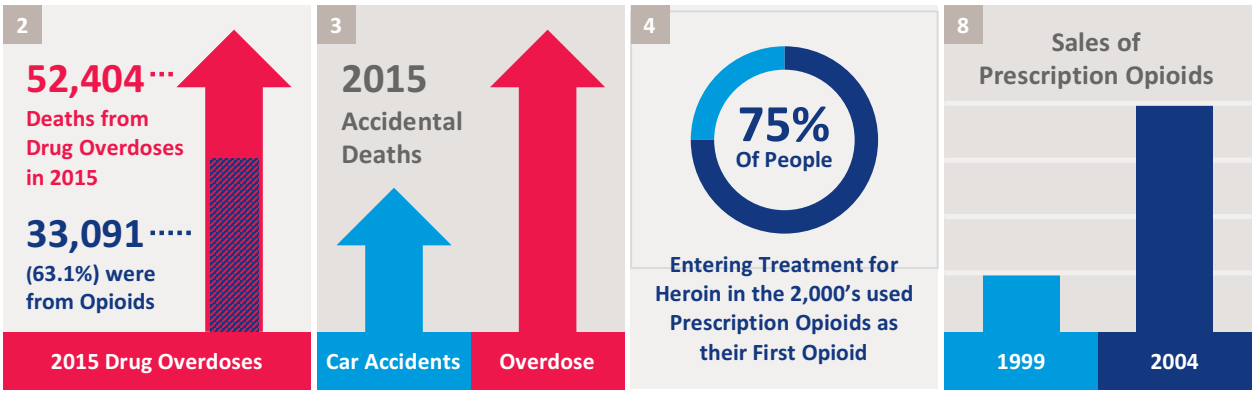
The consequences of opioid misuse are legion. In 2015, drug overdose in the U.S. accounted for 52,404 deaths, with 33,091 (63.1%) of these involving an opioid.[2] More deaths resulted from drug overdose than from either car accidents or gun-related violence.[3] Prescription opioids, not illicit drugs, are the most common gateway to opioid dependence. A full 75% of people entering treatment for heroin use between 2000 and 2010 were introduced to opioids through a prescription to relieve pain.[4] The National Academy of Medicine estimates that in 2011 more than 100 million Americans were affected by chronic pain[5] - that is nearly 1/3 of the U.S. population!

These figures all raise the multibillion dollar question of why pain and its pharmaceutical attenuators are more rampant today. While the answers may remain elusive, the need to address the problem presses down on us with urgency.

Our strongest are among the most vulnerable

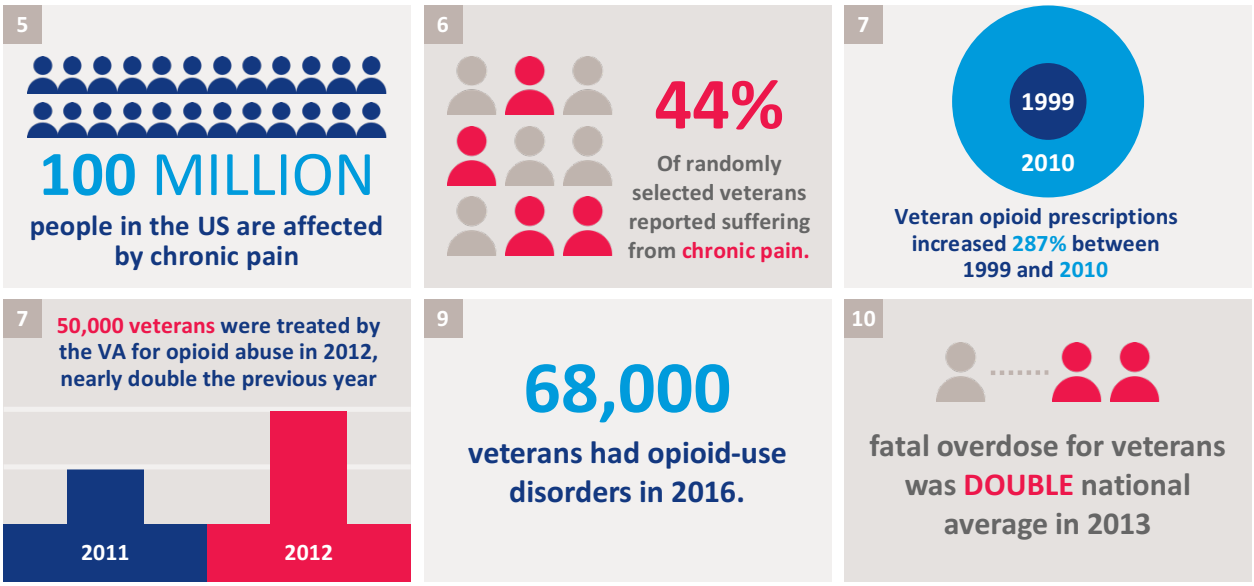
Where just under a third of all Americans suffer from some chronic pain, 44% of veterans report suffering from chronic pain.[6] Between 1999 and 2010 veteran opioid prescriptions shot up by a precipitous 287%,[7] while the overall sales of opioid medications quadrupled between 1999 and 2014.[8]

in 2012, over 50,000 veterans were treated by the US Department of Veterans Affairs (VA) for serious problems associated with opioid abuse, nearly double the number from the previous decade.[7] This number has increased to 68,000 veterans in 2016.[9] Additionally, the fatal overdose rate among veterans was nearly double the national average in 2013.[10]



It is daunting to try and unravel the many factors that contribute to chronic pain among civilians. However, we have greater visibility into what initiates the cycle of pain and pain medication for our veterans, even though questions of what is a physical vs. emotional wound still blur the lines and confound treatment plans. The prolonged warfare in the Middle East, guerrilla assault tactics and chemical exposure, all with their attendant long-term pain risks, have raised the need for stronger

medicines for chronic pain. Formulations with fewer overt or short-term side effects were there to meet the demand, making for unintended consequences.



Challenges with Current Adherence Monitoring under Chronic Opioid Therapy (COT)

The biggest challenge with current COT adherence monitoring is the inherent shortcomings of the screening algorithms themselves. The widely used urine screens detect the presence of an opioid, but lack the sensitivity to distinguish between substances of the same drug class, and are unable to discern the level of drug present within a patient's system. This lack of information obviously muddies the water for VA Primary Care Providers (PCPs) trying to make informed COT decisions.

Many VA PCPs are justifiably concerned about their liabilities. In cases of serious morbidity or a fatal event, their decision to write a COT prescription may be challenged. Yet the tools at their disposal have been, to date, limited and limiting.

The RxGuardian Difference

Ameritox developed a quantitative medication monitoring technology to address these limitations. The resulting product, RxGuardian, provides physicians with enhanced data on prescription adherence. Unlike other medication monitoring systems, this system differentiates between drugs of the same drug class, and analyzes drug level ranges. It can also distinguish between a prescribed opioid on a patient's

regimen and an illicit opioid like heroin, for example, or between Oxycontin and Vicodin. With this segregation possible, physicians know without a doubt whether the patient is adherent to their prescription regimen or using illicit or other non-prescribed substances within the same drug class.

RxGuardian's medication monitoring technology is quantitative vs. qualitative. A quantitative screening technology provides highly accurate readings of the levels of substances and medications in the urine sample. In contrast, qualitative screening, the mechanism existing CBOC tests employ, only indicates if a drug type -- opioids in this case -- is present. It neither differentiates between substances within the same drug type, nor provides data about drug levels. In our studies, RxGuardian generated results that differed from the default conclusions of the old monitoring system 12% of the time.

Beyond differentiating between drugs and discerning levels of concentration, RxGuardian also issues automatic recommendations for terminating medication use and supplies individual and group histories and other user-friendly reports to support decisions.

RxGuardian places, at your fingertips, an historical account of all the substances that a patient has taken and how much of each substance has been consumed. This differentiated data, identifying the types and volumes of various opioids in the urine stream, enables you to determine whether misuse of multiple substances is occurring, counsel your patient, and adjust prescriptions accordingly.

The increased visibility into patients' adherence levels enables earlier intervention, before addiction or patterns of abuse develop, and confidence in writing appropriate future prescriptions.

RxGuardian Advantages	
RxGuardian	**Other Screens**
Quantitative Medication Monitoring Technology	Qualitative Urine Screening Solution
• DIFFERENTIATES between drugs in same drug class • Provides analytics on drug level ranges	• DOES NOT DIFFERENTIATE between drugs in same drug class • Only indicates if drug classes are present

The Ameritox - Valor Healthcare Quality Improvement Initiative

With the RxGuardian tool in hand, Ameritox teamed up with Valor Healthcare in October, 2015, to launch a quality improvement initiative, using Valor's two Community-based Outpatient Clinics (CBOCs) as beta sites. Under this initiative, RxGuardian was deployed at these sites to determine whether these medical monitoring enhancements improved patient adherence, versus the existing urine screening tool.

The overall objective of the initiative was twofold:

1) to improve and encourage safety among patients prescribed opioid medications for chronic pain conditions, and
2) to provide physicians with greater insight into the adherence of chronic opioid therapy medication.

To support these goals, we established a clinically validated protocol for monitoring the success of the program and quantifying the benefits of using RxGuardian.

Putting RxGuardian to the Test

The initiative was executed by Valor Healthcare physicians in Denton, Texas and Sherman, Texas, both CBOCs within Veteran Integrated Service Network (VISN) 17. Six physicians at the Denton facility and three at the Sherman facility oversaw the testing, with 180 and 64 patients, respectively, included in the initiative.

To qualify for the initiative, patients had to be older than 21 years of age and receiving care within the Concentra North Texas CBOC system for the six months prior to their index specimen date. The patients also had to be receiving routine or as-needed opioid (schedule II) medication for non-malignant pain for at least three months prior to their participation in the initiative.

Since routine drug screening is standard procedure within the clinics, the patients did not need to be pre-selected or recruited. However, the patients were notified that the clinic was testing an alternative urine drug medication monitoring system as part of an initiative to improve safe use of medications.

The initiative began with each qualifying patient submitting a sample to be assessed by both the existing CBOC drug screen and the RxGuardian medication monitoring technology. This trial was conducted over Y months, providing a total of Y samples, or Z per individual, on average.

Cumulative reports on adherence prior to the initiative formed the baseline for the study. The researchers then recorded and calculated the percentage change in each patient's adherence before and after the start date. A patient was considered adherent to their regimen if their opioid levels were

within the prescribed range and there was no evidence of non-prescribed substances. A patient was considered non-adherent if there was evidence that their opioid levels were outside their prescribed range, and / or there was evidence of non-prescribed substances.

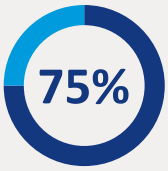
ADHERENCE	**Patient correctly taking medicine, and no other substances**
NON-ADHERENCE	Patient not correctly taking medicine, and is not taking other substances
NON- ADHERENCE	Patient is correctly taking medicine, and is taking other non-prescribed substances
NON-ADHERENCE	Patient is not correctly taking medicine, and is taking other non-prescribed substances

Results of the Study

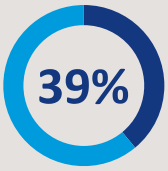
In reviewing the RxGuardian reports, we found that variance from the intended prescription regimens was striking, with 75% of all the patients found to be non-adherent. 39% of the subjects tested negative for their prescribed medication, 25.5% were positive for non-prescribed medications, 25% were adherent to their regimen, 8% were found to be taking their prescribed drug outside the prescribed range, and 2.5% of patients tested positive for illicit substances. We also found that RxGuardian generated results that differed from the default conclusions of the old monitoring system 12% of the time.

Armed with this rich information, physicians were able to intervene and impact patient behavior, resulting in an adherence improvement rate of 60% for the patients that had a non-compliant first sample.

Quality improvement initiative included 9 physicians, 2 locations (Denton and Sherman, Texas), 124 patients.

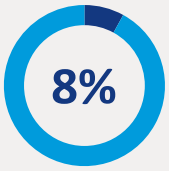


Patients non-adherent to their prescription regimen



Patients were not taking their prescription

Patients not taking their prescription



of patients had evidence of ranges outside of prescription level

Patients with drug levels outside prescribed range



Patients taking illicit substances

Patients taking illicit substances

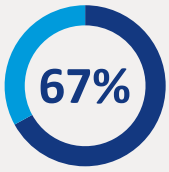
Because of the initiative, the participating Valor Healthcare locations were able to adhere closely and easily to VA guidelines on the treatment of chronic pain with opioids. The VA guidelines indicate that

long-acting opioids should not be started with patients who are opioid-naive, lowest doses should be used, and doses should be at or below the morphine equivalent daily dose (MEDD) of 90.[11] After using RxGuardian, these Valor Healthcare CBOC facilities were able to decrease the average MEDD of patients by 10%, exceeding VA expectations for reduced opioid dependence.

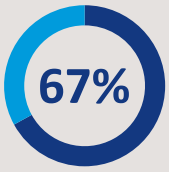
Armed with this rich information, physicians were able to intervene and impact patient behavior, resulting in an adherence improvement rate of 60% for the patients that had a non-compliant first sample.

Physician Responses

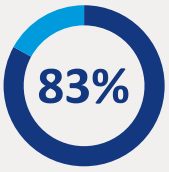
As part of the initiative, we conducted a physician survey on their experience with RxGuardian. Physicians responses exhibited strong support for making the switch to RxGuardian. 83% of physicians said that RxGuardian enabled them to better manage patients undergoing COT. 67% of physicians strongly agreed that they would recommend Ameritox medication monitoring to a colleague, and 67% strongly agreed that compared to the current CBOC screening tool, RxGuardian allowed physicians to feel more comfortable in assessing medication adherence.



of physicians strongly agree that they would recommend Ameritox medication monitoring to a colleague



of physicians strongly agree that compared to current CBOC screening tool, RxGuardian allows physicians to feel more comfortable assessing medication adherence



of physicians say they were better enabled to manage veterans undergoing COT with RxGuardian

The initiative demonstrated success in increasing physicians' abilities to more closely monitor patient adherence. RxGuardian allowed physicians to categorize patients in more detail, according to adherence and enabled them to understand if non-prescribed opioids were being used. With RxGuardian, cases in which there was potential for negative reactions were discovered, and previously undisclosed prescriptions from other physicians were brought to light.

The potential dangers of mixing opioids were reduced under RxGuardian medication monitoring. Many non-prescribed medications used by patients studied in the initiative may cause adverse reactions when combined with prescribed opioids. These include opiates, sedatives hypnotics, benzodiazepine, NPM, gabapentin, synthetic opioids, and oxycodone/morphone. Without a monitoring tool capable of analyzing and differentiating between substances, the dangers of these combinations go unaddressed. With RxGuardian, physicians felt better equipped to make informed decisions about their COT patients and decrease the potential for these negative reactions to occur.

In summary, the use of RxGuardian by the Valor Healthcare facilities met the initiative goals of enhancing safety among patients prescribed opioid medications for chronic pain conditions, and providing physicians with greater insight into the adherence of chronic opioid therapy medication. Physicians were able to realize improved patient adherence to clinic COT and, thereby, reduced rates of opioid abuse.

Some representative comments from physicians who participated in the initiative:

> *"The Ameritox drug screen provides objective data in an arena where important prescribing decisions are being made with limited, subjective information."*
>
> *"Ameritox testing has been most useful in guiding dosing and quantity decisions in this difficult era of an 'opioid epidemic'."*
>
> *"In my VA practice, where primary care providers are made primarily responsible for chronic pain patients, this test has given us an objective basis to make decisions more comfortably, appropriately, accurately, and safely."*
>
> *"There have been many "eye-openers" where patient noncompliance would have passed undetected with current, routine urine drug screen, (items such as):*
> - *Quantity requested/prescribed per month.*
> - *Patient on regular hydrocodone found to also be taking oxycodone prescribed by private physician.*
> - *Prescription methadone user with urine drug levels well outside expected mean."*

Cost Savings From Increased Adherence

Using traditional urine screens, physicians often continue prescribing COT medications to a non-adherent patient because they are unaware of the patient's non-compliance. Perhaps the patient is taking a non-prescribed or illicit substance. The physician just sees that opioids are present, and assumes that these are prescribed opioids. With RxGuardian, the distinctions are evident, and facilities can realize cost savings from not writing duplicative prescriptions.

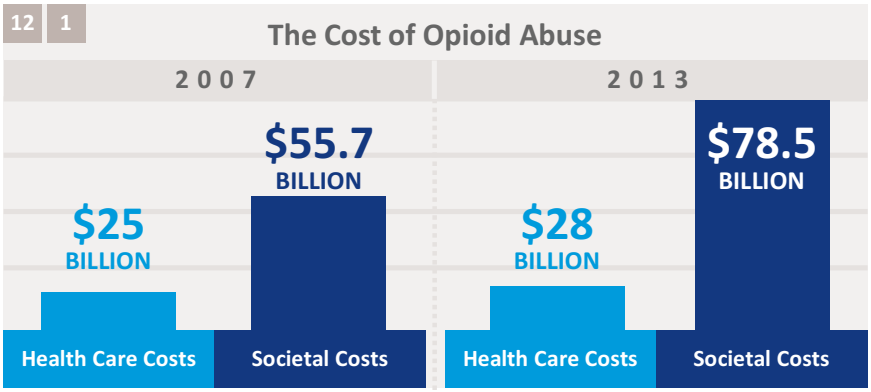
RxGuardian shifts much of the focus and resources away from *treatment* of addiction, toward the *prevention* end of the spectrum. Between overdose risks, lengthened hospital stays, medical side effects and the myriad destructive behaviors that accompany addiction, the costs of treatment exceed the costs of prevention many times over.

Few who pursue leadership in healthcare are concerned solely with the costs to their own facility. We are not immune to the frequent reminders that opioid abuse is a significant cost for a broad swath of American society.

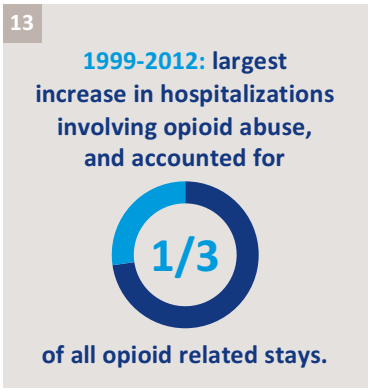
Through the abundance of specific information Rx Guardian generates for you to evaluate and share with patients, patients become less likely to abuse opioids. Further, you are in a strong position to move the needle to an "only as-needed" basis and manage a weaning off process based on concrete evidence. This translates into short- and long-term cost savings to your clinic. The historical data from many patients over time also enhances the collective judgment of clinic personnel and drives the development of better preventative measures.

Few who pursue leadership in healthcare are concerned solely with the costs to their own facility. We are not immune to the frequent reminders that opioid abuse is a significant cost for a broad swath of American society. From congested prison cells, lost workdays and premature death[12] to an unmanageable demand on our mental health resources, the menace of opioid abuse imposes financial and emotional hardships our increasingly fractured nation can ill afford. RxGuardian is a tool for broad improvements in pain management and patient counseling that has the potential to substantially impact these numbers.

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RxGuardian as Standard CBOC Protocol

Based on the promising results of the quality improvement initiative, Valor Healthcare and Ameritox will continue the partnership and extend RxGuardian to other Valor Healthcare CBOCs, VA medical centers, and VISNs. Widespread use in veteran treatment facilities provides the VA with a better chance to counteract the opioid epidemic plaguing veterans, civilians and their families across America. Since the initiative was designed within current Valor Healthcare facilities, the implementation of RxGuardian into other Valor Healthcare CBOCs can be rapidly achieved.

We recognize that to gain approval, clinics must make the case for RxGuardian. Through this paper, we have provided you with our study results for use in your proposal and are happy to supply any detailed study information you might need. The long-term benefits to VA medical centers, VA Primary Care Physicians, patients and their families are clear. In short, more information and better differentiated information make for better decisions and better outcomes.

Ameritox has been financially responsible for the RxGuardian screens that have been used as part of the initiative. Similarly, Valor Healthcare has been responsible for the protocols and management of the

quality initiative. It is our hope is that VA medical centers will take financial responsibility for implementing RxGuardian within their own healthcare systems, as well as manage the program oversight within the CBOCs and treatment facilities under their operation.

Valor Healthcare created a urine drug screen workflow (Appendix B) outlining procedures and protocols related to the initiative. Similar workflows can be used in other VA medical centers to quickly develop successful RxGuardian programs. These processes work to ensure a compliant urine drug screening process, and establish qualifications and standards for testing.

> ***"In my VA practice, where primary care providers are made primarily responsible for chronic pain patients, this test has given us an objective basis to make decisions more comfortably, appropriately, accurately, and safely."***
>
> *– Valor Healthcare Physician*

Answering the Call for Those Who Fought for Us

The need to stem the opioid epidemic among veterans and within the rest of the populace has never been more pressing. RxGuardian provides immediate opportunities for greater adherence monitoring within VA medical centers, and instills confidence in VA PCPs tasked with administering prescriptions for COT. RxGuardian promises a brighter future for patients in chronic pain, by arming care providers with superior tools for assuring successful COT.

With the opioid epidemic a high-visibility topic in the media and in Washington, the nation looks to Veterans Administration to take proactive steps for remedies. Instituting an accurate and actionable urine drug screening monitoring system within the VA medical center network signals a strong commitment to end opioid abuse and help heal the lives of injured veterans and their families.

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Appendix

Appendix A:
Chronic Opioid Therapy Quality Improvement Initiative Data Collection Tool

Baseline Patient Characteristics:

Patient name: _____
Patient medical record number: _____
Age:_____
Gender:_____
Primary diagnosis: _____
Secondary diagnosis (Maximum 2): _____
First Date Enrolled to Receive Care at the North Texas CBOC (years):

Required Data Collection (6 Months Before Index Specimen Date [t = 0])

Continuous release (CR) (every 8 to 12 hour dosing) opioid use only (yes/no):
Immediate release (IR) (every 3, 4, or 6 hours dosing) opioid use only (yes/no):
Simultaneous use of CR and IR opioid (yes/no):
Number of positive drug screens for prescribed opioid:
Number of negative drug screens for prescribed opioid:
Number of positive drug screens for illicit:
Number of positive drug screens for non-prescribed medication:
Primary site location (Sherman/Denton/both): _____
Number of different physicians prescribing opioid for patient:
Did patient opioid medication management change? (yes/no)
Type of change (check all that apply)

- □ Discontinue treatment because chronic opioid management is no longer considered medical necessary
- □ Discontinue opioid because alternative pain management strategy implemented
- □ Discontinue opioid because of concern of misuse and/or abuse
- □ Prescribe alternative opioid
- □ Increase dose of opioid
- □ Lower dose of opioid

3) Three-month Post-index Date Data Collection

Continuous release (CR) (every 8 to 12 hour dosing) opioid use only (yes/no):
Immediate release (IR) (every 3, 4, or 6 hours dosing) opioid use only (yes/no):
Simultaneous use of CR and IR opioid (yes/no):
Number of positive drug screens for prescribed opioid:
Number of negative drug screens for prescribed opioid:
Number of positive drug screens for illicit substance:
Number of positive drug screens for non-prescribed medication:
Primary site location (Sherman/Denton/both):_____
Number of different physician's prescribing opioid for patient
Did patient opioid medication management change? (yes/no)
Type of change (check all that apply):

- □ Discontinue treatment because chronic opioid management is no longer considered medical necessary
- □ Discontinue opioid because alternative pain management strategy implemented
- □ Discontinue opioid because of concern of misuse and/or abuse
- □ Short-term (less than 3 months) discontinuation of opioid
- □ Prescribe alternative opioid
  If yes, how many switches occurred over the past 3 months?
- □ Same opioid prescribed throughout but changes in dosing (higher/lower):
  If yes, how many dosing changes occurred over the past 3 months?
- □ Lower dose of opioid
- □ Other:_____

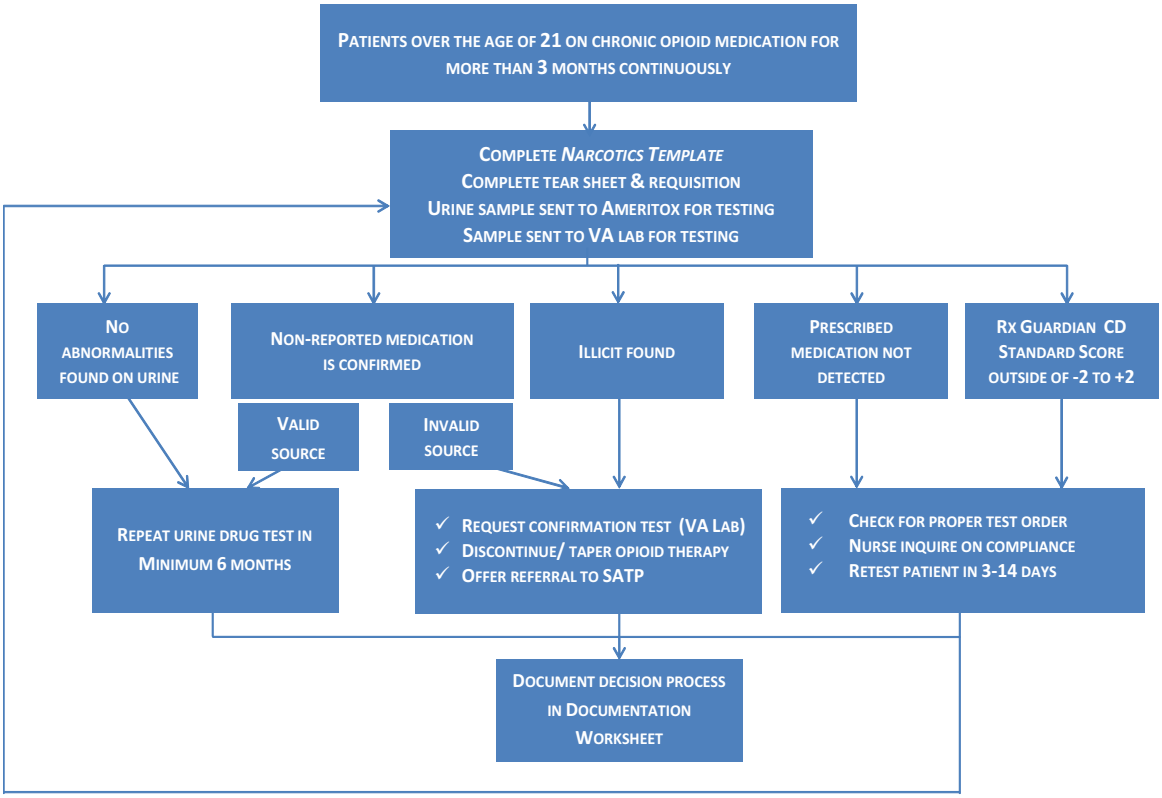
Final Data Collection (Assess 6 Months Post-index Date)

Continuous release (CR) (every 8 to 12 hour dosing) opioid use only (yes/no):
Immediate release (IR) (every 3, 4, or 6 hours dosing) opioid use only (yes/no):
Simultaneous use of CR and IR opioid (yes/no):
Number of positive drug screens for prescribed opioid:
Number of negative drug screens for prescribed opioid:
Number of positive drug screens for illicit substance:
Number of positive drug screens for non-prescribed medication:
Primary site location (Sherman/Denton/both): _____
Number of different physicians prescribing opioid for patient:
Did patient opioid medication management change? (yes/no)
Type of change (check all that apply)

- □ Discontinue treatment because chronic opioid management is no longer considered medical necessary
- □ Discontinue opioid because alternative pain management strategy implemented
- □ Discontinue opioid because of concern of misuse and/or abuse
- □ Short-term (less than 3 months) discontinuation of opioid
- □ Prescribe alternative opioid
  If yes, how many switches occurred over the past 6 months?
- □ Same opioid prescribed throughout but changes in dosing (higher/lower)
  If yes, how many dosing changes occurred over the 6 months?

Other:_____

Appendix B:
Urine Drug Screen Workflow



Testing to include screening for benzodiazepines and Soma® (Carisoprodol), which are commonly used with opioids