



For Those Who Fought for Us.

## Fighting Opioid Dependency



## Ameritox and Valor Healthcare

**Ameritox** delivers data-driven medication monitoring solutions to clinicians who treat patients suffering from chronic pain and/or severe mental illness. Ameritox offers laboratory services and practice management tools to help clinicians coordinate and optimize patient care. The company's mission is to improve patient outcomes while preventing human tragedy.

**Valor Healthcare** is the largest provider of contract Community Based Outpatient Clinic (CBOC) services to the U.S. Department of Veterans Affairs (VA), and is the only CBOC contractor with independent Joint Commission blanket accreditation for Ambulatory Care and PCMH (PACT) certification. In total, Valor Healthcare provides medical care to 122,000 veterans annually within 33 CBOC facilities. Of those patients treated by Valor Healthcare, 6% are currently undergoing Chronic Opioid Therapy (COT), totaling about 7,300 patients.

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



### Executive Summary

Pressure from the media and the populace is mounting for legislators, local leaders, the military and the 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.

For patients being treated for chronic pain or a severe mental illness, clinic physicians may perform a basic urine drug screening to monitor patient adherence to their prescription regimen. Common methods for drug screening have limitations in that they detect the presence or absence of opioids, but do not distinguish between individual types of drugs, nor do they detect quantities to a meaningful degree. This may cause difficulty for physicians to determine if a patient has duplicate opiate prescriptions or is consuming dangerous levels of a drug or combination of drugs.

Ameritox tackled this deficit in adherence monitoring in two parts: First, with confirmation testing (i.e., LC/MSMS) performed in an industry-leading lab that boasts a .02 percent error rate, compared with .05 percent error rate typical of other testing labs. This testing is sensitive enough to detect minute quantities of natural, synthetic, and semisynthetic opiates, including hydrocodone, naloxone, and buprenorphine, respectively. Second, Ameritox offered added knowledge with RxGuardian, a reference database of samples from patients who have been clinically assessed as adherent to their prescription medication

regimens. RxGuardian can improve upon existing urine screens by offering clinicians a baseline of medication adherence to compare their patients' urine test results against.

In 2015, Ameritox joined with Valor Healthcare, launching an initiative to provide VA clinic physicians with this tool to help them evaluate patients' medication adherence and establish safer opioid prescribing practices. This paper describes the use of LC/MSMS confirmatory testing and RxGuardian data analysis by VA clinicians in Valor Healthcare veteran treatment facilities. LC/MSMS confirmation results combined with RxGuardian data analysis generated results that differed from the conclusions of the existing monitoring system 12% of the time.

*RxGuardian can improve upon existing urine screens by offering clinicians a baseline of medication adherence to compare their patients' urine test results against.*

Based on the successes of the initiative, Ameritox and Valor Healthcare are poised to offer urine drug testing and RxGuardian to the other 31 CBOCs as well as civilian laboratories and clinics.

## Background

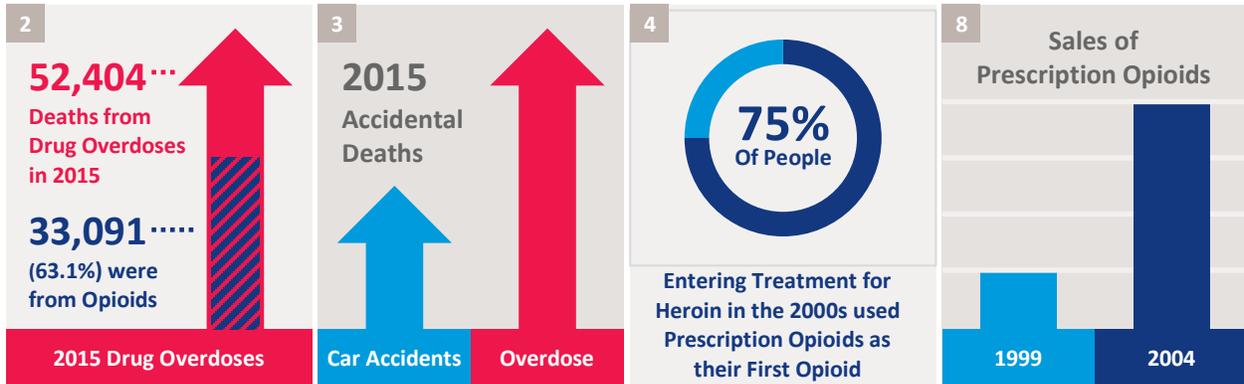
### The Scale of the Epidemic

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.<sup>1</sup>

The consequences of opioid misuse are significant. In 2015, drug overdose in the U.S. accounted for 52,404 deaths, with 33,091 (63.1%) of these involving an opioid.<sup>2</sup> More deaths resulted from all drug overdoses than from either car accidents or gun-related violence.<sup>3</sup> 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.<sup>4</sup> The National Academy of Medicine estimates that in 2011 about 1 in 3 Americans were affected by chronic pain.<sup>5</sup>

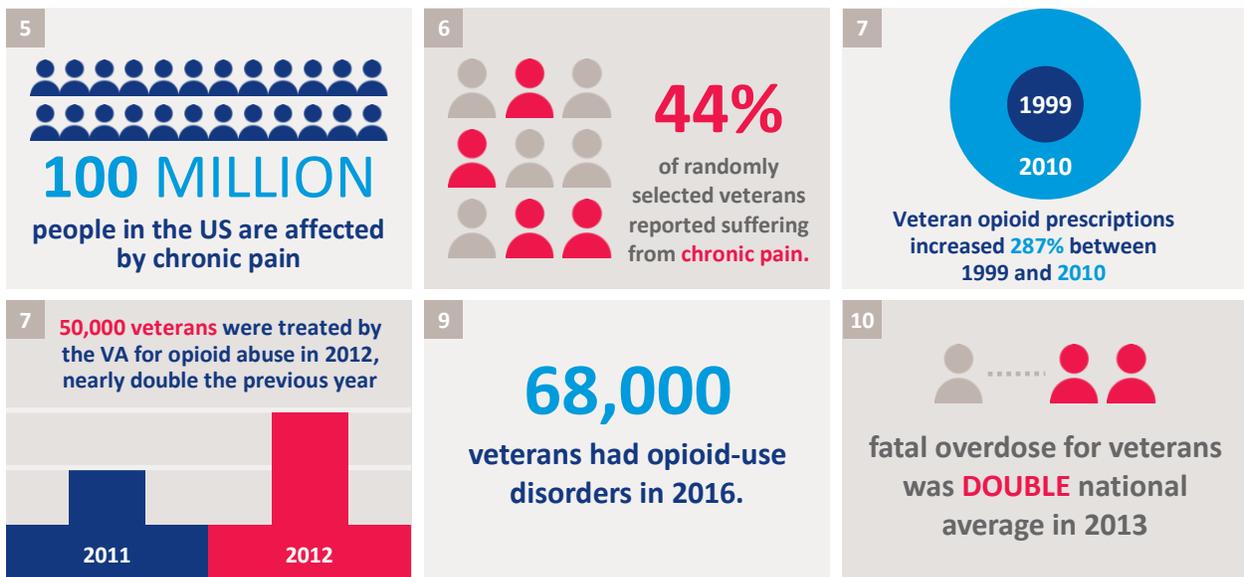
### Our strongest are also our most vulnerable

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



In 2012, over 50,000 veterans were treated by the VA for serious problems associated with opioid abuse, nearly double the number from the previous decade.<sup>7</sup> This number has increased to 68,000 veterans in 2016.<sup>9</sup> Additionally, the fatal overdose rate among veterans was nearly double the national average in 2013.<sup>10</sup>

It is daunting to try and unravel the many factors that contribute to chronic pain among civilians. However, there is greater visibility into what initiates the cycle of pain and pain medication for our veterans, even though questions of what is a physical versus emotional wound still confound treatment plans. Prolonged deployments, guerilla 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 COT

One of the biggest challenges with current COT adherence monitoring is the inherent shortcomings of enzyme immunoassay EIA screenings themselves. These widely used basic 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 accurately 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 decisions about patients receiving COT.

### The RxGuardian Difference

In 2011, using a quantitative medication monitoring confirmation technology, Ameritox introduced a data analysis system to help address these limitations. The resulting product, RxGuardian, provides physicians with enhanced data on likely prescription adherence. The RxGuardian data analysis provides a normalized and transformed database of likely adherent patients which can be used to assess the probable adherence of any given patient test result. Thus clinicians can feel confident not only in the identity of the drug in question, but in the consistency of that test result with the RxGuardian database population.

Unlike other urine screening systems, LC/MSMS confirmation can differentiate between drugs of the same drug class, and analyze drug levels as low as parts per billion (ng/mL, or PPB). Confirmation testing is able to 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, physicians can have much more specific information to help them assess if the patient is adherent to their prescribed medication(s) or using illicit or other non-prescribed substances within the same drug class.

Confirmation LC/MSMS technology is quantitative versus the qualitative results determined with EIA. A quantitative confirmation technology provides highly accurate readings of the levels of substances and medications in the urine sample. In contrast, CBOCs employ qualitative EIA screening, which only indicates if a drug class -- opioids in this case -- is present. It neither differentiates between substances within the same drug type, nor provides accurate data about drug levels. Within the Valor Healthcare veteran treatment facilities, LC/MSMS confirmation results combined with RxGuardian data analysis generated results that differed from the conclusions of the existing monitoring system 12% of the time.

*In our studies, LC/MSMS confirmation results combined with RxGuardian data analysis generated results that differed from the conclusions of the existing monitoring system 12% of the time.*

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

### RxGuardian Advantages

LC/MSMS, RxGuardian	Enzyme Immunoassay 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 Clinic Initiative

With the RxGuardian confirmation tool in hand, Ameritox teamed up with Valor Healthcare in October, 2015, to launch the clinic initiative, using two of Valor's CBOCs as beta sites. Under this initiative, RxGuardian confirmation testing and enhanced data analysis methodologies were deployed at these sites to determine whether these medical monitoring enhancements could improve 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, a validated clinical protocol was developed by Valor Healthcare, defining the initiative's design, patient qualifications, evaluation methods, and data analysis.

### 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 21 years of age or older, and receiving care within the VA 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.

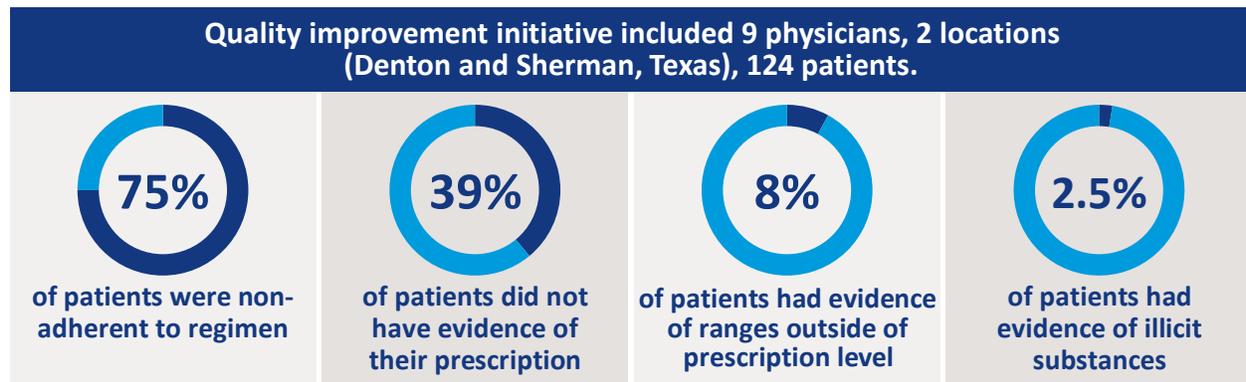


<b>ADHERENCE</b>	<b>Patient correctly taking medicine, and no other substances</b>
<b>NON-ADHERENCE</b>	Patient not correctly taking medicine, and is not taking other substances
<b>NON-ADHERENCE</b>	Patient is correctly taking medicine, and is taking other non-prescribed substances
<b>NON-ADHERENCE</b>	Patient is not correctly taking medicine, and is taking other non-prescribed substances

Cumulative reports on patient adherence prior to the initiative formed the baseline for the initiative. The clinic staff 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 his/her 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 his/her opioid levels were outside the prescribed range, and/or there was evidence of non-prescribed substances.

## Results of the Initiative

From the baseline tests, the clinic staff found that variance from the intended prescription regimens was striking, with 75% of all the patients found to be non-adherent. Of the non-adherent patients, 39% of 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.



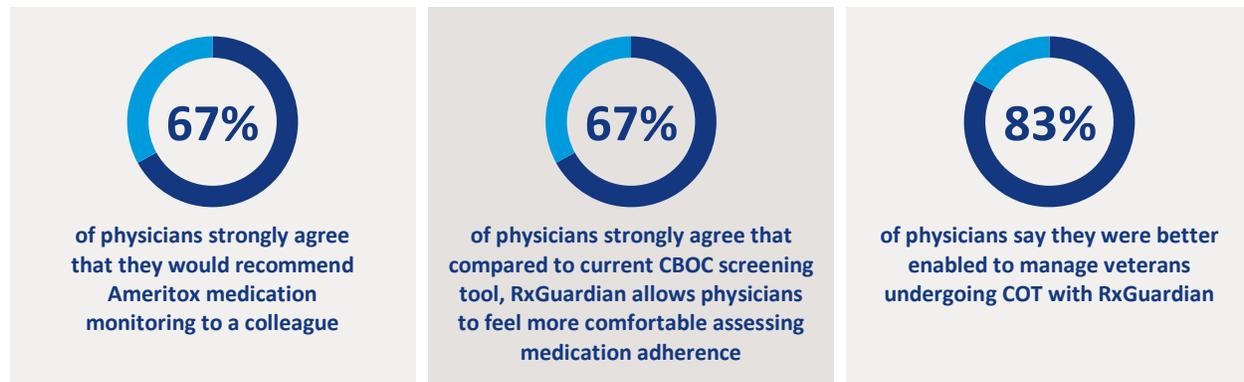
Armed with this information, physicians were able to intervene and impact patient behavior, resulting in a prescription adherence improvement rate of 60% for the patients that had a non-compliant first sample.

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, the lowest doses should be used, and doses should be at or below the morphine equivalent daily dose (MEDD) of 90.<sup>11</sup> After using RxGuardian confirmation testing, 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 a prescription adherence improvement rate of 60% for the patients that had a non-compliant first sample.***

### Physician Responses

As part of the initiative, a physician survey was conducted to gauge their opinions on RxGuardian. Physician responses displayed support for making the switch to RxGuardian. 83% of physicians said that they were better able to manage patients undergoing COT with RxGuardian. 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 EIA screening tool, RxGuardian confirmation testing allowed physicians to feel more comfortable in assessing medication adherence.



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 Ameritox medication monitoring program provides objective data in an arena where important prescribing decisions are being made with limited, subjective information.” – Valor Healthcare Physician***

The potential dangers of mixing opioids were reduced under RxGuardian medication monitoring starting with LC/MSMS confirmation testing. Many non-prescribed medications used by patients studied in the initiative may cause adverse reactions when combined with prescribed opioids. These include other opiates, sedatives, hypnotics, benzodiazepines, gabapentin, synthetic opioids, and oxycodone/morphine. Without a monitoring tool capable of analyzing and differentiating between substances, the dangers of these combinations go unrecognized and unaddressed. With RxGuardian confirmation testing, 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 confirmation and LC/MSMS testing 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 COT medication. Physicians were able to realize improved patient adherence to prescribed COT and thereby reduce 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

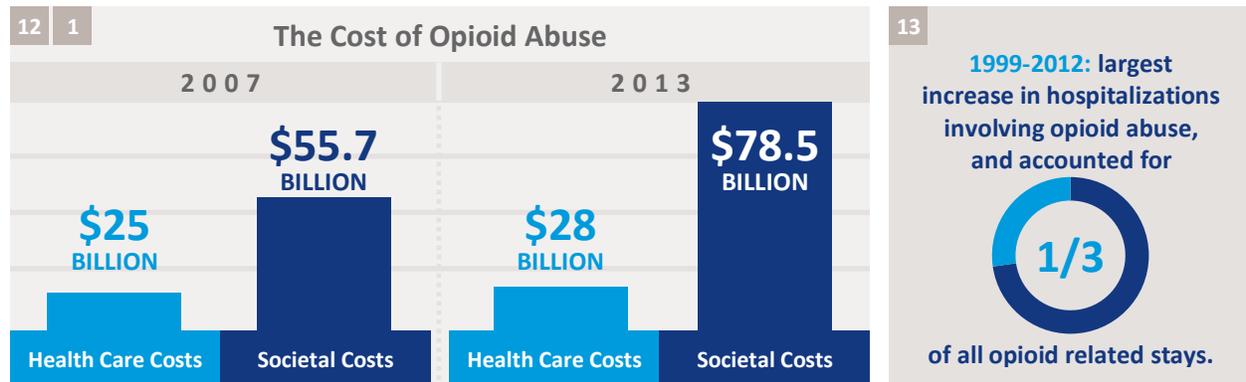
Using traditional, basic urine EIA screens, physicians may continue prescribing COT medications to a non-adherent patient because they are unaware of the patient’s non-compliance. The same is true if a patient is taking non-prescribed or illicit substances. The physician just sees that opioids are present and assumes that these are prescribed opioids. But with LC/MSMS confirmation testing combined with RxGuardian data analysis, the distinctions are evident and facilities can realize cost savings from not writing these 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 RxGuardian generates for clinicians to evaluate and share with patients, patients become less likely to abuse opioids. Further, clinicians are in a stronger position to move the needle to an "only as-needed" basis and/or manage the weaning off process based on concrete evidence. This translates into short- and long-term cost savings to clinics. 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 court dockets and prison cells, to lost workdays, premature death<sup>12</sup> and a demand on our mental health resources that we are far from prepared to handle, 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.



## RxGuardian Expansion

### Rollout to other clinics

Based on the promising results of the clinic initiative, Valor Healthcare and Ameritox propose to continue the partnership and provide the confirmation testing/data analysis to other Valor Healthcare CBOCs, VA medical centers, and VISNs. Results of the clinical improvement initiative were presented to Dr. Carolyn

Clancy, Deputy Undersecretary for Health Organizational Excellence at the VA, and she was eager to see the initiative expanded to all 33 Valor CBOCs. Expanding to other veteran treatment facilities provides the VA with an even 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 Valor Healthcare CBOCs can be rapidly achieved.

For this to occur, however, we recognize that clinics must undertake an administrative and financial approval process. Through this paper, we have provided you with our study results for use in your proposal and are happy to supply 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 testing results that have been used as part of the current beta test clinic initiative. Similarly, Valor Healthcare has been responsible for the protocols and management of the quality initiative. It is our hope 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.

As part of the initiative, Valor Healthcare created a urine drug testing workflow (Appendix B) for 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.

## Summary and Conclusion

The need to stem the opioid epidemic among veterans and within the rest of the populace has never been more pressing. RxGuardian testing 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 equipping 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 the U.S. Department of Veterans Affairs 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 medically 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

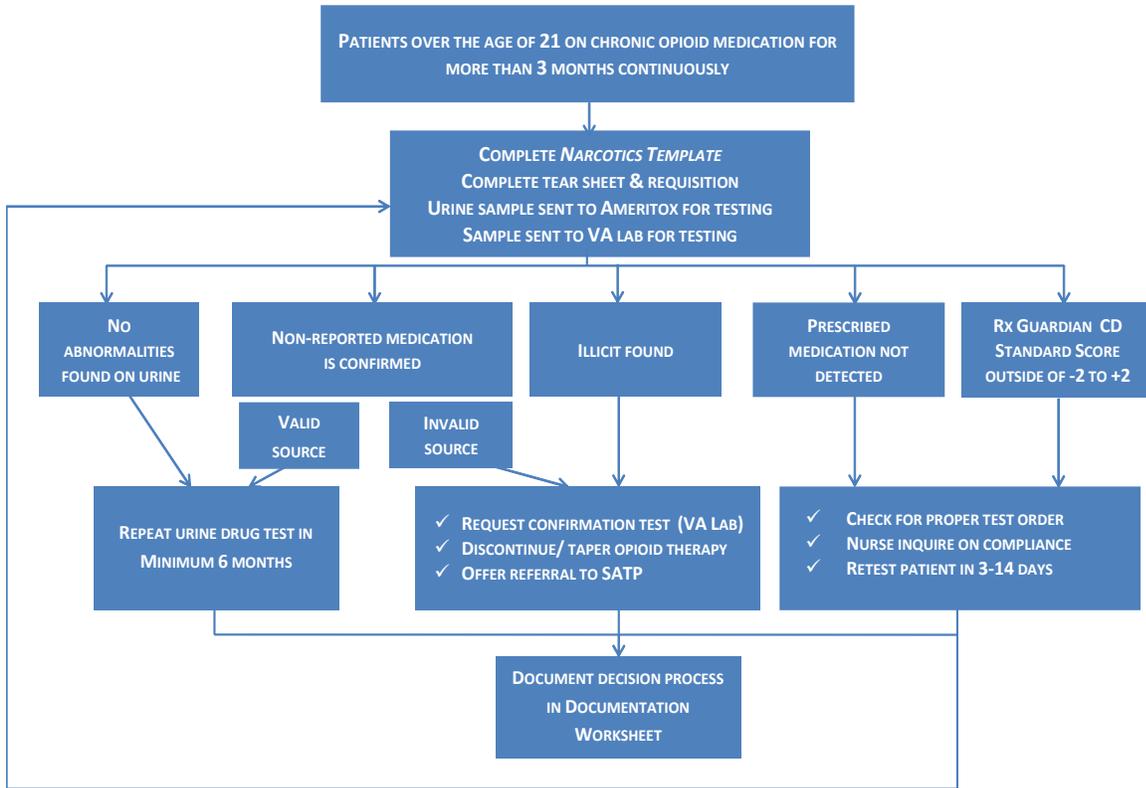
- Continuous release (CR) (every 8 to 12 hour dosing) opioid use only (yes/no):
- Immediate release (IR) (every 3, 4, or 6 hours dosing) opioid use only (yes/no):
- Simultaneous use of CR and IR opioid (yes/no):
- Number of positive drug screens for prescribed opioid:
- Number of negative drug screens 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 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 medically 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 medically 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