



toxicology benefit
management

TBM™

a clinical tool to reduce costs
and liability, minimize waste, and
improve patient outcomes

executive summary

Financial, societal, and potential liability costs of prescription drug abuse, misuse, and diversion have grown significantly over the past two decades, along with the number of prescriptions for opioids and benzodiazepines. This document provides:

- Statistics and trends on prescription drug abuse, misuse, and diversion
- Background information on clinical laboratory drug testing as a means to reduce drug abuse, misuse, and diversion and minimize waste
- Information on a Toxicology Benefit Management (TBM) solution to effectively engage payers and PBMs in managing the clinical drug testing benefit to reduce healthcare costs and liability, minimize waste, decrease fraud and abuse in the clinical drug testing marketplace, and improve patient outcomes

background

financial costs of prescription drug abuse, misuse, and diversion

Health economists from Johns Hopkins University writing in *The Journal of Pain* reported that the annual cost of chronic pain is as high as \$635 billion a year, which is more than the yearly costs for cancer, heart disease, and diabetes.¹ Based on their analysis of the data, the authors determined that the total cost for pain in the United States ranged from \$560 to \$635 billion. Total incremental costs of healthcare due to pain ranged from \$261 to \$300 billion, and the value of lost productivity ranged from \$299 to \$334 billion.¹

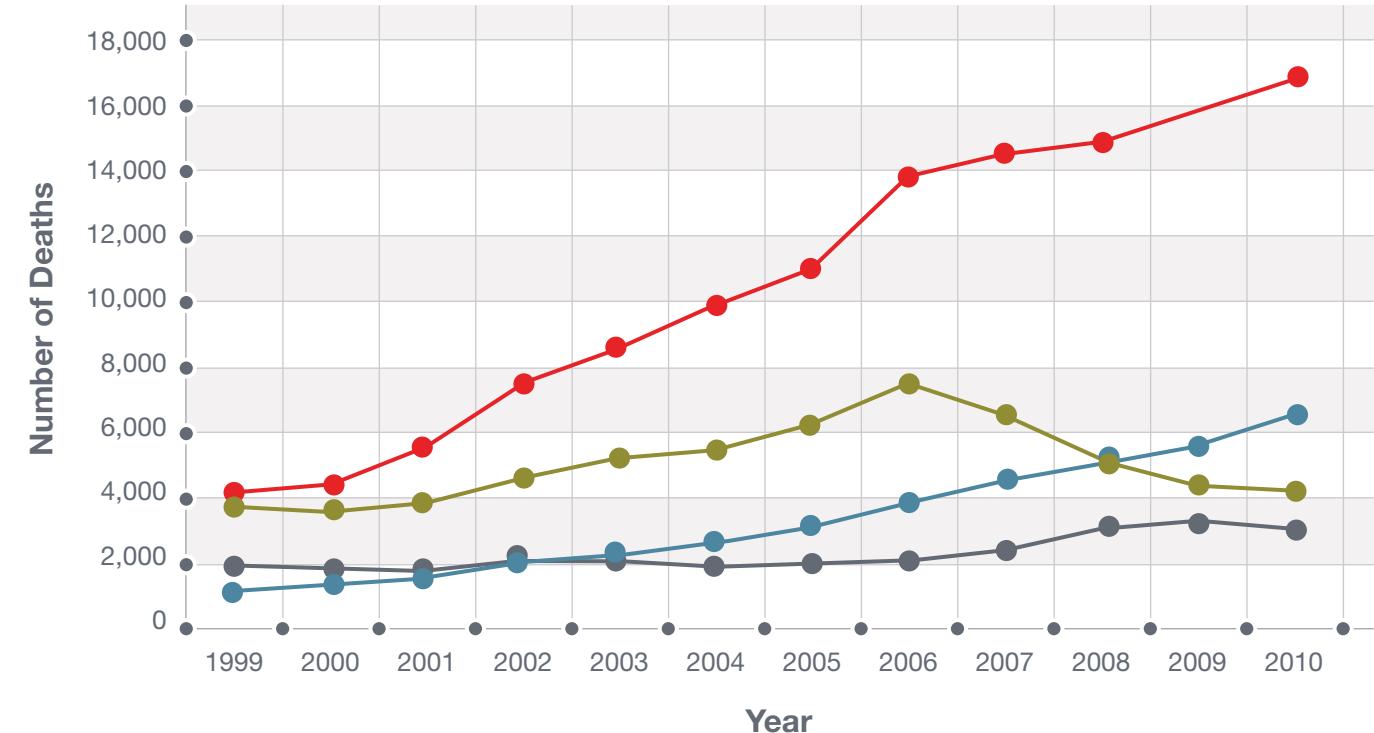
According to the *Insight Series* (December 2007) from the Coalition Against Insurance Fraud (CAIF) – a national alliance of consumer groups, insurance companies, and government agencies – the economic consequences of prescription drug abuse are substantial.² It is estimated that opioid analgesic abuse results in over \$72 billion in medical costs each year.² Other, more conservative studies estimate the cost of opioid abuse to be \$53-56 billion annually, accounting for medical and substance abuse treatment costs, lost work productivity, and criminal justice costs.^{3,4}

The same CAIF publication states that doctor shopping by addicted health plan members is the biggest form of drug diversion and takes the largest financial toll on payers.² There are several specific types of drug diversion, but, in general, the term comes from the definition of the “diverting” of drugs from their original purpose. Almost half of Aetna Inc.’s 1,075 member fraud cases in 2006, for example, involved prescription benefits. Most of those were doctor-shopping cases.² According to another study by WellPoint, Inc. – the nation’s largest publicly traded commercial health insurer – \$41 was paid in related medical claims for every \$1 paid in narcotic prescriptions for suspected doctor-shopping plan members.² In a study in the July/August 2005 edition of *Journal of Managed Care Pharmacy*, patients “who were opioid abusers had healthcare costs that were more than eight times higher than those of non-abusers.”⁵ The total average per-patient direct healthcare payer cost for opioid abusers was \$15,884, compared with \$1,830 for non-abusers, a difference of \$14,054 per patient in 2003 dollars.⁵ Assuming an average 3.5% annual increase in medical cost inflation, that difference would be \$20,518 per patient in 2014 dollars.

Societal Costs of Prescription Drug Misuse and Diversion⁶

In 2012, of the 41,502 drug overdose deaths in the United States, 22,114 (53%) were related to pharmaceuticals; 16,007 (72%) involved opioid analgesics.⁶

Opioids Heroin
Cocaine Benzodiazepines



CDC/NCHS National Vital Statistics, CDC Wonder. Updated with 2010 mortality.

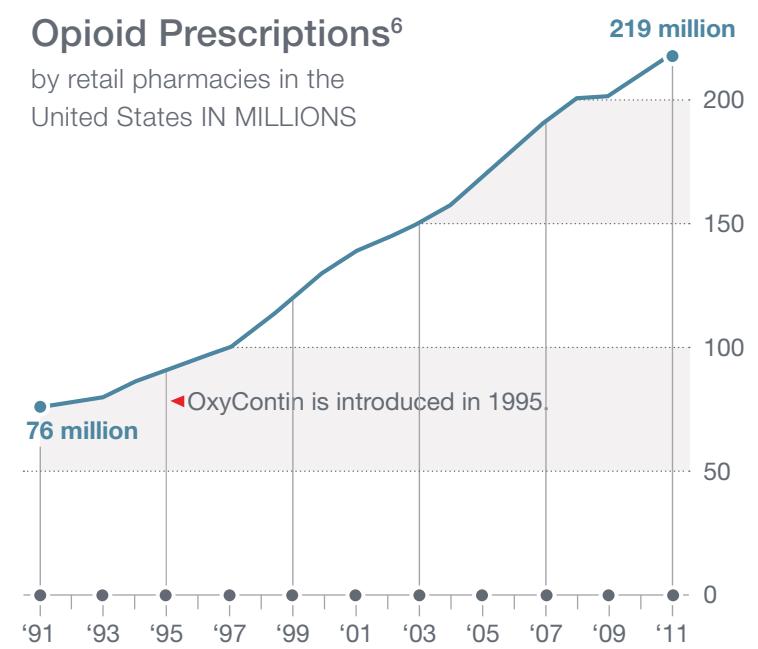
There is a strong correlation between the number of deaths from opioid use/abuse and the opioid prescription data from the past decade.⁶

In addition to concern over the increase in deaths from opioid prescriptions over the past decade, opioid abuse has also had a tremendous and increasing economic toll on the healthcare system in the form of emergency department visits.

Abusers were 12.2 times more likely to have had at least one hospital inpatient stay, and four times more likely to have had an ER visit.⁵ Opioid abusers average 18.7 physician for outpatient visits compared with seven for non abusers.⁵ Opioid abusers averaged 41.6 prescription drug claims each, compared with 13.8 for non-abusers.⁵

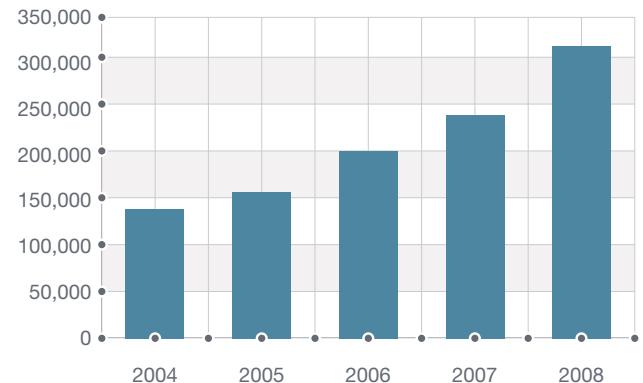
Opioid Prescriptions⁶

by retail pharmacies in the United States IN MILLIONS

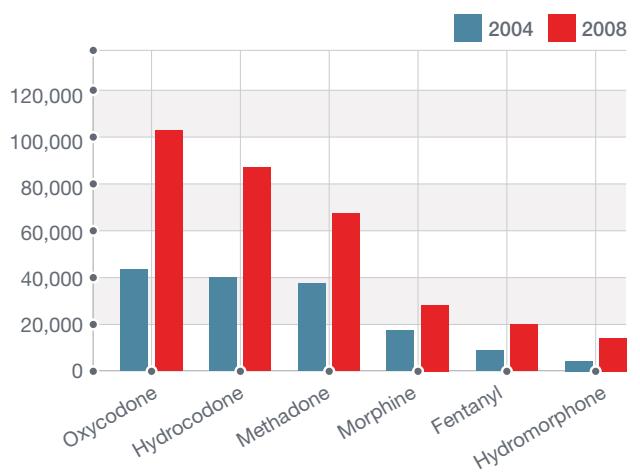


In 2011, about 1.4 million ER visits involved the non-medical use of pharmaceuticals. Among those ER visits, 501,207 visits were related to anti-anxiety and insomnia medications, and 420,040 visits were related to opioid analgesics.⁷

ER Visits Caused by Abuse of Narcotic Painkillers

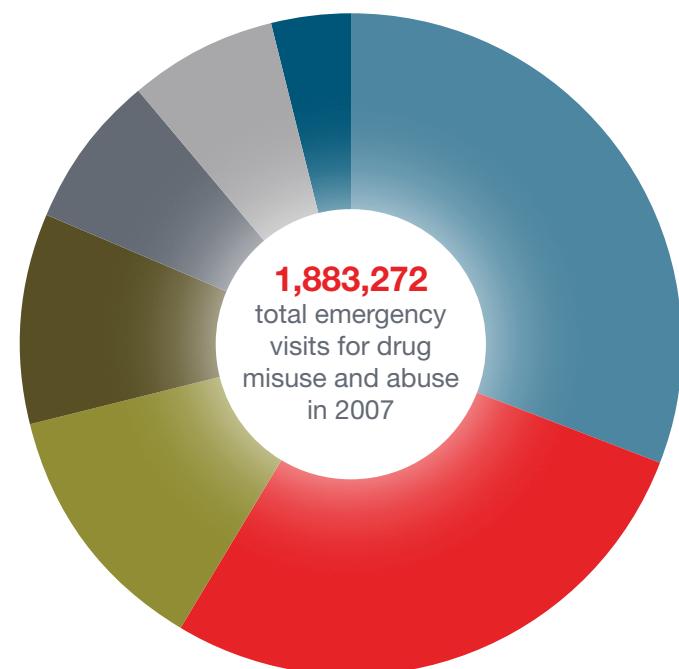


ER Visits Caused by Abuse of Certain Painkillers, 2004 - 2008



Emergency Room Visits Caused by Drug Misuse and Abuse in 2007, by Combination

- Nonmedical use of pharmaceuticals only (30.9%)
- Illicit drugs only (27.8%)
- Illicit drugs; alcohol (12.6%)
- Alcohol; nonmedical use of pharmaceuticals (10.1%)
- Illicit drugs; pharmaceuticals (7.6%)
- (Underage) Alcohol only (7.3%)
- Illicit drugs; alcohol; pharmaceuticals (3.7%)



insurer liability for prescription drug abuse, misuse, and diversion

It is clear that misuse and abuse of opioids in treating chronic pain are very costly to society and the healthcare system. What might not be as obvious is the potential liability that payers have for failing to reasonably prevent fraud schemes that kill and injure people from diverted prescription medications. According to the CAIF, private insurers could face a potentially enormous liability exposure from lawsuits by plan members and other victims who allege the insurer failed to detect diversion and forcefully act against it.²

The CAIF points out that insurers who passively pay claims without trying to forcefully uncover and curtail diversion could be found civilly liable if a plan member overdoses.² Liability also could arise from outside the plan if, for example, a truck driver high on prescription drugs kills or injures others in a crash.² The CAIF suggests that insurers should devote more attention to detecting suspicious activity in their prescription benefit plans, specifically:²

- Conduct ongoing data mining to identify schemes by prescribers, dispensers, and plan members
- Develop and implement protocols for comparing prescription and medical claims data

utility of clinical drug testing

When utilized appropriately, Clinical Drug Testing (CDT) – often referred to as Urine Drug Testing (UDT) prior to the wide acceptance of oral fluid (saliva) as a feasible specimen type for drug testing – is a valuable tool that many practitioners utilize to ensure their patients are taking the prescribed medications appropriately and to identify any concomitant use of detrimental substances. CDT is commonly used by physicians who prescribe opioids, in particular, due to their high potential for abuse, misuse, and diversion and the tremendous liability associated with prescribing Schedule II narcotics.

CDT can be extremely beneficial to health insurers for the same reasons. When implemented properly, a CDT solution can reduce a payer's cost, liability, and waste by minimizing the potential of abuse, misuse, and diversion of commonly abused prescription and illicit drugs covered by the health plan.

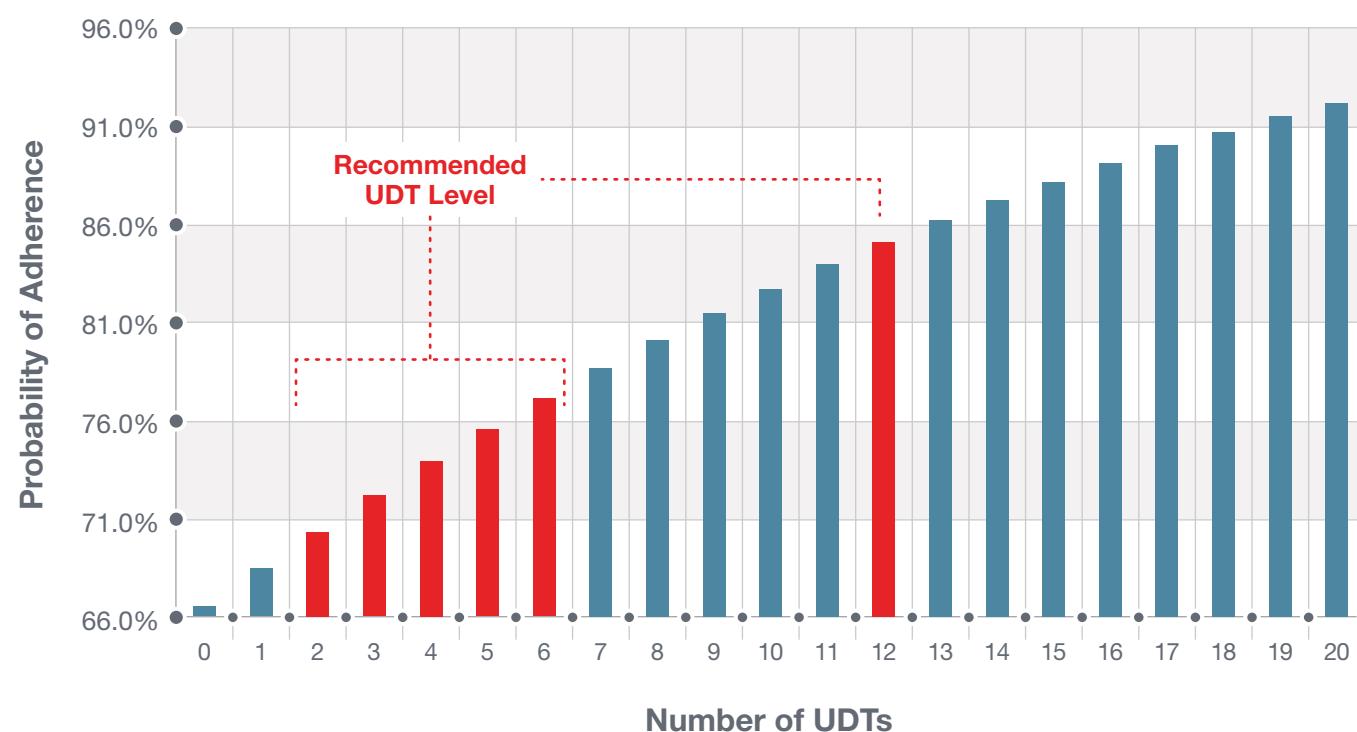
A study performed by Laffer Associates showed that the benefit/cost ratio of UDT is very high when comparing the relatively low cost of the service to the high cost of drug diversion and abuse.⁸

- A data set of 260K UDTs on individual patient IDs concluded that UDTs increased patient adherence.⁸
- Patients receiving 2 UDTs/year had a benefit/cost ratio of 2.5 to 4.3; those with 6 UDTs, 2.3 to 4.0; with 12 UDTs, 2.1 to 3.5.⁸
- In the pain population, this equates to \$7.4B to \$25.7B in aggregate benefits from 2 to 6 UDTs per year.⁸

Per Patient Annual Costs and Benefits of UDT

| Item | Costs (@ \$221 / \$363 per UDT) | | | Benefits | | |
|--------------------------------------------------------------------|---------------------------------|--------------------------|--------------------------|-------------------|-------------------|-------------------|
| | 2 UDT / Year | 6 UDT / Year | 12 UDT / Year | 2 UDT / Year | 6 UDT / Year | 12 UDT / Year |
| Subjective relief due to more effective treatment for chronic pain | \$422 / \$726 | \$1,266 / \$2,178 | \$2,532 / \$4,356 | \$651.17 | \$1,799.28 | \$3,153.02 |
| Extra productivity from more effective pain treatment | | | | \$290.00 | \$797.00 | \$1,399.02 |
| Reduced healthcare expenditures because of greater adherence | | | | \$428.57 | \$1,184.20 | \$2,075.17 |
| Reduction in total social costs from nonmedical use of opioids | | | | \$450.38 | \$1,266.16 | \$2,302.87 |
| TOTAL: | \$422 / \$726 | \$1,266 / \$2,178 | \$2,532 / \$4,356 | \$1,820.11 | \$5,046.63 | \$8,930.08 |

The Following Chart Illustrates the Correlation Between the Increased Number of UDTs Performed and the Probability of Adherence⁸



utilization of clinical drug testing

Although clinical drug testing can be a valuable tool to reduce drug abuse, misuse, and diversion, many practitioners often don't utilize CDT enough or implement a CDT solution at all. On the contrary, some practitioners may use CDT too often, which increases costs for medically unnecessary testing. Additionally, many CDT providers charge payers fees for their drug testing services that are substantially higher than the cost to perform said drug testing services; also, some of the tests may be redundant when the same tests are being performed at both the physician office and the reference laboratory.

Utilization of clinical drug testing by physicians can be financially driven in many cases. For physician offices that are lacking the financial means to sufficiently staff their clinic to maintain a well-managed clinical drug testing protocol, sufficient utilization of drug testing to curb drug abuse/misuse/diversion often doesn't occur. Conversely, some physician offices use clinical drug testing as a way to increase revenue and profit for the practice. Many physician offices have created Physician Office Laboratories (POLs) allowing them to perform and bill for clinical drug testing. On the cover of *The Wall Street Journal*, November 10, 2014, the article titled "Doctors Cash In on Drug Test for Seniors and Medicare Pays the Bill" pointed out that some pain doctors are making more from testing than from treating.⁹ In fact, the article reported that drug testing accounted for 82% of one medical practice's Medicare payments in 2012.⁹ Some providers are even investing in clinical drug testing laboratories that provide an opportunity to invest for an equity stake, based on the volume of test samples being sent to that clinical drug testing lab. Because of these market factors, there is potential for inappropriate clinical drug testing utilization – based not on patient risk and medical necessity, but instead on staff availability and profit motive.

summary of the clinical drug testing problem

Clinical Drug Testing (CDT) is not being utilized as effectively as it could be to improve outcomes and reduce costs, liability, and waste by minimizing drug abuse, misuse, and diversion.

causes of the problem

- CDT utilization protocol based on financial factors versus patient risk criteria
- Unreasonably high charges for CDT services
- System gaming by clinical drug test "cheaters" who adulterate urine samples or take advantage of a non-random testing environment
- Failure to fully utilize clinical drug test data to determine risk, pinpoint problem patients, and improve outcomes
- Higher drug cutoff levels and older technology currently used by most clinical laboratories
- Lack of a formal and integrated clinical tool...until now, with the introduction of the Precision TBM

related intervention: prescription drug monitoring programs (PDMPs)

States have attempted to curb drug abuse, misuse, and diversion by implementing PDMPs. Forty-nine states have implemented PDMPs, all but Missouri.

- PDMP is a statewide electronic database that collects designated data on controlled substances dispensed within the state
- Housed by a specified statewide regulatory, administrative, or law enforcement agency
- Agency distributes data from the database to individuals who are authorized under state law to receive the information for purposes of their profession

current PDMP barriers:

- Profound lack of prescription communication between providers and among healthcare systems
- State systems are not linked, allowing nefarious doctor shopping across state lines
- Ineffective communication
- Inconsistency between individual state monitoring programs
- Underfunded and underutilized
- Lack of incorporation into the patient care process

the solution

A Toxicology Benefit Management (TBM) solution in which payers and Pharmacy Benefit Managers (PBMs) partner with Precision Diagnostics to employ an effective medication adherence monitoring program. The TBM solution solves the problem by:

- Bringing all key stakeholders together: the physician, patient, pharmacist, payer, PBM, and laboratory
- Establishing a fair fixed price per test, eliminating the exorbitant fees often charged by clinical drug testing laboratories
- Minimizing drug test cheaters by employing a retail oral fluid saliva collection kit that can be directly observed at the physician office or at the pharmacy where patients pick up their prescriptions
- Utilizing patient prescription data, along with the drug test results, to better manage patient risk and to identify and focus attention on high-risk patients while more appropriately checking in on low and moderate risk patients (see the following pages for client reporting capability)
- Eliminating inappropriate clinical drug test utilization and replacing it with a risk-based algorithm that will increase medication adherence and reduce abuse, misuse, and diversion by focusing on the higher-risk patients

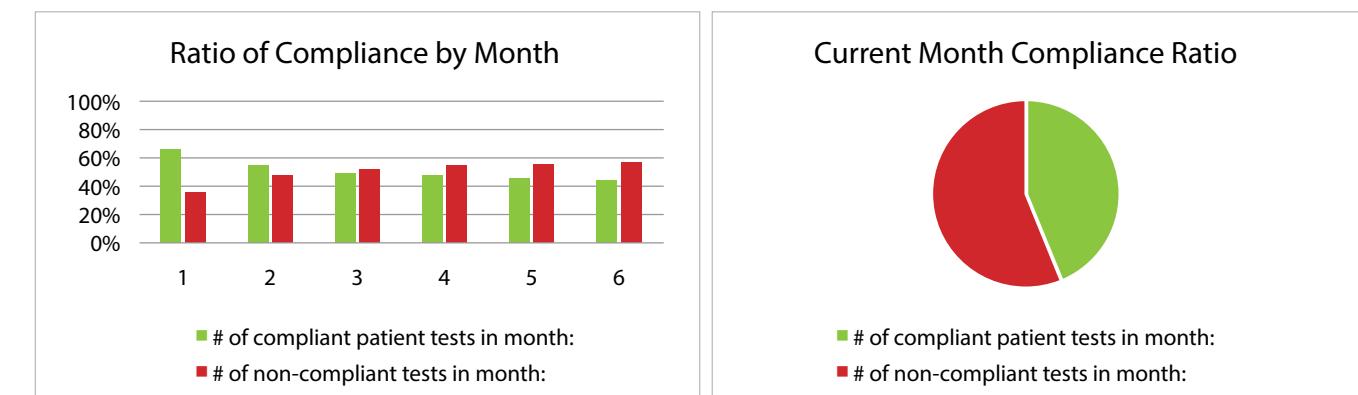
client reporting capability

Providing data analytics and reporting tools that are actionable while delivering lower costs, waste reduction, improved patient outcomes, and a reduction in payer/PBM liability due to drug abuse, misuse, and diversion is a pivotal benefit component of the Toxicology Benefit Management (TBM) solution. Patient adherence analysis and risk stratification are critical elements contributing to success.

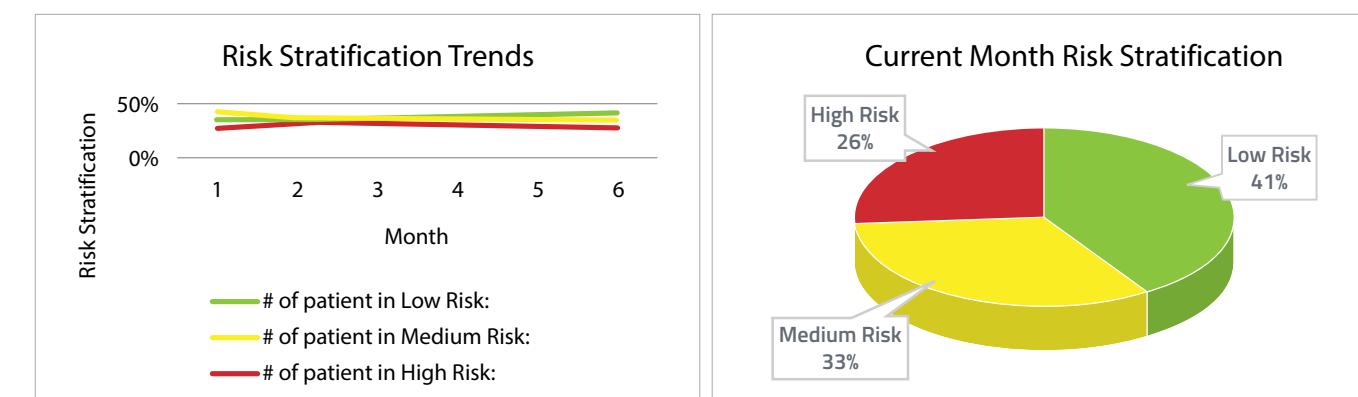
Below is a sample health insurance summary (total patient population) to aid a payer/PBM in quickly identifying the risk levels of their patient population.

Sample Health Insurance Summary Report

| Monthly Testing Statistics | | | | | | |
|----------------------------------------|-------|-------|-------|-------|-------|-------|
| | JAN | FEB | MAR | APR | MAY | JUN |
| # of patients enrolled in program: | 12420 | 13458 | 14565 | 15645 | 16854 | 17510 |
| # of tests performed in the month: | 3250 | 4125 | 4853 | 5684 | 6205 | 6523 |
| # of compliant patient tests in month: | 2125 | 65% | 2212 | 54% | 2356 | 49% |
| # of non-compliant tests in month: | 1125 | 35% | 1913 | 46% | 2497 | 51% |



| Patient Risk Stratifications | | | | | | |
|------------------------------------|-------|------|-------|------|-------|------|
| | JAN | FEB | MAR | APR | MAY | JUN |
| # of patients enrolled in program: | 15402 | 100% | 16212 | 100% | 16856 | 100% |
| # of patients in Low Risk: | 5235 | 34% | 5354 | 33% | 5625 | 33% |
| # of patients in Medium Risk: | 6251 | 41% | 5825 | 36% | 5965 | 35% |
| # of patients in High Risk: | 3914 | 25% | 5033 | 31% | 5266 | 31% |



Below is a sample of an individual patient summary report to assist a payer/PBM in quickly identifying the adherence score and risk level of any given patient at any time.

Sample Patient Summary Report

| Patient Demographics | | | | | | | | | |
|---------------------------------------|------------------|---------|---------|---------|---------|---------|---------|---------|---------|
| Patient Name: | John Doe | | | | | | | | |
| Date in Injury: | 5/12/12 | | | | | | | | |
| Insurance Company: | ABC Insurance | | | | | | | | |
| Employer: | ACME Corporation | | | | | | | | |
| Claim #: | ABC123456 | | | | | | | | |
| Cumulative Report for Test Compliance | | | | | | | | | |
| Date | 6/1/12 | 8/16/12 | 11/4/12 | 3/24/13 | 5/15/13 | 6/14/13 | 11/1/13 | 5/15/14 | 7/12/14 |
| Compliant? | YES | NO | YES | YES | NO | YES | YES | YES | YES |
| Risk Level: | LOW | HIGH | MED | MED | HIGH | MED | MED | MED | MED |
| Compliance Score: | 100 | 50 | 67 | 75 | 60 | 67 | 71 | 75 | 78 |
| Patient Test Data and Risk Assessment | | | | | | | | | |
| Total # of Tests Performed: | 9 | | | | | | | | |
| Total # of Compliant Tests: | 7 | | | | | | | | |
| Current Compliance Score: | 78 | | | | | | | | |
| Compliance Score Trend: | ACME Corporation | | | | | | | | |
| Current Risk Level: | MED | | | | | | | | |
| Date of initial test: | 6/1/12 | | | | | | | | |
| Date of last test: | 7/12/14 | | | | | | | | |

| Compliance Score Trend History | |
|--------------------------------|----------------------------------------------------------------|
| Compliance Score | 100 90 80 70 60 50 40 30 20 10 0 |
| Date of Test | 1 2 3 4 5 6 7 8 9 |

| Risk Level Frequency | |
|----------------------|-----|
| HIGH | 10% |
| MED | 85% |
| LOW | 5% |

| Risk Level Trend History | |
|--------------------------|-------------------|
| Risk Stratification | 1 2 3 |
| Date of Test | 1 2 3 4 5 6 7 8 9 |

Conclusion

Through the implementation of a Toxicology Benefit Management (TBM) solution, payers and PBMs have the opportunity to:

- Reduce drug abuse, misuse, and diversion and the high associated costs
- Reduce liability and litigation exposure
- Reduce waste
- Enhance patient treatment decisions by utilizing prescription drug regimen adherence analytics
- Eliminate the fraud and excessive pricing prevalent in the clinical drug testing marketplace
- Differentiate themselves by adding additional client value
- Improve patient outcomes
- Improve communication throughout the healthcare continuum with a standardized solution for coordinated, evidence-based care

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transforming healthcare through clinical laboratory science

Precision Diagnostics is a clinical laboratory unlike any other.

Our NextGen Precision™ Testing platform employs ultra-sensitive LC-MS/MS technology in a fully automated, robotic facility.

We are committed to transforming healthcare by delivering accurate, comprehensive, actionable clinical data needed to enhance population health and improve outcomes throughout the continuum of care.



INNOVATION

We relentlessly pursue research, technology, and quality – providing unparalleled, cutting-edge clinical laboratory science and delivery.



INTEGRITY

We accept and incorporate only ethical business solutions representing the highest quality standards, rooted in honesty, fairness, and transparency.



INSIGHTS

We integrate and deliver intelligent analytics that power objective, actionable clinical data – fulfilling our commitment to an evolved healthcare delivery system.



OUTCOMES

With a focus on the end goal, we continually explore new advances in delivering informed, coordinated, efficient patient care.



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