An Overview of Opioid Perspectives for Government Payers

A Telligen White Paper

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Scope

Since 2000, more than 300,000 Americans have lost their lives to opioid overdose. A staggering 74,000 individuals died in 2017 alone[1]. The combined cost of lives and literal dollars is having an exponential negative impact on our nation and on our healthcare system. On October 26, 2017, the President and Secretary of Health and Human Services declared the opioid crisis a public health emergency[2].

The public health emergency declaration allows for[2]:

- Expanded access to telemedicine
- Temporary appointments of specialists needed to respond effectively to the health emergency
- Increased funding to assist eligible people for substance abuse treatment
- And more

> "We will work to strengthen vulnerable families and communities, and we will help to build and grow a stronger, healthier, and drug-free society,"
>
> - *President Trump, March 19, 2018*

Additionally, on March 19, 2018, a website to bring together Americans to share stories of the dangers of opioid addiction was launched called CrisisNextDoor.gov[2].

Direct Medicaid/Medicare Impact

The opioid epidemic has hit particularly hard in the government sectors. In 2015, 33 percent of prescription opioids were paid for by Medicare and another 11 percent by Medicaid (see Figure 1 for details on all payment sources). In that same year, hydrocodone alone accounted for $5 billion of the nearly $11 billion cost of opioids[3].

On June 22, 2018, members of the House and Senate came together to pass bipartisan legislation to directly address the opioid crisis and further assist eligible Medicaid and Medicare individuals via the SUPPORT for Patients and Communities Act (H.R. 6)[5].

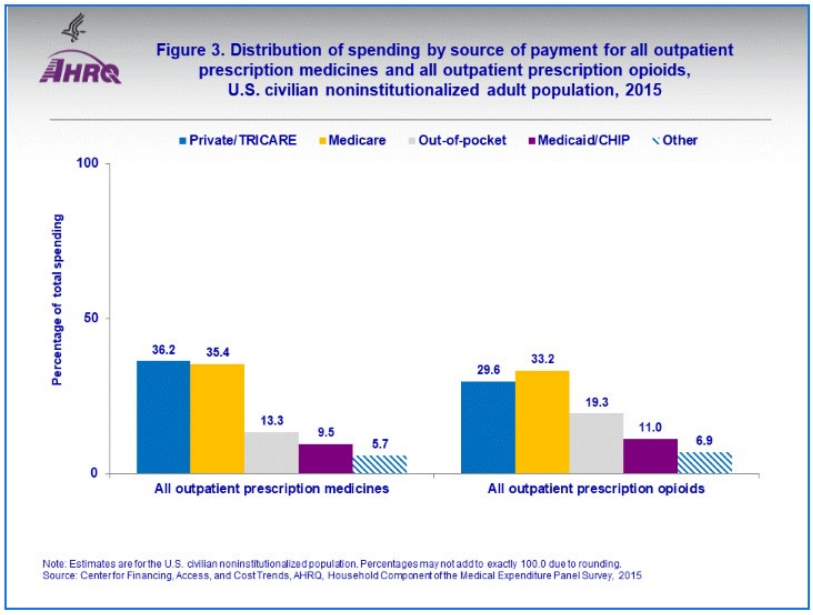


Figure 1. Source: http://meps.ahrq.gov

A brief synopsis of the act (signed into law by President Trump on October 24, 2018) includes:

- help to advance treatment and recovery initiatives,
- improve prevention,
- protect communities,
- increase the efforts to fight illicit synthetic drugs,
- stop illegal importation,
- safe disposal of unused medication, and
- substance use disorder loan repayment[6]

In total, H.R. 6 contains over 70 policies that will shape the way care is delivered including Medicare and Medicaid payment reform for both prescribing pain management and substance use disorder treatment[7].

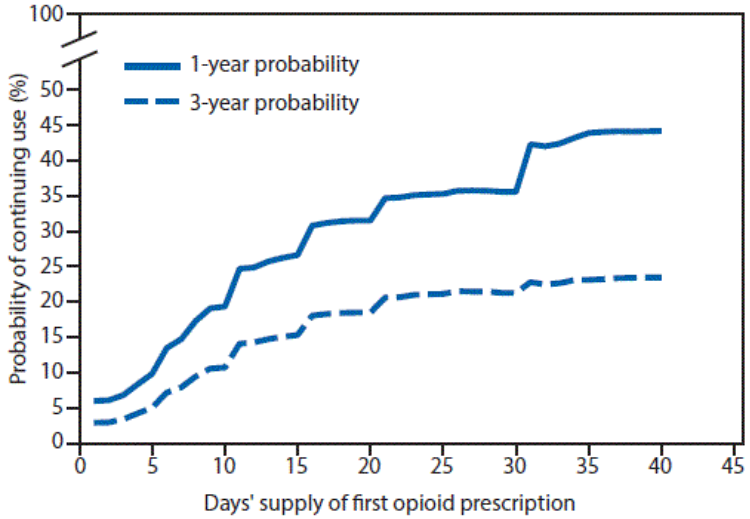
Did You Know?

- 75.1 million people are covered by Medicaid[4]
- 59.1 million people are covered by Medicare Parts A and/or B[4]

The need for legislation like H.R. 6 is vital, especially in the government sector. For example, the Agency for Healthcare Research and Quality published a series of briefs on opioid-related hospital use. Of note, from 2010 to 2015, the share of opioid-related stays increased 16.5 percent for Medicare, from 27.4 to 31.9 percent of all opioid-related stays, and increased 15.3 percent for Medicaid, from 34.8 to 40.2 percent of all opioid-related stays[8].

The Centers for Disease Control and Prevention looked into the likelihood of long-term opioid use based upon initial prescriptions[9]. The findings included the following points:

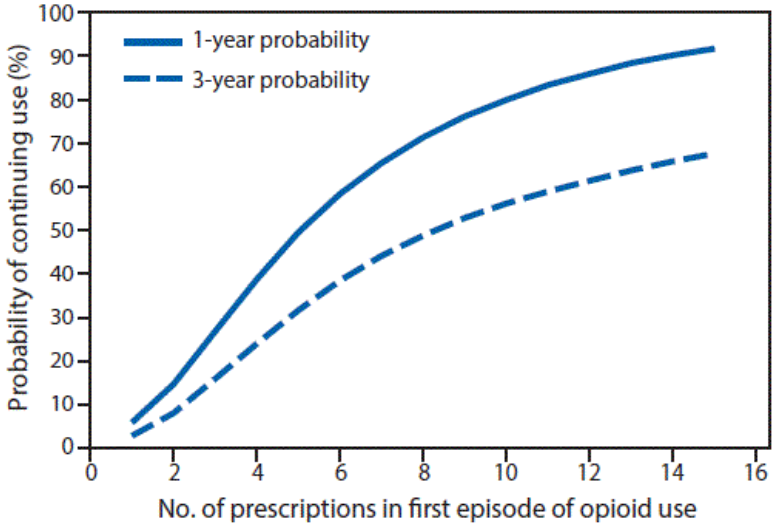
- Long-term opioid use increases most sharply in the first days of therapy, particularly after 5 days or 1 month of opioids have been prescribed, and levels off after approximately 12 weeks of therapy.
- The rate of long-term use was relatively low (6.0 percent on opioids 1 year later) for persons with at least 1 day of opioid therapy but increased to 13.5 percent for persons whose first episode of use was for ≥8 days and to 29.9 percent when the first episode of use was for ≥31 days.
- Although ≥31 days of initial opioid prescriptions are not common, approximately 7 percent do exceed a 1-month supply.
- As expected, patients initiated on long-acting opioids had the highest probabilities of long-term use.



One- and 3-year probabilities of continued opioid use among opioid-naïve patients, by number of days' supply* of the first opioid prescription – United States, 2006-2015

**Days' supply of the first prescription is expressed in days (1–40) in 1-day increments. If a patient had multiple prescriptions on the first day, the prescription with the longest days' supply was considered the first prescription*

Figure 2. Days' supply of first opioid prescription



One- and 3-year probabilities of continued opioid use among opioid-naïve patients, by number of prescriptions* in the first episode of opioid use – United States, 2006-2015

**Number of prescriptions is expressed as 1-15, in increments of one prescription*

Figure 3. Number of prescriptions in first episode of opioid use

Discussions with patients about the long-term use of opioids to manage pain should occur early in the opioid prescribing process, perhaps as early as the first refill, because approximately 1 in 7 persons who received a refill or had a second opioid prescription authorized were on opioids 1 year later[9].

Legislation to Impact Opioid Overuse

To directly tackle over use of opioids, one path is to put safety edits in place by prescription benefits managers, managed care organizations and state agencies. On June 12, 2018, H.R. 5799 was introduced and confronts the issue on three fronts: opioid refills, morphine milligram equivalents and electronic prior authorization. In addition, the bill also considers concurrent use of benzodiazepines and antipsychotics.

On a positive note, at least 33 states have mandated certain opioid prescription limits (see Figure 4)[10]. In 2016, the state of Massachusetts passed the first state law limiting opioid prescriptions; from that time until today, an additional 32 states have jumped on board with legislation regarding limits, guidance or requirements related to opioid prescribing. The legislation intact state by state are falling in line with the recommendations set in place with The President's Commission on Combating Drug Addiction and The Opioid Crisis pertaining to prescribing guidelines, regulations and education[11].

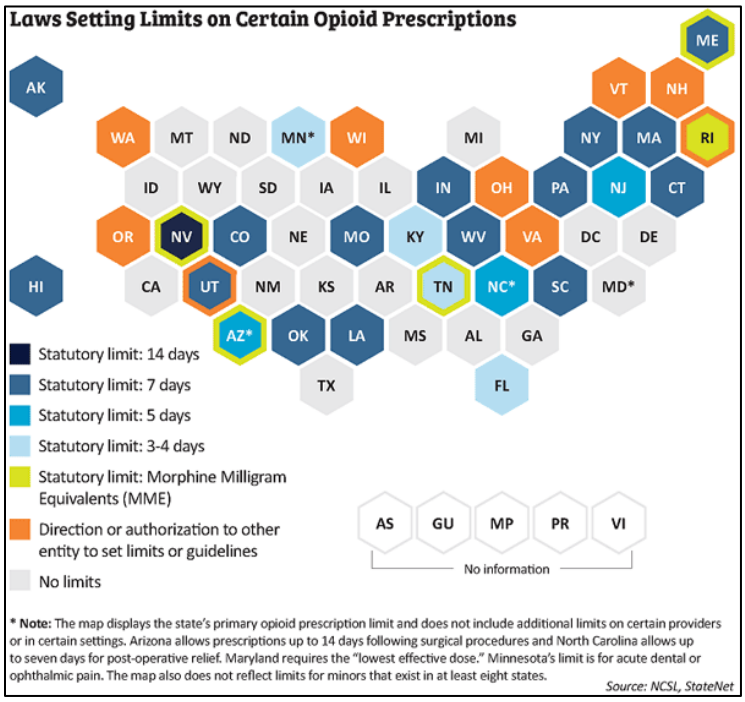


Figure 4. Opioid Prescription Limits

How We Got Here

It is startling to know that the United States is the world leader of opioid prescribing, opioid addiction and opioid overdose deaths; not the type of leader we want to be. It is also important to note this epidemic does not discriminate among age, financial status, where one lives and one's ethnic background or race[11]. The President's Commission report outlined that the crisis originated within the healthcare system and has been influenced by the following factors[11]:

1. ***Unsubstantiated Claims***: Articles published in the New England Journal of Medicine starting in 1980 stated the following claims; addiction is rare in patients treated with narcotics and opioid maintenance therapy can be safe and a better alternative to surgery or no therapy. Neither of those claims were substantiated with high quality evidence yet were accepted by federal agencies and oversight organizations.

2. ***Pain Patient Advocacy:*** The support for opioids in pain management was promoted by patients and also by some physicians as patients were encouraged to join the communication loop in a patient's therapy and the want for physicians to have positive patient satisfaction.

3. ***Opioid Pharmaceutical Manufacturing and Supply Chain Industry:*** Although research showed addiction possibilities for narcotics, a pharma company sponsored physician education sessions claiming opioid addiction potential was low. Another example; from 1997 – 2002, a huge promotional push for oxycodone led to 10-fold rise in prescriptions for treatment of moderate to severe noncancer pain as well as prescriptions for other opioids.

4. ***Rogue Pharmacies and Unethical Physician Prescribing:*** This pertains to unrestrained distributors, rogue pharmacies, unethical physicians and patients whose medication were diverted. Also, some patients sold and profited from legitimately prescribed opioids.

5. ***Pain as the "Fifth Vital Sign":*** In 1995, the American Pain Society introduced the phrase "pain as the 'fifth vital sign'" as a way to elevate awareness of pain treatment with healthcare professionals. Defining pain at the same level as other vital signs would ensure better chances for pain to be treated properly. This phrase was further elevated by accreditation by the Veteran's Administration and the Joint Commission.

   The Joint Commission also created standards for pain assessment in 2000. In addition, an opioid pharma company sponsored the Joint Commission for development of education materials which included claims and expert advice which was erroneous. However, the push of this material led to a surge in opioid prescribing, the supply of opioids and the escalation of opioid-related misuse, diversion, use disorder and overdose deaths.

6. ***Inadequate Oversight by the Food and Drug Administration (FDA):*** As the only federal authority overseeing public health on the safety, efficacy and security of human drugs, etc., the FDA accepted claims that new opioids were not addictive; leading to not imposing clinical trials or post-approval surveillance.

7. ***Reimbursement for Prescription Opioids by Health Care Insurers:*** Although sales for prescription opioids nearly quadrupled in 15 years (from 1999-2014), insurance carriers did not serve as a stop-gap examining this influx.

8. ***Medical Education:*** Education on pain management, prescribing, screening and treating addiction has long been inadequate and remains that way today.

9. ***Lack of Patient Education:*** Patients may not be aware they are being prescribed opioids, the risks they pose, control and diversion and more.

10. ***Public Demand Evolves into Reimbursement and Physician Quality Ratings Pegged to Patient Satisfaction Scores:*** Despite the potential for addiction, overdose and death there remains a strong public demand for opioids. In a recent study, Emergency Department physicians voiced

they feel pressured to continue to prescribe opioids to avoid administrative and regulatory criticism to try and address pain as the "fifth vital sign".

When patients report poor patient satisfaction score, reduced hospital reimbursement can occur; in addition, failing to provide adequate pain relief can lead to malpractice claims or medical board action.

11. ***Lack of Foresight of Unintended Consequences:*** Although prescription drug overdose numbers have gone down, the overall opioid-related deaths are continuing to climb. As more regulations are in place on prescribing opioids, the consequences of that is that patients are getting prescription quantities lowered or taken away without the physician determining if they have developed an opioid use disorder leading to the probability of illicit opioid use.

12. ***Treatment Services Insufficient to Meet Demand and to Provide Medication-Assisted Treatment (MAT):*** Although the number of opioid-use disorders have increased in the last 15 years, services to help treat individuals have not grown to keep up with demand.

13. ***Lack of National Prevention Strategies:*** There is a need to develop strategies to target the nation's most vulnerable population sets (e.g. adolescents, college age youth, etc.) yet they are not in existences or have not been tested sufficiently.

Please note, the contributors listed above are based upon the President's Commission report and differ from other assumptions that have been published (see Figure 5 highlighting CDC commentary).

With an average of 115 Americans dying every day from an opioid overdose, the Centers for Disease Control and Prevention took a look at the epidemic crisis and broke it down into three waves[12] (See Figure 5).

- Wave 1 (1990's): This wave was defined as increased opioid prescribing; overdose deaths with prescription opioids increasing since at least 1999.
- Wave 2 (2010): This wave represents rapid increases of heroin involved overdose deaths.
- Wave 3 (2013): This wave highlights overdose deaths involving synthetic opioids.

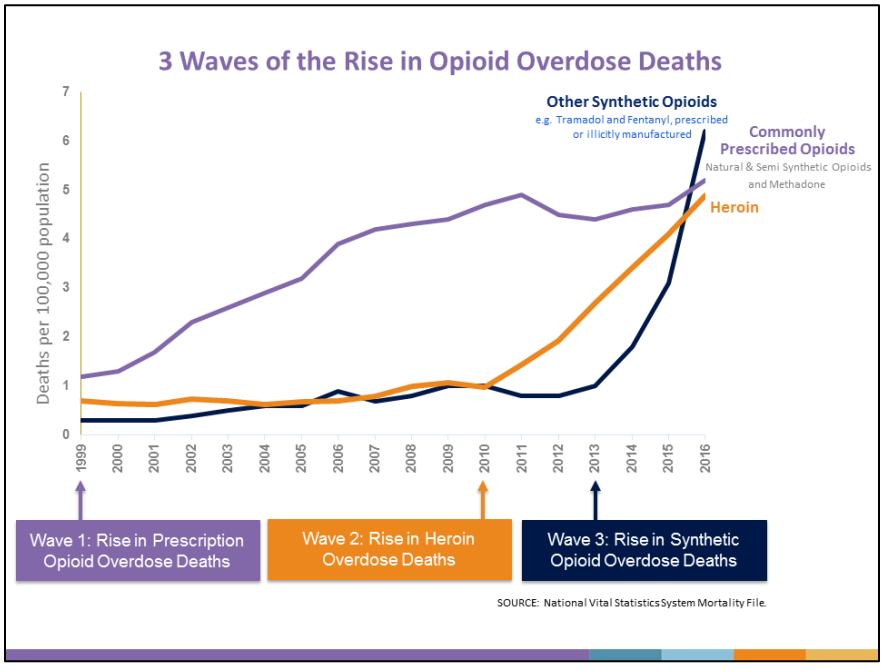


Figure 5. 3 Waves of the Rise in Opioid Overdose Deaths

Tangible Solutions

Historical precedent has demonstrated that this crisis can be fought with effective medical education, voluntary or involuntary changes in prescribing practices, and a strong regulatory and enforcement environment. The recommendations of the Commission are grounded in this reality, and benefit from modern systematic epidemiological and large data analytics, evidence-based treatments, and medications to assist in recovery or rescue of an overdose crisis[11]. The remainder of this section will highlight several examples of initiatives that are in place today to fight opioid misuse and addiction.

Some excellent examples of positive steps that are occurring to attack the opioid crisis include using Health IT and Prescription Drug Monitoring Program (PDMP) integration. Figure 6 contains examples of how Health IT solutions are being utilized by clinicians on the frontlines to address the opioid crisis in their practice.

Figure 6. Examples of Health IT and PDMP Integration

The Prescription Drug Monitoring Program Training and Technical Assistance Center (PDMP TTAC) provides services, support, resources and more to help combat the misuse, abuse and diversion of prescription drugs to PDMPs, federal partners and other stakeholders[13]. Positive strides have occurred. Specifically, as of November 2018, 47 states are engaged in interstate data sharing, 19 states have mandated PDMP query by prescribers and dispensers and 43 states have some level of PDMP data integration[14].

The use of electronic prescribing for controlling substances (EPCS) describes the use of technology and workflows to add safety and security measures for prescriptions of controlled substances[15]. Specifically, EPCS equips physicians, technology partners and pharmacies with the following:

- Safer, faster controlled substance prescribing
- The ability to continue prescribing with the physician's EHR

Despite these benefits, a gap remains in prescribers' readiness to e-prescribe and pharmacies' readiness to receive them. As of November 2018, only 31.3 percent of prescribers are enabled to EPCS whereas over 93 percent of pharmacies are enabled to receive EPCS. Payers can encourage or mandate EPCS and provide necessary supports to help make it happen. There may be a need for simplified certification processes or funding to prepare the electronic medical record systems for EPCS.

Good Samaritan Laws are policies put into place to provide protection for individuals who call for emergency assistance during a drug overdose event. These laws were designed to encourage individuals if they experience or witness a drug overdose. The laws may include legal protection from arrest/prosecution for crimes related to drug possession, paraphernalia possession, etc[16]. As of June 2018, 46 states have overdose immunity laws in place[17] (Figure 7).

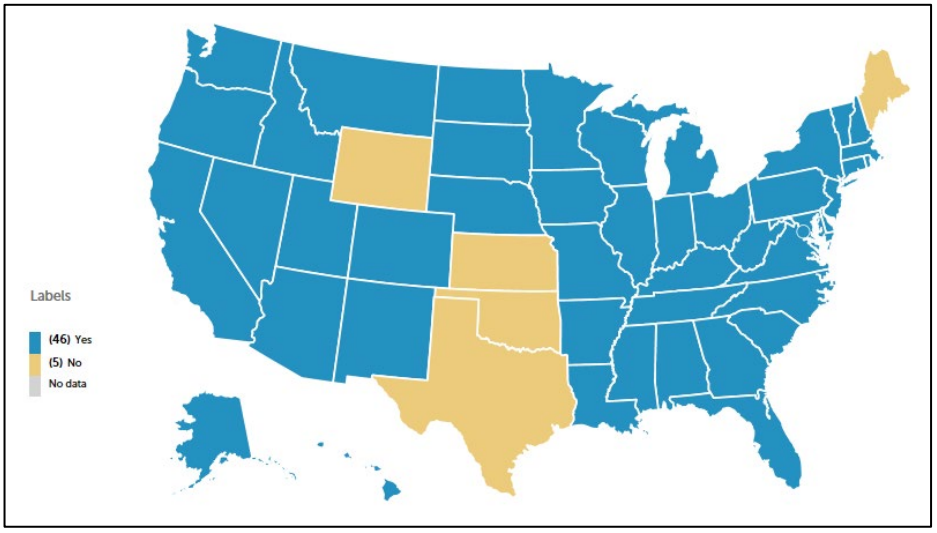


Figure 7. Map indicating states with overdose immunity laws in place

In February 2018, the Surgeon General released a notice regarding naloxone, a medication that can reverse the effects of opioid overdose[18]. In addition to first responders who already have been carrying this potential life-saving medication, the advisory also encouraged individuals (including friends and family) who are at-risk for an opioid overdose. As of January 2018, all community pharmacies have access to provide naloxone[19], although states do have differing prescribing protocols (see Figure 8 for more information).

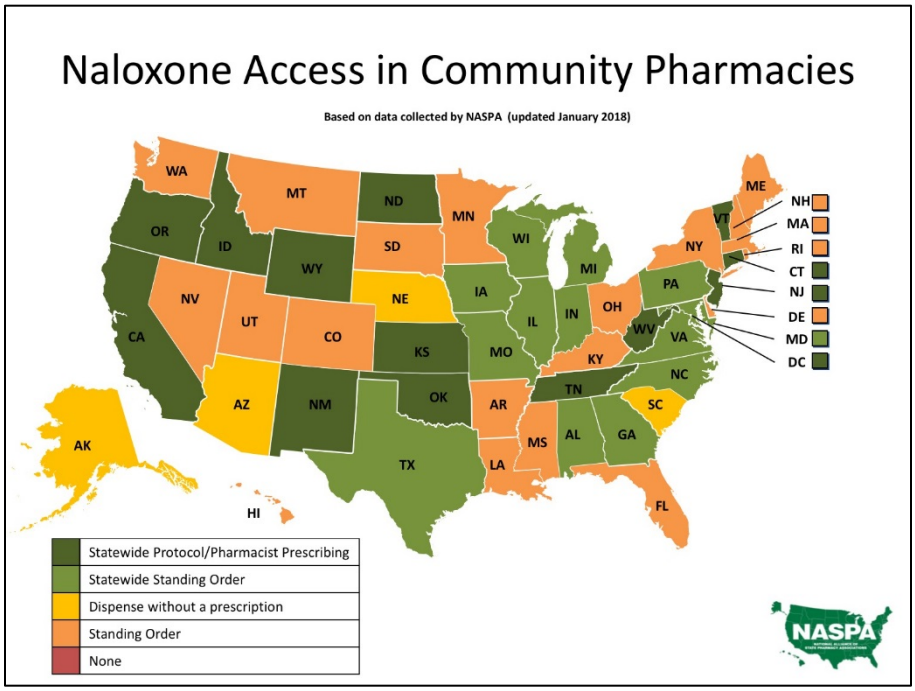


Figure 8. Naloxone prescribing protocols by state

State Medicaid Examples

According to the Henry J. Kaiser Family Foundation, Medicaid plays a central role in addressing the opioid epidemic[20]. This section focuses on what some states have been able to accomplish within their Medicaid population to do their part in tackling the opioid crisis.

Oklahoma

The SoonerCare Pain Management Program and Toolkit[21], designed by the Oklahoma Health Care Authority with the assistance of Telligen, launched in January 2016 to equip providers with the necessary tools to appropriately treat their members with chronic pain. At the time, Oklahoma was ranked 5th nationally for overdose deaths, necessitating bold steps to curb the problem. In the south and east quadrants of the state, overdose deaths rose to as high as 29 per 100,000, exceeding the state rate of 13.7. Oxycodone and hydrocodone topped the list of culprits.

The SoonerCare Pain Management Toolkit consists of:

- Treatment protocols
- Office policies and expectations (early refills)
- Patient education materials
- Referral process, and
- Oklahoma Prescribing Guidelines (includes checking the PMP and prescribing no more than four doses per day)

Today, Oklahoma ranks 6th in rate of opioid prescriptions dispensed per 100 persons (behind AL, AK, TN, MS, & LA)[22]. The CDC estimates that Oklahoma's drug overdose deaths decreased 15 percent from April 2017 to April 2018. This represents the 3rd largest percentage decrease in the nation behind Montana and Wyoming and better than the nationwide rate, which reports a 2.2 percent increase in overdose deaths[23] (see Figure 9).

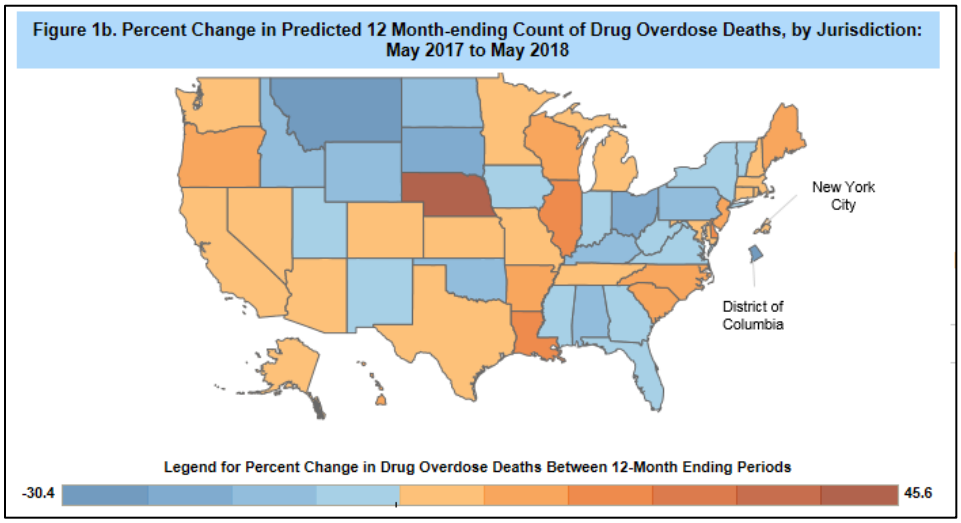


Figure 9. Percent change in drug overdose deaths over one year

Other States

- According to the Health Affairs blog[24], states can and are leveraging opioid policy treatment levers to promote local change in opioid outcomes. For example; states like Maryland[25] and Virginia[26] are testing new programs than reform reimbursement to incentivize medication-assisted treatment (MAT).
- Between June 2016 and May 2017, one in six Ohio Medicaid beneficiaries were prescribed at least one opioid through Medicaid; 40,500 of which were children ages 18 or younger; and nearly 91,000 Ohio residents received opioids on a regular basis.[27] To combat this, multiple initiatives to help ensure proper opioid use were implemented. One specific initiative issued guidelines that recommend providers reassess opioid prescriptions for beneficiaries who receive opioids for 12 or more weeks. Between 2012 and 2017, the total number of opioids dispensed in Ohio decreased by 28 percent.

Centers for Medicare & Medicaid Services (CMS)

CMS is also taking bold steps and new opioid rules will take effect January 1, 2019[28]. These include:

- Real-time safety alerts at the time of dispensing and drug management programs
- Part D plans will implement 7-day supply limits for opioid naïve patients and opioid care coordination alerts when their morphine milligram equivalents (MME) across all prescriptions surpasses 90 MME
- CMS has identified opioids and benzodiazepines as frequently abused drugs and may be subject to programs such as lock-in or case management.

Furthermore, in a letter to State Medicaid Directors, CMS urged the Directors to leverage PDMPs, public health data and technologies to coordinate care[29].

Analytical and Quality Improvement Experience

Since 2014, Telligen has been engaged in work to combat the opioid epidemic by applying many elements of our population health analytical tools, clinical and quality/safety expertise within all our primary markets – commercial, state and federal.

Today's health and healthcare information is partial, fragmented, and often not actionable – especially if the information is generated from sources of data that are outdated, not comprehensive and/or incomplete. Although in general there have been improvements in the various elements of the supply chain involved in turning raw opioid data in its sundry forms – into information – and finally into actionable knowledge - the production and timely use of actionable knowledge is still a challenge for most stakeholders in health and healthcare professions, further complicating the opioid epidemic.

From an information supply chain perspective, organizations whose core competencies include access to large, more comprehensive and complete data sources, and deeper wells of in-house expertise in the

areas of data warehousing, data science, clinical knowledge and more advanced analytic sciences/tools (e.g. – predictive modeling, econometrics, epidemiology, risk adjustment, geographic information system (GIS), statistical "machine" learning) are much more likely to be efficient and effective producers of timely, accurate and actionable knowledge.

Our population health analytics experience emanates from our 40-plus years of work with a diverse base of clients. We operate in three primary markets – Commercial, State, and Federal. Our clients include unions, municipalities, employers, state Medicaid programs, and the Centers for Medicare & Medicaid Services (CMS) under the Quality Innovation Network (QIN) / Quality Improvement Organization (QIO) 11th Scope of Work. Because our population health experiences span Commercial, Medicaid and Medicare populations – the products and services produced include:

- advanced analytics (e.g. – predictive analytics, value/outcome analytics),
- population health services (e.g. – health & well-being, disease management, case management, utilization management for commercial and state Medicaid clients), and
- policy/program support/development (e.g. – practice facilitation, evaluation of the structures, processes and outcomes for state Medicaid health home programs).

Telligen has known and worked on systemic health and healthcare-related cost, safety and quality issues for many years and in recent years, we have added a heightened focus in the arena of opioid harm reduction.

How It Relates Back to Telligen's Work

Through our work in the federal, state and employer markets, Telligen is also doing our part to target and fight back against the opioid crisis. This section will highlight some key areas where we are making a difference (see Figure 10).

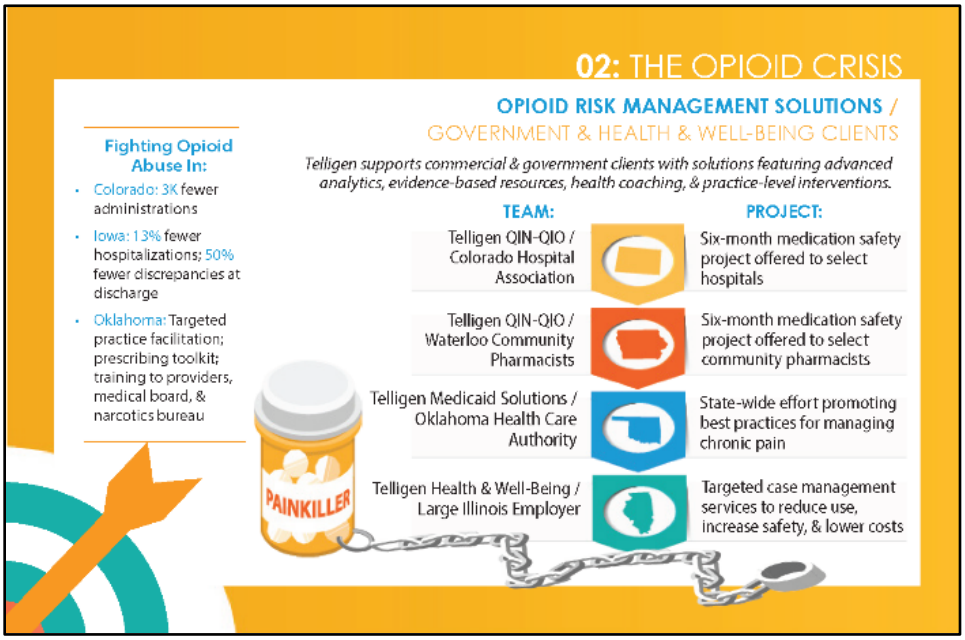


Figure 10. Overview of Telligen Projects Touching the Opioid Crisis

SoonerCare Program

As mentioned in a previous section of this paper, Telligen partnered with the Oklahoma Health Care Authority to develop the SoonerCare Pain Management Program and Toolkit[21].

Telligen QIN QIO

The Telligen QIN QIO collaborates with healthcare providers to create a wealth of information, resources and assistance on opioid safety[30].

Commercial

Telligen uses population health descriptive analytical tools to screen administrative pharmaceutical claims data for commercial clients' members that may have issues with opioid abuse as identified by irregularities with prescription fill patterns, location of fill and/or prescribing doctor. Knowledge gained from our analytics are then used by our clinicians to assist these members and their care team with a goal of avoiding adverse events related to opioid use or abuse.

Medicaid

Telligen uses population health descriptive analytical tools to identify Medicaid members with diagnosed substance abuse conditions in risk-adjusted, longitudinal evaluations of the efficacy of a state's Medicaid Health Home program. Substance abuse is a frequently prevalent comorbidity condition in Medicaid health home treated populations with serious emotional disturbance, serious mental illness, and/or multiple chronic conditions; and a frequently overlooked condition in more robust econometric-based analyses of the efficacy of Medicaid programs that aim to treat members with these conditions.

Medicare

Telligen uses population health descriptive analytical tools to identify Medicare FFS members with diagnosed adverse drug event-related conditions and concomitant use (filled prescriptions) for an opioid in Telligen-developed metrics of hospital admission and 30-day all-cause readmission[31]. These metrics are used to generate longitudinal run-chart reports of pharmacy-specific and comparative benchmark state-level admission and readmission rates. Telligen delivered these reports quarterly to > 120 participating pharmacies with the intention of making pharmacies aware of high-risk medication (HRM) outcomes – opioids inclusive – incurred by the beneficiaries they serve. In addition, risk factor analyses are conducted to identify principal diagnosed conditions and comorbidities related to beneficiaries' inpatient hospitalizations. This knowledge is then used as the foundation for action. Telligen provides quality improvement guidance to these pharmacies with the goal of improving HRM prescribing and medication use patterns that may be adversely affecting beneficiary outcomes and costs.

Telligen uses population health descriptive analytical tools to identify Medicare FFS Medicaid members with diagnosed opioid-related adverse drug event conditions, concomitant use for opioid, and naloxone prescription rates subsequent to hospitalization in several Telligen-developed metrics.

1. Current opioid prescription among all-cause ED/Obs room visits,
2. Opioid-related hospital ED/Obs utilization,
3. Opioid-related ED/Obs with subsequent admission,
4. 30-day ED/Obs Room revisits,
5. 30-day readmissions subsequent to a preceding ED/Obs Room visit,
6. Naloxone prescription fills within 30 days of an opiate-related ED/Obs Room visit, and
7. Opioid prescription refills within 3 days after a preceding ED/Obs Room visit.

These metrics are used to generate longitudinal run-chart reports of hospital-specific and comparative benchmarked state-level rates for all metrics. This knowledge is then used by Telligen and participating hospitals as the foundation for opioid-related quality improvement efforts[32].

Summary

The opioid crisis can be tackled head on and this white paper unveiled several strategies underway by local entities and government payers. Whether mandated or voluntary, a combination of innovative strategies and leveraging existing resources better (e.g. PDMP, HIE integration, prescribing guidelines) will accelerate our path to reduced incidence of harm from opioids. The current crisis warrants increased attention to payment for and access to medication assisted treatment and non-opioid pain management options. Government payers can tap into field experts such as Telligen to be at the forefront of making a difference.