

E-Prescribing: A Commonsense Solution To Opioid Abuse that Is Being Ignored

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Congress has taken up the growing problem of opioid abuse. Yet for all the talk there appears to be little discussion of a commonsense solution: mandatory electronic prescribing (e-prescribing). This would allow doctors, pharmacies and law enforcement to better monitor inappropriate opioid use, drug-seeking behavior and reduce drug diversion.



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Executive Summary

Chronic pain is a significant problem in the United State — affecting more than 100 million Americans. Some of the dangers include inappropriate nonmedical use, abuse and the danger that some addicts move on to street drugs like heroin. Inappropriate nonmedical use and abuse of prescription opioid drugs has skyrocketed in the past 15 years. The U.S. Department of Health and Human Services (HHS) surveys estimate that up to 25 million people used prescription opioids for nonmedical purposes between 2002 and 2011.

An estimated 80 percent of abused controlled substances are obtained by prescription and legally dispensed to the abuser, an abuser's friend or a family member. In many cases, opioids are obtained through so-called "doctor shopping" — seeing multiple doctors and obtaining a prescription from each. According to industry research, for every \$1 in fraudulent drug claims, an additional \$41 dollars is spent on associated medical claims — unnecessary physician visits, redundant medical tests, unnecessary emergency room visits and the like. Over the course of a dozen years, from 1999 to 2011, the rate of fatal prescription opioid overdoses nearly quadrupled, from 1.4 deaths per 100,000 population to 5.4.

Solution: Electronic Prescribing of Controlled Substances. Transmitting prescriptions electronically is a way for doctors to directly communicate with pharmacies — rather than handing patients a paper form ripped from a pad. E-prescribing facilitates detection of doctor shopping. In addition, once a prescription for a chronic condition has been prescribed, refills should require less effort by doctors and patients.

Ironically, most doctors have been using electronic prescribing of noncontrolled substances for a few years now. But until recently, federal regulations *prohibited* e-prescribing of controlled substances due to the perceived risks of drug

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abuse and diversion. Electronic prescribing of controlled substances is now permitted in all 50 states. Yet, not all pharmacies — and even fewer physicians' offices — are prepared to transmit prescriptions for controlled substances electronically.

The DEA has strict regulations governing the design of software certified for e-prescribing. The DEA certificate must be registered with the state board responsible for enforcing regulations on the distribution of narcotics. The process must also use the federally required two-factor identification.

On March 27, 2016, following Minnesota's lead, New York State became the second state to require all prescriptions to be transmitted electronically. One potential obstacle is that pharmacies must still accept paper prescriptions. The reason is that a pharmacy has no way of knowing whether a given physician has received an e-prescribing waiver from the state or if computer problems made it impossible to issue

electronic prescriptions.

In a study of dentists, within a few months after iSTOP was implemented in New York, opioid prescriptions fell by about half, from 31 percent of dental visits before iSTOP to 14 percent in the following three months. The quantity of pills per prescription also fell. The total numbers of opioid analgesics prescribed fell by three-quarters (78 percent).

Conclusion. Mandatory electronic prescribing with tracking of controlled substances is a solution that policymakers should consider. Better tracking and control of opioid drugs will help keep the next generation of potential abusers away from prescription narcotics. New York State, Minnesota and Maine have taken that step and several other states are considering similar moves. Many physicians and most pharmacies are already equipped to transmit or receive prescriptions electronically. Those who have, found the process less burdensome than they expected.

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Introduction

Congress has taken up the growing problem of opioid abuse. In May 2016 Congress considered more than a dozen bills designed to treat and combat opioid abuse, including funds for substance abuse treatment and training for emergency medical personnel.

Yet for all the talk about ways to deal with the problem of opioid abuse there appears to be little discussion of a commonsense solution: Mandatory electronic prescribing (e-prescribing) and tracking of controlled substances, which would allow doctors, pharmacies and law enforcement to better monitor drug-seeking behavior and reduce drug diversion.

Opioid Abuse Is a Growing Problem.

Inappropriate use and abuse of prescription opioid drugs has skyrocketed in the past 15 years, becoming widespread. In addition to the human cost of lives ruined, inadequate control of controlled substances drives up costs for drug plans, employers, insurers, taxpayers and society as a whole.

Opioid abuse has entire regions of the country enthralled. U.S. Department of Health and Human Services surveys estimate that up to 25 million people used prescription opioids for nonmedical

purposes between 2002 and 2011.¹ Furthermore:

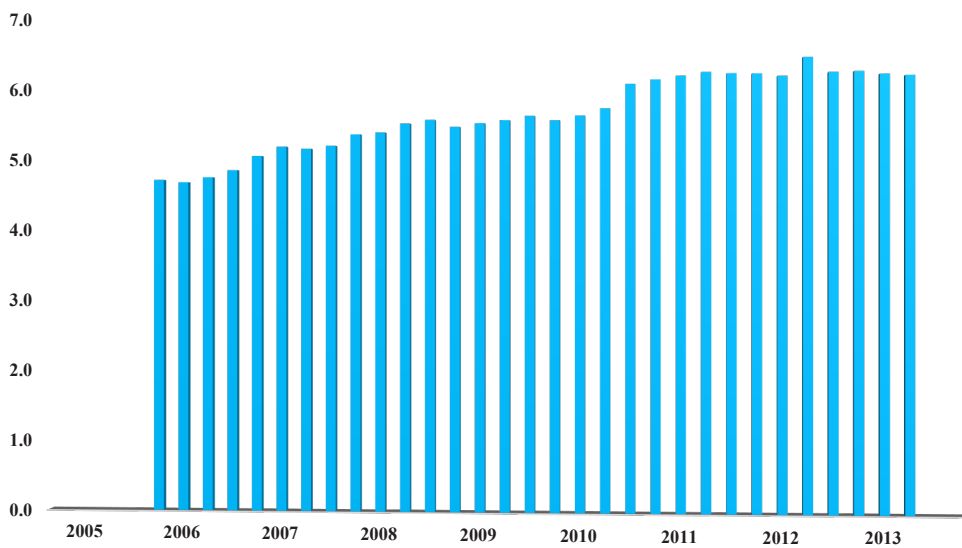
- A recent report estimates that 20 million people abuse prescription drugs each year, and not without consequences; nearly one-in-five injured drivers in fatal accidents in 2009 tested positive for drugs.²
- In 2010, the death toll from opioid pain reliever overdoses reached nearly 17,000 annually.³
- In 2013, admissions to rehab facilities for addiction to all types of opioids were up about 60 percent from a decade earlier, surpassed only by admissions for alcohol addiction.⁴
- Over the course of a dozen years, from 1999 to 2011, the rate of fatal prescription opioid overdoses nearly quadrupled, from 1.4 per 100,000 to 5.4.

The number of heroin overdose deaths began to skyrocket around 2010 as some people switched from prescription opioids to heroin.⁵ Some public health experts believe the recent rise in heroin overdose deaths is related to efforts to curb prescription opioids after the problem got out of hand.⁶ Lower prices for heroin also contributed to the problem.⁷

Estimates vary, but about 12 percent of prescriptions are for controlled substances.⁸ That adds up to nearly 1 in every 8 pills dispensed. Roughly 60 million scripts for opioids are dispensed in any given quarter.⁹ [See Figure I.]

Opioid Diversion. The Centers for Medicare and Medicaid Services (CMS) defines drug diversion as “the diversion of licit drugs for illicit purposes.”¹⁰ There are multiple causes for the rise in opioid use and abuse. One reason is that prescription opioids have historically been easy to obtain for recreational purposes. Although this is no longer the case, prescription opioids were once cheaper and easier to obtain than illegal drugs

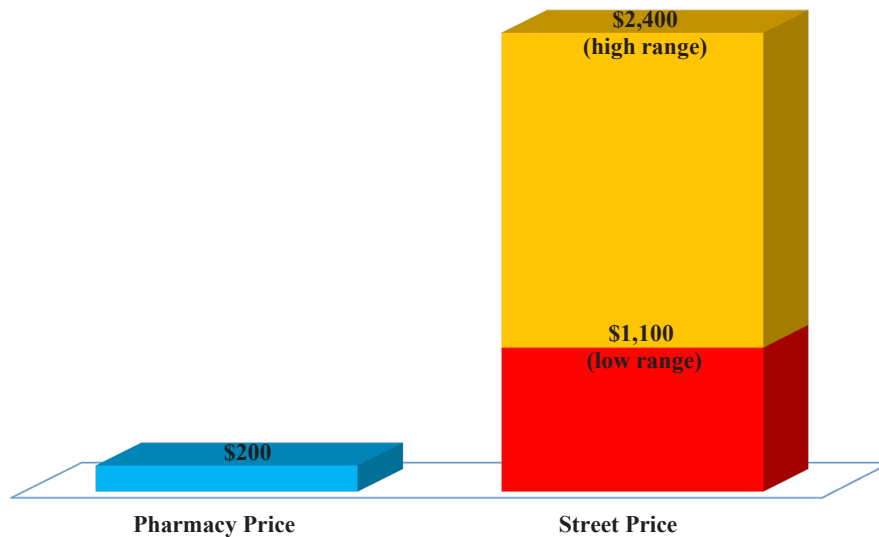
Figure I
Prescriptions Dispensed for Opioid Analgesics
(Per Quarter in Millions of Scripts)



Source: Richard C. Dart et al., “Trends in Opioid Analgesic Abuse and Mortality in the United States,” *New England Journal of Medicine*, Vol. 372, No. 3, January 15, 2015. Available at <http://www.nejm.org/doi/pdf/10.1056/NEJMs1406143>.

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Figure II
Street Price vs. Pharmacy Price of Oxycodone



Source: "Spotlight On... Drug Diversion," Office of Inspector General, U.S. Department of Health and Human Services. Available at <http://oig.hhs.gov/newsroom/spotlight/2013/diversion.asp>; Also see Jennifer Trussell, "Drug Diversion Overview," Office of Inspector General, U.S. Department of Health & Human Services, June 2013

— the mere possession of which is an offense for which more than 1 million people are arrested each year.¹¹

The U.S. Department of Health and Human Services, Office of the Inspector General (OIG) reports that drug diversion involves a variety of individuals: patients who are addicted, patients who profit from unneeded prescriptions, street dealers in prescription pain medications and unscrupulous providers. An estimated 80 percent of abused controlled substances are obtained by prescription and legally dispensed to the abuser, an abuser's friend or a family member.¹²

Some individuals seek drugs for recreational purposes, while others seek to sell them to others. The reality is that prescription opioids have become yet another commodity in the illicit drug trade. While opioids are the most common drugs diverted for resale, anxiety drugs and antipsychotic medications are also commonly diverted.

As more people become addicted and policy-makers clamp down on abusive pill mills, prices of prescription opioids on the street have increased and far exceed their pharmacy cost. This is especially true of narcotic pain relievers. The OIG reports the street price of Oxycodone is a dozen

times the normal retail pharmacy price. Its agents report the street value of a bottle of Oxycodone is \$1,100 to \$2,400 per bottle in Northern California.¹³ [See Figure II.] With prescription opioids becoming costly, heroin — an opioid drug synthesized from morphine — has flooded in from Mexico; by some accounts a small bag is cheaper than a pack of cigarettes.¹⁴

With a little persistence and creativity, prescription painkillers like oxycodone and hydrocodone can be obtained from retail pharmacies for retail prices. It is not uncommon for addicts to show up at the ER asking for painkillers, complaining of intense pain. Indeed, pain medications are the most commonly dispensed drug in the emergency room, and three-fourths of ER visits result in a dispensed drug.¹⁵

The costs of drug diversion include unnecessary office visits by doctor-shopping patients and 1.2 million expensive emergency room visits, some of which are due to the side effects of addiction and some are unnecessary visits by addicts hoping to get a narcotic pain reliever.¹⁶ [See Figure III.] Drug diversion costs insurers nearly \$75 billion per year, according to one estimate — with about two-thirds of the losses in such public programs as Medicare and Medicaid.¹⁷

According to industry research, for every \$1 in fraudulent drug claims, an additional \$41 is spent on associated medical claims — unnecessary physician visits, redundant medical tests, unnecessary emergency room visits and the like.¹⁸ [See Figure IV.] Express Scripts estimates that its collaborative approach — working with clients to identify and prevent fraud — saved about \$1.5 billion dollars in medical costs by detecting 881 cases of fraud in 2013.¹⁹

The Problem of Chronic Pain. Chronic pain affects about 100 million Americans — more than heart disease, diabetes and cancer combined.²⁰ Without proper management, patients in pain can become addicted to their medications. However,

Prescription Monitoring

Express Scripts is a pharmaceutical benefit management (PBM) company that administers drug plans for Medicare Part D and Medicaid, as well as for numerous insurers and employers. Express Scripts is the largest drug plan administrator in the country. It has developed a monitoring program using more than 290 indicators to predict the likelihood of fraud, diversion or drug seeking behavior. Some of these include:

- Number of physicians visited;
- Distance traveled to either physicians or pharmacies;
- Frequency of prescriptions;
- Type and mix of drugs dispensed;
- Geographic characteristics; and
- Patient demographics.

a push to treat unrelenting pain, dating back about two decades ago, may have led many physicians to underestimate the risk of addiction to opioids. Some early proponents are rethinking their approach.²¹ Until recently, some pain management practices were thinly veiled pill mills, and have been shut down in many states. But doctor shopping — that is, seeing multiple doctors for prescription narcotics — is still common. This often fools doctors because their patients are seemingly adhering to safe protocols. No one doctor realizes his or her patients are seeing three, four or five other physicians in search of quantities of pills no one doctor would prescribe.

Drug Abuse. When prescription opioids no longer satisfy their cravings, some addicts move on to stronger drugs like heroin.²² Policymakers should consider ways to alleviate drug-seeking behaviors and abuse by individuals prevented from procuring prescription opioids. (Though beyond the scope of this analysis, thefts by pharmacy employees or armed robberies could increase.)

According to the National Institute of Drug Abuse, about half of intravenous heroin users reported previously abusing prescription opioids.²³ Substituting street drugs like heroin for prescription opioids frequently has public health spillover effects. [See Figure V.] For instance, the small Indiana town of Austin in rural Scott County experienced 153 confirmed cases of HIV from intravenous drug use by individuals addicted to

painkillers in 2015.²⁴ By 2016, 188 people had been diagnosis with HIV, nearly 5 percent of the population. Many also contracted Hepatitis C.²⁵

Solution: Electronic Prescribing of Controlled Substances. Transmitting prescriptions electronically is a way for doctors to directly communicate their patients' prescription orders to pharmacies — rather than handing patients a signed paper prescription ripped from a pad. E-prescribing secures this information exchange from diversion. E-prescribing also facilitates detection of multiple prescriptions filled for an individual from various physicians — so-called doctor shopping. It also reduces the errors associated with poor handwriting. Once a prescription for a chronic condition has been prescribed, refills should require less effort by doctors and patients.²⁶ E-prescribing also allows doctors to monitor whether or not patients are filling their prescriptions — and how frequently — an indication of compliance and possible misuse. [See the sidebar on Prescription Monitoring.]

Ironically, most doctors have been using electronic prescribing of noncontrolled substances for a few years now. But until recently, federal regulations *prohibited* e-prescribing of controlled substances due to the perceived risks of drug abuse and diversion. Electronic prescribing of controlled substances is now permitted in all 50 states. Yet, not all pharmacies — and even fewer physicians' offices — are prepared to transmit prescriptions electronically because it requires sophisticated protocols and software that meets U.S. Drug Enforcement

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Administration regulations:²⁷

- The process must use the federally required two-factor identification.
- The DEA certificate must be registered with the state board responsible for enforcing regulations on the distribution of narcotics.

Mandatory e-prescribing of controlled substances adds electronic checks and balances to an existing system. When a patient sees their doctor and is prescribed, say, 30 Oxycodone tablets for pain, it is entered into a computer system that only a doctor can access. These systems require two-factor authentication for a prescription — preventing anyone but the doctor from ordering drugs. The prescription is generally sent to a specific pharmacy. When a patient visits his or her pharmacy, the pharmacy computer system pings the physician's computer system to validate the prescription and verify no other pharmacy has filled the prescription. The pharmacist and other prescribing doctors are alerted if two, three or five other physicians also prescribed narcotic painkillers to the same patient. The system also tracks customers who currently pay cash for their prescription to avoid tracking by their drug plan. In the event the pharmacy does not have a given drug on hand, the prescription is cancelled and a new one is sent to a different pharmacy.

Identification Protocols. DEA regulations require redundant, “two-factor” identity verification security protocols. For electronic prescribing, it often requires physical items such as smart cards, fingerprint scanners or other biometric authenticators. It often requires one-use software tokens, in addition to a user name and password.²⁸

One factor is the knowledge factor, such as a user name and password. The security code for a home security alarm meets this criterion. The second factor is a possession factor; that is something physicians keep with them to ensure its safekeeping. A house key meets this criterion. Rather than a physical key, the electronic prescribing system could require a fingerprint scan. Once the first factor is accepted, the second security factor is often a password. A few practitioners complain it is cumbersome, but most admit they will get used to it.²⁹ Patients are also required to show a form of identification when picking up medications.

Software Requirements. DEA has strict regulations governing the design of software certified for e-prescribing. The DEA regulations mandate:

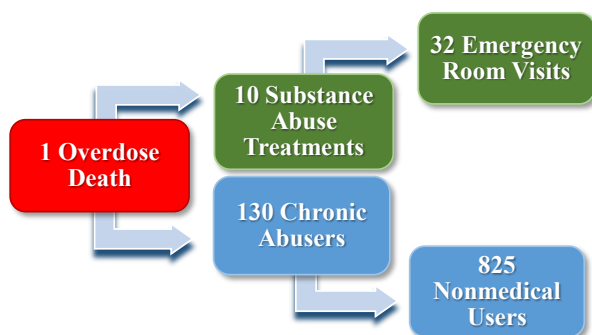
- E-prescribing systems must include a process for verifying the identity of the prescriber.
- Systems also must include a health information technology protocol for securely transmitting a digital signature and for the pharmacy to receive and archive prescription records.
- The stakeholders' systems are also subject to audits by regulators.

Improved Accuracy. Among the benefits of electronic prescribing is increased accuracy.³⁰ Handwritten prescriptions are prone to a variety of errors — especially legibility. A meta-analysis found the rate of adverse drug effects and errors was substantially reduced when prescriptions were sent electronically.³¹ Medication errors were reduced by 13 percent to 99 percent in about two dozen studies reviewed. The risk reduction of adverse drug events was 30 percent to 84 percent in one series of matched studies.

Better Monitoring. Another advantage of e-prescribing is better coordination of drug regimens and monitoring for abuse and drug interactions. Virtually all states now have drug monitoring programs. But they are not too difficult to circumvent. Merely paying cash and using

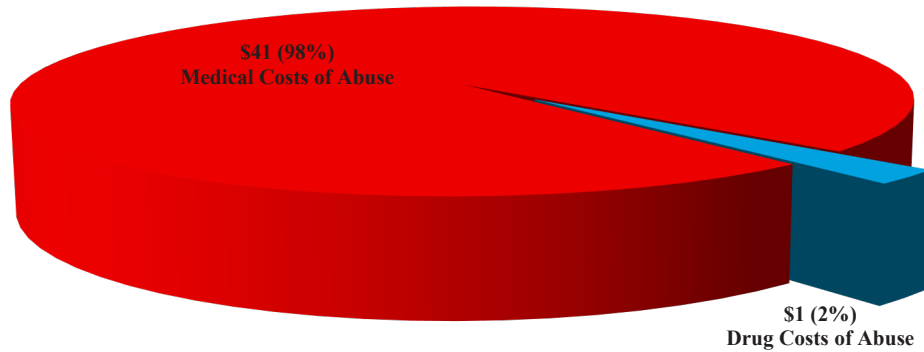
Figure III

Harm from Prescription Drug Misuse (For Every One Overdose Death)



Source: Angela Huskey, “The Cost of Pain and Economic Burden of Prescription Misuse, Abuse and Diversion,” Millennium Laboratories, 2013; and “CDC Vital Signs: Overdoses of Prescription Opioid Pain Relievers in the U.S. 1999-2008,” Centers for Disease Control and Prevention, November 2011.

Figure IV
The Cost of Prescription Drug Fraud



Source: "Prescription for Peril: How Insurance Fraud Finances Theft and Abuse of Addictive Prescription Drugs," Coalition Against Insurance Fraud, December 2007.

Physicians said they like the ability to monitor whether patients had a prescription refilled, but think software vendors need to incorporate more user-friendly interfaces to better align with physicians' workflow needs.³⁶ This is consistent with a later study that found software designers need to work more closely with the clinical end-users of electronic health record systems to ensure usability. Basically, doctors' practices and workflow are often not taken into account to the degree they should be.³⁷ Reports from

multiple, false identifications or misspelling one's name is often enough to avoid the scrutiny that one individual could receive after filling multiple prescriptions in a short time.

Although all states now have prescription drug monitoring programs, only one-third of prescribing physicians use them.³² An analysis of the prescription drug monitoring program and the associated state laws regulating so-called pill mills found that the monitoring program was associated with a modest decrease in opioid prescriptions and use. However, the decrease was greater among both prescribers and users with the highest baseline prescriptions and utilization, respectively.³³

National Experience with Electronic Prescribing. In a national survey of practitioners who had sent at least one prescription for a controlled substance electronically, most reported the experience was less troublesome than they had anticipated. Over half reported the process was easy to use and improved workflow; nearly 60 percent thought it made it easier to monitor prescriptions; and 70 percent thought it increased the accuracy of the prescriptions.³⁴ Pharmacists no longer have to decipher, guess or make follow-up calls concerning illegible handwriting.

A 2010 study of noncontrolled substances found electronic prescribing cut in half the time required for physicians to refill prescriptions. Electronic refills were also more convenient for patients. The survey also found the rollouts had a few bugs to work out.³⁵

Minnesota also concluded that to achieve its full potential, e-prescribing needs to be integrated with electronic health records.³⁸

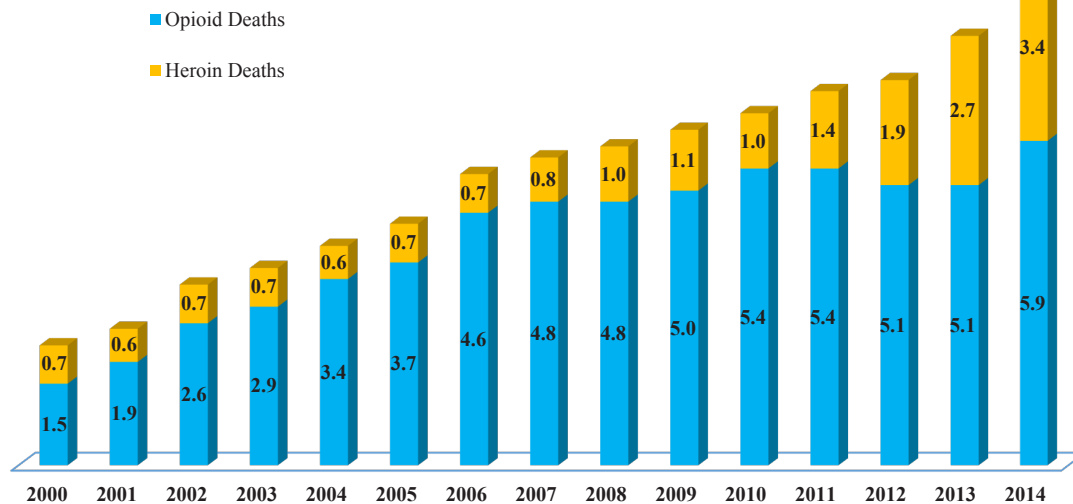
Results from Minnesota. In 2008, Minnesota became the first state to mandate e-prescribing. The deadline for doctors, pharmacies and drug plans to adopt e-prescribing was January 1, 2011. Minnesota now claims 95 percent of all pharmacies are e-prescribing and about 90 percent of hospitals and clinics.³⁹ It has taken Minnesota providers and pharmacies longer because the law had no enforcement mechanism. Stakeholders are encouraged to comply.⁴⁰ However, it is not clear that most Minnesota physicians are able to electronically sign a prescription for controlled substances.⁴¹

Case Study: New York State. On March 27, 2016, New York became the second state to do away with the prescription pad and require all prescriptions to be transmitted electronically. These regulations are indicative of what will likely be seen elsewhere because the DEA mandates the security protocols.

The State of New York rate of opioid overdose fatality rate is 6.5 per 100,000, higher than the national average. Fatalities are often due to opioids and benzodiazepines prescribed together.⁴² Under the law in New York, prescribers now must check a statewide electronic database for previous prescriptions before they can issue a new one.⁴³

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Figure V
U.S. Overdose Deaths
(Per 100,000 Population)



Note: Rates age-adjusted.

Source: Wilson M. Compton, Christopher M. Jones and Grant T. Baldwin, "Relationship between Nonmedical Prescription-Opioid Use and Heroin Use," *New England Journal of Medicine*, Vol., No. 374, January 14, 2016, pages 154-163.

The program is known as the Internet System for Tracking Over-Prescribing (iSTOP). It was delayed for a year while the DEA approved protocols for software vendors. The rollout in New York State went relatively smoothly after the mandate took effect:

- Just prior to the rollout of the law, nearly half of New York prescribers complied with the requirement to transmit prescriptions for controlled substances electronically, compared to less than 8 percent nationally.⁴⁴
- Today, 70 percent of New York physicians transmit scripts electronically, compared to only about 58 percent nationally.
- About 95 percent of New York pharmacies can accept electronic prescribing of narcotics, compared to about 84 percent nationally.

For doctors who are not yet using e-prescribing, the rollout has been more problematic; however, officials expect most will begin to comply with the regulations in the next few months. Practices that demonstrate exceptional circumstances, an economic hardship or technical limitations over which the physician has no control can apply to

the New York State Department of Health for a 1-year waiver.

One potential problem is that pharmacies must still accept paper prescriptions, since they have no way of knowing whether a given physician has received a waiver or if computer problems make it impossible to issue electronic prescriptions. In theory, physician prescribers have a duty to inform the Health Department about paper prescriptions when computers are not available or for out-of-state patients. However, the exception potentially opens the door to counterfeit paper prescriptions for drug diversion.

New York State's iSTOP program does not track pharmacy inventory and inform doctors when a prescription cannot be filled at a given pharmacy. Anecdotal reports after the rollout say that doctors are more likely to prescribe common medications and common doses to avoid the problems of an out of stock pharmacy. Although there are some exceptional cases where paper prescriptions are still allowed, doctors failing to abide by the mandate will face disciplinary action.⁴⁵

In the three months after iSTOP was implemented, opioid prescriptions by dentists fell by about half (31 percent before iSTOP compared to 14 percent in the three following months). The quantity of pills per prescription also fell. The total numbers of opioids prescribed fell by three-fourths (78 percent).⁴⁶

One problem with the New York law is that there are no provisions for comparison shopping at different pharmacies once doctors have input a prescription. Patients have to know which pharmacy they want their prescription sent to and inform their doctor while in the office. That

is fine for patients with a drug plan who use the same preferred pharmacy. But those who may not have a drug plan could find their drug costs rise. In addition, some pharmacies choose not to stock some controlled substances or are sometimes out of a given medication. In those cases, physicians have to cancel the prescription and resubmit it to a different pharmacy.

State of E-Prescribing and Obstacles to Overcome. The move to electronic prescribing is progressing slowly but surely. Some physicians still do not prescribe drugs electronically. Even when they do, they often don't use electronic prescribing systems to their full capacity. In 2008, just over 40 percent of office-based physicians had the capacity to prescribe any drug electronically. Of those with the capability:⁴⁷

- About one-fourth either did not use it or used it only occasionally.
- Only a small proportion — about one-fourth — used the advanced features, such as checking for drug interactions and formulary information, and transmitting to pharmacies electronically.

A national survey from July 2012 to December 2013 — an 18-month period — found the number of electronic prescriptions for controlled substances increased from 1,535 to 52,423. During the period the percentage of all pharmacies capable of receiving prescriptions for controlled substances electronically increased 130 percent.⁴⁸

Each state has slightly different regulations on e-prescribing.⁴⁹ The DEA issued an *interim Final Rule* in June 2010 allowing electronic prescribing of controlled substances, spelling out the standards for use.⁵⁰ However, it has taken years for the security measures to be developed.

Though physicians understand the reasons behind electronic prescribing of controlled substances, many worry about having to carry the security token. Yet, at the same time, they also believe e-prescribing will reduce calls to and from pharmacies and save the associated costs of having an office assistant or nurse field those calls. Some obstacles that systems engineers should consider when developing electronic prescribing protocols are how to deal with delays in processing the prescription at the pharmacy and the occasional unreliability of the network. System designers need to be concerned about problems caused by human

factors, such as poor interface and poor user entry design.

According to the U.S. Department of Health and Human Services, physicians' main concern is funding. Physicians and pharmacies are responsible for obtaining systems compliant with federal regulations. Physicians, especially small practices, do not want to be forced to invest funds that they perceive provide little benefit to their practice. The inertia of selecting computer systems — both hardware and software — can be a challenge. Another concern is that some pharmacies are not connected to networks capable of accepting electronic prescriptions. Chain pharmacies are almost entirely connected, while independent pharmacies have been much slower to adopt these systems. In a recent report, only about one-fourth of independent pharmacies were connected in a way that allows electronic prescriptions.

Better tracking and control of opioid drugs through mandatory prescribing of controlled substances will help keep the next generation of potential abusers away from prescription narcotics. But without treatment, the current generation of addicts will likely turn to other substances.⁵¹

Conclusion

Drugs derived from opioids are at high risk for diversion, abuse and addiction, and even overdose death. A byproduct of poorly tracked and managed controlled substances are adverse public health spillover effects manifested by other diseases.

Mandatory electronic prescribing with tracking of controlled substances is a solution that policymakers should consider. New York State, Minnesota and Maine have taken that step and other states are considering similar moves. Many physicians and most pharmacies are already equipped to transmit or receive prescriptions electronically. The next logical step is to integrate the two-factor authentication and tracking to inhibit abuse and diversion of prescription drugs to the illicit market.

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