

October 5, 2020

Submitted electronically via: <a href="http://www.regulations.gov">http://www.regulations.gov</a>

The Honorable Seema Verma, Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1734-P 7500 Security Boulevard Baltimore, MD 21244-1850

RE: <u>Medicare Program: CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; (CMS-1734-P)</u>

Dear Administrator Verma:

Surescripts operates the nation's largest clinical health information network. Founded in 2001 by pharmacies and pharmacy benefit managers (PBMs) to enable electronic prescribing (e-prescribing), the company has moved beyond e-prescribing and today offers a wide portfolio of clinical messaging services. Surescripts serves providers and patients in all 50 states and the District of Columbia and delivers over 700,000 clinical health transactions every hour. Everyday, more than 70 percent of all office-based providers use our services on behalf of over 3 million patients.

We connect to over 99 percent of all retail pharmacies and most mail order pharmacies in the country, and we delivered over 1.91 billion prescriptions and 1.77 billion medication histories to providers this past year. Our provider directory contains over 1.61 million prescribers and our Master Patient Index covers 258 million insured lives. Additional information about Surescripts is available at <a href="https://surescripts.com/news-center/national-progress-report-2019/">www.surescripts.com/news-center/national-progress-report-2019/</a>.

On August 4, 2011, a new era in e-prescribing began when the first legal Electronic Prescribing of Controlled Substances (EPCS) prescription was transmitted by a prescriber to a pharmacy via the Surescripts network. Since then, Surescripts has processed over half a billion e-prescriptions for controlled substances. Surescripts has garnered a wealth of experience regarding EPCS since adopting the technology, not only by implementing the Drug Enforcement Agency (DEA) e-prescribing intermediary requirements, but also by assisting its EHR and pharmacy customers to adopt and make available EPCS capabilities.

According to our 2019 National Progress Report, the number of e-prescriptions filled for controlled substances reached 134.2 million, representing 38% of controlled substance prescriptions—up 12% from the year prior. In the first six months of 2020, Surescripts facilitated the transmission of another 110 million EPCS transactions. We also crossed an important milestone: more than half (56.3%) of prescribers nationwide are now enabled for EPCS. Clearly, those with a need to prescribe opioids are finding this technology valuable.

Surescripts very much appreciates the opportunity to comment on the CY2021 Physician Fee Schedule Proposed Rule (the "Proposed Rule") issued by the Centers for Medicare & Medicaid Services ("CMS"), which includes a proposal to mandate that Part D prescribers use an electronic prescribing module to prescribe controlled substances as required by the SUPPORT for Patients and Communities Act (the "SUPPORT Act").

We believe there is an absolute and urgent need to comply with the statutory requirement that the EPCS mandate be implemented on January 1, 2021. Nearly six Americans died every hour from opioid-related overdoses in 2019, and signs indicate that the 2020 overdose rate will be even worse. Over the past 9 months more than 40 states have reported increases in opioid-related mortality. The COVID-19 pandemic and its adverse psychological and financial ramifications has exacerbated the opioid abuse epidemic, including the misuse and fraudulent proliferation of opioid medications. The EPCS mandate that CMS is proposing to delay will help to reverse this trend by making it more difficult for individuals to obtain controlled substances through the use of fraudulent paper prescriptions.

Of equal concern is the increase in risk of COVID-19 infection that seniors will face if the mandate is delayed. With seniors particularly vulnerable to more severe outcomes if infected by COVID-19, health care providers are increasingly using telemedicine to treat them and avoid unnecessary infection risks posed by in-office visits. Health care providers in practices that have not yet implemented EPCS are in many cases nevertheless forced to ask seniors to come into the office to pick up a prescription for a controlled substance. Seniors affected by this must then make two visits to their pharmacy to drop off and pick up the prescription, or wait at the pharmacy as their prescriptions are filled, increasing potential points of exposure to the virus for seniors, providers, staff, pharmacists, and others. This paper-based workflow also creates unnecessary burdens for the prescribers, pharmacists, and the patients they serve.

For these reasons, we implore CMS to not delay implementation a full calendar year beyond the January 1, 2021 deadline mandated by Congress in the SUPPORT Act for prescribers of controlled substances under Part D to use EPCS. Instead, CMS should adhere to the January 1, 2021 deadline imposed by Congress in the SUPPORT Act. CMS could then elect to use enforcement discretion to limit penalties until a later date.

<sup>&</sup>lt;sup>1</sup> Centers for Disease Control, National Center for Health Statistics, Provisional Drug Overdose Death Counts, <a href="https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm">https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm</a>.

<sup>&</sup>lt;sup>2</sup> American Medical Association, <u>Issue Brief: Reports of increases in opioid-related overdose and other concerns during COVID pandemic</u>, September 8, 2020.

Below, we provide our comments to the EPCS proposals in the Proposed Rule.

# Comments

I. Feasibility of Proposed January 1, 2022 Deadline

We understand that the proposal to require electronic prescribing for controlled substances for covered Part D drugs under a prescription drug plan or MA-PD plan would uniquely affect physicians. As a result, we seek to gain the insight and perspective of prescribers and others. We welcome comments on this proposal, including the feasibility for prescribers to meet the proposed January 1, 2022 deadline.

<u>Surescripts Comments:</u> We do not believe that the implementation of the EPCS mandate would be costly or overly burdensome for physicians. Many EHRs include EPCS within the cost of their EHR systems and therefore would not impose additional implementation costs on prescribers to implement EPCS. Other EHRs charge an annual per-provider fee to implement. For those EHRs that do charge a fee for EPCS capabilities, the annual fee ranges from \$75 per provider per year to \$5,988 per provider per year according to a <u>2018 survey performed by Point-of-Care Partners</u>, with the majority in the \$90-\$150 per provider range.<sup>3</sup> One-time setup fees for EPCS modules range from \$0 to \$340 per provider.

Further, we agree with the reasons that CMS listed in the Proposed Rule for why EPCS is critical:

- EPCS can deter and help detect prescription fraud and irregularities as a result of the extra layer of identity proofing required to send an electronic prescription for a controlled substance.
- EPCS minimizes the likelihood that a prescription can be tampered with, as electronic prescriptions are securely transmitted directly to pharmacies.
- EPCS is more timely and accurate than paper prescriptions, avoiding data entry errors and pharmacy calls to a prescriber to clarify written instructions.
- EPCS reduces the burden on prescribers who would otherwise need to coordinate and manage paper prescriptions between staff, patients, facilities, other care sites, and pharmacies. EPCS also reduces prescriber burden by creating a single electronic workflow for prescribing both controlled and non-controlled drugs.
- EPCS reduces burden for patients, particularly during the COVID-19 Public Health Emergency, as
  patients with a paper prescription might need to make multiple trips to providers and pharmacies to
  receive and fill needed prescriptions trips that could potentially put seniors at risk of exposure.

Given the wide-ranging benefits of EPCS adoption, including the added convenience and administrative savings gained by prescribers, we believe that the proposed implementation on January 1, 2022 is eminently feasible but ill-advised. Instead, implementation should occur on January 1, 2021, as called for in the SUPPORT Act.

<sup>&</sup>lt;sup>3</sup> Point-of-Care Partners, "The Impact of Cost on EPCS Adoption", <a href="https://www.pocp.com/hit-perspectives-cost-EPCS-Adoption">https://www.pocp.com/hit-perspectives-cost-EPCS-Adoption</a>, April 2018.

Under the SUPPORT Act, Congress originally considered an implementation date of January 1, 2020 before settling on January 1, 2021 to give providers extra time to implement EPCS. We note this in order to point out that Congress had already built in implementation time for providers when establishing the January 1, 2021 deadline. We believe providing a full year beyond January 1, 2021 is unnecessary, and could cause prescribers to deprioritize their implementation of EPCS despite the clear feasibility of implementation. We strongly discourage CMS from pushing back the implementation date any further.

# We are also soliciting comments regarding the impact of this proposal on overall interoperability and the impact on medical record systems.

<u>Surescripts Comments:</u> The implementation of electronic prescribing represents one of the greatest success stories of nationwide interoperability. Over 79% of prescribers and 98.7% of pharmacies have adopted e-prescribing, and about 86% of non-controlled substances were transmitted to pharmacies electronically in 2019.<sup>4</sup> The reason the adoption of e-prescribing has been successful is twofold: 1) CMS created an expectation of prescriber adoption and use of e-prescribing modules for non-controlled substances through the E-Prescribing Incentive and Meaningful Use Programs; and 2) as prescribers began to adopt e-prescribing modules in response to the CMS mandate, patients and prescribers found that they preferred the ease and convenience of e-prescribing.

Without any similar mandate or incentive program in place at the federal level for prescribing controlled substances, nearly 40% of prescriptions for controlled substances were transmitted electronically in 2019. CMS' adoption and implementation of a mandate for EPCS will further accelerate prescriber adoption and use of e-prescribing for controlled substances. Once the mandate is in place, we are confident that prescriber and patient preference for e-prescriptions will minimize prescribers' use of the waivers established under the SUPPORT Act. Further, we are confident that EHR developers are prepared to facilitate adoption of EPCS modules. Every major EHR system already offers EPCS, either as part of their standard e-prescribing modules or as an optional add-on. Implementation of the EPCS mandate will therefore not require new software development or expensive updates to existing EHR systems.

We are interested in receiving comments on whether the proposed change would be significant enough for a January 1 implementation date, which is required for all significant changes affecting Part D plans.

<u>Surescripts Comments:</u> We do not believe the EPCS mandate is a significant change affecting Part D plans. Explicitly under the SUPPORT Act, neither Part D plans nor their network pharmacies are expected to verify that a prescriber has a waiver. They also are explicitly not required to refuse to cover/dispense a controlled substance as a result of a prescriber sending an otherwise valid written, oral or fax prescription. As a result, Part D plans are unaffected by the change – as it will not affect the cost of controlled drugs or Part D plans' ability to cover and pay for them. As a result, if CMS wanted to adopt an implementation date in the middle of the calendar year, it could. If CMS will not adopt January 1, 2021 as the compliance date for the EPCS mandate, we ask that CMS at least consider a date prior to January 1, 2022 as the initial compliance date.

<sup>&</sup>lt;sup>4</sup> Surescripts, 2019 National Progress Report, https://surescripts.com/news-center/national-progress-report-2019/.

#### II. EPCS Burden Estimate

In the first year of implementation, we expect that prescribers would have to revise their policies and procedures and train staff on this new requirement. Based on our conversations with the industry, we understand that because electronic prescribing is so widespread and vendors train the staff directly and set-up their systems, we estimate that this transition could be completed with a one-time burden of 5 hours at \$36.62/hr by an Administrative Assistant or Medical Secretary. However, we seek comment on this assumption.

<u>Surescripts Comments:</u> We agree with CMS's calculation of the cost of EPCS implementation. We note that most EPCS solutions integrate into providers' existing e-prescribing solutions, making the transition fairly seamless. The majority of staff training for the new requirement would address the provider's process for issuing a credential for EPCS and how prescribers complete multi-factor authentication to access the EPCS module.

Based on internal CMS data, there are 425,000 Part D prescribing practices. Based on the increasing rate of doctors conducting e-prescribing thus far and the benefits of e-prescribing, in light of the current social distancing guidelines, we estimate that by January 1 2022, 65 percent of Part D prescribers will have electronic prescribing capabilities absent the requirement. Therefore, the one-time burden to implement this provision is 743,750 hours (148,750 prescribers \* 5 hr) at a cost of \$27,236,125 (743,750 hr \* \$36.62/hr). Based on the modeling that we have seen, we have found that EHR companies provide the initial set-up of e-prescribing software free of charge, provided the prescribers pay the per transaction cost of \$1.88 mentioned previously. However, we seek comment on this assumption and all other assumptions in this burden estimate.

<u>Surescripts Comments:</u> Based on our experience, not all EHR developers charge a per transaction fee. Rather, many EHR developers instead charge annual fees based on the number of prescribers – generally ranging from \$90 per prescriber per year to \$150 per prescriber per year according to the <u>Point-of-Care Partners' 2018 survey</u>. Additionally, we think it would be more accurate for CMS to calculate the time burden for EPCS adoption on a per practice basis rather than on a per prescriber basis. As CMS noted in its burden estimate, the transition could be quarterbacked by a medical staff assistant of a prescribing practice, who could then train prescribers for perhaps one hour each (as opposed to five hours per prescriber).

Therefore, the total costs of the existing ePA activity is \$2,855,390.85 per year as compared to \$526,804.20 for using the standard. This amounts to an annual savings of \$2,328,586.65 in prescriber expenses with the first year resulting in an added cost of \$24,907,538.35 (\$27,236,125 - \$2,328,586.65).

<u>Surescripts Comments:</u> The comparison that CMS attempted to make in this portion of the Proposed Rule was unclear to us, as we do not see how current electronic prior authorization (ePA) activity is relevant to the EPCS mandate. We urge CMS to clarify this calculation in the final rule, and we suggest that CMS

<sup>&</sup>lt;sup>5</sup> Point-of-Care Partners, "The Impact of Cost on EPCS Adoption", <a href="https://www.pocp.com/hit-perspectives-cost-EPCS-Adoption">https://www.pocp.com/hit-perspectives-cost-EPCS-Adoption</a>, April 2018.

perhaps intended to compare the administrative costs of using written, faxed, or oral prescriptions for controlled substances as opposed to electronic prescriptions for controlled substances. We ask that CMS provide additional detail in the final rule about how it quantifies the administrative costs for existing prescribing activity involving controlled substances. We agree that providers will experience a savings as a result of not having to respond to pharmacy inquiries about written prescriptions, or ask a patient to come into the office to obtain another prescription if a pharmacy is out of the medication and cannot transfer it to another pharmacy. According to a 2018 report prepared by Point-of-Care Partners for PCMA, attached hereto as Appendix A, physician offices, dentists and pharmacies could save \$439 million annually thanks to reduced numbers of callbacks to clarify prescriptions. The report also concluded that the United States would save \$53 billion annually overall by implementing an EPCS mandate thanks in part to a reduction in opioid fatalities, decreased treatment costs, workforce productivity gains, and greater efficiencies for prescribers, pharmacies and consumers.

Thank you for the consideration of our views. Please do not hesitate to contact me with questions or for further information.

Sincerely,

Mary Ann Chaffee

Vice President for Policy and Federal Affairs

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# Mandatory Electronic Prescribing of Controlled Substances (EPCS) Can Help Combat the Opioid Crisis and Save the United States up to \$53 Billion Annually

Prepared for



April 2018

## I. Executive Summary

According to government estimates, the opioid epidemic has reached crisis proportions, and now costs the US more than \$500 billion annually. Of this total, \$432 billion is from the total cost of fatalities and \$72 billion is from non-fatality costs such as increased health care costs, lost productivity, and criminal justice costs. More than 80% of the \$500 billion in costs is related to individuals who are abusing prescription drugs (i.e., this problem is not limited to illicit drug abuse, like heroin). The opioid epidemic is a complex problem with multiple, complex solutions. However, one of the most important solutions lies in gaining better control of the prescribing and dispensing of controlled substances.

E-prescribing has been shown to dramatically reduce medication errors and limit fraud, and in 2010 the Drug Enforcement Agency allowed its use for prescribing of controlled substances; these are drugs that are regulated by state and federal laws due to their nature of potential addiction, abuse, and trafficking by illegal means (e.g., opioids, morphine, valium). All states now permit the use of e-prescribing for Controlled Substances (EPCS), and an increasing number of states require its use. EPCS, combined with comprehensive medication history, helps circumscribe prescriber and pharmacy shopping, enables better prescription tracking, and reduces fraud.

Some of the benefits associated with EPCS have been quantified in published studies, but others have not. Visante and Point-of-Care Partners have completed a comprehensive review of the literature to create an economic analysis of the benefits associated with mandatory use of EPCS across the United States. In addition, a recent state law in New York requiring e-prescribing of opioids may soon demonstrate that such policies deliver significant savings by reducing inappropriate utilization. However, data on actual fiscal savings achieved through New York's program were not yet available at the time of publication and are not factored into our findings.

EPCS with comprehensive medication history helps inform and improve prescribing decisions, which in turn reduces overprescribing, overuse, and resulting addiction. Likewise, EPCS improves security associated with controlled substance prescriptions, helping to reduce fraud and diversion. Finally, EPCS with comprehensive medication history improves efficiencies, with significant benefits for physicians, pharmacies, and consumers.

The broader adoption of EPCS will also complement other efforts to curb opioid abuse, such as "lock-in" programs designed to prevent inappropriate prescriptions from crossing the pharmacy counter by requiring those at risk of abusing opioids to use a single pharmacy.

#### Major Findings

 In 2016, e-prescribing for non-controlled substances was used by 98% of pharmacies and 64% of prescribers, with 1.6 billion (73% of total) new prescriptions transmitted electronically. Unfortunately, the adoption of ECPS lags far behind, with only 14% of controlled substances prescribed electronically in 2016.<sup>2</sup>

- Mandatory use of EPCS and comprehensive medication history provided through the Prescription Drug Monitoring Programs (PDMPs) was implemented smoothly and successfully in New York State in 2016, with 72% of prescribers using EPCS to prescribe 92% of controlled substances electronically. A similar mandate in other states, or a federal requirement nationwide, would have a significant positive impact.
- If the use of EPCS with access to comprehensive medication history were required nationally and its use by prescribers and pharmacies rose to optimal levels, the United States would realize annual savings of up to \$53 billion, based on estimated annual savings of:

<sup>&</sup>lt;sup>1</sup> IOM report on preventing medication errors. Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, DC: National Academy Press, 2001.

<sup>&</sup>lt;sup>2</sup> Surescripts EPCS Report Progress Update Report – November 2017. Presented at NCPDP Task Group Meeting November 2017.

- \$18 billion to \$37 billion in reduced costs associated with fatalities related to opioid abuse;
- \$7 billion to \$14 billion saved due to decreased health care costs, decreased treatment costs, workplace productivity gains, and reduced criminal justice costs; and
- \$1.6 billion saved from greater efficiencies in physician offices and pharmacies, and increased convenience for consumers given they do not have to spend time at the pharmacy waiting for their prescriptions to be filled.
- If the use of EPCS with access to comprehensive medication history were required for <u>Medicare Part D</u>
   <u>prescriptions</u> and its use by prescribers and pharmacies rose to optimal levels, the federal government
   would realize savings of more than \$2 billion annually, based on estimated annual savings related directly
   to Medicare beneficiaries of:
  - \$2 to \$4 billion saved due to decreased health care costs, decreased treatment costs, workplace productivity gains, and reduced criminal justice costs; and
  - \$0.5 billion saved from greater efficiencies in physician offices and pharmacies, and increased convenience for consumers.

# II. Costs of the Opioid Epidemic

The abuse of opioids has reached epidemic proportions in the United States. According to a recent study by the White House Council of Economic Advisors, <sup>3</sup> the opioid epidemic is costing the nation more than \$500 billion per year, which includes:

- Both prescription and illicit drugs; and
- The value of lives lost, as well as health care spending, criminal justice costs, and lost productivity due to addiction and incarceration.

More than 80% of these costs are related to individuals with a <u>prescription</u> opioid disorder, alone or in combination with a heroin disorder.

#### Prescription Opioids Lie at the Heart of the Problem

Opioid prescriptions lie at the heart of the opioid epidemic. As the epidemic has unfolded, it has become apparent that overdoses and addiction often start with legal prescriptions. This is reflected in the fact that the amount of prescription opioids sold to pharmacies, hospitals, and prescribers' offices nearly quadrupled from 1999 to 2010. Some 249 million prescriptions for opioids were written in 2013—enough for every American adult to have a bottle of pills. Significant geographic variation in opioid prescribing is also troubling, with prescribers in some counties writing six times more opioid prescriptions per person than the lowest-prescribing counties. In 12 states, there are more opioid prescriptions annually than there are people. Both Alabama and Tennessee have 143 prescriptions per 100 adults in the state. The impact is that more than 2 million Americans had a prescription opioid addiction as of 2015, and 97.5 million Americans used, or misused,

The Underestimated Cost of the Opioid Crisis. White House Council of Economic Advisors. November 20, 2017.

<sup>&</sup>lt;sup>4</sup> PDMP Fact Sheet, Centers for Disease Control and Prevention.

Schuchat, A, et al. New Data on Opioid Use and Prescribing in the United States, JAMA. 2017;318(5):425-426.

Opioid Painkiller Prescribing, CDC Vital Signs, Centers for Disease Control and Prevention, July 2017.

Medicaid's Role in Addressine the Opioid Epidemic, Kaiser Family Foundation, December 2017.

#### prescription pain pills.8

Moreover, overdoses from prescription opioids are a driving factor in the 15-year increase in opioid overdose deaths. Nearly half of all opioid overdose deaths involve a prescription opioid. Survey data indicate that tens of millions of Americans misuse prescription opioids, sedatives, tranquilizers, and stimulants. Others use illicit drugs such as heroin, fentanyl, cocaine, and methamphetamine, and most people using heroin have a history of misusing prescription opioids first. And as discussed in the literature, the misuse of prescription drugs is related to high levels of prescribing of such medications. For example, in 2016 prescribers wrote 66.5 opioid and 25.2 sedative prescriptions for every 100 Americans. <sup>10</sup>

The human and economic tolls of the opioid epidemic are staggering. According to a recent study from the White House Council of Economic Advisors (CEA), <sup>11</sup> of the estimated 50,000 Americans who died of drug overdoses in 2015, more than 33,000 of the deaths involved opioids. That's more than four times the rate of overdose deaths involving opioids in 1999. The annual cost of these 33,000 fatalities is estimated to be \$432 billion.

In addition, the CEA report estimates 2.4 million individuals had an opioid disorder in 2015. There were associated costs of \$72 billion, which were related to increased health care costs, treatment costs, lost productivity, and criminal justice fees. However, the CEA report notes that only 14% of the 2.4 million individuals with an opioid use disorder in 2015 presented with a heroin use disorder in isolation—more than 80% either had a prescription opioid disorder alone or both disorders. 12

While the overall costs of the epidemic are significant, the impact on health is substantial. About a third of the overall costs of the opioid epidemic can be attributed to health care. <sup>13</sup> These costs impact all payers, including Medicare and Medicaid, as well as hospitals and local public health systems. This does not take into account the impact on lives, which is not quantifiable, including the emotional toll on families, marriages, and children.

#### Opioids and the Burden on the Health Care System

Impact on Medicare. Surprisingly, America's senior citizens have the potential for prescription opioid abuse, which cost Medicare an estimated \$6.3 billion in 2016. <sup>14</sup> In fact, heavy use and abuse of painkillers remains a serious problem for certain Medicare beneficiaries. <sup>15</sup> One in three Medicare Part D beneficiaries (or roughly 14.4 million seniors) filled at least one prescription for an opioid in 2016. In addition, half a million Part D beneficiaries received high amounts of opioids in 2016. Of 58 million Medicare beneficiaries, almost 90,000 beneficiaries are at serious risk of opioid misuse or overdose. The Medicare population not only mirrors the larger population in its addiction rate, it has among the highest and fastest-growing rates of diagnosed opioid use disorder, currently at more than 6 of every 1,000 beneficiaries. <sup>16</sup>

Two main groups of beneficiaries are at serious risk of opioid misuse or overdose: (1) beneficiaries who

<sup>13</sup> Curtis, et al. <u>The Economic Burden of Prescription Opioid Overdose</u>. <u>Abuse</u>. and <u>Dependence in the United States</u>. 2013. Medical Care. 2016;54(10):901-906.

Prescription Drug Use and Misuse in the United States: Results From the 2015 National Survey on Drug Use and Health. NSDUH Data Review. SAMSHA. September 2016.

Understanding the Epidemic. Centers for Disease Control and Prevention.

Annual Surveillance Report of Drug-Related Risks and Outcomes, United States, 2017. Centers for Disease Control and Prevention. 2017.

The Underestimated Cost of the Opioid Crisis. White House Council of Economic Advisors. November 20, 2017.

<sup>12</sup> Ibid.

<sup>&</sup>lt;sup>14</sup> Ryan, CN. The Potential Societal Benefit of Eliminating Opioid Overdoses, Deaths, and Substance Use Disorders Exceeds \$95 Billion Per Year, November 2017.

<sup>&</sup>lt;sup>15</sup> Opioids in Medicare Part D: Concerns About Extreme Use and Questionable Prescribing. HHS OIG Data Brief. OEI-02-17-00250. July 2017.

<sup>&</sup>lt;sup>16</sup> Lembke, A, Chen, J. Use of Opioid Agonist Therapy for Medicare Patients in 2013. JAMA Psychiatry. 2016;73(9):990-992.

received extreme amounts of opioids (these beneficiaries had an average daily dose that exceeded 240 mg for the entire year; this extreme amount is more than two and a half times the dose Center for Disease Control and Prevention (CDC) recommends avoiding for chronic pain patients); and (2) beneficiaries who appeared to be prescriber shopping. A total of 89,843 beneficiaries were in these two groups in 2016. Specifically, 69,563 beneficiaries received extreme amounts of opioids, and 22,308 beneficiaries appeared to be prescriber shopping (i.e., received high amounts of opioids and had multiple prescribers and pharmacies). The following are two examples of patients who were prescriber shopping: <sup>17</sup>

- A patient in Washington, DC, received prescriptions for opioids from 42 different prescribers and filled them at 37 different pharmacies in a year. These drugs included oxycodone, hydromorphone, and morphine.<sup>18</sup>
- A second patient in Illinois received 73 prescriptions for opioids from 11 different prescribers and filled
  them at 20 different pharmacies in a year. On multiple occasions, this beneficiary filled opioid
  prescriptions at multiple pharmacies on the same day. For example, one day he filled two 30-day
  prescriptions for fentanyl patches at two nearby pharmacies and another 30-day prescription for
  morphine at a third pharmacy more than 40 miles away.<sup>19</sup>

Drug misuse and abuse in the elderly is problematic because it can cause cognitive and physical impairment. CDC guidelines advise prescribers to use additional caution in prescribing opioids to patients aged 65 and older, because the drugs can accumulate in the body to toxic levels. This in turn can cause greater risk for falls, motor vehicle accidents, hospitalizations and emergency care, and inability to care for daily needs. However, despite these guidelines, Medicare does not permit plans to deny beneficiaries legitimate opioid prescriptions and is considering changes to allow plans to limit an initial fill to seven days.

Impact on Medicaid. State Medicaid programs bear the brunt of the opioid epidemic. For Medicaid beneficiaries, the prevalence of diagnosed opioid use disorder is even higher than Medicare or the overall population, at 8.7 per 1,000, a figure estimated to be over 10 times higher than in populations that receive coverage under private insurance companies. Medicaid covers three in 10 adults with opioid addiction. Research indicates that Medicaid beneficiaries are prescribed opioids at twice the rate of the rest of the population and are at a three to six times greater risk of a fatal overdose. In addition, prescriber and pharmacy shopping by Medicaid patients is problematic. Medicaid members received prescriptions from an average of 1.8 prescribers, with almost 8.9% using four or more prescribers. These Medicaid beneficiaries utilized an average of 1.4 pharmacies to fill their medications, with 3.4% using more than three pharmacies. State Medicaid programs use a variety of indicators to identify individuals who are potentially misusing prescription opioids, but pharmacy and prescriber shopping can be considered a proxy for potential misuse. Total cost to Medicaid programs amounted to more than \$500 million for over 34 million claims for opioid

20 Prescription Opioids: Medicare Needs to Expand Oversight Efforts to Reduce the Risk of Harm. United States Government Accountability Office. October 2017.

<sup>&</sup>lt;sup>17</sup> Opioids in Medicare Part D: Concerns About Extreme Use and Questionable Prescribing. HHS OIG Data Brief. OEI-02-17-00250. July 2017.

<sup>&</sup>lt;sup>18</sup> Ibid.

<sup>19</sup> Ibid.

<sup>&</sup>lt;sup>21</sup> Ghate, SR, Haroutiunian, S, Winslow, R, McAdam-Marx, C. Cost and Comorbidities Associated With Opioid Abuse in Managed Care and Medicaid Patients in the United States: A Comparison of Two Recently Published Studies. Journal of Pain & Palliative Care Pharmacotherapy. 2010;24(3):251-258.

Medicaid's Role in Addressine the Opioid Epidemic, Kaiser Family Foundation, December 2017.

<sup>23</sup> Overdose Deaths Involving Prescription Opioids Among Medicaid Enrollees—Washington, 2004—2007. Centers for Disease Control and Prevention. MMWR Weekly. 2009;58(42):1171-1175.

<sup>&</sup>lt;sup>24</sup> Poisoning Deaths Involving Opioid Analgesics—New York State, 2003–2012. Centers for Disease Control and Prevention. MMWR Weekly. 2015;64(14):377-380.

<sup>&</sup>lt;sup>25</sup> Bernstein, A, Minor, N. <u>Medicaid Responds to The Opioid Epidemic: Regulating Prescribing and Finding Ways to Expand Treatment Access.</u> Health Affairs blog, April 2017.

drugs in 2012.26

Opioid addiction increases costs and use of health services covered by Medicaid. Medicaid covers a broad range of services for people with opioid addiction. Medicaid provides both addiction treatment services, such as inpatient detoxification, intensive outpatient treatment, and medication-assisted treatment, as well as other services for health conditions either associated with or independent from opioid addiction.

Those services amounted to \$9.4 billion in fiscal year 2013; that total will have increased along with Medicaid expansions initiated under the Affordable Care Act. This figure also does not count the billions of dollars spent since 2013 on expensive treatments for hepatitis C, which is prevalent among those addicted to opioids. Nor does it include the \$929 million Medicaid spent between 2011 and 2016 on such treatment medications as buprenorphine and naloxone. In North Carolina, for example, Medicaid spending on buprenorphine alone jumped from \$11.4 million in 2011 to \$25.3 million in 2016.

Opioid addiction and overdoses strain local hospitals. Hospitals feel the strain of the opioid crisis because their resources are stretched to meet demand. They also absorb, as uncompensated care, a proportion of the costs of emergency room visits and inpatient care related to the opioid crisis. Hospital admissions due to heroin and painkillers rose 64% and emergency department visits more than doubled over the past decade. Opioid-related inpatient visits cost about \$15 billion in 2012 and are likely to have increased significantly due to Medicaid expansions. In addition, hospital-related costs for treating overdose patients are skyrocketing because those who are admitted arrive in poor condition and those who survive to be admitted have longer stays and significant complications.

Rising costs and use of naloxone burden local health departments. Local jurisdictions are on the front lines in treating opioid overdoses through administration of naloxone, which immediately binds to opioid receptors and reverses an overdose. States and localities increasingly are making the drug available to first responders and pharmacies. The prices of naloxone are skyrocketing. A two-pack auto-injector of Naloxone, called Evzio, increased from \$690 in 2014 to \$4,500 in 2017. Even the price of basic injectable naloxone has increased to \$39.60—a 95% increase since2014. While Medicaid and other insurers may cover some of the costs, local health departments still incur considerable costs for this life-saving drug above and beyond the availability of grants and charitable contributions. For example, the Baltimore City Health Department spent \$118,236 for 3,340 doses in fiscal year 2016. That was up from \$33,540 for 1,540 doses in fiscal year 2014, or an increase of almost 63% per dose. Moreover, these costs do not include what is needed for training, thus making the overall price of this life-saving drug a serious drain on local budgets.

<sup>26</sup> Ibid.

<sup>&</sup>lt;sup>27</sup> Young, K, and Zur, J. Medicaid and the Opioid Epidemic: Enrollment, Spending, and the Implications of Proposed Policy Changes Medicaid and the Opioid Epidemic: Enrollment, Spending, and the Implications of Proposed Policy Changes. Kaiser Family Foundation Issue Brief, July 14, 2017.

<sup>&</sup>lt;sup>28</sup> Clemons-Cope, I., et al. <u>Rapid Growth in Medicaid Spending on Medications to Treat Opioid Use Disorder and Overdose</u>. Urban Institute, June 2017.

Spending on Opioid Addiction Medications Rose Sharply Since 2011, North Carolina Health News.

Weiss, AJ, et al. Patient Characteristics of Opioid-Related Inpatient Stavs and Emergency Department Visits Nationally and by State, 2014. H-CUP Statistical Brief 224. June 2017.

<sup>&</sup>lt;sup>31</sup> Ronan, MV, and Herzig, SJ. <u>Hospitalizations due to Opioid Abuse/Dependence and Associated Serious Infections Increased Sharply</u>, 2002-2012. Health Affairs blog, May 2016.

<sup>32</sup> Stevens, JP, et al. The Critical Care Crisis of Opioid Overdoses in the United States. Annals ATS. 2017;14(12).

<sup>&</sup>lt;sup>35</sup> Gupta, R, et al. The Risine Price of Naloxone—Risks to Efforts to Stem Overdose Deaths. N Engl J Med. 2016;375:2213-2215.

<sup>&</sup>lt;sup>36</sup> Cohn, M. Costs of Overdose Drue Could Hamper Access in Maryland and Elsewhere, Baltimore Sun. February 13, 2017.

#### III. The Promise of EPCS

Even though legal prescriptions lie at the heart of the opioid crisis, the majority of opioid prescriptions are still being written on paper. There were roughly 225,000,000 prescriptions of opioids, including hydrocodone and oxycodone, dispensed in 2016.<sup>35</sup> Based on these figures, it can be estimated at least 80% of opioid prescriptions (or 180,000,000) were written as paper prescriptions.

This fuels the opioid epidemic in three important ways:

- The drugs that are improperly prescribed by physicians and other health professionals cannot be easily tracked or known to other prescribers.
- 2. Written prescriptions can be easily forged and prescription pads can be easily stolen.
- Use of paper prescriptions allows patients to prescriber shop (i.e., request prescriptions from multiple
  prescribers), with each prescriber unaware of the prescriptions written by the other prescribers, and
  "pharmacy shop" until the patient finds a pharmacy that will fill a prescription another might have found
  suspicious.

Increased use of electronic prescribing of controlled substances (EPCS) can help put a stop to all three of these facilitators of opiate abuse and complement other efforts to curb this abuse. Electronically prescribing opioids and Schedule II narcotics became legal on the national level in June 2010, according to an interim final rule from the Drug Enforcement Administration (DEA). <sup>36</sup> Until this time, use of EPCS was barred by DEA despite the fact that electronic prescribing of non-controlled substances has been shown to dramatically reduce medication errors and limit fraud. <sup>37,38,39</sup> DEA had worried that electronic prescriptions were hard to authenticate and easier to fake and would not allow its use for electronic prescribing of controlled substances until additional security was put in place to ensure the electronic prescription could not be accessed or tampered with once it was sent to the pharmacy. A discussion below addresses these concerns. Since then, states gradually have implemented laws and regulations for EPCS. All states now permit EPCS, and an increasing number of states require its use.

EPCS is a way to securely transmit electronic prescriptions for controlled substances—including opioids—to the pharmacy from the point of prescribing. Using EPCS protocols mandated by DEA, prescribers are authenticated before prescribing a controlled substance, and prescriptions are sent using specially equipped electronic health records (EHRs). This complements what already is being done for prescriptions for non-controlled substances, nearly all of which are sent to pharmacies via electronic prescribing modules in EHRs.

Several events are triggered when the prescriber is ready to "write" an electronic prescription for controlled substances using the EHR's electronic prescribing module. The system checks the proposed medications against the medication history information downloaded into the EHR. This includes prescriptions paid by the patient's insurance (mostly commercial claims, but it may include some Medicare payments) and the majority of those prescribed by providers in any and all states, and in retail and independent pharmacies across the country. This can identify possible drug interactions and allergies, and the system alerts the prescriber if any potential problems are detected.

The system also displays the patient's medication history, as described above, so the provider can see

<sup>35</sup> King, R. Number of Opioid Prescriptions Down 16 Percent in Last Four Years. Washington Examiner. December 19, 2017.

<sup>&</sup>lt;sup>36</sup> Drug Enforcement Administration. Electronic Prescribing for Controlled Substances. <u>Federal Register</u>, March 31, 2010 (Volume 75, Number 61).

<sup>&</sup>lt;sup>37</sup> Institute of Medicine, ed. <u>Preventing Medication Errors: Quality Chasm Series.</u> Washington DC: National Academies, 2006: 1-24.

Markaushal, et al. Electronic Prescribing Improves Medication Safety in Community-Based Office Practices. Journal of General Internal Medicine. 2010;25(6):530-536.

Abramson, et al. <u>Ambulatory Prescribine Errors Amone Community-Based Providers in Two States</u>. J Am Med Inform Assoc. 2012:19:644-648.

previously prescribed medications including prescriber name, date, and location. Increasingly, this will also include prescriptions purchased outside of insurance with cash. The data come from Pharmacy Benefit Management companies (PBMs) and insurance companies which provide prescription claims data. The data includes nearly 100% of pharmacy claims and 80% of retail pharmacy claims, the latter of which includes cashpay, which is critically important as it relates to opioid prescribing. Also, in an increasing number of states, EHRs can access the state Prescription Drug Monitoring Program (PDMPs), which show all the Schedule II drugs dispensed in the state. Currently, all 50 states and the District of Columbia have PDMPs, although they vary significantly in the information's timeliness and completeness, and are not easily compared.

#### **EPCS Benefits**

Over 90% of pharmacies are enabled to accept electronic prescriptions for controlled substances. <sup>40</sup> A small but growing number of physicians and health systems have already adopted EPCS despite implementation requirements created by DEA that make it more complex than e-prescribing for non-controlled substances. Another advantage of EPCS is that it already is in the prescriber's workflow. Providers currently document within and are supported by EHRs during a visit, and most visits result in an e-prescription.

EPCS promotes patient safety because the systems have access to comprehensive medication history, which can check for allergies to the proposed medication and drug interactions, thus preventing adverse drug events. Some EHRs present the information in a logical manner so that the prescriber can infer adherence with dispensed medications, which also can prevent the deadly and costly results of patients not taking their medications as prescribed. EHR representations of a patient's medication history can also highlight if the patient has had multiple opioid prescriptions filled.

EPCS also helps ensure prescriptions for opioids and other controlled substances are transmitted to pharmacies securely without the risk of alteration or diversion by the patient. This helps avert drug diversion by eliminating patients' hands-on access to the prescription. This is in contrast to paper prescriptions, which can be easily forged, altered, and duplicated. By eliminating the need for paper prescription pads, EPCS ensures prescriptions are securely sent directly to the pharmacy without the opportunity for fraud. With up to 9% of paper prescriptions tied to fraud or forgery, broad adoption of EPCS could have a significant impact on the epidemic. 41 42

According to DEA. 43 EPCS will positively affect the following types of diversion:

- Stealing prescription pads or printing them, and writing non-legitimate paper prescriptions;
- Altering a legitimate prescription to obtain a higher dose or more dosage units (e.g., changing a "10" to a "40");
- Phoning in non-legitimate prescriptions late in the day when it is difficult for a pharmacy to complete a confirmation call to the practitioner's office; and
- Altering a prescription record at the pharmacy to hide diversion from pharmacy stock.

EPCS can additionally help prevent overprescribing and thwart prescriber shopping. The EHRs' medication history feature lets the prescriber see what medications have been prescribed—by him or her and by other clinicians—paid for by patients' insurance as well as cash, and filled at pharmacies anywhere in the United States. This allows prescribers to see what other prescriptions have been filled and potentially identify prescriber shoppers and potential drug abusers even before the prescription is "written." The prescriber then

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<sup>40</sup> Surescripts EPCS Report Progress Update Report - November 2017. Presented at NCPDP Task Group Meeting. November 2017.

<sup>&</sup>lt;sup>43</sup> Butler, et al. National Addictions Vigilance Intervention and Prevention Program (NAVIPPRO): A Real-Time, Product-Specific, Public Health Surveillance System for Monitoring Prescription Drug Abuse. Pharmacoepidemiol Drug Saf. 2008;17:1142-1154.

<sup>&</sup>lt;sup>42</sup> Rosenblum, et al. <u>Prescription Opioid Abuse Among Enrollees Into Methadone Maintenance Treatment</u>. Drug Alcohol Depend. 2007;90:64-71.

<sup>49</sup> Economic Impact Analysis of the Interim Final Prescription Rule, DEA, US Department of Justice, March 2010

has the opportunity to engage the patient about the health conditions that prompted the opioid prescriptions and the drug-seeking behavior that must be addressed. One hospital emergency department experienced a significant decline of prescribed opioids after EPCS went into effect, with diagnoses such as back pain, dental pain, and abdominal pain showing a statistically significant drop in opioid prescriptions.<sup>44</sup>

EPCS also complements additional efforts and programs to help fight abuse—for example, the Comprehensive Addiction and Recovery Act, which allows for the creation of a "lock-in" program for Medicare Part D participants that helps to prevent prescriber shopping by requiring those at risk to get their prescriptions from only selected pharmacies.

EPCS has other useful functionalities to help fight opioid abuse and overprescribing. For example, it offers clinical decision support, which can provide alerts when a medication quantity is excessive or if a potential prescription is out of compliance with state laws and regulations. CDC has developed guidelines for safe and appropriate prescribing of opioids and other controlled substances, which can also be incorporated into the EPCS workflow in the EHR.

In addition to delivering value in reducing overuse and abuse of opioids and other controlled substances, EPCS also increases efficiencies for prescribers, pharmacies, and consumers. The Drug Enforcement Administration (DEA) published a study<sup>45</sup> that quantified three types of benefits:

- Reduced number of callbacks to clarify prescriptions
- 2. Reduction in wait time for patients picking up prescriptions
- 3. The cost savings pharmacies will realize from eliminating storage of paper records

The DEA report on EPCS estimated significant cost savings due to efficiencies for physicians, pharmacies, and patients. In addition to qualitatively describing benefits associated with reduced diversion, medication errors, and abuse, the report estimated that EPCS could realize \$1.6 billion in annual savings:

- Savings to physician offices, dentists, and pharmacies from reduced numbers of callbacks to clarify prescriptions could save \$439 million annually.
- Cost savings that pharmacies will realize from eliminating storage of paper records could amount to \$1.4 million annually.
- Cost savings for patient wait time totaling \$1.1 billion annually assuming average wait time for a
  prescription is 15 minutes.

Positive early return-on-investment (ROI) analyses are also emerging directly from those health systems that have implemented EPCS. One example is ROI results presented at the March 2018 meeting of the Healthcare and Information Management Systems Society by Geisinger Health, a large, integrated delivery system in Pennsylvania. Geisinger demonstrated calculated savings of \$1,000,000 in the first year as a result of implementation of EPCS across 126 clinics and 1,661 physicians. These savings were achieved through reductions in call center and diversion control related to human resources, as well as prescribing efficiency for physicians and nurses. Using EPCS, prescribers reduced the amount of time spent per controlled substance prescription from 3-5 minutes to 30 seconds.<sup>46</sup>

#### Opportunities to Accelerate Adoption of EPCS

There are two main opportunities to accelerate adoption of EPCS: mandates and enhancement of medication histories

<sup>&</sup>lt;sup>44</sup> Danovich, et al. Effect of New York State Electronic Prescribing Mandate on Opioid Prescribing Patterns. Annals of Emergency Medicine. 2017; 70(4): S67-S68.

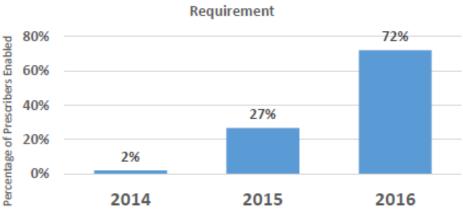
<sup>45</sup> Economic Impact Analysis of the Interim Final Prescription Rule, DEA, U.S. Department of Justice. March 2010.

Geisinger Health presentation, March 2018 meeting of the Healthcare and Information Management Systems Society, March 2018.

Mandates will help drive adoption of EPCS. The use of e-prescribing for non-controlled substances by both prescribers and pharmacies is now the norm. Nationally, 98% of pharmacies and 64% of prescribers are connected with electronic prescribing systems, with 1.6 billion (73% of total) new prescriptions transmitted electronically. However, the adoption and use of electronic prescribing for controlled substances is still quite low, with the exception of the state of New York, where EPCS use was mandated in March 2016. Nationwide, only 17% of prescribers are currently enabled with EPCS. 47

States are looking toward mandatory EPCS to fight the opioid epidemic. A frequently cited example is New York's I-STOP (Internet System for Tracking Over-Prescribing), which was enacted in 2013, with the EPCS requirement implemented in March 2016.

New York's program has driven dramatic increases in adoption, especially by prescribers. The chart below illustrates how prescriber enrollment increased from 2% in 2014 to 72% in 2016, with that number expected to increase further in 2017. 48,49,50



EPCS Adoption in NY Increased Dramatically With

Another 10 states are implementing or considering laws to help drive greater adoption and utilization of eprescribing for controlled substances. 51 At the federal level, bipartisan legislation, HR 3528, was introduced in Congress in mid-2017, which would require electronic prescribing of opioids and other medications for Medicare Part D patients. It is likely that other payers would follow the Medicare requirement if this legislation is enacted.

#### Benefits of Comprehensive Medication History

E-prescribing systems currently have access to nearly all of the medication history from claims paid by commercial insurance companies, as well as dispensed medications including cash-pay from 80% of retail pharmacies. Some display the information in a manner that helps clinicians see if the patient is adhering to medication therapy and possibly filling prescriptions at multiple pharmacies. Mandatory EPCS combined with comprehensive medication history and a more intelligent display (e.g., a risk score) can help the clinician observe patterns and address concerns with the patient.

49 Ibid.

<sup>50</sup> Ibid.

<sup>&</sup>lt;sup>47</sup> 2016 National Progress Report. Surescripts.

<sup>46</sup> Ibid.

<sup>51</sup> Federal Government Responds to Opioid Epidemic, Surescripts. August 2017.

In addition to medication history available through the EHR, PDMPs also offer a view into a patient's medication history. PDMPs have been built for law enforcement, government agencies, and prescribers, and are available in all 50 states. Access to them, however, currently requires prescribers to interrupt their workflow to enter the PDMP, search for and identify the patient, look at patterns, print a report, and then return to the workflow and document the effort, taking time away from patient care. Some states are taking steps to integrate EHRs with PDMPs. Enhanced efforts could make EPCS more effective for patient care.

New York requires prescribers to check the state medication history database before prescribing controlled substances. Since the mandate began in 2013, the state reported a 75% drop in the number of patients using multiple prescribers and pharmacies to acquire controlled prescription drugs. Standard Another study of prescriptions by dentists in an urgent care center found that when New York's mandatory program went into effect, opioid pill prescriptions went down by 78%. Standard Prescriptions went down by 78%.

In concert with related policies targeting inappropriate opioid prescribing, Florida found that oxycodone-caused mortality declined 25% in the month immediately following implementation of its PDMP. Subsequently, amounts of opioids prescribed decreased in 80% of Florida counties from 2010 to 2015. During this time period, Florida also experienced reductions in prescription opioid—related overdose deaths. In just one year (2012), Florida saw oxycodone overdose deaths decrease by more than 50%.

#### IV. Conclusion

We have presented ideas that we believe could significantly curb the opioid crisis to save billions of dollars and reduce the significant but unquantifiable emotional suffering related to the opioid crisis. No single solution will solve the problem, and new challenges often appear even as solutions are introduced. Yet, public policy can and should address problems where it can be effective, especially when lives are at risk. That is the case here. We believe the evidence is strong that EPCS can be a very important tool to help curb the opioid epidemic.

A Helpful Tool to Combat the Opioid Crisis. New York Times. September 11, 2017.

<sup>52</sup> PDMPs Fight Against the Opioid Epidemic, HealthTechZone.com. March 2017.

<sup>&</sup>lt;sup>54</sup> <u>Decline in Drug Overdose Deaths After State Policy Changes—Florida, 2010–2012</u>. Centers for Disease Control and Prevention. MMWR. 2014;63(26):569-574.

# V. Estimated Savings Associated With Required Use of EPCS and Medication History

Based on a comprehensive review of the published literature and interviews with industry experts, we estimate potential annual savings of \$27-\$53 billion, associated with the required, optimal use of EPCS for all prescriptions in all 50 states.

Savings Categories	Annual Savings to	
Savings Categories	United States	
Reduced fatalities	\$18-\$37 billion	
Reduced non-fatalities (increased health care costs,	67 644 billion	
treatment costs, lost productivity, criminal justice fees)	\$7-\$14 billion	
Increased efficiencies	\$1.5 billion	
Total	\$27-\$53 billion	

In addition, we believe that a mandate for prescribers to use EPCS for all Medicare Part D prescriptions could deliver the following annual savings to the federal government.

Savings Categories	Annual Savings to Federal Government*
Reduced fatalities	zero
Reduced non-fatalities (increased health care costs, treatment costs, lost productivity, criminal justice fees)	\$2-\$4.2 billion
Increased efficiencies	\$0.5 billion
Total	\$2-\$5 billion

<sup>\*</sup>Reflects a conservative, minimum estimate. Includes only direct impact on Medicare beneficiaries.

A summary of our methodology and key assumptions used to create these savings estimates is outlined in the next section.

# VI. Methodology and Key Assumptions

In order to estimate the savings associated with reducing prescription opioid diversion and abuse, we started with the recent study from the White House Council of Economic Advisers, 55 which estimated the national annual costs of prescription opioid abuse to be \$504 billion, with 86% involving prescription opioids.

Type of Costs	Annual Costs	Percentage Related to Individuals Abusing <u>Prescription</u> Opioids	Annual Costs Related to <u>Prescription</u> Opioids
Fatalities	\$432 billion	86%	\$371.5 billion
Non-fatalities (increased health care costs, treatment costs, lost productivity, and criminal justice fees)	\$72 billion	86%	\$61.9 billion
Total	\$504 billion	86%	\$433.4 billion

We then estimated a potential reduction in these costs from required use of EPCS and medication histories, based on conservative assumptions and the evidence summarized in the table below.

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<sup>55</sup> The Underestimated Cost of the Opioid Crisis. White House Council of Economic Advisors. November 20, 2017.

Type of Cost Savings	Evidence Suggests	Conservative Estimate for Savings Model
Fatalities	50% reduction in oxycodone mortality 2% reduction in mortality due to overdose	5-10% reduction in fatality costs
Non-fatalities	10-85% reduction in opioid prescribing 36-75% reduction in patients using multiple prescribers Reduced drug diversion of 3-9%	10-20% reduction in non-fatality costs

Finally, we applied these conservative savings assumptions to the estimated costs of prescription opioid abuse.

Type of Savings	Annual Costs Related to Prescription Opioids	Savings Estimate	Savings (annual)
Reduced fatalities	\$371.5 billion	5-10% reduction	\$18-\$37 billion
Reduced non-fatalities (increased health care costs, treatment costs, lost productivity, criminal justice fees)	\$61.9 billion	10-20% reduction	\$7-\$14 billion
Total	\$433.4 billion		\$25-\$51 billion

# Savings From Increased Efficiencies

A study by DEA identified a number of benefits associated with EPCS. <sup>56</sup> DEA qualitatively described benefits associated with reduced diversion, medication errors, and prescription drug overuse and abuse, but did not try to quantify these benefits. However, the study did quantify three other types of benefits from EPCS, related to increased efficiencies.

Benefits From Greater Efficiencies	Annual Savings
Reduction in wait time for patients picking up prescriptions	\$1,100 million
Savings to physician offices, dentists, and pharmacies from reduced number of callbacks to clarify prescriptions	\$439 million
Cost savings pharmacies will realize from eliminating storage of paper records	\$1.4 million
Total Savings From Increased Efficiencies	\$1,540 million

DEA estimates of annual savings resulting from increased efficiencies for pharmacies assume that pharmacies are receiving prescriptions for controlled substances electronically and would be able to eliminate paper records. DEA requires pharmacies to store EPCS prescriptions electronically for two years.

## **Evidence Summary**

References	Percentage Reduction
Reducing Fatalities	
Florida mandated PDMP reporting of dispensed prescriptions combined with pain clinic regulation from 2010 to 2012, and experienced more than a 50% decrease in oxycodone overdose deaths in two years, after continuous large increases in each of the previous five years.	50% (oxycodone mortality)
In 2015 more than 33,000 Americans died of drug overdoses involving opioids. <sup>50</sup> One study estimates that if states enhanced existing medical history programs with more robust features, there would be more than 600 fewer overdose deaths nationwide in 2016, or about two deaths prevented each day. <sup>50</sup> Reducing Costs Associated With Non-fatalities	2% (overdose mortality)
A New York study of prescriptions by dentists in an urgent care center found that when its mandatory program went into effect, opioid pills prescribed went down 78%. Ohio and Kentucky mandated clinicians to review prescription drug monitoring program data and implemented pain clinic regulation. In these states, morphine milligram equivalents per capita	78% (number of prescribed pills) 62-85% (prescribing of opioid dosing
decreased in 85% and 62% of counties, respectively, from 2010 to 2015. **  Prescription drug monitoring programs were associated with a decline in the chance a patient with pain will receive a Schedule II opioid prescription, to 3.7% from 5.5% (i.e., 33% reduction). The study was based on a sample of 26,275 prescriber's office visits in the 24 states that started drug monitoring operations during 2001-2010. **  A study published in 2016 used data from a national survey to assess the effects of prescription drug monitoring programs on the prescribing of opioid analgesics and other pain medications in ambulatory care settings at the point of care in 24 states from 2001 to 2010. It found that the implementation of a prescription drug monitoring program was associated with more than a 30% reduction in the rate of prescribing of Schedule II opioids. This reduction was seen immediately following the launch of the program and was maintained in the second and third years afterward. **	units) 33% (chance a patient will receive Schedule II opioid prescription) 30% (prescribing of Schedule II opioids)
States that required prescriber registration saw a 10-percentage-point reduction in use of Schedule II opioids among Medicaid enrollees, relative to states that did not require registration. 64	10 percentage points (prescribing of Schedule II opioids)
In 2012, New York required prescribers to check the state's medication history before prescribing opioids. In 2013, they saw a 75% drop in patients' seeing multiple prescribers for the same drugs. Tennessee implemented a similar mandate in 2012, and saw a 36% decline. 65	36-75% (patients using multiple prescribers)
In one pilot program, prescribers were provided an early indicator as to whether special attention should be paid to a patient's controlled substance history. In 9% of the cases, the system displayed alerts notifying providers that the patient was at a high risk for opioid abuse; 75% of patients who identified as high risk received no opioid prescription.  3-9% of diverted drugs for abuse are tied to fraud and forgery of paper prescriptions.	Prescribers received alert for 9% of patients, which stopped opioid prescription 75% of time 3-9% of diverted drugs from fraudulent prescriptions

<sup>57 &</sup>lt;u>Decline in Drug Overdose Deaths After State Policy Changes—Florida, 2010–2012</u>. Centers for Disease Control and Prevention. MMWR. 2014;63(26):569-574.

The Underestimated Cost of the Opioid Crisis. White House Council of Economic Advisors. November 20, 2017.

Patrick, et al. Implementation of Prescription Drue Monitorine Programs Associated With Reductions in Opioid-Related Death Rates. Health Aff. 2016;35(7):1324-1332.

<sup>&</sup>lt;sup>60</sup> A Helpful Tool to Combat the Opioid Crisis. New York Times. September 11, 2017. <sup>61</sup> Ibid.

<sup>62</sup> Ibid.

<sup>63</sup> Bao, et al. Physicians. Health Affairs. 2016; 35(6).

Wen, et al. States With Prescription Drug Monitoring Mandates Saw a Reduction in Opioids Prescribed to Medicaid Enrollees. Health Affairs, 2017;36(4).

<sup>65</sup> Mandating PDMP Participation by Medical Providers: Current Status and Experience in Selected States. PDMP Center of Excellence at

Brandeis University. 2014.

66 Connecting for Impact: Integrating Health IT and PDPMs to Improve Patient Care. Office of the National Coordinator for Health IT. 2013.

<sup>67</sup> Butler, et al. National Addictions Vigilance Intervention and Prevention Program (NAVIPPRO): A Real-Time, Product-Specific, Public Health Surveillance System for Monitoring Prescription Drug Abuse. Pharmacoepidemiol Drug Saf. 2008;17:1142-1154.

Rosenblum, et al. Prescription Opioid Abuse Among Enrollees Into Methadone Maintenance Treatment. Drug Alcohol Depend. 2007;90:64-71.

#### Impact of Mandated Use of EPCS in Medicare Part D

In addition to examining the impact of broad use of EPCS across the entire United States, we have also examined the potential savings that might occur to the federal government with an effective <u>EPCS mandate</u> focused only on Medicare Part D.

Key Assumptions for Medicare EPCS Mandate

#### 1. Percentage of savings related to fatalities in Medicare beneficiaries

The study from White House Council of Economic Advisers indicates that:

- Most deaths occur among those between the ages of approximately 25 and 55 years old, and less than 5% of opioid-related deaths occur in Medicare beneficiaries over the age of 65.
- Furthermore, the model assumes that the "value of a statistical life" is higher for younger people with more earning potential ahead of them, and lower for older people.
- Therefore, we estimate the "cost of fatalities" associated with Medicare beneficiaries to be negligible, and we use 0% in the table below for reduced fatalities.

#### 2. Percentage of non-fatality and efficiency savings related to Medicare or federal government

Another recent study published in November 2017 70 estimated that:

- 30% of health care costs associated with opioid misuse are related to Medicare (with approximately 30% for private insurance and uninsured, and 40% for Medicaid).
- 30% of total costs associated with opioid misuse (i.e., health care costs, productivity gains from saved lives and reductions in substance use, and lower spending on other services currently addressing the burden of opioids like law enforcement and child/family assistance).
- Therefore, we estimate the savings from non-fatalities and greater efficiencies associated with Medicare and the federal government to be 30%, and we use 30% in the table below for reduced non-fatalities and for increased efficiencies.

Type of Savings	TOTAL US Savings (annual)	Percentage of Total Savings Directly Associated With Medicare Beneficiaries	Estimated Savings Directly Associated With Medicare Beneficiaries (annual)
Reduced fatalities	\$18-\$37 billion	0%	zero
Reduced non-fatalities (increased health care costs, treatment costs, lost productivity, criminal justice fees)	\$7-\$14 billion	30%	\$2.1-\$4.2 billion
Increased efficiencies	\$1.5 billion	30%	\$0.5 billion
Total	\$25-\$51 billion		\$2.6-\$4.7 billion

We believe that these savings estimates are understated, because this economic analysis is limited solely to Medicare beneficiaries, which is unrealistic. In other words:

 We are excluding any savings to Medicaid or other state programs, even though some of those state/Medicaid costs are shared by the federal government.

The Underestimated Cost of the Opioid Crisis. White House Council of Economic Advisors. November 20, 2017.

Ryan, CN. The Potential Societal Benefit of Eliminatine Opioid Overdoses, Deaths, and Substance Use Disorders Exceeds \$95 Billion per Year, November 2017.

Use of EPCS Could Save Up To \$53 Billion per Year

- The savings estimates above assume that physicians and other prescribers would use EPCS solely for Medicare patients, and that they would NOT use EPCS for all their other patients. We do not believe this is what would actually occur. In fact, we would anticipate a significant spillover effect, wherein prescribers who begin using EPCS for their Medicare patients would probably then use EPCS for all their prescriptions for all their patients.
- Therefore, we believe our estimate of annual savings of \$2.6-\$4.7 billion to Medicare and the federal government is conservative.

#### Other Assumptions

Adjusting for EPCS and Medication History Activities Already in Place

Most of the published evidence for savings is based on comparing "little or no use of EPCS with medication histories" with "mandatory EPCS." But some states have already encouraged or mandated use of EPCS, so our savings estimates do not assume a current baseline of "no use." Therefore, the potential savings estimated in this report is less than would be available if there was no use of EPCS in all 50 states.

However, we also know that current adoption and use of EPCS is very low in all states except New York. The Further, while many states have mandated use of medication histories such as PDMPs, the challenges associated with incorporating these data into physician and pharmacy workflows has limited the actual, practical use of medication histories by prescribers and pharmacists. Use of medication history data is likely to remain limited until these data are integrated into physician and pharmacy workflows via the EHR and EPCS systems in physician offices and via the computer systems in pharmacies.

We believe that our savings estimates reflect the lower range of potential savings, suggested by the evidence, and adequately accounts for the fact that some limited use of EPCS and medication histories has already occurred.

Is Mandating EPCS Feasible, Realistic?

For purposes of our analysis, we assume that a requirement for the use of <u>both</u> EPCS and medication histories is feasible because:

- New York's I-STOP law that was passed in 2013 mandated use of both PDMPs and EPCS. The EPCS mandate was delayed slightly but was implemented smoothly and effectively in 2016.
- Surescripts reports that it has a database that covers approximately 80% of all cash pay prescriptions, in addition to covering virtually 100% of prescription claims submitted to PBMs.<sup>72</sup>
- Many EHR technology vendors are also moving functionality into production designed to deliver medication histories from state PDMPs.<sup>73</sup> For example, a major technology platform used for PDMPs in 30 states has announced steps toward integrating PDMP data into EHR and pharmacy systems and workflows.<sup>74</sup>

72 Personal correspondence with Surescripts, January 2018.

<sup>&</sup>lt;sup>71</sup> 2016 National Progress Report. Surescripts.

PDMPs Fight Against the Opioid Epidemic, HealthTechZone.com. March 2017.

<sup>&</sup>lt;sup>74</sup> Ten Appriss Health press releases related to EHR integration in 2017.