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THE OPIOID CRISIS: THE ROLE OF TECHNOLOGY AND DATA IN PREVENTING AND TREATING ADDICTION

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED FIFTEENTH CONGRESS

SECOND SESSION

ON

EXAMINING THE OPIOID CRISIS, FOCUSING ON THE ROLE OF TECHNOLOGY AND DATA IN PREVENTING AND TREATING ADDICTION

FEBRUARY 27, 2018

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C O N T E N T S

STATEMENTS

TUESDAY, FEBRUARY 27, 2018

THE OPIOID CRISIS: THE ROLE OF TECHNOLOGY AND DATA IN PREVENTING AND TREATING ADDICTION

Tuesday, February 27, 2018

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The Committee met, pursuant to notice, at 10:07 a.m. in room SD–430, Dirksen Senate Office Building, Hon. Lamar Alexander, presiding.

Present: Senators Alexander [presiding], Isakson, Cassidy, Young, Roberts, Murray, Casey, Bennet, Murphy, Warren, Hassan, Kaine, and Smith.

OPENING STATEMENT OF SENATOR ALEXANDER

The CHAIRMAN. Good morning. The Senate Committee on Health, Education, Labor, and Pensions will please come to order.

This is the fifth in a series of hearings this Congress has had on the opioid crisis to date.

Today, we are looking at the role data and technology can play in combating the opioid crisis. The Committee plans to hold a mark-up on legislation to address opioids as soon as the end of March.

We are getting a number of good ideas from all directions. We had a meeting yesterday with Governors, and more than 30 Senators attended to hear their thoughts. We will have a hearing with Governors in another week or 10 days to formally receive many of their thoughts.

Like many doctors, Johns Hopkins surgeon, Martin Makary, was taught to prescribe opioids for patients during medical school and, quote, "Gave out opioids like candy. My colleagues and I were unaware that about 1 in 16 patients became chronic users."

After seeing his own father recover from gallbladder surgery with a single Ibuprofen tablet, Dr. Makary realized the extent to which the medical community had been over prescribing opioid painkillers.

Data and technology can help identify these intentional or unintentional actions so that behaviors can be improved.

For example, Dr. Makary said, quote, "My colleagues at Johns Hopkins and I have used data to identify the average number of opioids a doctor prescribes after a routine C-section. The range of doctors' prescribing patterns is stunning. Some doctors average 3

to 10 opioid tablets after a C-section, while other doctors still average 30 or 60."

As we have examined this crisis over the last 5 months, we have learned that strong local communities are key to finding solutions, and Washington's role is usually to support those efforts and create an environment for success.

When we look at what the Federal Government can do, sharing more data and utilizing new technologies may be the most helpful thing we can do. Data can paint a more complete picture of the opioid crisis, for example, revealing which communities are seeing a spike in prescriptions such as a West Virginia town of 3,191 people that saw 20.8 million painkillers shipped to its two pharmacies for over a decade.

Helping doctors avoid prescribing opioids to someone recovering from addiction; we have suggested that in Jessie's Law, which the Senate passed last year. We can make it easier for doctors to be alerted to a patient's opioid abuse history, and recording the last time someone who overdosed had filled a prescription by checking health records and the prescription drug monitoring system.

Tennessee has found that less than 50 percent of people who died from an overdose in 2017 had filled a prescription in the prior 60 days, suggesting that more people dying from an overdose are buying heroin or fentanyl illegally.

Quality data gives everyone the ability to make informed decisions about how best to address the opioid crisis.

For state and local governments, it means having Prescription Drug Monitoring Programs, or PDMP's, that are easy to use. PDMP's are data bases that nearly every state uses to track controlled substance prescriptions so state officials can see what is happening at the community level, and doctors and pharmacists can check a patient's history with controlled substances before writing or filling a prescription.

For Tennessee, this has proved to be an invaluable tool. Between 2015 and 2017, the number of prescriptions written for opioids has decreased by 14 percent. The Tennessee Department of Health attributes these decreases to doctors and pharmacists using a PDMP more. However, in our state of 6.6 million people, there were still 7.6 million opioid prescriptions written in 2016.

For individual doctors, nurses, and patients, data can mean helping prevent more people from sliding down the slope of addiction.

As we consider new legislation, I want to hear specific suggestions about how the Federal Government can help states and local communities take full advantage of the amazing potential that technology has to offer in solving the opioid crisis.

Then there are prescription drug monitoring programs. Questions we have about those include the Federal Government preventing states from using the PDMP's in ways they think would best help their communities, as well as other questions.

E-prescribing, while we do not want to mandate burdensome rules for doctors to follow, how can we encourage doctors to prescribe medications, especially controlled substances, electronically wherever possible?

Then, predicting problems and avoiding them. In the private sector, healthcare companies like clearinghouses, hospitals, and insur-

ance companies have a lot of data, and these businesses use that data to their advantage to make improvements in their businesses.

I would like to hear about how the Federal Government can start using all the data it collects to identify and prevent over prescribing before it leads to addiction and overdoes.

Finally, privacy. New technology and more data can be useful tools, but we have to consider everyone's privacy and there is a lot at stake.

Addiction can impact every aspect of a person's life from their ability to find a job, and housing, and keeping custody of their child. So we need to ensure that whatever action we take, privacy is protected.

Senator Murray.

OPENING STATEMENT OF SENATOR MURRAY

Senator MURRAY. Well, thank you very much, Mr. Chairman.

Last week, I was home in Washington State, and I heard firsthand from families and communities who are facing this epidemic. I heard from a young man who ended up in foster care because his parents struggled with drug use and mental health issues.

I heard from a mother who felt helpless as her son experienced addiction. He sought help. He struggled with relapse and tragically died of an opioid overdose.

I heard from another young parent whose children were taken away because she was unable to overcome her addiction.

I heard from an elementary school principal, whose students should be learning to read and write, should be running around full of energy and excitement, but are, instead, struggling to focus at school because of the trauma of their parents' addiction at home.

On a previous trip to a hospital in Longview, Washington, I heard how half—half—of the babies there were born to mothers addicted to opioids.

Just as I have been listening to voices back in Washington State, this Committee has been listening here in Washington, DC and learning more about what our communities need to fight this national epidemic.

I am very grateful to all of our witnesses today for adding your voices to this discussion.

Technology and data offer important opportunities to address the opioid crisis, to prevent addition, and avoid the tragedy so many families are facing.

While we can see the promise of this approach through efforts, such as Prescription Drug Monitoring Programs, which almost every state has established, there is a lot more we can do.

These electronic data bases, which keep track of prescriptions for controlled substances, can be a great resource to fight opioid misuse. However, Big Data, by itself, does not guarantee a big impact. We need to use that data creatively, protecting the privacy of patients while finding innovative ways to protect their safety and health. Some states are pioneering ways to make that happen.

For example, some states require doctors to check the data base so they are aware of a patient's existing prescriptions before they write new ones. States that require this saw a drop in opioid prescriptions, drug-related hospitalizations, and overdose deaths.

Others have built-in systems that alert doctors of alarming patterns or signs that a patient may be at-risk of drug misuse. Others have made PDMP's easier to access and use by integrating them with Electronic Health Records.

Still, while many states are looking at new ways to put their data to good use, there is also important data that many still cannot use, like the data collected by their neighboring states. Too many of the PDMP systems are not sufficiently interoperable, and that means they are not sharing data and working effectively with each other.

As a result, the prescription a patient receives in one state may not show up in the system of another state. Two doctors in different states may not see they are writing prescriptions for the same patient. They may not have the data to see a pattern of substance misuse or to prevent one from developing.

We need more states to move toward an interoperable PDMP system so that we can put the pieces together and give doctors a full picture of a patient's prescription history.

It is not just states that have to understand the role that technology and data can play in addressing this epidemic. Pharmacies, prescribers, patients, all stakeholders have to take a look at how advances can help prevent and address opioid misuse, whether through more responsible prescribing based on risk factors, safe disposal of controlled substances, or safety checks by pharmacists when they dispense.

We must also be mindful of the importance of patient privacy; data has to be easy to use, but hard to misuse. People dealing with addiction already face stigma and may fear speaking out or seeking help. We have to ensure that our data practices and protocols do not create new risks or fears that a patient's most private battles might be made public against their wishes.

Striking that balance is not an easy task, but it is an important one. We have made great progress so far in striking difficult balances in responding to this crisis with bipartisan solutions.

I am hopeful that through conversations like the one we are having today, we can continue that bipartisan progress as we look at how technology can empower partners fighting this crisis at every level, from Federal, state, and local governments, to healthcare providers, to educators, to public safety officials, and to families like the ones I meet in Washington State.

I look forward to hearing from all of our witnesses today, and learning more from your expertise and experience.

Mr. Chairman, I very much look forward to our continued work together, and with many Senators to find and move forward key legislative solutions to the challenges we face fighting this crisis.

The CHAIRMAN. Thank you, Senator Murray.

Thanks for your cooperation, and that of your healthcare staff and others, for working on the bipartisan legislation we hope to mark-up soon.

I am pleased to welcome our four witnesses. I thank each of you for being here.

The first witness we will hear from is Snezana Mahon. Ms. Mahon serves as the Vice President of Clinical Product Development at Express Scripts.

In this role, she oversees the company's clinical initiatives and utilization management programs that aim to make the use of prescription medicine safer, more affordable, and more accessible for both patients and payers.

Prior to this role, she served as the Senior Director of Medicare Strategy at Express Scripts, providing guidance to Medicare Advantage and Part D plans.

Next, is Ms. Sherry Green. She has 24 years of experience in developing opioid and other drug abuse-related policies. She draws on this expertise to consult state legislators and healthcare professionals on strategies to prevent opioid abuse.

She is the co-founder of the National Alliance for Model State Drug Laws where she served as the Chief Executive Officer for 20 years.

Next, is Dr. Westley Clark. He serves as the Dean's Executive Professor of Public Health at Santa Clara University in California.

Previously, Dr. Clark served as Director of the Center for Substance Abuse Treatment at the Substance Abuse and Mental Health Services Administration, which we call SAMHSA. He led the agency's effort to provide individuals with addictive disorders effective and accessible treatments.

He has also been Chief of the Associated Substance Abuse programs at the U.S. Department of Veterans Affairs Medical Center in San Francisco and Associate Clinical Professional in the Department of Psychiatry at the University of California at San Francisco.

Last, we will hear from Mr. Sanket Shah. Mr. Shah is a Clinical Assistant Professor of Health Informatics in the Department of Biomedical and Health Information Sciences at the University of Illinois at Chicago.

Mr. Shah has developed course curricula focused on healthcare business intelligence, healthcare data, knowledge management, and consumer informatics. He is also Director at Blue Health Intelligence, an independent licensee of the Blue Cross Blue Shield Association and home to one of the Nation's largest commercial healthcare data bases of medical and pharmacy claims.

Welcome, again, to our witnesses.

Ms. Mahon, we will hear from you to begin.

STATEMENT OF SNEZANA MAHON, PHARM.D., VICE PRESIDENT, CLINICAL PRODUCT DEVELOPMENT, EXPRESS SCRIPTS, ST. LOUIS, MISSOURI

Dr. MAHON. Good morning, Chairman Alexander, Ranking Member Murray, and Members of the Committee.

I am Snezana Mahon. I am the Vice President of Clinical Product Development at Express Scripts.

It is an honor to come before the Committee today to discuss the solutions that can address the opioid epidemic that is not only devastating our healthcare system, but also splintering American families. I applaud the Committee's attention to this crisis.

I am a registered pharmacist and received my Doctorate of Pharmacy from the St. Louis College of Pharmacy. Before joining Express Scripts, I practiced in the retail pharmacy setting for 7 years. Now, I lead a clinical product organization that is responsible for

focusing on systematic programs and changes that can address this crisis on a broader scale.

Express Scripts is the Nation's largest standalone Pharmacy Benefit Manager. We manage the pharmacy benefit for more than 80 million Americans. I want to leave the Committee today three figures and three ideas. I will tackle the figures first.

Sixty percent; that is the amount our program has reduced the average day supply of first-time opioid users.

Eighty-seven percent of new prescriptions initially written for a long-acting opioid were subsequently filled for a short-acting opioid.

Ninety-six percent of initially written prescriptions for a longer day supply were rewritten and filled for a 7-day supply.

How did we achieve these results?

First, pharmacies and pharmacists are frequently not aware of other medications patients may be taking. At the pharmacy counter, we leveraged several utilization management strategies.

We have instituted a 7-day limit for first-time opioid users. We also implemented morphine equivalent dose interventions on new and current users in line with the CDC guidelines, as well as we preferred a short-acting opioid before a long-acting one.

Second, our program also engages patients by educating them about the risks before it occurs, and sending them educational letters in their home after their first fill.

If the patient continues to refill their prescription, we have a specialized pharmacist reach out to the patient and talk to them about the risks of overuse and abuse, and we also give them instructions on proper safe disposal.

We directly provide patients with a drug deactivation disposal bag that enables them to safely dispose of their unused medications.

Third, for prescribers, we focused on making information more readily available to them. Similar to pharmacies, the average prescriber is not always aware of prescriptions their patients are taking from other prescribers.

We alert the provider via the Electronic Health Record, or fax, or letter on the potential of misuse and abuse, as well as the member's morphine equivalent dose, so the prescriber has a more complete picture of the patient's entire history.

So far, our data suggests that the program is working. However, we continue to develop new strategies and implement new best practices. As a result of our program, we are now launching additional point of sale interventions regarding fentanyl.

We also are recommending the addition of Naloxone for patients via Electronic Health Record, as well as a fax or a letter to the provider for certain individuals. And finally, we are educating providers on their prescribing pattern by comparing them to their peers, as well as communicating with them to encourage more conservative opioid prescribing.

These private sector efforts could be accelerated by policies that support safe opioid utilization. The first is electronic prescribing. Currently, increasing numbers of states now require its use for these medications.

Encouraging e-prescribing controlled substances would restrict pharmacy shopping, enable better prescription tracking, as well as reducing fraud, waste, and abuse.

Express Scripts supports H.R. 3528, the Every Prescription Conveyed Securely Act, which would move Medicare to a system of e-prescribing for opioids.

We also support requiring a 7-day fill for initial opioid prescriptions with exceptions for hospice, cancer, and palliative care.

The S. 892 Opioid Addiction Prevention Act introduced by Senators Gillibrand and McCain would be a positive step forward in preventing addiction before it begins.

The final policy recommendation is one we would continue to recommend the Committee avoid is mandating coverage of so-called abuse deterrent opioids.

Manufacturers have been developing and selling these novel approaches with a goal of making their products less susceptible to abuse. Unfortunately, abuse deterrent is not the same as abuse proof.

Mandating the coverage of abuse deterrent opioids is a flawed approach and the FDA acknowledges that these products are not abuse proof. We do not want prescribers or patients to believe that these products are less addictive and cause over-utilization patterns to continue.

Again, thank you for the incredible opportunity to present Express Scripts' data-driven solutions today as we continue to lead the industry in developing strategies to prevent addiction.

[The prepared of Dr. Mahon follows:]

PREPARED STATEMENT OF SNEZANA MAHON

Good morning Chairman Alexander, Ranking Member Murray, and Members of the Committee. My name is Snezana Mahon and I am the Vice President of Clinical Product Development for Express Scripts. It is an honor to come before the Committee today to discuss solutions that can address an epidemic that is not only devastating our health care system but also splintering American families: opioid addiction. I applaud the Committee's attention to this crisis, having already held two hearings this year following two other hearings last fall, and I am honored that you asked me before the Committee today to share what Express Scripts is doing to address opioid addiction—namely, developing and offering new tools aimed at preventing addiction from starting even before a patient picks up their first opioid prescription at the pharmacy counter.

About Express Scripts

Headquartered in St. Louis, Express Scripts is the Nation's largest stand-alone pharmacy benefit manager (PBM). We manage the pharmacy benefits for more than 80 million Americans, including those in health plans, union-sponsored plans, state employee health plans, and public purchasers, including TRICARE, Medicare Part D, and Medicaid. Our services include providing network-pharmacy claims processing, home delivery pharmacy care, specialty pharmacy care, benefit-design consultation, drug utilization review, formulary management, and medical and drug data analysis services.

Because Express Scripts interacts with patients, pharmacies, prescribers, and payers, our company is uniquely situated to collect data when patients receive and fill a prescription for an opioid under their pharmacy benefit. We can leverage that data across the care continuum in order to design interventions aimed at preventing opioid addiction from beginning in the first place. With 2 million Americans addicted to prescription narcotics, and more than 1,000 people treated daily in emergency departments for misusing prescription opioids, this is a $53 billion public health crisis.

Our Advanced Opioid Management Program

To test out how we could help minimize early opioid exposure and prevent progression to overuse and abuse, we started with a pilot in 2016. In a study of just more than 100,000 Express Scripts members new to opioid therapy, we observed a 38 percent reduction in hospitalizations and 40 percent reduction in emergency room (ER) visits in the intervention group versus control group during 6 months of follow-up. Half of the members received an educational letter from the Express Scripts Neuroscience Therapeutic Resource Center (TRC) and half no intervention at all. A subset of those receiving the TRC educational letter who had high-risk patterns of opioid use also received a counseling call from a Neuroscience TRC specialized pharmacist. Among this subset, we observed a 19 percent decrease in the days' supply of opioid dispensing during 6 months of follow-up. Most importantly, patients got the medicine they needed while we helped prevent unnecessary refills that could put patients at risk of harm.

With such success, we expanded the program as an offering to our clients more broadly. This past September, Express Scripts launched our comprehensive Advanced Opioid Management (AOM) solution focused on opioid abuse education and prevention. This product was developed by leveraging our substantial healthcare data analytics capabilities and works across the full prescription drug continuum: from providing new tools for physicians at the point of care, patient education and outreach—including safe disposal of unused opioids—to safety checks for dispensing pharmacies.

More specifically:

Engaging Prescribers——

A prescription from a physician or other prescriber remains the only lawful means for a patient to receive an opioid from a pharmacy. These clinicians are not always aware of prescriptions from other prescribers that their patients are taking. Nor are they necessarily aware of CDC recommendations to start short acting opioid therapy before advancing to longer acting forms.

- The AOM solution delivers automated messages at the provider point of care via Electronic Health Record (EHR) on potential misuse and abuse, along with morphine equivalent dose (MED) communications to ensure prescribers have a more complete picture of their patient's history;
- Enhanced Prior Authorization is applied to long-acting opioid prescriptions for patients without such drugs existing in their claim history to help encourage use of such a medication only where clinically appropriate; and
- When data suggests potential "doctor shopping" behavior, limiting patients to a single provider for obtaining these medications.

Patient Education and Outreach——

Using our data analytics capabilities as a PBM, we have found that one of the keys to address prescription drug abuse is patient outreach and education, and believe this approach could be applied across both the public and private payer-based healthcare insurance marketplace. The AOM solution engages patients by communication, specifically:

- Proactive Member Education: An important step in preventing opioid overuse is educating members about such risks before they occur. Through our AOM solution, ESI provides proactive education to members new to opioid therapy through an educational letter;
- Proactive Member Education through Specialized Pharmacist Outreach: If the member continues opioid therapy, specific utilization trends will trigger an Express Scripts specialized pharmacist from our Neuroscience Therapeutic Resource Center (TRC) to contact that member and provide a live clinical consultation educating the member on potential risks, and instructions on safe use—including proper storage and disposal of unused pills; and
- Providing Drug Disposal Bags: The AOM solution also directly provides patients with drug deactivation disposal bags that chemically neutralize opioids that enables them to safely dispose unused medications and thereby prevent future opioid diversion or misuse.

Engaging Pharmacies——

Similar to prescribers, pharmacies and pharmacists are frequently not aware of other medications a patient is taking. AOM endeavors to close these gaps in care by aggregating a patient's entire opioid utilization profile and limit initial opioid prescriptions.

• The AOM solution involves an intervention at the pharmacy point of sale (POS) for members accumulating greater than 200mg Morphine Equivalent Dose (MED)—a widely accepted clinical threshold at which greater quantities of Morphine Milligram Equivalents (MME) may be considered dangerous and potentially an indicator for misuse/abuse. Pharmacists are alerted at doses of 90 mg MME. A prior authorization is required for members accumulating quantities of opioid medication exceeding 200mg MME per day;

• Concurrent drug utilization review programs are run to help pharmacists identify the most pertinent clinical patient safety and utilization concerns; and

• First-time users prescribed short-acting opioids are restricted under the solution to an initial 7-day supply.

Most importantly, we know the AOM solution works, based on data collected from both our initial pilot test on 100,000 members conducted in 2016, and the first 2 months of full operation for 4.6 million patients currently benefiting from this program. Key results include:

• Since becoming fully operational for nearly five million patients beginning on September 1, 2017 we have seen:

• 59.5 percent reduction in the average days' supply per claim for first time opioid users

• 95.9 percent of the prescriptions that were reprocessed because of our utilization management edits were filled for a 7-days' supply or less;

• Only 4.1 percent of opioid prescriptions providing more than a 7-day supply were approved for patients after a prior authorization (PA) requirement was triggered; and

• 87 percent of new opioid prescriptions initially written for a long-acting opioid were subsequently filled with a short-acting opioid first due to implementation of the new enhanced prior authorization program.

Continuing to Develop and Implement Best Practices

In less than 6 months, our program has grown to nearly 7 million Americans enrolled. As a data driven firm, we're constantly evaluating marketplace behavior and trends and recommending changes to our program as a result. We recently announced some changes to our opioid program:

• New point-of-sale alerts: Fentanyl is being targeted specifically, as it is an incredibly potent drug, and fentanyl-related deaths are on the rise. New requirements are being added to the coverage approval criteria to tighten the criteria for fentanyl products.

• Additionally, a new drug quantity management (DQM) program for fentanyl patches has been created for a complete and comprehensive DQM solution for opioids.

• New physician care alert: We're recommending the addition of naloxone for potentially high-risk members who are receiving a large number of opioid prescriptions where treatment does not appear to be coordinated.

• Physician education/peer comparison: Prescriber educational messaging that leverages behavioral science and social norming based on area of practice and peer comparison to encourage more conservative opioid prescription.

Policies Lawmakers Should Consider

Given the success of our program, Express Scripts also advocates for meaningful policy change that we think could expand on the some of the lessons we've learned. Acknowledging that some of the following policy options extend beyond the scope of this Committee's jurisdiction, should the Senate take up another legislative package on opioid abuse, I wanted to highlight them today given this Committee's comprehensive look at the problem.

Electronic Prescribing——

Electronic prescribing (or "e-prescribing") has been shown to dramatically reduce medication errors and fraud; yet, until 2010 the Drug Enforcement Agency (DEA) barred its use for ordering controlled substances. Currently, increasing numbers of states now require its use for these medications. Mandating e-prescribing controlled substances would restrict pharmacy shopping, enable better prescription tracking, and reduce fraud and waste as well. ESI supports H.R. 3528, the Every Prescription Conveyed Securely (EPCS) Act, as it would move Medicare to a system of mandatory e-prescribing for opioids as this would go a long way toward saving lives and

stopping addiction by eliminating the possibility of fraudulent paper claims. Express Scripts urges the Senate to examine policies that increase the use of electronic prescribing for controlled substances, whether it is through the Medicare program, the DEA, or through the commercial insurance market through policies in this Committee's jurisdiction.

Mandating 7-Day Fill Limit on Initial Opioid Prescriptions——

Another effective tool for reducing opioid abuse in the program would involve implementing a 7-day supply limit for first fills of short acting opioids, with exceptions allowed for hospice and palliative care patients. S. 892, the Opioid Addiction Prevention Act, introduced by Senators Gillibrand and McCain, would also be a positive step forward to preventing addiction before it begins. Though this legislation falls outside of the HELP Committee's jurisdiction, the bill would benefit commercially insured patients across the country.

Currently, there is a patchwork of state laws around the country on fill limits. To illustrate this, below is a table that shows how these laws currently vary depending on geography:

Table 1: Opioid Related Quantity Limit Laws

State	Qty	1st Fill Qty	Qty for Minors
Alaska	——	7 days	7 days
Arizona	——	5 days	——
Connecticut	——	7 days	7 days
Delaware	31 days	7 days	7 days
Hawaii	30 days	——	——
Illinois	30 days	——	——
Louisiana	——	7 days	7 days
Maine	7 acute, 30 chronic	——	——
Massachusetts	30 days	7 days	——
New Hampshire	34 days	——	——
New Jersey	30 days	5 days	——
New York	30 days	7 days	——
Ohio	90 days	14 days	——
Pennsylvania	——	——	7 days
Rhode Island	30 days	20 doses & 30 MME/day	——
South Carolina	30 days	——	——
Tennessee	30 days	——	——
Utah	30 days	7 days	——
Vermont	——	7 days & 50 MME/day	3 days & 24 MME/day
Virginia	7 acute, 14 surgical	——	——
West Virginia	30 days	——	——

Resisting the False Appeal of Incentivizing Use of Abuse Deterrent Opioid Formulations——

Opioid manufacturers have been developing and selling novel (and expensive) approaches with a stated goal of making their products less susceptible to abuse, which typically means the product is engineered in some way to make it more dif-

ficult (but not impossible) to crush it up and make it injectable. Unfortunately—as tacitly admitted by use of the term "abuse deterrent" vs. "abuse *proof*"—these efforts are consistently defeated and, in any event, remain equally susceptible to misuse as any other oral medication. Nevertheless, over the last 2 years approximately 50 pieces of legislation *requiring coverage of Abuse-Deterrent Formulations (ADF)* of opioid products have been introduced in more than 30 different states. While the goal of these bills—to reduce opioid abuse—is laudable, mandating coverage of ADF opioids fails to take into account several substantial flaws with this approach, namely:

- The FDA fully acknowledges that these products are not abuse proof;
- Concerns expressed by clinical experts that ADF opioids will mislead prescribers and patients into thinking the products are less addictive, and thus overprescribing patterns will continue or, potentially, increase; and
- While ADF opioids make tampering more difficult, these products are considerably more expensive than non-ADF opioids, thereby shrinking available coverage dollars for other drugs offered by a health plan payer.

Instead of mandating first-line coverage for ADF opioids, we reiterate that the best approach to reducing opioid misuse is through comprehensive, well-coordinated efforts among providers, public and private healthcare payers, and law enforcement that emphasizes patient education on drug safety—including counseling and addiction treatment.

Again, thank you for the incredible opportunity to present Express Scripts' data-driven solutions as we continue to lead our industry in developing strategies to prevent addiction. I am happy to answer any questions you may have, and offer to continue to be a resource to this Committee as you consider further legislation to address this epidemic and save lives.

[SUMMARY STATEMENT OF SNEZANA MAHON]

Express Scripts has developed a novel and comprehensive opioid management program for plan sponsors of prescription drug benefits. The program touches the entire patient care continuum and has promising early outcomes.

Express Scripts Advanced Opioid Management Program

- The AOM solution delivers automated messages at the prescriber point of care via Electronic Health Record (EHR) on potential misuse and abuse, along with morphine equivalent dose (MED) communications to ensure prescribers have a complete picture of their patient's history.
- If the patient continues opioid therapy, specific utilization trends will trigger an Express Scripts specialized pharmacist from our Neuroscience Therapeutic Resource Center (TRC) to contact that member and provide a live clinical consultation educating the member on potential risks, and instructions on safe use—including proper storage and disposal of unused pills.
- Intervening at the pharmacy point of sale (POS) for members accumulating greater than 200mg Morphine Equivalent Dose (MED).

Outcomes Data

- 59.5 percent reduction in the average days' supply per claim for first time opioid users.
- 95.9 percent of the prescriptions that were reprocessed because of our utilization management edits were filled for a 7-days' supply or less.
- Only 4.1 percent of opioid prescriptions providing more than a 7-day supply were approved for patients after a prior authorization (PA) requirement was triggered.
- 87 percent of new opioid prescriptions initially written for a long-acting opioid were subsequently filled with a short-acting opioid first due to implementation of the new enhanced prior authorization program.

Policies Lawmakers Should Consider

- *Electronic Prescribing*—Mandating e-prescribing controlled substances would restrict pharmacy shopping, enable better prescription tracking, and reduce fraud and waste as well.

- *7-Day Fill Limit on Initial Opioid Prescriptions*—S. 892, the Opioid Addiction Prevention Act, introduced by Senators Gillibrand and McCain, would also be a positive step forward to preventing addiction before it begins.
- *Resisting the False Appeal of Incentivizing Use of Abuse Deterrent Opioid Formulations*—We remain concerned that ADF opioids will mislead prescribers and patients into thinking the products are less addictive, and thus overprescribing patterns will continue or, potentially, increase.

The CHAIRMAN. Thank you, Dr. Mahon.
Ms. Green, welcome.

STATEMENT OF SHERRY L. GREEN, J.D., CHIEF EXECUTIVE OFFICER, SHERRY L. GREEN AND ASSOCIATES; CO-FOUNDER, NATIONAL ALLIANCE FOR MODEL STATE DRUG LAWS, SANTA FE, NEW MEXICO

Ms. GREEN. Thank you, Chairman Alexander, Ranking Member Murray, and Members of the Committee.

Thank you for this opportunity to make recommendations about the proper role of policy and technology in data projects. I am going to recommend three quality control principles that should be involved in all data and technology projects.

The first is that the best practices for healthcare that we want the technology projects to actually achieve need to remain very clear and very consistent. When those standards appear to be uncertain or sometimes in conflict, the result is that the technology projects lose their focus. And what we see is that the measures of success for some vendors simply becomes staying ahead of their competitors.

This is less about what technology can do and more about what technology should do to achieve the best practices that we believe are necessary to help address the opioid epidemic.

Second, the legislative and policy changes that we actually need to be in place to optimize technology projects need to keep pace with the adoption of those technology projects.

When those legislative changes, as often happens, lag behind they actually hinder, not support, the technological enhancements. And that causes the enhancements to be completely unable to fully operationalize the best practices we want them to achieve.

The third principle is that the federally funded projects from now on should actually breakdown data silos, not incentivize the creation of new silos. We need to continue to heed the lessons that we learned from the Federal efforts to computerize medical records.

While we obviously gained many benefits from that effort, we also now understand that the significant Federal funding that was put out there actually incentivized data vendors to make data sharing difficult and more costly. So much so, the Congress had to step back in and actually prohibit information blocking.

We should proactively avoid this kind of situation again with any new funding for data projects by proactively including in technology grants and contracts those safeguards that will actually facilitate data sharing, as well as prevent the exclusionary data access that sometimes happens when people are simply trying to increase their market dominance.

I want to thank you again for this opportunity to make these recommendations, and at the end of the panel, I am happy to answer any questions you might have.

[The prepared statement of Ms. Green follows:]

PREPARED STATEMENT OF SHERRY L. GREEN

Chairman Alexander, Ranking Member Murray, and Members of the Committee, I thank you for this opportunity to share recommendations regarding the proper role of policy in data and technology projects intended to help address the opioid crisis. My recommendations represent quality control principles necessary to ensure that the activities of such projects remain aligned with the goals of congressional opioid abuse prevention strategies, including the Protecting Our Infants Act, the Comprehensive Addiction and Recovery Act, and the 21st Century Cures Act. Based on 24 years of drafting and helping implement drug and alcohol policies, including those for opioid abuse, I respectfully offer the following points of consideration.

Health care standards of quality and best practices which technology and data projects are to facilitate must remain clear and consistent. Technology and data solutions can significantly advance improved responses by health care professionals and public health officials to the opioid epidemic. The unrelenting misuse, abuse, addiction to and diversion of opioids and other potentially addictive substances place new demands on prescribers and dispensers. Training and beliefs of years past must be set aside. Professionals and officials must learn and use new approaches to manage pain, particularly chronic noncancer pain, and treat drug and alcohol addiction. More than ever before treatment decisions for each patient must represent a careful weighing of multiple factors to balance appropriate patient care with prevention of misuse, abuse, addiction to and diversion of medication. This transition in practice must be expeditious rather than gradual. Technology and data solutions can effect a more timely transition through (1) efficient delivery of new education and training, and (2) improved coordination and analysis of data relied upon for clinical treatment and public health decisions.

As the search for tools to address the opioid epidemic ramps up, so too do the competing claims that various technology and data solutions can do more, and do more faster. But the true value of a solution can only be realized in its use to achieve or improve upon new standards and best practices for clinical care and public health. Where the standards are uncertain or seemingly in conflict, the focus for a technology and data vendor can become doing more, and doing more faster than its competitors.

The use of technology and data solutions to enhance prescription drug monitoring programs (PDMPs) is informative. Over the past 18 months, numerous well-intended technology and data vendors promoted their solutions to PDMP Administrators (Administrators). The vendors described in detail how their solutions can improve the Administrators' ability to "catch" doctor shoppers and detect fraud. Detecting and preventing fraud is certainly one of the goals of PDMPs. However, states are transforming their programs into better health care information delivery tools. The vendors were silent regarding how their solutions can help accomplish PDMPs' health care goals. Policymakers, professionals, and officials must articulate consistently and repeatedly the standards which technology and data solutions are to facilitate.

Only by doing so will technology and data solutions remain effective as means to a new health care and public health practice and approach to addressing the opioid epidemic.

Legislative and regulatory changes necessary to optimize technology and data solutions must keep pace with the adoption of the solutions. Processes for refining and updating technology and data often proceed at a faster pace than amendments to statutes or even regulations. Technology and data solutions do not operate in a vacuum; they must comply with applicable policies that govern access, use, and disclosure of various types of data. When those policies fail to support the standards of quality and best practices for use of data that implementation of a solution is designed to achieve, the solution is unable to fully operationalize the standards and best practices.

A primary objective of Federal and state PDMP enhancement initiatives is integrating PDMP data into health and pharmacy information technology (IT). Millions of public dollars are being spent on integration technology. This integration removes barriers to easy access of PDMP data and allows health care professionals to efficiently rely upon the data to inform patient care decisions. Access, use, and disclosure rules for PDMP data may differ from those for medication history traditionally

maintained by health and pharmacy IT. The variances may be in one or more of the following categories: (1) authorized users of data, (2) methods of accessing data, (3) allowable purposes for accessing data, (4) storage and retention of data, (5) presentation of data to authorized users, (6) disclosure and use of data in health and pharmacy IT, and (7) tracking of requests for data. Failure to reconcile these governance rules prior to PDMP data integration can impede effective use of PDMP data in the clinical workflow. Simultaneously, health and pharmacy IT systems are at greater risk of violating idiosyncratic PDMP data usage provisions. Policymakers and regulators must proactively modify laws and rules to timely support rather than hinder technology and data enhancements needed to improve prescribing and dispensing of potentially abused substances.

New or expanded technology and data solutions to address the opioid epidemic must strive to break down data silos, not incentivize the creation of new silos. Prior Federal efforts strove to encourage an interconnected web of health care providers and consolidation of patient information. Significant Federal dollars intended to bring about the web and consolidation inadvertently incentivized the practice of data siloing. Health IT vendors were reluctant to share information for fear of losing customers to their competitors. Based on this fear, the vendors made the existence of data sharing costly and inconvenient. Congress responded by prohibiting and penalizing information blocking. The National Academy of Sciences (NAS) reviewed electronic systems developed from initiatives to computerize medical records (EMRs). NAS found that EMRs "offer potential improvements to health care delivery" through collection of and quicker access to key patient data.[1] Clinical notes, urine drug tests results, and signed opioid treatment agreements may now be included in EMRs.

However, EMRs still have data gaps. Often missing is information important to understanding a patient's comprehensive, and sometimes complex, relationships with potentially addictive substances. These gaps contribute to ongoing pressure for health care professionals and officials to use PDMPs, tools originally designed to assist investigations of violations of controlled substances laws. The data in PDMPs already exist throughout health care systems, but the data are maintained in piecemeal fashion. A PDMP has value for health care professionals because it provides in a single location a more complete picture of a patient's prescription history than can often be found in any other single source. The consolidation of patient data has yet to be fully realized in the health care sector. As a result, state and Federal agencies are spending millions of public dollars to transform PDMPs into optimal health care information delivery tools.

Policymakers must heed the lessons learned from the EMR development process. Federally funded technology and data projects to address the opioid epidemic must incorporate requirements to effect proper data sharing and prevent exclusionary data access primarily used to gain a competitive advantage and increase market dominance. Examples of such requirements can be found in the Prescription Drug Monitoring Act of 2017 as introduced, S. 778 (Act). Funding a single hub for sharing PDMP data, the Act retains states' ownership rights to determine disclosure parameters, and ensures cost efficient data access for patient care and public health surveillance activities.

With the urgent need to save lives and stop other devastating consequences of opioid abuse, hundreds of millions of taxpayer dollars are and will be expended to expeditiously respond to the need. As technology and data projects race forward to make quick progress, the projects risk losing focus unless proper guidance is in place. I urge Committee Members to take a lead in adopting appropriate quality control measures and safeguards to ensure that the projects remain aligned with congressional goals for effectively tackling opioid abuse.

[SUMMARY STATEMENT OF SHERRY L. GREEN]

Chairman Alexander, Ranking Member Murray, and Members of the Committee, I thank you for this opportunity to share recommendations regarding the proper role of policy in data and technology projects intended to help address the opioid crisis. My recommendations represent quality control principles necessary to ensure that such projects remain aligned with the goals of congressional opioid abuse prevention strategies, including the Protecting Our Infants Act, the Comprehensive Addiction and Recovery Act, and the 21st Century Cures Act.

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[1] National Academy of Sciences, *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use*, p.306 (2017).

Health care standards of quality and best practices which technology and data projects are to facilitate must remain clear and consistent. As the search for tools to address the opioid epidemic ramps up, so too do the competing claims of various technology and data vendors. Where the standards are uncertain or seemingly in conflict, the focus for a technology and data vendor can become doing more, and doing more faster than its competitors. Only by consistently repeating the standards which technology and data solutions are to facilitate will the solutions remain an effective means to a new health care practice and approach to addressing the opioid epidemic.

Legislative and regulatory changes necessary to optimize technology and data solutions must keep pace with the adoption of the solutions. Technology and data solutions do not operate in a vacuum; they must comply with access, use, and disclosure policies for various types of data. When those policies fail to support the standards of quality and best practices for use of data that implementation of a solution is designed to achieve, the solution is unable to fully operationalize the standards and best practices. Policymakers and regulators must proactively modify laws and rules to timely support rather than hinder technology and data enhancements needed to improve patient care and public health.

New or expanded technology and data solutions to address the opioid epidemic must strive to break down data silos, not incentivize the creation of new silos. Policymakers must heed the lessons learned from Federal efforts to computerize medical records. Federal funds for the initiative inadvertently incentivized health IT vendors to create data silos and Congress had to prohibit information blocking. Consolidation of patient data still has yet to be fully realized in the health care sector. As a result, health care professionals are required or encouraged to use PDMPs, tools originally designed to assist law enforcement. A PDMP has value because it provides in a single location a more complete prescription history for a patient than exists in other single sources. Federally funded technology and data projects must include requirements to effect data sharing and prevent exclusionary data access used to increase market dominance.

I urge Committee Members to take a lead in adopting appropriate quality control measures and safeguards to ensure that technology and data projects remain aligned with congressional goals for effectively tackling opioid abuse.

The CHAIRMAN. Thank you, Ms. Green.

Dr. Clark, welcome.

STATEMENT OF H. WESTLEY CLARK, M.D., J.D., M.P.H., DEAN'S EXECUTIVE PROFESSOR, PUBLIC HEALTH PROGRAM, SANTA CLARA UNIVERSITY, SANTA CLARA, CALIFORNIA

Dr. CLARK. Thank you, Mr. Chairman, and Ranking Member, Senator Murray, other Members of the HELP Committee.

Thank you for inviting me to participate in this important discussion about the opioid crisis. I have submitted my full testimony for the record and will not attempt to repeat it here.

It is clear that the roles of technology and data are important in preventing and treating addiction. However, those roles need to be approached with care and sensitivity. Data can be abused; technology can be misused.

Under the guise of addressing the opioid crisis, there is an assault against individuals who present for substance use disorder treatment. There are those who would strip away the privacy protections offered by 42 U.S. Code Sec. 290dd-2 and 42 CFR Part 2. In so doing, they would be decreasing the demand for substance use disorder treatment and increasing the demand for illegal substances.

While the theme of this hearing involves opioids, Federal substance use disorder confidentiality regulations cover a broad range of psychoactive substances including alcohol, marijuana, cocaine, methamphetamine, and others. Although 2.1 million people meet

criteria for opioid use disorders, 18 million people meet criteria for disorders of other substances of abuse.

The core principles underlying the existing substance use disorder confidentiality provisions include providing patients the opportunity to be informed about who is requesting their substance use records and the opportunity to consent to whom their information should be disclosed.

While the technology exists to allow patients a role in determining what can happen to their substance use disorder treatment records, in terms of to whom that information is disseminated, the Electronic Health Record industry and the integrated service provider community have shown little interest in exploiting that technology. Instead, they argue, somewhat disingenuously, that asking for patient consent to disclose sensitive information is too burdensome, too cumbersome, and unnecessary. They say, "All you need is HIPAA."

The Federal Substance Use Confidentiality regulations were promulgated because it was recognized that harm could occur to those who present for treatment, as treatment records could be misused, either willfully or negligently.

Keep in mind that 42 CFR Part 2 has been changed twice in the past year, but that is not enough for those who would ignore the potential loss of employment, loss of child custody, discrimination, and stigma often associated with substance use.

Comparing the phenomena associated with substance use with such conditions as hypertension, diabetes, asthma, or HIV is disingenuous from a confidentiality point of view as those conditions are not illegal under the law, and are protected by the Americans with Disabilities Act, while active substance use is not protected by the ADA.

Trust is the cornerstone of effective behavioral health treatment particularly for the treatment of those substances for which no medication is available. Unconsented disclosure of sensitive information derived from the therapy records of those in substance use disorder treatment may actually precipitate relapse and overdoses given the violation of trust associated with the unconsented release of information. Without trust, the data from patients will be fraught with omissions, evasions, or deception. Data analytics will become an illusion.

It is well known that behavioral health treatment records need to contain descriptive narratives about a patient's life experiences including information about trauma, marital problems, violence, incarceration, sexual encounters, as well as substance issues.

While HIPAA allows for separate psychotherapy notes, currently used EHR's actually discourage those separate notes. How is a substance use treatment provider going to explain to a patient inquiring about the confidentiality of their treatment records that HIPAA allows for providing such descriptive information when that information includes information going to non-healthcare providers, cost management, customer service, and business planning among other things?

The HITECH Act failed mental health and substance use disorder treatment providers by providing almost no incentives to

them while promoting technology to primary care providers and hospitals.

To compensate for that failure, advocates for eviscerating or abandoning 42 U.S. Code Sec. 290dd-2 or 42 CFR Part 2 proposed to abandon the very people we are trying to encourage into treatment. Please, do not allow this to happen.

Incidentally, HIPAA contains a self-pay out of pocket provision that allows those with the financial means to withhold sensitive information from their health plans. The 42 CRF Part 2, on the other hand, does not discriminate based on economic status, thus permitting respect for the agency and autonomy of the rich and poor alike.

Existing data segmentation strategies, such as consent to share, would actually facilitate patient consent under the 42 CFR Part 2, an information exclusion under HIPAA. However, there is little interest in this technology among those who should be interested.

[The prepared statement of Dr. Clark follows:]

PREPARED STATEMENT OF H. WESTLEY CLARK

My name is Dr. H. Westley Clark. I am a psychiatrist and addiction medicine specialist. I retired from Federal service after proving clinical care to our Nation's veterans for 14 years and after directing the Center for Substance Abuse Treatment in the Substance Abuse and Mental Health Services Administration for 16 years.

I am currently teaching undergraduates about substances of misuse to undergraduates at Santa Clara University, recognizing that the young men and women of this Nation are both at risk for substance misuse and have the potential to changing the cultural dynamic which puts their age cohort at greatest risk for misuse and overdose.

I am here to advocate for maintaining the integrity of 42 USC 290-dd and to keeping those Federal regulations that protect individuals with substance use disorders who would be discouraged from seeking substance use disorder treatment, because they would be subject to discrimination and legal consequences in the event that their information is improperly used or disclosed.

As you well know, we are in the midst of the worse opioid epidemic that this Nation has ever seen. And, at the same time, less than 10 percent of people who need treatment seek treatment. Instead of recognizing that we need to reassure those in need of treatment that they can trust the weakening 42 USC 290-dd and 42 CFR Part 2.

It is argued that the opioid epidemic justifies modifying 42 CFR Part 2 to address the opioid overdose deaths and the misuse of opioids. While the issue of opioid misuse is of major importance, we should keep in mind that 42 CFR Part 2 does not just apply to opioids.

Data from the National Survey on Drug Use and Health reveals that 65 million Americans 12 and Older admit to binge drinking in the past month. Of these, 16 million admit to being heavy drinkers. We should also be aware that 24 million people admit to being past month users of marijuana. [1]

These numbers alone suggest the magnitude of the issues we are confronting today, as they exceed the 3.4 million people who admit to past month use of pain relievers and the 475,000 who admit to past month users of heroin.

The critical question today is how do we get the 28.6 million Americans who are current illegal drug users and the 65 million people who are binge drinkers to discuss their substance use with the medical community? Sally Satel, psychiatrist, author and commentator asked:

> "[W]hat should we do about the opioid crisis? First, we must be realistic about who is getting in trouble with opioid pain medications. Contrary to popular belief, it is rarely the people for whom they are prescribed. Most lives do not come undone, let alone end in overdose, after analgesia for a broken leg or a trip to the dentist. There is a subset of patients who are vulnerable to abusing their medication—those with substance use histories

[1] Source: SAMHSA, Center for Behavioral Health Statistics and Quality. National Survey on Drug Use and Health, 2016.

> or with mental health problems. Ideally, they should inform physicians of their history, and, in turn, their doctors should elicit such information from them." [2]

Although the use of alcohol is legal for those over the age of 21, the medical community should also communicate with their patients about alcohol use. However, as for all psychoactive substances, communications between clinician and patient require trust. Trust is not possible if the function of disclosure is the release of sensitive information into a virtual data storm sewer.

It is often argued that substance use should be treated like HIV, the flu, diabetes or hypertension and therefore should be treated like those conditions. Those who make this argument blind themselves to the reality that many substances of misuse are illegal, and that disclosure of such information can give rise to harm to the individual affected.

The harms to which a person who admits to substance use may suffer includes the loss of employment, the loss of housing, the loss of child custody, the loss of benefits, stigma and discrimination, the loss of privacy and the loss of autonomy. [3] Medical records can also be used to incriminate a person and subject that person arrest, prosecution, and incarceration.

It is irresponsible to ignore the real harms to which a person with a history of substance use could be subject. It is also irresponsible to ignore the implication that modern electronic health information has for privacy and confidentiality. It is sometimes said that computers have eidetic memories—they don't forget. Thus, people in recovery from alcohol and drug use who have long since stopped using are still at risk for discrimination and stigma.

The case is often made that the health care delivery systems need to know about the substance use history of a patient. You don't hear why providers can't simply ask patients themselves about their substance use histories. You hear that it is too confusing for clinicians to know about 42 CFR Part 2 and to apply the rules. Yet, these same clinicians and health care systems spend quite a bit of time learning about and executing reimbursement rules, licensing rules, administrative rules, quality standard rules, and all the other rules that are necessary to get paid for the services delivered to the very people whose agency and dignity are now deemed too inconvenient to respect.

No, I rarely hear or read about concern about the harm to the patient. Instead, I hear concern for the convenience of the delivery system, a concern that creates an adversarial relationship between patient and practitioner rather than respect for and trust from the patient. What appears to underlie the argument for administrative efficiency and systems needs is distrust of the patient, if not contempt for the patient.

Now is the time to welcome people with substance use disorders into the health care delivery system, not with the demand that such individuals concede their agency, dignity and privacy to the administrative convenience of the health care delivery system, but with the old adage of "First, do no harm."

Distrust and Contempt for people with substance use disorders has led to distortions and misinterpretation of 42 CFR Part 2. Emergency room clinicians argue that a patient with an opioid use disorder comes into the ED following an overdose and is unresponsive, 42 CFR part 2 keeps them from getting lifesaving information. Not true, 42 CFR Part 2 allows those emergency room clinicians to access Part 2 protected information kept either by a health information exchange or a substance use disorder treatment program in order to treat the patient in the emergency status.

Internists may argue that it is critical not to prescribe an opioid to an opioid dependent patient who is on methadone. However, they don't establish that asking the patient about their methadone treatment is ineffective. Furthermore, they don't establish that checking the PDMP is ineffective. If the PDMP is ineffective, they don't argue for improving PDMPs by making them real time and regional.

Family members, concerned about the welfare of their opioid dependent adult relative, are not precluded from getting information when an unconscious adult is brought into the ER following an opioid overdose. Emergency room clinicians under this situation are not prohibited from sharing information with those concerned family members.

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[2] Satel, Sally, "The Myth of the Roots of the Opioid Crisis", Politico Magazine, February 21, 2018, *https://www.politico.com/magazine/story/2018/02/21/the-myth-of-the-roots-of-the-opioid-crisis-217034*, accessed 02/24/2018.

[3] Lopez, Karla and Reid, Deborah, "Discrimination Against Patients with Substance Use Disorder Remains Prevalent and Harmful: The Case for 42 CFR Part 2, "Health Affairs Blog, April 13, 2017, DOI: 10.1377/hblog20170413.059618, accessed 02/25/2018.

It is argued that 42 CFR Part 2 perpetuates the stigma of addiction. This disingenuous argument ignores the laws, regulations, policies and social view about addiction and substance use disorders. It is not illegal to be depressed. It is not illegal to have diabetes. It is not illegal to have a broken leg. It is illegal to use heroin. People with untreated or active diabetes are protected by the Americans with Disabilities Act. People with untreated or active substance use are not. There are no signs posted at the employment office of employers declaring that the workplace is a hypertension free workplace and that all new applicants will have their blood pressure checked; there are no signs saying that anyone with evidence of hypertension shall be denied employment.

The Department of Health and Human Services has already moved to accommodate the modernization of 42 CFR Part 2 through two rounds of rulemaking, including a 2017 Final Rule and a 2018 Final Rule. However, the EHR community and a number of health systems remain restless, impatient and intolerant of those with substance use disorders, suggesting that information sharing is more important than the people about whom that information is shared. Thus, the regulatory efforts to allow patient to provide a general disclosure for substance use disorder information, to offer some flexibility in transmitting substance use data electronically, and to clarify the circumstances in which providers can disclose patient information to contractors and subcontractors for payment and healthcare operations is not enough. The critics of 42 CFR seek to expose those with substance use disorders who seek treatment, making the exercise of treatment a dangerous proposition.

Patient Attitudes Toward Treatment

We spend millions of dollars collecting information about the substance use patterns of people in the US. Perhaps we should be concerned about the reality that 89 percent of people, who meet criteria for needing substance use disorder treatment, did not receive such treatment. [4]

Of the 28.6 million people who misused illicit drugs and the 65 million people who were binge drinkers in the past month, only 3.8 million people received treatment in the past year. Of course, mere use does not equate with dependence or needing treatment. However, NSDUH data indicate that over 20 million people 12 or older met criteria for a substance use disorder in the past year in 2016, with 2.1 million meeting criteria for an opioid use disorder.

What is equally interesting is that of the people who met criteria for needing treatment and did not receive treatment, 95.5 percent perceived no need for treatment. In short, 18.7 million people needed but did not receive treatment; of these, 17.9 million perceived no need for treatment.

Now comes the critics of 42 CFR Part 2, under the flag of bringing integrated treatment to those in need, claiming that it is 42 CFR Part 2 that operates as a barrier to effective and efficient treatment of opioid use disorders, claiming that there is no need for special concerns about substance use disorders, today, never mentioning how they will explain to those actually seeking treatment and those in need of treatment the ramifications of attenuating 42 CFR Part 2.

Changing 42 CFR Part 2 and the Response of Substance Users

It is important to recognize that 42 CFR Part 2 does not apply to most clinicians or most clinical settings. In fact, 42 CFR Part 2 only applies to programs that hold themselves out "as providing, and provides, alcohol or drug abuse diagnosis treatment, referral for treatment or prevention." Of course, 42 CFR Part 2 governs substance use disorder patient records for those patients who receive, diagnosis, referral or treatment from (a) an identified unit of a general medical facility that holds itself out as providing, and provides alcohol or drug use disorder diagnosis, treatment or referral for treatment or (b) medical personnel or other staff in the general medical care facility whose primary function is to provide those services.

It is the patient records of a substance use disorder program (which includes the substance use patient records clinicians who hold themselves out as treating people with substance use disorders in even in non-specialty settings), that are controlled by 42 CFR Part 2. This creates a responsibility for the substance use disorder program to explain to the patient the meaning of confidentiality as it applies to information disclosed to the treatment program.

For the millions of people whose substance use does not meet criteria for protection under 42 CFR Part 2, HIPAA controls. HIPAA regulations allow for

[4] Source: SAMHSA, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, 2015 and 2016.

unconsented disclosure of patient information for, among other things, healthcare operations.

Healthcare operations include:

- Underwriting, enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance)
- Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities;
- Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, development or improvement of methods of payment or coverage policies
- Business management and general administrative activities of the entity, including, but not limited to:

(i) Management activities relating to implementation of and compliance with the requirements of this subchapter;

(ii) Customer service, including the provision of data analyses for policy holders, plan sponsors, or other customers, provided that protected health information is not disclosed to such policy holder, plan sponsor, or customer.

(iii) Resolution of internal grievances;

(iv) The sale, transfer, merger, or consolidation of all or part of the covered entity with another covered entity, or an entity that following such activity will become a covered entity and due diligence related to such activity; and

(v) Consistent with the applicable requirements of § 164.514, creating de-identified health information or a limited data set, and fundraising for the benefit of the covered entity.

Do non-42 CFR Part 2 covered providers explain the width and depth of the health care operations provision under HIPAA? Would patients exempted from 42 CFR Part 2 protections feel that disclosing histories of substance use is wise under HIPAA, even if experimental or rare use of psychoactive substances is involved? Much of the literature favoring weakening 42 CFR Part 2 or aligning it much more substantively does not discuss this perspective.

Moving from HIPAA into those programs whose records are controlled by 42 CFR Part 2, it is clear that those with moderate to severe substance use disorders requiring treatment already do not believe that treatment is warranted. How are we going to encourage them to participate in treatment when we propose to broadcast their personal information through network of uncertainty entities with uncertain purpose?

Unfortunately, there are more serious consequences to voiding the patient's right to consent to the disclosure of sensitive information. The unconsented disclosure of sensitive information resulting in harm to the patient could easily give rise to suicide, relapse to substance use or overdose; these are tragic events that we should be avoiding rather than pretending that the agency and dignity of the patient has no value and can be compromised for the convenience of EHR vendors, data miners and health care operations. Furthermore, we should recognize that many in substance use disorder treatment are at risk for depression, anxiety and other psychiatric disorders, any of which would be made worse by a breach of trust by substance use disorder treatment programs and the health care delivery system.

Blaming the Vulnerable

The Health Information Technology for Economic and Clinical Health Act (HITECH Act) was enacted under Title XIII of the American Recovery and Reinvestment Act of 2009.[5] It provided billions of dollars of incentives to an array of primary care hospitals and to physicians to adopt electronic health records and to promote

[5] The American Recovery and Reinvestment Act of 2009, (Public Law 111–5).

the exchange of health information. However, that same act essentially ignored the behavioral health community; as a result, there were no incentives available for substance use disorder treatment programs to adopt electronic health records. In addition, there were no incentives to the electronic health record industry to develop software and protocols specific to the behavioral health community and the sensitive information generated by behavioral health providers, information of little use to most primary care providers.

At the time of the unfolding of the HITECH Act, I was the Health Information Technology Strategic Initiative Lead for SAMHSA. My team and I met with a number of software vendors in an effort to address the unique needs of the behavioral health community and to compensate for the omission of behavioral health from the promulgated incentives provided to general medicine. We met with little success.

However, in order to compensate for excluding behavior health from the incentives, standards, and designs for the evolving EHR systems, information exchanges, and the growing recognition that comprehensive health care required addressing behavioral health, efforts were mounted to promote the fiction that behavioral health patient information contained nothing unique and distinct from the general health care environment.

The notion that all health care information is equivalent runs counter to the historical status recognized in the psychotherapist-patient privilege which was justified on the grounds that some personal health information was more sensitive than others. Discussions of mental health, substance use, and sexual health are inhibited unless the patient has certain reassurances that highly sensitive personal health information would remain between themselves and their health care providers. Indeed, "the prevailing legal default and ethical norm in Western nations both strongly favor the preservation of patient confidence in the absence of compelling grounds to act otherwise." 1A[6]

As Shenoy and Appel point out, the behavioral health record "often combines data related to the patient's present symptoms, with a descriptive narrative of the patient's life experience, including sensitive details of psychological trauma, domestic violence, incarceration, sexual encounters, and substance abuse. Much of this information is of great value to a therapist, but not always of clinical use to many other medical providers. The stigma attached to mental healthcare among some individuals and in certain cultural communities even leads some patients to avoid using their insurance for psychiatric care in order to protect their privacy."[7]

At SAMHSA, we recognized the continued sensitivity of behavioral health information, especially for substance use in particular. As a result, we developed an open source codebase through a contract that would provide an inexpensive software application for the behavioral health community.[8] Unfortunately, due to complaints of unfair competition we discontinued our efforts.

The HITECH Act with its focus on meaningful use and information exchange did not change the unique character of behavioral health information. As a result, we developed Consent2Share, an open-source data segmentation platform that could be incorporated into existing electronic health records to allow patients to be able to consent to the disclosure of highly sensitive patient information.[9]

Consent2Share was developed evolved within the Data Segmentation for Privacy (DS4P) initiative within ONC's Standards and Interoperability (S&I) Framework to improve the interoperability of the plethora of EHRs containing sensitive information that must be protected. The DS4P initiative met its two goals, which were to: Demonstrate how standards can be used to support current privacy policies, including 42 CFR Part 2, for sharing sensitive health information across organizational boundaries; and develop standards that will enable sensitive electronic health information to flow more freely to authorized users while improving the ability of health IT systems to implement current privacy protection requirements for certain Types of health care data, such as substance use disorder patient records.

Unfortunately, the EHR vendor community felt no need to support data segmentation, dismissing the importance of privacy and confidentiality to patients. Furthermore, health information exchanges chose to ignore the importance of privacy and confidentiality to the patients by choosing not to embrace the utility of data segmentation and patient choice. Naturally, without data segmentation and consent management capacities, substance abuse treatment programs operating under 42

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[6] Shenoy, A and Appel, JM, "Safeguarding Confidentiality in Electronic Health Record", Cambridge Quarterly of Healthcare Ethics (2017), 26, 337–341.

[7] Ibid.

[8] *http://www.feisystems.com/what-we-do/learn-about-wits/why-choose-wits-2/*.

[9] Department of Health and Human Services: 42 CFR Part 2: Confidentiality of substance use disorder patient records; proposed rule. Federal Register 81: 6988–7024, 2016.

CFR Part 2 requirements have diminished capacities to share information with integrated treatment models that ignore patient choice.

In short, SAMHSA was able to demonstrate that patient choice could be respected without compromising the agility and flexibility of required for integrated information exchange. However, for matters of mere convenience and low market demand, most EHR vendors and health information exchanges chose to support the less expensive and ethically problematic position of eviscerating 42 CFR Part 2.

Economic Disparities, HIPAA, and Confidentiality

What is remarkable about the industry and provider objections to having patients weigh in on whether their private medical information should be disclosed is the loophole in HIPAA that allows rich people or middle people to have the right to restrict certain disclosures of protected health information to a health plan where the individual pays out of pocket in full for the health care or service received.[10] Health care providers, under HIPAA, are required to include such a statement in the notice of privacy practices provided to the patient. Thus, if a patient is rich and can pay for their own treatment in full, including substance use disorder treatment or if they are middle class and can mortgage their home to pay for their treatment in full, they can avoid disclosing the fact that they are in substance use disorder treatment to their health plan. What is amazing is that providers who are committed to doing no harm are willing to sacrifice poor whites, poor blacks, poor Hispanics, poor Native Americans, poor Alaskan Natives, poor Hawaiians, and poor Asians in the service of a fiction of needing highly sensitive personal information without a patient's consent when they could most likely receive that information simply by asking the patient. In situations where a patient refuses consent to disclose sensitive information to entities outside of the treatment situation, that should be the patient's prerogative.

Given the well documented harm that can happen to a person who is an admitted substance user, it should not be EHR vendors or health systems that should decide what sensitive information should be disclosed outside of a substance use treatment process. Financial ability should not be the deciding factor on whether a person retains a modicum of control over their personal information.

Increased Liability for Substance Use Disorder Treatment Programs

Substance Use Disorder treatment programs have a duty to inform patients about the limits of confidentiality. Given the spectrum of entities under the rubric of healthcare operations, it would be difficult for a substance use disorder treatment program to accomplish this with any degree of effectiveness; this would expose the covered program to liability.

Given that the potential harms from inappropriate disclosure of sensitive information garnered during substance use disorder treatment is real, the disclosure of that information may give rise to legal claims including lawsuits for some form of negligence. Unfortunately, since substance abuse treatment programs will be the entities releasing information under the proposed modified 42 CFR Part 2, undoubtedly they will bear the brunt of the legal burden. Increased liability insurance, legal costs, and impaired reputations will ensue. After all, once sensitive information is released into the entity that releases that information has no control over its distribution. The question would become should substance abuse treatment program that released the information have known that it contained information that could be used to the detriment of their current or past patient.

Substance use disorder treatment programs caught up in lawsuits may have to withdraw from the treatment marketplace. Treatment programs that close under the weight of malpractice claims will only diminish the number of available treatment slots. The cost of care will also increase as treatment programs have to compensate for the increased administrative costs of doing business.

Conclusion

We cannot adequately address the current opioid epidemic if we remove the protections that 42 CFR part 2 and its authorizing legislation, 42 USC § 290dd-2, offers. We cannot treat those experiencing substance use disorders with contempt by

[10] Department of Health and Human Services; 45 CFR Parts 160 and 164: Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules. Federal Register 78 (17: 5566–5702)

weakening the protections that they currently have. We cannot treat those who experience substance use disorders as a means to an end, attempting to compensate for the lack of public investment in electronic health records for the behavioral health treatment communities following the HITECH Act's focus on primary care.

Efforts to balance the health information technology requirements of integrated systems while preserving a patient experiencing a substance use disorder's right to consent to the disclosure of their substance use treatment history and sensitive matters subsumed under that history have been thwarted by the EHR industry and by health information exchanges. The claim that it would cost too much is overshadowed by the existence of open source strategies that could accomplish the necessary consent management strategies and by the inherent right of a person to determine what happens to sensitive information.

In truth, 42 CFR Part 2 has been changed in 2017 and 2018. Now is the time to leave it alone, to let the health care delivery system gain a modicum of expertise to those changes, and to allow the information technology industry an opportunity to further pursue technological accommodations to existing information systems to permit patient consent to sensitive information.

[SUMMARY STATEMENT OF H. WESTLEY CLARK]

1. 42 USC 290-dd, the authorizing legislation for substance use disorder (SUD) treatment should remain as is.

2. Because two changes to 42 CFR Part 2, the implementing regulations of 42 USC 290-dd, have already occurred, once in 2017 and once in 2018, no further changes should be executed at this time.

3. The promulgated changes to 42 CFR Part 2 promoted a closer alignment with HIPAA.

4. The public policy purpose of 42 USC 290-dd and 42 CFR Part 2 is to encourage people in need of SUD disorder treatment to enter such treatment, fostering (a) an increased demand for SUD treatment and (b) a decrease demand for illegal substances. Although new technologies have arisen, including electronic health records (EHRs), and new service models have evolved, the original purpose of 42 USC 290-dd and 42 CFR Part 2 has not changed. Additional efforts to align 42 CFR Part 2 with HIPAA may eviscerate the purpose of 42 CFR Part 2 and also impose burdens on those who are in Recovery from SUDs.

5. Epidemiological data demonstrate that most people in need of SUD treatment do not receive it and do not perceive a need for such treatment. Violating their confidentiality will not encourage a demand for treatment for those with active SUDs.

6. While the opioid epidemic is a major public health concern, 42 USC 290-dd and 42 CFR Part 2 also encourage those with other SUDs to enter treatment; this includes individuals with alcohol dependence and dependence on substances subject to the Controlled Substances Act such as, marijuana, cocaine, methamphetamine and other psychoactive substances.

7. The core principles underlying the existing substance use disorder confidentiality provisions are providing patients the opportunity to be informed about whom is requesting their substance use records and the opportunity consent to whom their information should be disclosed.

8. Despite new EHRs and integrated service models, the information disclosed by patients in substance use disorder treatment is uniquely sensitive, often involving illegal acts, psychological trauma, domestic violence, and potentially compromising activities the disclosure of which can result in substantial harm to patients.

9. Comparing the phenomena associated with substance use with such conditions as hypertension, diabetes, asthma, or HIV is disingenuous as those conditions are not illegal under the law and are protected by the Americans with Disability Act, while active substance use is.

10. Trust is the corner stone of effective SUD treatment, particularly for the treatment of those substances for which no medication is available. Unconsented disclosure of sensitive information derived from the records of those in substance use disorder treatments may precipitate relapse and overdoses, given the violation of trust associated with the unconsented release of such information.

11. Acquiring patient consent to disclose sensitive information preserves trust and permits a balancing of policy interests associated with facilitating integrated care.

12. The technology exists, although resisted by EHR vendors and some health care systems, to facilitate patient consent to the disclosure of sensitive information. The lack of interest in this technology may be a product of the lack of incentives within the HITECH Act for behavioral health treatment providers; patients interested in SUD treatment should not be punished by this policy omission.

13. Further weakening of 42 USC 290-dd and 42 CFR Part 2 will increase the administrative costs of substance use disorder treatment programs due to liability issues associated with inappropriate disclosures.
14. HIPAA contains a self-pay, out-of-pocket provision, that allows those with the means to withhold sensitive information from their health plans. 42 CFR Part 2, on the other hand, does not discriminate based on economic status, thus permitting respect for the agency and autonomy of the rich and the poor alike.

The CHAIRMAN. Thank you, Dr. Clark.
Mr. Shah, welcome.

STATEMENT OF SANKET J. SHAH, CLINICAL ASSISTANT PROFESSOR, HEALTH INFORMATICS, UNIVERSITY OF ILLINOIS AT CHICAGO, HINSDALE, ILLINOIS

Mr. SHAH. Good morning, Chairman Alexander, Ranking Member Murray, and Members of the HELP Committee.

My name is Sanket Shah and today, I am going to provide you my view on how technology, specifically analytics, can help curb the overuse, misuse, and abuse of opioids.

Healthcare data and analytics can play a key role in helping to combat this national crisis. Descriptive, diagnostic, predictive, and prescriptive analytics make it possible to identify individuals who are at-risk of becoming opioid dependent. Armed with this information and the right technologies, healthcare providers and communities can make better informed decisions and understand the risk of possible dependency.

The first area we all should start with is descriptive analytics. Descriptive analytics identify what is happening and where.

According to a 2017 study published by the Blue Cross Blue Shield Association, opioid use disorder diagnoses increased 493 percent from 2010 through 2016. The same study identified that women aged 45 and older have higher rates of opioid use disorder than males, while males under the age of 45 have higher rates of opioid use disorder than females. We also know that females fill more opioid prescriptions across all age groups than males.

Once we understand what is happening, our focus must shift to why it is happening. This is where diagnostic analytics come into play.

For instance, we know potential determinants for opioid dependency include gender, age, whether the patient sought treatment for an acute injury or a chronic condition, and the size and dosage of the prescription.

We also know that many patients engage in doctor and pharmacy shopping practices to obtain harmful, large quantities of opioids from various sources.

According to a report published by the Inspector General of the United States Department of Health and Human Services, one such egregious case in Illinois revealed a Medicare enrollee received 73 prescriptions for opioid drugs from 11 prescribers and filled them at 20 different pharmacies.

When you couple these factors with the lack of effective risk assessment and decision support tools available to providers, we miss the early warning signs for potential opioid dependency.

Here we are. We already know the what and the why. The role of technology and analytics can help prevent addiction. Here is

where we must focus on predictive analytics. Predictive analytics enables us to leverage data to anticipate what is to come.

For example, according to a study published in the "British Medical Journal," the duration of opioid treatment is a far more potent predictor of abuse and overdose than just dosage alone. In fact, each additional week of opioid use increased the risk of dependence, abuse, or overdose by nearly 20 percent. Each additional refill boosted the risk by 44 percent with the first refill doubling that risk.

To truly have predictive analytics, we need more data sources. Currently, we find ourselves in data silos across the public and private healthcare sectors.

My recommendation is to open the lines of communication and pathways to share data for a holistic view to help combat this epidemic.

The Federal Government has the means and infrastructure to create an integrated data environment which we can source from at the local and state levels. Having access to such a vast data repository would enable us to create robust predictive analytics that leverage multiple sources, including social determinants of health, medical, and family history, and also true episodes of care.

A secure and encrypted data repository would empower our healthcare informaticists to administer and deploy innovative technologies to enhance our predictive capabilities. We can collaborate on advanced machine learning algorithms for deeper pattern analyses from both the provider and patient fronts.

The insights gained could be tremendous. We all can potentially benefit from these new technologies by knowing which patients might respond better to non-pharmacologic, multimodal therapies, or targeted care management programs.

To accomplish this, we simply need access to more substance abuse data. I ask you all to consider and support the Prescription Drug Monitoring Act of 2017 which requires any state that receives Federal grant funding to establish a Prescription Drug Monitoring Program to share their data with other states.

In addition, I also ask you to consider supporting the Protecting Jessica Grubb's Legacy Act, which calls for modernizing Part 2, and allows for closer alignment with HIPAA regulations, and sharing of substance abuse disorder records for true, accurate diagnoses and effective treatment.

Our predictive analytics have identified at-risk individuals for developing an addiction. We can use prescriptive analytics to offer up actionable insights. Providers and health plans can predict what may happen and make the necessary changes to true, proper treatment plans.

Armed with actionable insights, new treatment models and alerts can be developed to deemphasize opioid medication use for at-risk individuals. This includes the right decision support tools at the point of care.

Ultimately, technology alone will not help curb this epidemic. We must also use the information and insights we have gained to educate our providers, patients, and communities about proper adherence and potential risks of opioid use.

America's prescription opioid epidemic continues to be a public health crisis. However, using descriptive, diagnostic, predictive, and prescriptive analytics, may provide an opportunity to identify at-risk individuals and change the course to help address this epidemic.

We have the data. I ask your help to share that data.

Thank you.

[The prepared statement of Mr. Shah follows:]

PREPARED STATEMENT OF SANKET J. SHAH

Good morning Chairman Alexander, Ranking Member Murray, and Members of the HELP Committee. My name is Sanket Shah and today I am going to provide you my view on how the role of technology, and more specifically, analytics may help curb the overuse, misuse, and abuse of opioids. Healthcare data and analytics can play a key role in helping to combat this national crisis. Descriptive, diagnostic, predictive, and prescriptive analytics make it possible to identify individuals who are at risk of becoming opioid dependent. Armed with this information and the right technologies, healthcare providers and communities can be better informed about the risk of possible dependency.

The first area we all should start with is descriptive analytics. Descriptive analytics identify what's happening and where. According to a 2017 study published by the Blue Cross Blue Shield Association, opioid use disorder diagnoses increased 493 percent from 2010 through 2016. The same study also has identified that women aged 45 and older have higher rates of opioid use disorder than males, while males under the age of 45 have higher rates of opioid use disorder than females. We also know females fill more opioid prescriptions than males across all age groups. [1]

Once we understand what is happening, our focus must shift to why it's happening. This is where diagnostic analytics come into play. For instance, we know potential determinants for opioid dependency include gender, age, whether the patient sought treatment for an acute injury or a chronic condition, and the size of the dosage and duration of the prescription. [2] We also know that many patients engage in doctor and pharmacy shopping practices to obtain harmful quantities of opioids from various sources. According to a report published by the Inspector General of the United States Department of Health and Human Services, one such egregious case in Illinois revealed a Medicare enrollee received 73 prescriptions for opioid drugs from 11 prescribers and filled them at 20 different pharmacies. [3] When you couple these factors with the lack of effective risk assessment and decision support tools available to providers, we miss the early warning signs for potential dependency.

Here we are, we already know the *what* and the *why*. The role of technology and analytics can help prevent addiction. Here is where we must focus on predictive analytics. Predictive analytics enables us to leverage data to anticipate what is to come. For example, according to a study published in the British Medical Journal, the duration of opioid treatment is a far more potent predictor of abuse and overdose than just dosage. In fact, each additional week of opioid use increased the risk of dependence, abuse, or overdose by nearly 20 percent. Each additional refill boosted the risk by 44 percent with the first refill more than doubling the risk. [4]

To truly have accurate predictive analytics we need more data sources. Currently, we find ourselves in data silos across the public and private healthcare sectors. My recommendation is to open the lines of communication and pathways to share data for a "holistic view" to help combat this epidemic. The Federal Government has the means and infrastructure to create an integrated data environment which we can source from at local and state levels. Having access to such a vast data repository will enable the creation of robust predictive analytics that leverages multiple variables such as social determinants of health, family and medical history, and access to complete episodes of care. A secure and encrypted data repository would empower our healthcare informaticists to administer and deploy innovative technologies to

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[1] "America's Opioid Epidemic." Blue Cross Blue Shield Association (BCBSA), 29 June 2017, *www.bcbs.com/the-health-of-america/reports/americas-opioid-epidemic-and-its-effect-on-the-nations-commercially insured*.

[2] America's Opioid Epidemic. BCBSA.

[3] "Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing." HHS OIG Data Brief, July 2017, *oig.hhs.gov/oei/reports/oei-02-17-00250.pdf*.

[4] Brat, Gabriel A, et al. "Postsurgical Prescriptions for Opioid Naive Patients and Association with Overdose and Misuse: Retrospective Cohort Study." Bmj, Dec. 2017, doi:10.1136/bmj.j5790.

enhance our predictive capabilities. We can collaborate on advanced machine learning algorithms for deeper pattern analyses from both the provider and patient fronts. The insights gained could be tremendous. We all can potentially benefit by knowing which patients might respond better to non-pharmacologic, multi-modal therapies, or targeted care management programs.

To accomplish this, we simply need access to more substance abuse data. I ask you all to consider and support the Prescription Drug Monitoring Act of 2017 (S. 778) which requires any state that receives Federal grant funding to establish a prescription drug monitoring program to share their data with other states. In addition, this act also contains components to help fund a data sharing hub which I spoke of earlier. I also ask you all to consider supporting the Protecting Jessica Grubb's Legacy Act (S. 1850) which calls for modernizing Part 2 to align with HIPAA regulations and will grant appropriate sharing of substance use disorder records to ensure persons with opioid use disorder and other substance use disorders receive accurate diagnoses and effective treatment.

Once predictive analytics have identified at-risk individuals for developing an addiction, we can use prescriptive analytics to offer up actionable insights. Providers and health plans can predict what may happen and make the necessary changes to treatment plans. Armed with actionable insights, new treatment models and alerts can be developed to de-emphasize opioid medication use for at-risk individuals. This includes the right decision support tools for our providers at the point of care.

Ultimately, technology alone will not be able to curb this epidemic. We must also use the information and insights we have gained to continue to educate our providers, patients, and communities on the proper adherence and potential risks of opioid use. America's prescription opioid epidemic continues to be a public health crisis. Using descriptive, diagnostic, predictive, and prescriptive analytics, we have an opportunity to identify at-risk individuals and change the course to help address the epidemic.

We have the data. We need your help to share it.

List of recommendations to consider:

- Pass S. 778—Prescription Drug Monitoring Act of 2017
- Pass S. 1850—Protecting Jessica Grubb's Legacy Act
- Create and enable authorized access to an integrated, secure data repository for opioid prescriptions, treatments, overdoses, and individuals at risk

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[SUMMARY STATEMENT OF SANKET J. SHAH]

Using healthcare data and analytics can play a key role in helping to combat this national crisis. Descriptive, diagnostic, predictive, and prescriptive analytics make it possible to identify individuals who are at risk of becoming opioid dependent. Armed with this information and the right technologies, healthcare providers and communities can be better informed about the risk of possible dependency.

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Using descriptive, diagnostic, predictive, and prescriptive analytics, we have an opportunity to identify at-risk individuals and change the course to help address the epidemic.

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- Pass S. 1850—Protecting Jessica Grubb's Legacy Act
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The CHAIRMAN. Thank you, Mr. Shah, and thanks to each of you.

We will now have a round of 5 minute questions from Senators. We have a number of Senators, so if you will try to keep the questions and answers within 5 minutes, everyone can participate.

Senator Young.

Senator YOUNG. Mr. Shah, I enjoyed your testimony where you spoke, quite a bit, about the potential descriptive, diagnostic, predictive and prescriptive analytics, and their potential to make it possible to identify individuals who are at-risk of becoming opioid dependent.

I see limitless opportunities to harness these tools. Not just in the area of healthcare and improving health outcomes, but proactive policing. We are starting to see it in various geographies. Our office is working on child abuse prevention through the utilization of some of these tools.

What can the Federal Government do now to encourage exploration, more exploitation of these analytic tools while ensuring patient protections?

Mr. SHAH. Thank you for the question.

Well, there are a couple of things I mentioned in my testimony here. I think that the Prescription Drug Monitoring Act of 2017, first of all, allows opening up the doors, if you will, for states to access data from states that are currently employed in the Prescription Drug Monitoring Programs. So sharing of that data will enable opening up some insights that we can share at local, state, and Federal levels.

In addition to that, I think part of the question also revolves around privacy and ensuring that we have our communities protected. When you are looking at this epidemic and you are looking at patient safety, it is imperative that we do leverage substance abuse disorder records to identify patterns, identify deeper analytics, and then share that amongst communities.

As it relates to safety and privacy, part of that includes protecting the data and accessing it in a protected environment and in an encrypted environment, if you will. So I think that would address some of the concerns from the public as it relates to sharing

some of their data. Again, the focus here is to really handle the data with care and then ultimately benefit these communities across the U.S.

Senator YOUNG. Yes, there are some serious privacy concerns. We need to make sure we do our very best to address, and not confuse, wherever possible correlation with causation, as they say, as well. Right?

I see some affirmative nods from our panelists.

Mr. Shah, specifically talking about predictive analytics, which you brought up, analytics that enable us to leverage data to anticipate what is to come.

In order to use this tool, you claim we need more data sources and open communication. We need to break down the data silos across the private and public healthcare sectors, and then connect the dots, as it were.

Can you elaborate on what those data silos are and then tell me why we cannot tear down these silos right now? Does this have, in part, to do with market power and vendor interest? Or are there other legal barriers or are there other dynamics that you would like to speak to, sir?

Mr. SHAH. Sure.

Well, there are a lot of stakeholders, and data is very important to these individual stakeholders. You have the provider systems. You have the payer systems. You have pharmaceutical companies. And then, you also have consumer-created data as well.

A part of the barrier here is just identifying an environment and creating an environment to access the information, collaborate.

Part of the concern here is that most organizations are very protective of their data because it is certainly an asset for that particular organization.

We are starting to get there, as it relates to sharing some of our important data from a consumer perspective and it is also from a private industry perspective. But the challenges remain and I think we need assistance to help break down those barriers.

Senator YOUNG. What options, if you have some in mind, do we have for action at the Federal level to catalyze or incentivize change in this area that facilitates more data sharing?

Mr. SHAH. One suggestion I would have is to, again, part of that Prescription Drug Monitoring Act of 2017 is to create an integrated data source that we can all pull from. It would be a secure data source leveraging public data that is available.

Senator YOUNG. Yes.

Mr. SHAH. Ultimately with the goal to, hopefully, bring in some of the private data as well so we can start to leverage this for not only research and development purposes, but also, as you mentioned, for some predictive capabilities across various different industries.

Senator YOUNG. Would you sit down with me, obviously after this hearing, but to dive a little deeper on this issue? I am not sure, in terms of methodology, how we get there.

Maybe the National Academy of Sciences could help. We could commission them to establish data standards that, over a period of years, would be adopted.

Mr. SHAH. Sure.

Senator YOUNG. The private sector would understand that. There, no doubt, would be resistance to this idea. I am Okay with resistance, if it is the right thing to do.

Would you, or other stakeholders, other panelists, or people watching these proceedings, I just welcome them to work with our office on this?

Thanks so much for being here, all of you.

The CHAIRMAN. Thank you, Senator Young.

Senator Murray.

Senator MURRAY. Well, thank you, to all of our panelists today.

Dr. Mahon, let me start with you.

Throughout our hearings, we have heard about the need for more options for states' opioid disposal. I was particularly interested in the drug disposal bags you mentioned during your testimony, which offer, I assume, individuals a way to dispose of dangerous drugs on their own.

Tell us a little bit about those bags. Who provides them? How do they work and whether they could be made more widely available?

Dr. MAHON. Absolutely.

As part of our disposal bag that we provide to all of our patients, any time a patient fills a first-time opioid prescription, we mail them a disposal bag. Express Scripts will mail the member a disposal bag to their home with instructions on how to properly, safely dispose their unused medications.

Then we also subsequently offer the consultation by the specialized pharmacists who can continue to have the conversation with the member on any questions that they may have about proper disposal.

The way the bags work, they have activated carbon inside the bag where the member just simply pours a little bit of water and their pills in the bag. It immediately renders the drug deactivated and the bags themselves are biodegradable. They are safe to be disposed in the member's home.

We really feel that that is the best mechanism to allow members safe disposal in their home.

Senator MURRAY. Are you finding that people use them?

Dr. MAHON. Yes. We even are having members respond back to us. They are writing us letters and notes back.

One, thanking us for the educational letters we are sending them and basically saying, "Thanks for the heads up."

Two, "Thank you for letting me or giving me large enough of a bag where I can dispose not just my own medications, but my family's unused medications," to be able to properly get them out of the homes.

Senator MURRAY. Is there any way we can make these more widely available? Do you have any ideas?

Dr. MAHON. What we have seen in our program, what works really well, is having a targeted, data-driven approach. So not just giving the disposal bags at random times during the year, but really, when it matters the most: when the patient is just leaving the pharmacy counter and they are going home.

We know that they have gone home with that medication. They are probably going to have some additional meds left; giving it to them at that time, and then having that correlation with that spe-

cialized pharmacist that is coaching them through the process, really helps.

Senator MURRAY. Interesting. Thank you.

Ms. Green, you talked about the potential use of PDMP's to combat the opioid crisis, but also the need for data standards, so these programs can be effective.

Can you provide some examples to us about how data and requirements for maintaining data can be different across PDMP's, and how that can lead to systems that are not able to communicate or share information effectively?

Ms. GREEN. Certainly.

Right now, we have a number of standards about who can access the data and under what conditions, and those can vary from state to state.

For example, one of the best options we have with PDMP's is to facilitate widespread integration of the data into Electronic Health Records. And yet, we have a number of states that do not allow the PDMP report to actually be placed into the Electronic Medical Record, and they have different standards for access and use of that data, once it is actually in the medical record.

We need consistent standards for placing the PDMP report in a medical record and upon placement, allowing all of the same standards for use and disclosure that apply to other information in that medical record to apply to the PDMP data.

Those are the kinds of standards we now need to be reconciling and making more uniform.

Senator MURRAY. Do we need some single data hub to ensure interoperability or is there another way to do it?

Ms. GREEN. We already have 44 states that are actually sharing data and the others that are in the process of making legal changes.

But I would suggest, yes, we need a federally funded, single hub that is based on the interests and the needs of states and the public officials at the Federal level because that is what will generate the reconciling and the uniformity of some of these standards so that we can maintain the interest.

Some of the differences are occurring in different states because of some of the particular interests that have been affecting the laws and policies that go through some of the states.

If we can create uniformity at the Federal level, have it be federally funded, then we can create the kind of uniformity and standards that we are all looking to do at this point in time. And that would be under the Prescription Drug Monitoring Act of 2017.

Senator MURRAY. And Dr. Clark, real quick, I am encouraged by data sharing, but I am concerned about individual privacy, especially when people with substance use disorders are worried that their treatment could impact their job or family, and may discourage them from getting care.

What issues do we need to be aware of when it comes to protecting patient privacy?

Dr. CLARK. First, we need to distinguish between those people who are at-risk from those people who already have developed a substance use disorder problem and are seeking treatment. Those are two different populations of people.

Predictive analytics work very well for those people who are at-risk, but for those people who are attempting to present their treatment, we need to keep in mind they are much more vulnerable than the former group.

What we do not want to do is to discourage people, who are trying to get treatment, from postponing that treatment. Because if they postpone treatment, then they continue their demand for illicit substances or the misuse of alcohol while their children, and their employer, and others are trying to cope with them.

As Sally Satel, M.D. pointed out, "We must be realistic about who is getting in trouble with opioid pain medications. Contrary to popular belief," she said, "It is rarely the people for whom they are prescribed. Most lives do not come undone, let alone end in overdose after analgesia for a specific problem." We should not let these different populations of people——

Perhaps that is what we could use predictive analytics for, is to differentiate the populations so that we could have appropriate standards with that.

Senator MURRAY. Thank you.

The CHAIRMAN. Thanks, Senator Murray.

Senator Cassidy.

Senator CASSIDY. Thank you all.

Ms. Green, I came in on the tail end of Senator Murray's criticism of PDMP data, but what I heard, I am thinking, "Right on."

You say 44 states—and I am not challenging you, I am just exploring—44 states share data, but do they share all of each other or just interstate compact?

Ms. GREEN. It depends on the states. Some states share widely across, some states have decided to only share within their region, and the reason for that——

Senator CASSIDY. That is fine.

Ms. GREEN. Yes, Okay.

Senator CASSIDY. We have limited time. I do not mean to be rude.

Ms. GREEN. That is all right.

Senator CASSIDY. As I know, and I have mentioned before, Missouri, for example, does not have PDMP.

But it is also my understanding that a lot of states do not real time put up their data. There is a delay and that most states do not allow it to be shared with law enforcement. And I read—I do not know if it is up to date—that in 17 states, the Veterans Administration does not share data with the PDMP.

Is all of that correct as far as you know?

Ms. GREEN. Not quite.

Law enforcement is able to access in every state, but the standard is different. Twenty-eight states allow it based on bone fide investigation, others use a court ordered subpoena.

Senator CASSIDY. But in terms of Mr. Shah's hope that it can be used proactively, relatively few allow a proactive sharing.

Ms. GREEN. That is correct because PDMP laws are very specific about who can access the system for what purpose, and that purpose of proactive sharing would have to actually be written into the laws.

Senator CASSIDY. Now, Ms. Mahon, after Hurricane Katrina, it was amazing. All these patients had been displaced on chemotherapy, everything else. And somebody flipped a switch, and every doctor treating a Katrina evacuee had access to their prescription data. It was amazing.

A doctor in Oklahoma City seeing one of my patients could access my patient's records and would call me, but he then knew the Interferon my patient was on, and the complications, et cetera, etc.

It tells me—and I have actually seen an even more robust data base than this—that we are futzing around with PDMP's, but someone like you, Express Scripts, already has a more robust dataset than PDMP's.

Is that a fair statement?

Dr. MAHON. We have the dataset of the information if the member is using their pharmacy benefit card at the pharmacy counter. So if the patient chooses not to use their pharmacy benefit, and they are paying cash for their prescription, those are the claims that we would not see.

Senator CASSIDY. When I say I have seen a more robust version, I have seen a robust version of a dataset which now includes the cash payment. Every Veterans Administration is real time as in when the pharmacy fills it, it is uploaded. This is a mechanism to avoid for a compliance with anti-kickback regulations with government programs.

We are, again, futzing around with PDMP with all its limitations and we have before us a robust dataset that is even better than what I saw after Hurricane Katrina.

Mr. Shah, this seems like nirvana for someone like you. You can sort by provider. You can sort by patient and, I presume, geolocate within this dataset.

Would you agree?

Mr. SHAH. Yes, absolutely. I would definitely agree with that, especially from an analytic point of view.

When we have a conformed dataset like that, you can slice and dice from various different factors, get to the root cause drivers of certain trends.

Certainly to your point, Senator Cassidy, it absolutely would be ideal.

Senator CASSIDY. To believe that this dataset exists and is compliant with current law, then we should be exploring how to use it.

By the way, I have a bill in for PDMP because right now, that is the only weapon you have to fight this war against opioid abuse. You need to use it, but I keep on saying, we should go nuclear. We should be using this dataset, not the PDMP, and I just say to assert.

Dr. Clark, you probably gathered I am a doctor, hepatologist, treated a lot of patients with liver disease, and some patients with liver disease got theirs from shooting drugs. Some are actively shooting drugs.

I say this not to challenge, but again to explore. If you looked at the history of somebody I was treating, I would have everything. He shot drugs in the past or he is still shooting drugs. When did you stop? Did you share a needle? Sexually transmitted disease.

Have you had a blood transfusion? Did your mother have hepatitis when you were born? All this stuff. What is your mental health history? Because if I am going to treat him with Interferon, that is what we were using at the time, mental health was very important.

Now all that was covered under HIPAA, not under the mental health provisions. So your sensitivity, I thoroughly respect. My gosh. If somebody had come for those records, I would have barred the door and used whatever weapons I could to keep somebody from using those. But at the same time, you sense that there should be a greater sensitivity. But I would, again, point out that I had all that information whether the person was bipolar, for example.

Knowing that you are the advocate, and not challenging you, but just to explore. Why would HIPAA not be adequate when, frankly, I am already getting that data and I am only covered by HIPAA because I am not a mental health professional?

Dr. CLARK. I think we need to be careful about a presumption of dysfunction. We also need to distinguish monitoring from surveillance.

If we are not careful, we will wind up viewing patients as dysfunctional by definition and we will be using healthcare records for purposes of surveillance for purposes beyond——

Senator CASSIDY. Okay. Now that is totally foreign from what I was saying.

Dr. CLARK. No, it is not, sir. I am not just trying to argue with you.

I am just saying when you start creating larger scale data bases for the purposes of predictive analytics, you need to be concerned about surveillance. When you start regarding every patient as being dysfunctional from the outset, then you need to be concerned about surveillance, and that is what concerns me.

One of the things about 42 CFR Part 2 is you inform the patient. You ask the patient. Dr. Mahon's perspective——

Senator CASSIDY. You have to be brief, because the Chairman is about to start rapping on us.

Dr. CLARK. Yes. In Dr. Mahon's perspective, you have the patient actively involved.

The CHAIRMAN. We are over time.

Dr. CLARK. The patient's consent is a guarantee.

Senator CASSIDY. I yield back. Thank you for your forbearance.

The CHAIRMAN. Thank you, Dr. Cassidy. I am sure we will get back into that subject.

Senator Bennet.

Senator BENNET. Thank you, Mr. Chairman.

Thank you to the panel for sharing your expertise on this important issue.

One Coloradan dies every 17 hours from an opioid overdose. Our state, as a result, is already trying to make strides to prevent the spread of opioids with technology.

When I recently visited the University of Colorado Health Emergency Room, I saw how they used Electronic Health Records, in conjunction with their prescription drug monitoring program, to obtain the information they need in just one click. Patients leaving

the E.R., as a result of this, are leaving with prescriptions for pain medications have dropped from 20 percent of patients to 12 percent over a 3-year period.

Last year, the state also passed a bill to expand provider access to PDMP, so they can better identify patients at high risk of doctor shopping or opioid diversion.

Today, I will be introducing the Every Prescription Conveyed Securely Act along with Senators Warren, Heller, and Toomey. The bill directs providers to use electronic prescribing for opioids and other controlled substances prescribed under Medicare Part D. The aim is to reduce fraudulent prescriptions, give providers and pharmacists real time information on opioid use, and streamline prescribing for both the provider and the patient.

I wonder, Dr. Mahon, if you could say a word about that bill and what you have seen in states that have required doctors to e-prescribe controlled substances?

Dr. MAHON. Absolutely, and thank you very much for the work on this, Senator.

What we have seen specifically, there are seven states today that currently do utilize electronic prescribing. In particular, the State of New York mandated not just electronic prescribing for all prescriptions, but in particular, controlled substances.

What we have seen in our data, looking at the 2017 data in our claims that 89.8 percent of all controlled substances are now being e-prescribed in the State of New York compared to only 21 percent nationally.

That really tells us that having this information is going to be critical and crucial in helping identify, track, and manage these controlled substances that, today, we certainly do not have the ability to do so.

Senator BENNET. Thank you.

Before I go to Mr. Shah, Mr. Chairman, I wonder whether I could enter into the record a letter of support for that bill from a number of organizations, including one represented here.

The CHAIRMAN. It will be.

Senator BENNET. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Senator BENNET. Mr. Shah, in your testimony, you spoke about the problems associated with doctor and pharmacy shopping. You gave an example about a Medicare enrollee that received 73 prescriptions, I think it was——

Mr. SHAH. Yes.

Senator BENNET [continuing]. For opioid drugs from 11 prescribers and filled them at 20 different pharmacies.

Do you think by expanding electronic prescribing, would that help to reduce these kinds of fraudulent transactions?

Mr. SHAH. Yes, absolutely. I mean, there are two factors to that.

One, prescribers are able to pull up information about where this particular patient has gone or how many times they are refilling it in near real time.

Quite importantly, I think what Senator Murray had talked about a little earlier, is in some states having providers actually look at the PDMP data bases to identify, "There is something going on with a particular individual. They just had a refill 7 days ago.

Maybe I want to consider an alternative pain therapy or some member education or patient education options."

To answer your question, I think that would certainly be something that would help curtail this doctor, pharmacy shopping that we are seeing amongst our communities.

Senator BENNET. Thank you. I appreciate that testimony.

I hope, Dr. Clark, that we will be able to overcome our own presumption of dysfunction in the U.S. Congress and actually move some of this legislation forward.

Grateful to the panel.

The CHAIRMAN. Thank you very much, Senator Bennet.

Senator Isakson.

Senator ISAKSON. Mr. Shah, is there any convincing evidence and data that shows how many people overdose on opioids that were prescribed and how many overdosed on opioids that were obtained—it might have been prescribed to somebody—but were obtained illegally in some other mechanism?

Mr. SHAH. Sir, your question, I believe is there any evidence on where individuals that have obtained——

Senator ISAKSON. Get it illegally.

Mr. SHAH. I do not have any of those figures with me right now, but I know there are studies of individuals that have obtained prescriptions through legal means, quite frankly, and then there are also figures in articles that I have read where individuals are stealing prescriptions or obtaining them illegally.

I do not, unfortunately, have the statistics to answer your question right now.

Senator ISAKSON. But it is true that a lot of legally obtained opioids are, in fact, sold or otherwise distributed to people.

Mr. SHAH. Absolutely. Yes. One hundred percent.

Senator ISAKSON. I will tell you a number. My staff is responsible for the credibility of this number. I am not taking responsibility for it, although I have a great staff and he is behind me.

[Laughter.]

Senator ISAKSON. I am sure he is right, but I could not believe it when I read my homework last night.

In the State of Georgia, we have over 541 million doses of opioid circulating in the state. That is 54 doses for each man, woman, and child living in our state. That is a state of 10.5 million people.

How does that sound to you in terms of accuracy?

Mr. SHAH. It does sounds accurate, yes.

Senator ISAKSON. It is way too much and it is way too many.

A year ago Monday, I had some major surgery. When I became conscious and started recognizing what was going on post-surgery, I got into an educational session with my physician and the pharmacist on opioids, Oxycodone, Hydrocodone, all kinds of things like that.

Because of being a United States senator, and having a great Chairman like Lamar Alexander, and people who focus on things like the opioids, and people like you testifying—even though I was still recovering from the surgery and anesthetic that I had—I knew that was dangerous stuff.

I asked him, "Are there alternatives to Hydrocodone and other things that I could go ahead and take? I do not want to run the risk of getting anything bad."

Basically, I was prescribed 6 Tylenols a day and dealt with my pain with 6 Tylenols a day. My discomfort, it did not deal with all the pain.

Do we do a good enough job of aggressively counseling patients who have procedures that are painful by recommending alternative sources other than opioids?

Mr. SHAH. I have a personal example to share with you as well. To answer your question, I think not enough of a good job, but we are getting there.

My father actually had knee surgery in Chicago where, a very similar situation. An immigrant here, does not speak a lot of English that well, and the provider had come in and just said, "Here are your prescriptions." They happened to be opioid prescriptions, of course, for pain management after the knee surgery without much follow-up or education in that sense. So, I think, to answer your question.

Then, there are all these alternatives, but we have to be careful with those alternatives because of the CDC, I believe, had released a study here on morphine equivalents which, in high dosages, can be just as detrimental as what you are seeing with traditional opioids like you said with the Hydrocodone, OxyContin, and Percocet, and whatnot.

We are getting there. It is still about education. I think we continue the education of the providers and our member communities as well.

Senator ISAKSON. Well, everybody's testimony has been fantastic, and I appreciate it a lot, but you have all really, in one way or another, endorsed the more data, the better. Better for predictive analytics, which is a great term. It sounds like I went to Georgia Tech when I say that. I did not go there, but it sounds good anyway.

We can better cast when somebody would be at-risk and hopefully get them into a preventive environment before they ever are tempted with drugs would help us an awful lot. And I think it would be one of the roles this Committee can take.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Isakson.

Senator Kaine.

Senator KAINE. Thank you, Mr. Chairman.

Thank you to the witnesses.

Here is a question that was suggested to us from my Medical Society of Virginia physicians. They indicate that in Virginia, Federal requirements for electronic prescribing software for opioid medications and other controlled substances are very onerous, expensive, and they are not easily compatible with existing e-prescription software so that the Federal requirement does not match the existing software.

The barriers make many small and medium sized providers reluctant to e-prescribe controlled substances, leading to gaps in data and less secure prescriptions.

What regulatory barriers exist to making opioid related e-prescribing software more affordable and accessible to providers? What

is Express Scripts, or other EHR vendors, doing to make the opioid e-prescription software more affordable and more integrated with existing e-prescribing platforms?

Dr. MAHON. Thank you for the question, Senator.

I will start this off with just really understanding the technology. While certainly there may be some initial humps and hurdles you have to get through, once the providers are on an e-prescribing platform, it really is pretty simple to go through the authentication processes.

This technology has advanced, especially just in the last 12 months. We went from having to require a key fob authentication to now just requiring your fingerprints to be scanned to now just even using a smart application to get through the system. So it really is just moving with the technology, where it is going, and really allowing providers to get through the process much more simply.

In terms of other barriers or it could be rural barriers, lack of Internet access or things like that, we do believe that those can be overcome as well.

Then in terms of the expense or the cost piece of getting approved for e-prescribing, it is relatively inexpensive. It is typically around $100 to get e-prescribing software and licenses once you are on an e-prescribing platform.

Overall, we definitely see the technology is evolving that this is really going to become a pretty simple process.

Senator KAINE. Do the other witnesses have anything additional to add on that?

Mr. Shah.

Mr. SHAH. Yes, I will speak to the data interchange issues that you had alluded to.

To address that, there is certainly technological advances that are happening every day. Quite frankly, we can work with some of these private vendors through API's to get data interchanged in a conformed format. But that requires collaboration, quite frankly.

To answer your question about some of the challenges, yes, that is part of the sharing, getting that data from various different sources unstructured or not. We have the means through technology to integrate and assimilate that data in a conformed fashion.

I think that is a barrier that can be easily overcome, but it will require some collaboration, as I mentioned earlier.

Senator KAINE. Let me ask one other question, and actually, Dr. Clark, this might be a good question for you, but others could weigh in too.

In the immediate preceding Congress, Senators Toomey, Portman, Brown, and I acted together to include a provision to establish a lock-in program for Medicare Part D for controlled substances, similar to the lock-in program that was already existing in Medicare.

These lock-in programs, as you know, prevent inappropriate prescriptions from crossing the pharmacy counter by locking in certain beneficiaries at-risk of drug abuse into choosing, and they get to choose, but then once they choose, they choose a sole prescriber and pharmacy.

Those who worked on the provision, we were having some real concerns about the way CMS is approaching it, that they are taking a very limited approach to the kinds of at-risk beneficiaries that should be included in the lock-in program in Medicare Part D.

I wonder if you would talk about what you think are the benefits and disadvantages of lock-in programs, and what we might do to make sure that we do it in an effective way.

Dr. CLARK. Well, sir, first to your earlier point, I wanted to point out that we want to make sure that technology does not change so fast that the practitioners in the field cannot keep up with it, and that is an essential point. As a physician, that is something that you struggle with.

That gets to the next question about the lock-in program.

As a senior citizen, I want to make sure I can have access to geographically accessible and administratively accessible prescription programs. I do not object to lock-in programs per se, but we want to make sure that senior citizens are not precluded from accessing care. I have a 99-year-old mother. She has limited physical abilities. I am 72 this year myself.

If, in fact, we create programs that prevent people having access, then basically we get back to my earlier assumption of the presumption of dysfunction and senior citizens will bear the burden of that.

Senator KAINE. It is not just senior citizens, because Medicaid is a similar program.

But are there other comments on lock-in programs quickly?

Ms. GREEN. Yes, if I can quickly say this.

Lock-in programs are great for reducing the use of specific drugs, but we need a corresponding increase in support by public and private payers for non-opioid alternatives for treatment.

Senator KAINE. Great. Thank you very much.

Thanks, Mr. Chairman.

The CHAIRMAN. Thanks, Senator Kaine.

Senator Roberts.

Senator ROBERTS. Thank you, Mr. Chairman.

Many thanks to you and Senator Murray. I think this is the fifth hearing that we have had here. Thank you for your leadership.

I am the co-Chairman of the Senate Rural Healthcare Caucus and I am particularly concerned with the growing rise of the opioid epidemic and substance abuse in rural areas.

Senator Donnelly and I introduced legislation last year that would help our rural areas develop substance abuse prevention, treatment, and recovery facilities.

Tomorrow, this Committee will mark-up legislation that I introduced to reauthorize the State Offices of Rural Health. These offices, obviously, play a very critical role in strengthening the rural healthcare delivery system by collecting and disseminating data that helped inform the Senate to make good decisions.

Ms. Green, how can we ensure that Federal, state, and local efforts to combat the opioid crisis take into account the unique situation faced by rural Americans?

Ms. GREEN. We need to increase our efforts for tele-health in projects like Project ECHO out of New Mexico, which is specifically

designed to match up practitioners in rural areas with specialists on opioid addiction at various specialty hubs.

That would be one of the best efforts we can make to ensure that there are appropriate resources available to address the opioid problem.

Senator ROBERTS. What role can state offices of rural health play in ensuring that the opioid policies are based on reliable data and sound evidence?

Ms. GREEN. In terms of getting reliable data, one of the best things we can do in making sure we have reliable data is to ensure that there is effective coordination at the state level, as well as the Federal level, for the types of data, patient data that we should be consolidating and making available to different practitioners at different levels—local, state, and Federal—to be able to address the opioid crisis.

We do not have enough consolidation of patient data, and there is no comprehensive patient prescription history or patient history in any one single source yet.

Senator ROBERTS. We are at the base of the mountain.

On the Senate Finance Committee, I am interested in the potential for the electronic authorization—I may be going over plowed ground here—or e-prior authorization within Medicare Part D to strike a proper balance between limiting the unnecessary dispensing of opioids and avoiding overly burdensome requirements.

Dr. Mahon, you mentioned in your testimony some successful opioid management initiatives, including the use of prior authorization for certain prescriptions. But I have consistently heard from constituents with concerns about the burdens this practice can place on physicians and patients.

How can e-prior authorization be used by Medicare Part D and Medicare Advantage plans to help uphold responsible dispensing of opioids while reducing the physician and patient burden?

Dr. MAHON. Thank you for the question, Senator.

Certainly, as we have seen in our data in our program that if a physician absolutely needs to provide more medication to any given member, they have the ability to request an authorization, a prior authorization of that drug.

Where our electronic prescribing is going to be critical is prior to the point of prescribing, the physician will already know if this particular drug requires the quantity level or a prior authorization. So they are able to go through that process pretty quickly without having to do it after the fact, which is what is really important as we continue to manage this opioid epidemic.

But in particular, what we saw in our data was that only 4 percent of all providers who initially wrote a prescription for a 30-day supply—subsequently got reduced to a 7-day supply—requested an authorization to give the member more than seven.

Senator ROBERTS. Four percent.

Dr. MAHON. Only 4 percent of doctors requested an authorization where they basically said, "Thank you. This patient only needs a 7-day supply and it is sufficient."

Senator ROBERTS. Well, I thank you for that.

The FDA has approved several Abuse Deterrent Formulations, or the ADF's, in recent years, which have shown effectiveness in re-

ducing opioid misuse and abuse. However, many patients still lack the proper access to these drugs due to all sorts of factors.

What policy should the Federal Government consider to increase patient access to ADF's and what is the relationship between the ADF's and prior authorization?

Dr. MAHON. From our standpoint, we do caution you to avoid allowing more ADF's into the system. The reason for that is these medications are not necessarily abuse-proof. So they could be an abuse deterrent, but they are not abuse-proof and that is really the big difference that individuals can still continue to overdose on these medications.

There are many different techniques online that you can just go and look. How do I boil, or cook, or do whatever you can do from these medications?

It is really critical that we do not rely just on ADF medications as a single tool. We need to rely on this epidemic to really solve it from multiple angles. Educating the physicians, working with the pharmacies, consulting the members to really solve the problem, and ADF's alone are not going to be able to do that.

Senator ROBERTS. I appreciate it.

I yield back, Mr. Chairman. Thank you very much.

The CHAIRMAN. Thank you, Senator Roberts.

Senator Smith.

Senator SMITH. Thank you very much, Chairman Alexander and Ranking Member Murray.

I really appreciate this meeting today and all of your testimony.

We all know, because we have been sitting through these conversations, that roughly 75 percent of people who began abusing opioids in the 2000's got there through an opioid prescription. We are so focused on trying to figure out how we can tackle this by improving the use of data.

Chairman Alexander, I have a letter from Prime Therapeutics, which is a company headquartered in Minnesota, which is also doing some really good work on this.

I would like to ask consent to enter this into the record on their behalf.

The CHAIRMAN. It will be included.

Senator SMITH. This letter identifies that Prime has figured out how to achieve a 71 percent decline in the number of high risk opioid users through their work which, I think, gives us some hope in this difficult time.

But Ms. Green, I wanted to ask you, and really, anybody on the panel, just one more question about this issue of what we can do at the Federal level to facilitate the sharing of information.

This is fresh in my mind because I have talked to so many providers in Minnesota and have really found that our PDMP is cumbersome, that they have to log-in and then log-out. We do not require people to do this, in part, because it is so cumbersome. I am sure there are lots of reasons for this.

But what are the top one or two things that we could do to facilitate this data sharing?

Ms. GREEN. In every Federal grant and contract that is let out, including CDC, the Justice Department, SAMHSA, they all address trying to improve PDMP's.

We need to include consistent standards in all of those grants and contracts that indicate, "The following standards must be met. There must be comprehensive data sharing, and there must be data made available for public health surveillance purposes," and all the other purposes that we need that data made available for, because that is the funding that is primarily being used now to improve PDMP's.

Senator SMITH. Thank you.

Does anybody else want to make any other comment on that?

Dr. Clark?

Dr. CLARK. Yes, I want to echo what she said because, in fact, if we can enhance our PDMP's, which is something we have been struggling with almost now for 10 years, if we can enhance the technology.

We do not have the kind of information that people argue that we need. What we need to know is that the epidemic is actually subsiding. And so, we want to make sure we do not put something in place that, as they say, closes the barn door after the horse is gone.

Senator SMITH. Yes.

Dr. CLARK. PDMP's have been around. We have known for 10 years what some of the limitations are. We just have not done much about those limitations. It would be useful if we did something about those limitations.

Senator SMITH. I would like to just change direction a little bit here.

We have been hearing a lot how technology can help prevent opioid abuse, which is so important. But I am also really interested in how technology can help us provide good care to people who are in the process of recovery.

I have had a chance to talk with some folks in Minnesota that are working on this. Particularly, we have an example in Little Falls, Minnesota, rural Minnesota, which is how they describe it as sort of a hub and spoke strategy, which is really about coordinating care and providing all of the services that somebody needs when they are in the middle of recovery.

I would be very interested to know from this panel, maybe Dr. Mahon, you could address this because you talked about patient engagement.

How can we better use technology to coordinate care as we address this epidemic?

Dr. MAHON. Absolutely. Thank you for the question, Senator.

What we have seen as part of our program, it becomes really critical to collaborate with the provider. So one of the many things that Express Scripts is doing is we are actually communicating with the doctors via the Electronic Health Record and sending them information at the point of care when the individual is about to receive the next prescription.

Giving them information, not just on what the morphine equivalent dose is of that individual, which is really, really important, but then also giving them recommendations on subsequent therapy or care.

Whether it is if we see somebody is on 600 mgs of morphine equivalent, this individual should probably be on a Naloxone, or

giving them additional information on how to properly counsel them on where else services are available in-network, whether it is a treatment facility and relaying and sharing that information within the Electronic Health Record becomes really, really important. So we definitely see that.

Then the second piece is using telemedicine and virtual pharmacists, which is what we are leveraging to actually be communicating with the members as well, and then sharing that information back to the pharmacy. So the way we view it is really encapsulating the member within the care continuum of the pharmacy, their home, and the physician office. It becomes really important.

Senator SMITH. Right. Thank you very much.

Mr. Shah, I can see you are eager to respond, but I am out of time. So we will look forward to hearing your comments later.

Thank you.

The CHAIRMAN. Thank you, Senator Smith.

Let me operate here as a little bit of a skeptic on the Federal Government's ability to deal with lots of data. I think of HealthCare.Gov. I think of the actual mess with Electronic Healthcare Records that we got into. We ended up having six hearings on that that we did not plan to have during our 21st Century Cures.

Vanderbilt University has been trying for years with health records that Meaningful Use One was helpful; Meaningful Use Two was Okay; Meaningful Use Three was terrifying. And when the government tried to combine that with the ability of getting everybody to change to a method of payment that had to do with outcome, it became an even bigger difficulty.

I have two questions I would just like to ask you to comment. One involved e-prescribing. One involves the Federal data hub.

We have a million doctors out there, many of whom are still having a hard time with Electronic Health Records. The best way to get your healthcare record from one hospital to another is to put it in your suitcase, and carry it over there, and give it to the doctor, even though we spent more than $30 billion encouraging people to do that.

Would it not be a good idea on e-prescribing, to the extent we move ahead, to do it slowly, to try it out? You have, I think, seven states are already doing it. If the technology is evolving, why should we not let it evolve before we impose it on doctors who are already struggling with lots of burdens?

What suggestions would you have about making the movement to e-prescribing, if that is where we need to go, as something that we can do in an evolving way? If McDonald's was introducing a new sausage gravy, they would do it in Dallas and Nashville and see how it tasted before they imposed it in 14,000 stores. So that is one.

As far as the prescription drug data base, do you really want that at the Department of Justice or do you really want it at all?

Why not, instead, establish the standards that states can use and why not leave room for Amazon, Google, and Delta? We can do our airline reservations just instantly with these things. We can order from Amazon, why not let the private sector come in and

offer a way to fill in whatever gap remains after we have gradually improved the state PDMP's?

Count me as a skeptic. Express Scripts is not a Government company, and if it were, it would probably not be nearly as successful.

What would you do about evolving e-prescription and improving the state PDMP's, but leaving room for the private sector to fill in the gaps?

Ms. Mahon.

Dr. MAHON. Yes, I will start first.

We certainly understand that there are limitations of prescribers and I think we can definitely look at what the State of New York did when they launched the mandated controlled substance prescribing. They did leave out some exceptions: long term care facilities, certain situations. So because we have an epidemic, I do not think we have time to wait.

Now, what we can do is carefully figure out what are some of those areas that we could leave some exceptions and give them extended dates of when they should be ready to be mandated for controlled substance prescribing.

But certainly, the rest of the physician practices that do have the ability to do so, we should move on them now.

Ms. GREEN. The private sector can assist with certain innovations, but their focus is ultimately market dominance and competition. That is the nature of the laissez-faire economic system we have and this is part of the problem we have had with some of the data systems already. That starts to take hold.

What I am interested in is, yes, the standards but also I want the Federal Government to maintain those standards that are appropriate for the public interest.

The CHAIRMAN. But standards do not require establishing an entire Federal hub of data in the Justice Department, does it?

Ms. GREEN. Well, but it would require it if it were federally funded.

The CHAIRMAN. What makes you think the Federal Government has that competence?

Ms. GREEN. Well, first of all, I would say that I never assume the Federal Government has competence in anything.

The CHAIRMAN. Yes, well then, why would you suggest a Federal hub for all this data in the Justice Department?

Ms. GREEN. Because the Federal Government is not going to be maintaining the hub; they are going to be setting out the Federal funding for it and the standards are going to be within the Federal funding. So they are not actually going to be, there is not going to be a Federal agency that is actually doing the hub.

The CHAIRMAN. They did a great job with HealthCare.Gov.

Ms. GREEN. I agree with you that there were mistakes there, but what I am suggesting——

The CHAIRMAN. It was a disaster.

Ms. GREEN. There were mistakes there, but what I would suggest is that we learn from those mistakes.

The CHAIRMAN. It took a year and a half to fix it.

Ms. GREEN. Then what I would suggest is that this body is the perfect body to heed the lessons learned from health-dot-com or

health-dot-gov and to translate those into the standards that are actually put in the hub.

The hub that is in the Prescription Drug Monitoring Act does not suggest that the Federal Government is actually going to run that. What it does is it says the Federal Government——

I have no particular concerns if it is the Department of Justice or HHS, but what I am concerned about is that Federal funding is a mechanism by which to ensure that the standards for public interest actually are maintained.

The CHAIRMAN. Thank you, Ms. Green.

I am out of my own time and I do not want to set a bad example.

Senator Warren.

Senator WARREN. Thank you, Mr. Chairman.

I am actually going to pick up where you are. My view is we do need data, and we need the data in order to inform better decisions. The Federal Government collects all kinds of data right now.

We get the monthly data reports on how many people are employed and whether the unemployment rate is going up or going down.

We collect data on education, how many people are in school, how many college graduates there are, how much student loan debt is outstanding.

We collect data on highways, and transit, and all kinds of things because we think it informs making better decisions going forward. Our alternative is to grope around blindly and it seems to me that is not the best way to make a decision.

With e-prescriptions, so that the doctor instead of handing you a piece of paper, which you could lose, which you could alter, which you could photocopy, particularly where an opioid is concerned, a doctor who says, "Wait. I am going into a secure system. I am doing my authorization. This is how much I am prescribing," it cannot be altered at that point. As Dr. Mahon says, someone can then come back and even say to the doctor, "Really? That is how much you want to prescribe for somebody who only weights 70 pounds? Or you may want to consider other concerns or ways to help protect this client."

I see this exactly the other way that e-prescribing is something that is enormously valuable.

We are in the middle of a crisis and that, right now, the latest data I have for 2016—I think some of our panelists may have later data—that only about 14 percent of doctors are e-prescribing controlled substances, and that these are the prescriptions that are most likely to be misused and diverted. And yet, we are sending them to pharmacies on little pieces of paper.

I want to ask the question the other way. Dr. Mahon, you work at Express Scripts, which is one of the largest Pharmacy Benefit Mangers in the country.

If more doctors were using e-prescribing to write prescriptions for opioids, would we have a better understanding of the opioid crisis in America?

Dr. MAHON. Absolutely. One quick comment.

The numbers did go up last year. Now we are at 20 percent of physicians that are e-prescribing.

Senator WARREN. Great.

Dr. MAHON. But still, not enough.

Really, absolutely, we would because one of the biggest gaps that we have today, as a Pharmacy Benefit Manager, is we do not have access to cash claims.

Those members who are getting the paper copy prescription, walking into the pharmacy under the radar, obtaining those medications, we have no visibility and no ability to intervene subsequently.

All of the things that we are doing right now with sharing information with doctors, sending a member a disposal bag, educating them in their home, we do not have the ability to do it if it is going under the radar in the cash processing system.

Giving them the ability to e-prescribe would automatically give all of us the visibility to these claims, and we would have the ability to appropriately intervene on these members when it is most needed in real time.

Senator WARREN. In a large sense, it lets us see how many opioids are being prescribed.

Dr. MAHON. Yes.

Senator WARREN. Who is prescribing them, where there are pockets of use in the country, and that alerts us to problems as we go through.

I want to ask another part of this, because I think you have worked on this question.

Does e-prescribing actually have the potential to change how many opioids doctors prescribe?

Dr. MAHON. Absolutely.

In terms of these limits that we have set from an over-utilization perspective, the physician would be able to see if I am limited to, let us say, two 7-day fills within a certain time period, that would be visible in the system.

Ideally, we would be in a world where anytime a physician would write a prescription, they would see how are they adhering to the CDC guidelines, to the state prescribing requirements of opioids that would ultimately help us limit.

Senator WARREN. The advantages to collecting this data in e-prescribing are not only how we use them from a public health point of view. From an enforcement point of view, we actually have some evidence, it makes a difference in the decisions that doctors make patient by patient in using the best practices in prescribing opioids.

I am about to run out of time, but I just want to push on one more part and that is, Ms. Green, you have spoken today about the need to make sure that the PDMP's in different states can talk to each other.

Do we also need to make sure that the PDMP's can talk to Electronic Health Records and e-prescribing systems?

Ms. GREEN. Yes, all three of the systems need to efficiently and seamlessly talk to one another so that we can timely transfer the data and proactively monitor patient and prescriber behavior, which will allow us to intervene at an early point to address any problems.

Senator WARREN. Good, just powerfully important. Thank you very much. I see I am out of time, but count me in for more data.

The CHAIRMAN. I already was, Senator Warren.

Thank you.

[Laughter.]

The CHAIRMAN. Thank you for your good questioning.

Senator Casey.

Senator CASEY. Thank you, Mr. Chairman.

I want to thank you and the ranking member for these hearings. I guess this is the fifth and we are grateful for that. This is an epidemic, a challenge that warrants that kind of attention. I wish every serious subject in the Senate was the subject of this kind of a review, all these hearings. So we are grateful for that.

I wanted to start with the challenge. There are lots of ways to describe this crisis and we are grateful to have the expertise in the room to help us understand one part of the challenge.

This is a trauma which is affecting every member of the American family in one way or the other. It does not matter where you live. It does not matter what age you are. It does not matter who you are. It is affecting all of us in some way or another; everyone from infants born addicted, so-called Neonatal Abstinence Syndrome, all the way to other members of the American family.

One of the real telling indicators in my state is rural and urban. We have data that tells you that in urban America, it could not be worse. Here is an example.

Overdose deaths in Philadelphia estimated to have reached 1,200 last year with fatal overdose death rate in 2015 of almost 47 deaths per 100,000. In Chicago, it is a fraction of that, 15. In New York, it is 11. So Philadelphia at 47, unfortunately, is a high number.

You can actually make the case that it is worse in rural Pennsylvania. We have 48 rural counties out of 67. We are told that the pace of rural deaths is actually faster; a 42 percent increase year over year of 15 to 16 versus 34 in urban areas.

Fulton County, that is a county of about 14,000 people on the Maryland border, a small county, a rural county, in 2016, the opioid death rate was 74 per 100,000. Compare that to what I thought was a high number of 47 in Philadelphia and much higher in those other urban areas around the country.

The President declared a so-called public health emergency, but we have not heard nearly enough from the Administration on this issue. We need leadership there. It is a big vacuum. Even as we are here having five hearings here, work being done in the Congress, we need the President to lead on this because of the nature of the crisis.

The last point I will make before questions is the importance of Medicaid, the Medicaid program as well as the Medicaid expansion.

Pennsylvania, 127,000 people receive treatment via Medicaid for one of two general conditions: mental health challenges, as well as the broader category of substance use disorder, not just the opioid crisis.

We need Medicaid badly and we need Medicaid expansion. So those who talk about cutting Medicaid had better square that with what they are saying about the opioid crisis.

I wanted to start with Professor Shah. I worked on a number of bills that speak to these concerns. We have a grandparents bill that will be marked up in the Aging Committee tomorrow. I am working with Senator Collins to create a Federal taskforce charged

with supporting grandparents who are raising grandchildren and other manifestation of the family trauma.

I worked with Senator McConnell on a bill to deal with this Neonatal Abstinence Syndrome that I mentioned before. We got that legislation passed to do two things, really. One is to have a new strategy to address research and program gaps in the Federal Government mostly across HHS. The second part of the bill requires recommendations for preventing and treating so-called NAS, Neonatal Abstinence Syndrome.

We are told by the "Philadelphia Inquirer and Daily News" that the number of drug exposed babies born in Philadelphia and the four surrounding counties doubled between 2009 and 2016.

Tell us, if you can, in light of the data that hospitals in Pennsylvania are collecting, tell us how we can use that data to positively impact what you mentioned in your testimony, the so-called predictive analytics to reduce either the numbers or the mortality when it comes to infants.

Mr. SHAH. In addition to just actual data collected at facilities of claims out of EMR data, we have to couple all of that information together to really identify meaningful insights.

But then, there is additional data sources that we need to bring in. Some of the conversations revolved around social determinants of health data. Where are these individuals living? What is their income, their education level? These are all factors that contribute to meaningful and targeted analytics.

To answer your question, it is a collaboration of various different institutions to share that data.

Secondly, it is to bring in additional data too and then break down those data silos. And by having that historical data and in that context from an analytic perspective, we will be able to better identify certain instances where there may be an individual, perhaps a neonatal, or whatever the case may be that may be headed in that direction. Perhaps identify opportunities for intervention early to help curb that.

To answer your question, it is, again, revolving around data and integration.

Senator CASEY. Collection of the data is obviously the foundation of it.

Mr. SHAH. That is correct.

Senator CASEY. I know I am out of time. I will maybe submit a question for a couple of the members of the panel.

Ms. Green, I wanted to ask you a question. I will submit in writing, about the challenge with regard to different states, especially a state that borders, like ours does where we have states that are nearby having both different standards and requirements for the Prescription Drug Monitoring Programs.

But in the interest of time, I will submit that for the record.

Senator CASEY. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Casey.

Senator Murray, do you have additional comments?

Senator MURRAY. I just have one comment for the record I want to make clear on that.

That actually the data hub on HealthCare.Gov was the part that actually worked. And it was responsible for identity proofing and eligibility verification.

The part that did not work, that failed, was the Web site's ability to support high traffic and allow enrollees to actually browse through the options. That was actually a private contractor, CGI Federal; so just for the record.

But I did want to thank all of the witnesses today. This was an excellent hearing and very helpful as we work to develop and pass legislation on this critical topic.

Mr. Chairman, I want to thank you for holding this hearing today and for remaining very focused on building a bipartisan effort to address this issue.

Thank you.

The CHAIRMAN. Thank you, Senator Murray.

These have been bipartisan hearings, which mean we agree on them. The witnesses have been very helpful, very good.

I am going to pursue my point a little bit. I have been around long enough to know that everybody assumes, "Here is a great idea. Let us get the Federal Government do it." But the Federal Government lacks the capacity, in many cases, to do things well.

Do any of you have any suggestions?

A couple of you commented about what to say to doctor. Let us say 20 percent are e-prescribing now. That means 800,000 are not. They might say back to you, "Well, look. You have me all tied up in a knot on Meaningful Use Three. You have new regulations on merit-based payment and I am mad about that. And now, here you come with a whole big set of regulations about how I am going to do e-prescribing."

What can you say to that doctor or what can you say to us about how we can avoid creating an oppressive burden?

Mr. Shah, do you have any suggestions?

Mr. SHAH. Going back to your example, the McDonald's example that you had shared with us, it is about a phased approach.

I think what we need to do is identify communities and organizations that are a little bit ahead of the curve from a technological perspective, and really institute and showcase the value of the e-prescribing as it relates to curbing this opioid epidemic.

We talked a little bit about New York and Maine, as an example, as a success story. I think we need to model that instance there to a broader community. But, again, that is doing it in a phased type of approach. That is what I would recommend to those providers, those that are willing to participate and then working your way out.

The CHAIRMAN. Would there be any merit to saying that if you do not do it within a certain period of time, the Federal Government will do it? E-prescribing, obviously, could be required by states, seven are. Right?

Dr. Clark.

Dr. CLARK. I think providing incentives to states to adopt these strategies would be another approach. That way, you can phase it in to those jurisdictions that saw the utility of it and would be early adopters, and then you could move from there.

You would have states and then perhaps regional endorsers or adopters of the strategy. That way, you can avoid the encumbrance of, say, federally mandated strategies. So incentives versus mandates would be an approach that could address your concern.

I think practitioners, clinicians, and it is not just physicians who are prescribers. There are practitioners and physician assistants who also prescribe, and it is not just opioids. It is benzodiazepine and other medications.

People would be interested in facilitating better care. As you are suggesting, people just do not want to have so many obstacles that it interferes with the ability to provide that care.

The CHAIRMAN. Any other comments?

Dr. Clark, do you have any concerns about a Federal hub of data in the Justice Department?

Dr. CLARK. Yes, sir. I have large concerns about a Federal hub of data in the Justice Department.

I love our Justice Department. They do a great job, but I do not think a repository of clinical information belongs in the Justice Department. As I pointed out, there is a difference between monitoring and a difference between surveillance, and the Justice Department is very much interested in surveillance.

What we are trying to accomplish here is enhancing the care of people and not create an "I got you" kind of environment where practitioners and patients feel that they cannot rely on the healthcare delivery system.

The CHAIRMAN. Thanks to all four of you. This is very helpful. I agree with Senator Murray. Very useful to us.

You can see that we are about to write a bill, so if you have very specific suggestions beyond what you have already discussed or if you want to reiterate something that you said toady or had in your testimony you would like to make sure we pay attention to, we would welcome that. That will help us write a better bill.

The hearing record will remain open for 10 days. Members may submit additional information for the record within the time, if they would like.

The CHAIRMAN. Our Committee will meet again tomorrow, Wednesday, February 28 at 9:45 a.m. for an executive session.

Thank you for being here.

The Committee will stand adjourned.

[Whereupon, at 11:45 a.m., the hearing was adjourned.]

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