"**The Opioid Crisis: The Role of Technology and Data in Preventing and Treating Addiction**"

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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% reduction in hospitalizations and

40% reduction in emergency room (ER) visits in the intervention group versus control group during six 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% decrease in the days' supply of opioid dispensing during six 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[SM] (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 two months of full operation for 4.6 million patients currently benefitting 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% reduction in the average days' supply per claim for first time opioid users
    - 95.9% of the prescriptions that were reprocessed because of our utilization management edits were filled for a 7-days' supply or less;
    - Only 4.1% of opioid prescriptions providing more than a 7-day supply were approved for patients after a prior authorization (PA) requirement was triggered; and
    - 87% 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 six 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 towards 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 difficult (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 two 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.