EXPRESS SCRIPTS®

Feb 16, 2018

The Honorable Orrin Hatch
Chairman
United States Senate Committee on Finance
Washington DC, 20510

The Honorable Ron Wyden
Ranking Member
United States Senate Committee on Finance
Washington DC, 20510

Dear Chairman Hatch and Ranking Member Wyden:

Express Scripts (ESI) applauds your initiative in seeking different perspectives on potential solutions to the opioid epidemic and appreciates this opportunity to provide feedback on this critically important topic. Headquartered in St. Louis, Express Scripts is the nation's largest stand-alone pharmacy benefit manager (PBM). We manage drug 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.

In light of the increasing severity of this rising national crisis, we believe that pending changes to federal programs—as authorized through CARA—along with other coordinated efforts across the spectrum of healthcare will help address these challenges; however, even more innovative approaches such as those outlined below are needed to tackle this crisis head-on.

1. ESI's Innovative, Industry-Leading Approach to Reducing Prescription Opioid Abuse:

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 Physicians—

- The AOM solution delivers automated messages at the provider point of care via 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
- An Auto-lock management feature triggers an intervention that directs patients to a single provider for obtaining these prescriptions and to prevent potential "doctor shopping" behavior for at-risk patients.

Patient Education and Outreach—

Using our data analytics capabilities as a PBM, we have found that one of the keys to addressing 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—

- 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 may be considered dangerous and potentially an indicator for misuse/abuse;
- 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:

- The 2016 pilot's opioid education approach saw:
  - 19% decrease in the average days' supply of opioids dispensed to members who had high-risk patterns of use; and
  - 38% reduction in hospitalizations and 40% reduction in emergency room (ER) visits.

- Since becoming fully operational for nearly five million patients beginning on September 1, 2017 we have seen:
  - 61.1% reduction in the average days' supply per claim for first time opioid users;
  - 95.8% of the prescriptions that were reprocessed because of our utilization management edits were filled for a 7-days' supply or less;
  - Only 4.2% of opioid prescriptions providing more than a 7-day supply were approved for patients after a prior authorization (PA) requirement was triggered
  - 75% 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.

ESI is eager to share additional information on our AOM solution and welcomes any future opportunity to meet with you and staff to do so. With regard to several of the topics outlined in your letter requesting comments from stakeholders, we offer additional comments and suggestions detailing our perspective as follows:

2. The False Appeal of Incentivizing Use of Abuse Deterrent Opioid Formulations:

Opioid manufacturers have been developing and selling novel (and expensive) approaches to making their products less susceptible to abuse, but unfortunately—as tacitly admitted by use of the term "abuse deterrent" vs. "abuse *proof*"—these efforts are consistently defeated and remain their capacity for misuse. 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 reduced 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.

3. Potential Changes to Medicare and Medicaid Program Rules that can Reduce Risks of Opioid Abuse without Sacrificing Clinically Appropriate Access:

Electronic Prescribing—

Electronic prescribing (or "e-prescribing") has been shown to dramatically reduce medication errors and fraud; yet, until 2010 the Drug Enforcement Agency 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 Committee to consider advancing similar language.

Improving Pending Lock-In Rules—

In November of last year, the Centers for Medicare and Medicaid Services (CMS) issued a notice of proposed rulemaking (NPRM) for the 2019 Medicare Prescription Drug Benefit contract year to codifiy the CARA lock-in requirements. Before those proposed lock-in

provisions are finalized, we recommended CMS not finalize and withdraw the following proposals: exemption from lock-in for long-term care beneficiaries; the 6 month delay preventing lock-in of beneficiaries identified as being at-risk of abusing opioids, and treating pharmacies with multiple locations as a single pharmacy. ESI strongly recommends that Congress scrutinize these proposals if finalized, as we believe they undermine the intent of CARA as passed.

Mandating 7-Day Fill Limit on Initial Opioid Prescriptions—

Another effective tool for reducing opioid abuse in the program would involve implementing a 7-days' 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 Grassley, would also be a positive step forward to preventing addiction before it begins. Though this legislation falls outside of the Finance Committee's jurisdiction, the bill would benefit Medicare beneficiaries and their family members and provide Medicare Part D plans tools to better prevent fraud.

Allowing plan sponsors flexibility in general to administer the tools that are best suited for their membership to prevent fraud would not only allow plan sponsors to target interventions specific to their members' needs, but also provide CMS with data and recommendations regarding effective interventions and outcomes. We would also recommend proposing quality ratings that align with CDC and FDA opioid recommendations.

With regards to Medicaid specifically, we recommend:

Mandating Prior Authorization for Long-Acting Opioids—

In situations where a patient has no prior history of using short-acting opioids and is prescribed a long-acting opioid, CMS should require a Prior authorization and give Medicaid plans credit for opioid management and predictive Fraud Waste Abuse (FWA) costs in their MLR requirements.

Developing and Implementing Value-Based Care Features in Managed Care—

Adopting appropriate performance measures and rewarding MCOs that achieve high standards accordingly should be pursued. Examples of such measures are the Healthcare Effectiveness Data and Information Set (HEDIS) metrics that require patients diagnosed with opioid use disorders (OUD) or other substance abuse disorders (SUD) receive treatment by an addiction specialist and to receive follow-up care at clinically indicated intervals.

Additionally, network adequacy requirements for Managed Care Organizations (MCOs) could be enacted to ensure appropriate availability of addiction specialists and treatment centers within their networks, possibly with HEDIS metrics monitoring the use of OUD and SUD pharmacological treatments along with appropriate drug testing to verify patients are adhering to therapy guidelines.

4. Improving Data Sharing and Coordination between Medicare, Medicaid, and State Programs:

Express Scripts supports efforts that make state Prescription Drug Monitoring Programs (PDMPs) mandatory and interoperable with each other nationally. PDMP databases must also be improved by

making them: fully accessible to appropriate stakeholders such as prescribers, pharmacies, and health plan sponsors; more user-friendly; and lastly, able to make prescription data accurate and available in real time.

ESI supports legislation such as the Prescription Drug Monitoring Act (S. 778/ H.R. 1854), co-sponsored by Senators Amy Klobuchar (D-MN) and Rob Portman (R-OH) that mandates creation and use of prescription drug monitoring programs by states that receive federal funding to fight opioid abuse as a condition of continuing to receive such support. The bill also requires that states compel pharmacies to check PDMPs *prior to* filling prescriptions involving high risk drugs, and also to submit such prescription data to the PDMP within 24 hours of making those fills. Further, PDMPs would also have to notify providers when patients showed worrisome opioid prescription patterns so as to allow appropriate interventions that may help prevent abuse, diversion, or treat addiction as needed.

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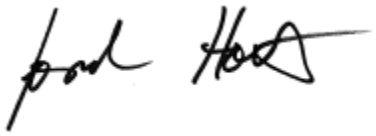
Thank you for the opportunity to comment on solutions that are needed now more than ever to prevent addiction and save lives. Please let me know if I can answer further questions as you explore policies that would advance federal programs to combat this crisis plaguing American families.

Sincerely,



Jonah Houts
Vice President, Corporate Government Affairs
Express Scripts, Inc.
300 New Jersey Ave. NW, Suite 600
Washington DC, 20001