Pharmaceutical Care Management Association

Statement for the Record

Prepared for the

UNITED STATES HOUSE OF REPRESENTATIVES

COMMITTEE ON ENERGY AND COMMERCE

SUBCOMMITTEE ON HEALTH

"Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients"

April 11, 2018

Introduction

PCMA appreciates this opportunity to submit a statement for the record for the hearing, "*Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients."* PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million[i] Americans with health coverage provided through self-insured employers, health insurers, labor unions, Medicare, Medicaid, SCHIP, and the Federal Employees Health Benefits Program (FEHBP). America's PBMs process the vast majority of the nation's 4.5 billion annual prescriptions.[ii]

We appreciate the Health Subcommittee's and full Energy and Commerce Committee's ongoing efforts to address the nation's opioid crisis. Our industry especially appreciates the Committee's efforts to limit Medicare beneficiaries at risk of abusing opioids to a specific pharmacy or prescriber. The bills under consideration today build on the Committee's prior work.

PBMs Are a Key Part of Mitigating the Opioid Crisis

PBMs can be an important partner for curbing the nation's opioid crisis. Given their role administering prescription drug benefits in real time and through the software systems they use to assess eligibility, determine cost sharing, and adjudicate claims, PBMs can see whether patients are using multiple prescribers and pharmacies, are getting a morphine-equivalent dosage well beyond that recommended by the Centers for Disease Control and Prevention (CDC), and are getting a longer days' supply than necessary.

Increasingly, as health information networks improve and physicians move to e-prescribing controlled substances, PBMs and prescribers will have almost complete information, in real time, on how, where, and when prescriptions for controlled substances are obtained and dispensed. Where the law will allow it, PBMs also will be able to use coverage determinations to address opioid prescriptions exceeding the CDC-recommended days' supply or morphine-equivalent dosage. PBMs already can lock in patients at risk to an appropriate pharmacy or pharmacy chain for their controlled substances in most state Medicaid programs and the commercial insurance market, and because of congressional action in CARA, next year will start a similar program in Medicare Part D.

There are significant additional steps policymakers can take to help private sector efforts to reduce opioid abuse.

Common-Sense Policy Solutions to Curb the Opioid Crisis

While the factors driving America's opioid crisis are complex and do not lend themselves to easy solutions, targeted policy changes can help curb prescription opioid abuse and diversion. Below we suggest a number of policy measures to curb the crisis.

Mandatory Electronic Prescribing for Controlled Substances (EPCS): We believe that using federal program payment policy to require electronic prescribing (e-prescribing) for controlled substances could help reduce over-prescribing. In addition, e-prescribing has been shown to dramatically reduce medication errors and limit fraud,[iii] and after the Drug Enforcement Administration allowed e-prescribing for controlled substances in 2010, states followed. Currently all states permit EPCS, and as of spring 2018, seven states have passed laws requiring its use, and another 14 states have introduced bills to make EPCS mandatory.[iv]

We recommend that the Subcommittee use federal health program payments to require e-prescribing for controlled substances in Medicare and Medicaid. The PBM industry stands ready to help facilitate such a policy change. We believe H.R. 3528, the Every Prescription Conveyed Securely Act, would accomplish these goals and urge the Energy and Commerce Committee to pass this bill or one very similar to it. We would like to thank Congressman Markwayne Mullin for his leadership on this important legislation, which is also cosponsored by Committee Members Joe Kennedy, Paul Tonko, Billy Long, Chris Collins, Bill Flores, and Diana DeGette.

Evidence shows EPCS produces measureable savings and decreases opioid use. One health system in Pennsylvania found that after implementing EPCS, it reduced opioid prescriptions by approximately 50 percent (from 60,000/month to 31,000/month).[v] The switch also resulted in significant cost savings. Across the health system, savings averaged $850,000 per month, which has thus far added up to ongoing cost savings of $5.1M from EPCS tools.[vi] Similarly, one New York hospital examined its emergency department prescription volume for opioids from before and after New York State adopted an EPCS mandate. The hospital reported a decrease of 53 percent of prescribed opiates, seeing decreases in all 15 common emergency diagnoses studied.[vii]

Further, e-prescribing platforms typically provide physicians a patient's medication history, which informs physicians of prescriptions that other prescribers have written and pharmacies have dispensed, even ones for which patients have paid cash. This can be especially important for controlled substances, where patients may engage in doctor shopping to find one or more doctors to write a prescription for a dangerously addictive drug.

According to a recent study by Visante and Point of Care Partners, if the use of EPCS with access to comprehensive medication history were required nationally and its use by prescribers and pharmacies rose to optimal levels, the United States would realize annual savings of up to $53 billion, based on estimated annual savings of:

- $18 billion to $37 billion in reduced costs associated with fatalities related to opioid abuse;
- $7 billion to $14 billion saved due to decreased health care costs, decreased treatment costs, workplace productivity gains, and reduced criminal justice costs; and
- $1.6 billion saved from greater efficiencies in physician offices and pharmacies, and increased convenience for consumers given they do not have to spend time at the pharmacy waiting for their prescriptions to be filled.

If the use of EPCS with access to comprehensive medication history were required for Medicare Part D prescriptions and its use by prescribers and pharmacies rose to optimal levels, the federal government would realize savings of more than $2 billion annually, based on estimated annual savings related directly to Medicare beneficiaries of:

- $2 to $4 billion saved due to decreased health care costs, decreased treatment costs, workplace productivity gains, and reduced criminal justice costs; and
- $0.5 billion saved from greater efficiencies in physician offices and pharmacies, and increased convenience for consumers.[viii]

Improve and Integrate State Prescription Drug Monitoring Program (PDMP) and Require Prescriber Check: As described above, PDMPs can be an important tool to help identify and prevent prescription drug abuse. A key problem keeping PDMPs from operating optimally is that state PDMPs vary as to who may use a PDMP or receive its data. States also vary with respect to the agencies operating PDMPs and some fund their PDMPs adequately while others devote few resources. While there are efforts to

make PDMPs interoperable across state lines, at present many are not. Some state PDMPs have up-to-date data, while in others the data lags by months. The differences in data access, material support, and administration can make it difficult to make the best and timely use of PDMP data.

The Subcommittee could use federal health program payment policy to encourage PDMP data be updated in a timely manner, be interoperable across state lines, and easily accessible to prescribers and pharmacies. Requiring the use of, and integrating EPCS with, PDMPs may be particularly helpful in this regard. Additionally, prescribers should be required to check state PDMP databases when prescribing opioids, at least until EPCS is widely adopted and supplies similar information.

Suspension of Claims in Part D Where There Is a Credible Allegation of Fraud or Misuse: In Medicare Parts A and B, Medicare Administrative Contractors may suspend payment of claims upon a credible allegation of fraud. There is no similar policy for Medicare Part D. Part D plans may have evidence of fraud or diversion, but at present, they can do little more than refer the concern to a MEDIC, which may or may not act on the suspected fraud. To close this loophole, Part D plan sponsors should be allowed to suspend payment of suspect claims where there is a credible allegation of fraud. When a Part D plan sponsor suspects fraud with respect to a particular claim, the plan should have the latitude not to pay the pharmacy until the claim has been investigated further.

A recent Department of Health and Human Services Office of the Inspector General (OIG) report found that one in three Medicare Part D beneficiaries received a prescription opioid in 2016, and 400 prescribers had questionable opioid prescribing patterns for beneficiaries at serious risk of overuse—patterns far outside the norm, which the OIG says warrant further scrutiny.[ix] The same report also found over 22,000 Part D beneficiaries who appeared to be doctor shopping (i.e. they received high amounts of opioids and had multiple prescribers and pharmacies).[x] Allowing Part D plan sponsors to suspend payment pending investigation would limit fraudulent transactions and could discourage those who seek to commit fraud from filing fraudulent claims in the first place.

In the specific case of the Part D stand-alone plans, the Bipartisan Budget Act of 2018 (BBA) allows them access to their enrollees' Part A and Part B Medicare data as of 2020. If the implementation of this provision could be accelerated to occur in 2019, it could allow Part D plan sponsors to better detect potential opioid fraud and misuse sooner. Additionally, policymakers should make it clear that the use of Part A and Part B

data to detect and ameliorate opioid fraud and misuse should not be interpreted as making "coverage determinations" as otherwise restricted in the BBA.

Reconsider Limits on Use of Medicare Parts A and B Data by Medicare Part D Plans: In the recent two-year budget deal, Congress included language that made Medicare Part A and Part B data available to Part D plans, but forbade Part D plans from using the data in any way to inform coverage decisions. As a result, plans will be unable to use data gleaned from a beneficiary's inpatient and outpatient record to help guide patient-specific decisions on step therapy or prior authorization. Indeed, given the constraints, it is uncertain what the utility of the data would be and many Part D plans likely will not request the information. We recommend that the Subcommittee reconsider the new statutory limit on how Medicare Parts A and B data may be used by Part D plans.

Electronic Prior Authorization: PCMA supports innovations like electronic prior authorization that reduce physicians' administrative burden and supports the use of the National Council for Prescription Drug Programs standards for facilitating it. We believe the Subcommittee should consider policies such as those in H.R. 4841, the Standardizing Electronic Prior Authorization for Safe Prescribing Act of 2018. We believe standardizing the electronic prior authorization process will make it a more effective tool for providers and plans and increase safety for patients.

Refrain from Requiring Abuse Deterrent Formulations (ADFs) for Opioids: ADFs for opioids may be one small part of more comprehensive efforts to stanch abuse of opioids, but when taken orally as intended, ADFs are just as easily abused as any other opioid. Thus, and as evidenced by the continued deepening of the crisis despite wide ADF availability, ADFs should not be seen as a magic bullet to stop opioid abuse. Further, any policy disallowing generic substitution of existing non-ADF generics in favor of using these alternative, much more expensive formulations will dramatically raise costs but do little to reduce opioid abuse. PCMA welcomed Food and Drug Administration (FDA) Commissioner Gottlieb's recent pronouncement that FDA will be "taking a flexible, adaptive approach to the evaluation and labeling of ADF opioids."[xi]

Public policy that promotes ADF-only opioids assumes that all patients who use opioids are drug abusers, and, moreover, ignores research showing that a large percentage of those abusing opioids ingest the drug. While technological innovations such as ADF have been developed to prevent opioid medications such as OxyContin from being crushed, dissolved, chewed, or cut, this does not prevent abuse and potential overdose

because an individual can still ingest opioids as intended and in increasing amounts, whether they are ADF opioids or non-ADF opioids.

The Institute for Clinical and Economic Review (ICER) recently released a report examining the evidence on abuse-deterrent opioids.[xii] ICER rated the net health benefits of the ADF formulation of OxyContin and found no compelling evidence it was better than non-abuse-deterrent opioids, for producing lower rates of opioid abuse.[xiii] Despite the fact that the evidence for abuse reduction isn't compelling, the pharmaceutical industry persists in advocating for their mandatory use because they are far more expensive than generic opioids,[xiv] and therefore more profitable for the drugmakers.

Align Substance Abuse Treatment Privacy Laws with HIPAA to Encourage Better Care Coordination: To help facilitate care coordination for those suffering from substance abuse, we encourage the Subcommittee to harmonize substance abuse records privacy policies with the Health Insurance Portability and Accountability Act (HIPAA) privacy rule. Under current substance abuse treatment privacy law at 42 CFR Part 2, addiction treatment providers must obtain individual, written consent from patients in order to share any information with non-addiction clinicians — the only exception being for "true emergencies." The HIPAA privacy rule, by contrast, allows for health care providers and insurers to disclose information for treatment, payment, and health care operations, without further patient consent and subject to a minimum information necessary standard, so long as patients are given a notice explaining how their information will be used and disclosed. Obtaining multiple consents from a patient, as required under 42 CFR Part 2, is challenging and creates barriers to integrated approaches to care that produce the best outcomes for patients. The separate and different treatment in the law of substance-abuse-disorder patient history creates virtual care silos, and hinders good medical care. It also perpetuates the unnecessary division between physical and behavioral health and may serve to perpetuate stigma in the contemporary era of electronic health records integrated health care, and HIPAA privacy protections.

Conclusion

We thank the Subcommittee for this opportunity to share our views on how common-sense policy proposals can help curb America's opioid crisis. PCMA stands ready to work with the Subcommittee, the full Committee, and all Members of Congress to address the overuse of opioids.

[i] PR Newswire, “PBMs Provide Policy Solutions to Increase Competition, Reduce Rx Costs,” Feb 04, 2016.
[ii] Script volume figure from Quintiles IMS Institute, “Medicines Use and Spending in the U.S.: A Review of 2016 and Outlook to 2021,” May 2017.
[iii] See, e.g., Amber Porterfield, Kate Engelbert, and Alberto Coustasse, “Electronic Prescribing: Improving the Efficiency and Accuracy of Prescribing in the Ambulatory Care Setting” Perspect Health Inf Manag. 2014 Spring;
April 1, 2014. See also, U.S. Department of Health and Human Services (HHS), “Electronic Prescribing of Controlled Substances (EPCS)” November 4, 2016. https://www.healthit.gov/opioids/epcs
[iv] Imprivata, “State EPCS Adoption Legislation,” 2018. https://www.imprivata.com/state-epcs-legislation
[v] Geisinger Health System, “Doing Well by Doing Good: Fighting Opioid Abuse While Achieving Cost Savings of EPCS at Geisinger,” 2018 Slide Presentation .
[vi] Ibid.
[vii] D. Danovich et al. “Effect of New York State Electronic Prescribing Mandate on Opioid Prescribing Patterns”, J. Chacko, J. Greenstein, B. Ardolic, N. Berwald Staten Island University Hospital, Staten Island, NY DOI: https://doi.org/10.1016/j.annemergmed.2017.07.195
[viii] Visante, “Mandatory Electronic Prescribing of Controlled Substances (EPCS) Can Help Combat the Opioid Crisis and Save the United States up to $53 Billion Annually,” Prepared for PCMA, April 2018.
[ix] HHS OIG, “Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing,” July 2017. https://oig.hhs.gov/oei/reports/oei-02-17-00250.pdf
[x] Ibid.
[xi] FDA, “Statement from FDA Commissioner Scott Gottlieb, M.D., on Steps to Promote Development of Generic Versions of Opioids Formulated to Deter Abuse.” November 21, 2017.
https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm586117.htm
[xii] ICER, “Abuse-Deterrent Opioids: Final Evidence Report,” August 8, 2017. https://icer-review.org/wp-content/uploads/2016/08/NECEPAC_ADF_Final_Report_08_08_17.pdf
[xiii] Ibid.
[xiv] C. Bernie Good, Chronis Manolis, And William Shrank “There’s Little Evidence Abuse-Deterrent Opioids Work. Why Should We Use Them?” Stat News, August 8, 2017.