PCMA

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Sent via e-mail to: opioids@finance.senate.gov

The Honorable Orrin Hatch
Chairman
U.S. Senate Committee on Finance
United States Senate
104 Hart Office Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
U.S. Senate Committee on Finance
United States Senate
221 Dirksen Office Building
Washington, DC 20510

Dear Chairman Hatch and Ranking Member Wyden:

We thank you for the opportunity to contribute to finding ways to stem the opioid epidemic. The Pharmaceutical Care Management Association (PCMA) is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans and operate specialty pharmacies for more than 266 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, and the Federal Employees Health Benefits Program.

In its February 2 solicitation for stakeholder input, the Committee solicited policy proposals to curb the opioid crisis. We are pleased to offer the following comments addressing specific questions the Committee raised.

How can Medicare and Medicaid payment incentives be used to promote evidence-based care for beneficiaries with chronic pain that minimizes the risk of developing opioid use disorder (OUD) or other substance abuse disorders (SUDs)?

> **Mandatory Electronic Prescribing:** We believe that leveraging 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,[i] and after the DEA allowed e-prescribing for controlled substances in 2010, states followed. Currently all states permit it and a few states require its use. By directing a prescription electronically to a specific pharmacy, e-prescribing controlled substances would help circumscribe pharmacy shopping and reduce fraud.

In addition, e-prescribing platforms usually 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.

The opioid crisis has caused such widespread and significant devastation and misery that an extraordinary level of intra-government and industry cooperation may be necessary to curtail it. We recommend that the Committee build on its earlier e-prescribing efforts in Medicare and 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.

Lowest Effective Dose: According to The Centers for Disease Control and Prevention (CDC), "when opioids are started, clinicians should prescribe the lowest effective dosage."[ii] Specifically, CDC recommends that clinicians should carefully reassess evidence of individual benefits and risks when increasing dosage to 50 morphine milligram equivalents (MME) or more per day, and should avoid increasing dosage to 90 MME or more per day or carefully justify a decision to move a dosage to 90 MME or more per day.[iii] The Committee should consider policies that would encourage the use of lowest effective doses for opioids, consistent with CDC guidelines.

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 FDA Commissioner Gottlieb's recent pronouncement that FDA will be "taking a flexible, adaptive approach to the evaluation and labeling of ADF opioids."[iv]

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 continue to ingest increasing amounts of ADF opioids.

The Institute for Clinical and Economic Review (ICER) recently released a report on examining the evidence on abuse-deterrent opioids.[v] 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, due to the clear limitations in the real-world evidence on the drug.[vi] Despite the fact that the evidence isn't compelling that ADF products result in lower rates of opioid abuse, the pharmaceutical industry persists in advocating for their mandatory use because they are far more expensive than generic opioids,[vii] and therefore more profitable for the drugmakers.

How can Medicare and Medicaid payment incentives be used to remove barriers or create incentives to ensure beneficiaries receive evidence-based prevention, screening, assessment, and treatment for OUD and other SUDs to improve patient outcomes?

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 would encourage the Committee to explore ways to leverage federal health payment policy to harmonize substance abuse records policies with the Health Insurance Portability and Accountability Act (HIPAA). Under current substance abuse treatment privacy laws 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." Obtaining multiple consents from a patient, as required under current law, 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, hinders good medical care, and perpetuates the unnecessary division between physical and behavioral health and may serve to perpetuate stigma in the contemporary era of electronic health records (EHRs), integrated health care, and HIPAA privacy protections.

Are there changes to Medicare and Medicaid prescription drug program rules that can minimize the risk the risk of developing OUD and SUDs while promoting efficient access to appropriate prescriptions?

Mandatory Electronic Prescribing: For similar reasons explained in the answer to the first question, we believe that one of the best policy steps to take would be

leveraging program payment policy to require e-prescribing for controlled substances.

Allow Pharmacies to Dispense Shorter Fills than Prescribed: CMS is already moving to change existing guidance that prevents Part D plans from limiting coverage for first prescriptions of opioids for acute pain to less than that prescribed so that coverage is consistent with CDC guidelines. PCMA asks the committee to urge CMS to provide clarifying guidance that address current barriers to simplify its policy, especially with respect to transition and provisional fills, to make implementing a shorter-fill policy feasible while ensuring that patients continue to get needed pain relief.

Implement Thoughtfully the Comprehensive Addiction and Recovery Act of 2016: PCMA supported the passage of the lock-in provisions in CARA. We also support the flexibility to lock a beneficiary into a specific prescriber(s) or specific pharmacy or both for controlled substances, based on the beneficiary's utilization. We encourage the Committee to see that CMS implements its provisions as Congress intended.

To that end, we think that CMS's proposal in the proposed Part D rule promulgated November 28, 2017, to require a Part D plan sponsor to wait six months from the date the beneficiary is first identified as potentially at-risk before limiting that beneficiary to a given pharmacy or prescriber for frequently abused drugs, is too long. Indeed, a six-month delay works against the goal of the CARA the lock-in program, which is to take steps quickly to protect beneficiaries and reduce fraud. Without a more timely intervention, these beneficiaries will continue to abuse and potentially divert opioids. Furthermore, CMS should preserve the flexibility of the current Drug Utilization Review (DUR) and Overutilization Monitoring System (OMS) programs while also providing flexibility for Part D plan sponsors and their PBMs to develop and implement their lock-in programs.

What can be done to improve data sharing and coordination between Medicare, Medicaid, and state initiatives such as Prescription Drug Monitoring Programs?

Improve and Integrate State Prescription Drug Monitoring Program (PDMPs) and Require Prescriber Check: Prescription drug monitoring programs, or 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 Committee could explore leveraging its oversight of federal health programs to encourage PDMP data be updated in a timely manner, be interoperable across state lines, and easily accessible to prescribers and pharmacies. Additionally, prescribers should be required to check state PDMP databases when prescribing opioids, at least until e-prescribing is widely adopted and supplies similar information.

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 committee reconsider the new statutory limit on how Medicare A and B data may be used by Part D plans.

What best practices employed by states through innovative Medicaid policies or the private sector can be enhanced through federal efforts or incorporated into Medicare?

Implement Thoughtfully the Comprehensive Addiction and Recovery Act of 2016: For this question we would reiterate our answer above concerning timely and thoughtful implementation of CARA. Lock-in programs have worked in Medicaid programs and commercial insurance, and we encourage the Committee to ensure that CMS implements its provisions in both letter and spirit of the law.

Conclusion

We thank the Committee 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 Committee and all Members of Congress to address the overuse of opioids. Should there be any questions, please contact Jonathan Heafitz at jheafitz@pcmanet.org or (202) 756-5735.

[i] 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
[ii], Dowell, Op. Cit.
[iii] Dowell, Op. Cit.
[iv] 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
[v] 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
[vi] Ibid.
[vii] 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.