July 24, 2017

Commissioner Scott Gottlieb
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

I’m writing on behalf of the Pharmaceutical Care Management Association (PCMA), the trade association representing the nation’s pharmacy benefit managers (PBMs). We appreciate your interest in reaching out to PBMs to discuss policies to address the rampant opioid abuse in the United States. We share your concerns, and ahead of a discussion wanted to outline solutions that would help assure people receive opioid prescriptions only when medically appropriate. These common-sense measures include:

- **Endorse the Centers for Disease Control and Prevention’s (CDC’s) Guideline for Opioid Prescribing:** PCMA supports CDC’s “Guideline for Prescribing Opioids for Chronic Pain.” When followed, the guidelines would improve communication between clinicians and patients about the benefits and risks of using prescription opioids for chronic pain; provide safer, more effective care for patients with chronic pain; and help reduce opioid use disorder and overdose. More information is available here: [https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf](https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf)

- **Require E-prescribing (e-Rx) for Controlled Substances:** E-prescribing has been shown to dramatically reduce medication errors and fraud, yet until 2010 the Drug Enforcement Agency (DEA) barred its use for controlled substances. An increasing number of states now require its use. E-prescribing controlled substances would circumscribe pharmacy shopping, enable better prescription tracking, and reduce fraud.

- **Seven-Day Opioid Prescription Limits for Acute Pain:** To prevent patients from getting addicted to pain medication, prescriptions for acute pain should be limited to a seven days’ supply. The limit would not apply to treatment of cancer or chronic pain, or the use of opioids in treating addiction or for patients in hospice care.

- **Improve and Integrate State Prescription Drug Management Programs (PDMPs) and Require Prescribers to Check PDMPs:** State governments should make their PDMP databases more easily accessible, more user-friendly, and better integrated across the country, and also make the data accurate in real time. The goal would be to create prescriber, pharmacist, and insurer access to real-time data.

- **Give Part D Plans More Tools to Fight Pharmacy Opioid Fraud:** Part D plans should be allowed to suspend payment of suspect pharmacy claims where there is a credible allegation of
fraud. When a Part D plan suspects fraud with respect to a particular claim, payment should not be made until the claim has been investigated further. In addition, current Part D pharmacy network requirements should be revised to enable plans and PBMs to remove any of the small minority of pharmacies that engage in fraudulent practices from contracted networks.

- **Achieve Timely and Flexible Implementation of the Comprehensive Addiction and Recovery Act (CARA) Lock-In:** CMS should provide as much flexibility as possible to Part D plans on pharmacy and prescriber lock-in implementation, and should issue all program requirements with adequate lead time to allow for Part D plan programming and testing to ensure successful implementation of the program in January 2019.

We look forward to working with you on this pressing issue.

Sincerely,

[Signature]

President and CEO
Pharmaceutical Care Management Association

cc: Mr. Richard Baum, Acting Director, Office of National Drug Control Policy (ONDCP)
Governor Chris Christie, Chairman, President’s Commission on Combating Drug Addiction and the Opioid Crisis