

Submitted electronically via: <http://www.regulations.gov>

December 28, 2017

Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No.: FDA-2017-N-5608: Opioid Policy Steering Committee; Establishment of a Public Docket; Request for Comments

Dear Sir or Madam:

Thank you for the opportunity to submit our comments on the Food and Drug Administration's ("FDA") request for comments entitled "Opioid Policy Steering Committee; Establishment of a Public Docket; Request for Comments."

The National Community Pharmacists Association ("NCPA") represents the interests of America's community pharmacists, including the owners of more than 22,000 independent community pharmacies. Together they represent an \$80 billion health care marketplace and employ more than 250,000 individuals on a full and part-time basis. Independent community pharmacies play a critical role in ensuring patients have immediate access to medications. Our members have extensive knowledge and experience in caring for patients with chronic pain as well as those in their communities with substance use disorders.

NCPA is committed to working collaboratively with the Administration, Members of Congress, and other stakeholders in adopting viable solutions to prevent drug abuse and diversion. We believe there are efforts in the marketplace that are currently making a difference in the battle against opioid abuse and are scalable such as expansion of consumer access to Naloxone. We address many of these efforts in the context of FDA's request for comments below.

I. Steps to Promote Prescribing and Dispensing

NCPA agrees with the FDA that proper prescribing and dispensing are critical to successfully reducing opioid misuse and abuse. To this end, NCPA has identified many strategies and policies that promote proper prescribing and dispensing.

Expand Consumer Access to Naloxone: NCPA supports and advocates for pharmacists to participate in wider distribution of naloxone under pathways approved by state regulatory boards. The least restrictive means to increasing access to naloxone is to allow pharmacists to directly prescribe.

Also, there are promising policies that would have a positive impact on mitigating or preventing abuse, without compromising legitimate patient access to needed pain medications. Establishing limits on maximum day supply for certain controlled substances is one such policy.

Establish Limits on Maximum Day Supply for Certain Controlled Substances: Federal or state based policies to limit initial fills of opioids should be standardized for consistent implementation, taking into consideration certain patient populations, such as hospice patients and those residing in skilled nursing facilities. Any policy to limit initial fills of opioids should include a list of circumstances in which a prescriber be allowed to deviate from the mandate.

Prohibit Certain Controlled Substances from Being Delivered to Patients via Physician Offices or via Mail: Prohibiting delivery of controlled substances to patients via physician offices or the mail is another policy that can have a positive impact on mitigating or preventing abuse by offering added assurances against diversion. Utilizing the triad of care between a prescriber, pharmacist, and patient is vital with opioid therapies.

Expand Electronic Prescribing of Controlled Substances: NCPA also supports expanding electronic prescribing of controlled substances via requiring prescriptions for controlled substances to be electronically prescribed where feasible.

Enhance Prescription Drug Monitoring Programs: We also support enhancing prescription drug monitoring programs by increasing operability of robust electronic databases to track all prescriptions for controlled substances. National standards to provide timely, reliable information at point of prescribing and dispensing should also be leveraged.

II. Requirements for Prescriber Education

Increase Health Care Provider Education: Further, NCPA believes that increasing health care provider education should be a priority for the FDA. For any required prescriber education program, a verification infrastructure with minimal administrative burden should be considered. For example, automatic checks related to prescriber status on completion of educational requirements prior to transmission of impacted prescriptions and mechanisms for pharmacists to be informed about the requirements of the program must be considered. We would offer the Transmucosal Immediate Release Fentanyl (“TIRF”) REMS program as an example. Overall, the pharmacist’s role is to provide continuity of education and monitoring.

III. Additional Matters for Consideration

Finally, NCPA would like to offer two other policies and strategies that may be viable solutions to prevent drug abuse and diversion.

Increase Use and Access to Medication Assisted Treatment: NCPA supports expanding practitioner eligibility for DATA waivers, including pharmacists. Advancement of the pharmacist's role in MAT for opioid use disorders can help improve access and outcomes, while reducing the risk of relapse. Pharmacists are already partnering with physicians to provide MAT. When such relationships form, pharmacists have taken the lead in developing treatment plans, communicating with patients, improving adherence, monitoring patients, identifying treatment options, and performing tasks to alleviate the physician's burden. Thus, pharmacists have both the knowledge and experience to provide MAT, but treatment is limited because of regulatory barriers.

Expand the Ability of Pharmacies to Identify Individuals with Substance Use Disorders: Pharmacists should be allowed to participate in SBIRT or Screening, Brief, Intervention and Referral to Treatment activities. For example, Virginia Medicaid's Addiction Recovery Treatment Services ("ARTS") is a transformative new benefit being offered for Medicaid patients. The benefit includes coverage for SBIRT provided by pharmacies. The purpose of SBIRT is to identify individuals who may have alcohol and/or other substance use problems. Following screening, a brief intervention is provided to educate individuals about their use, alert them to possible consequences and, if needed, begin to motivate them to take steps to change their behavior.

IV. Conclusion

NCPA greatly appreciates the opportunity to share with you our comments and suggestions. If you have any questions, please contact Kala Shankle, Director of Policy and Regulatory Affairs, 703-683-1178, kala.shankle@ncpanet.org.

Sincerely,



Ronna Hauser, Vice President, Pharmacy Affairs
National Community Pharmacists Association