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July 10, 2017

Janelle Derbis
Center for Drug Evaluation and Research
Food and Drug Administration
20 North Michigan Ave., Suite 510
Chicago, IL 60602

RE: Docket No. [FDA-2017-D-2497]

Dear Ms. Derbis,

On behalf of the American Society of Addiction Medicine (ASAM), the nation's oldest and largest medical specialty society representing more than 4,500 physicians and allied health professionals who specialize in the treatment of addiction, I would like to thank you for the opportunity to provide comments on the FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioids.

ASAM is a member of the CO*RE collaborative, one of the approved providers of the extended-release long-acting opioids risk evaluation and mitigation strategy (ER/LA REMS) training. Started in 2010, CO*RE's mission is **to promote individual and population health and public safety through timely, evidence-based, outcome-oriented and interprofessional education related to the comprehensive management of pain, addiction, and their co-morbidities.** The organizations that compose the CO*RE partners represent more than 750,000 clinicians in a wide spectrum of clinical specialties and subspecialties and who work in a variety of clinical practice settings. The ten CO*RE member organizations include:

- American Academy of Hospice and Palliative Medicine
- American Academy of Physician Assistants
- American Association of Nurse Practitioners
- American Osteopathic Association
- American Pain Society
- American Society of Addiction Medicine
- California Academy of Family Physicians
- Healthcare Performance Consulting
- Interstate Postgraduate Medical Association
- Nurse Practitioner Healthcare Foundation

Also working with the CO*RE member organizations are several key strategic partners including Medscape, Physicians Institute for Excellence in Medicine (working with 15 state medical societies), American College of Emergency



Physicians and the American Academy of Family Physicians. More information about CO*RE is available [here](#). CO*RE has been an approved provider of ER/LA REMS training since 2013 and has reached more than 170,000 total learners.

As a member of CO*RE and provider of the ER/LA REMS training, and as a medical specialty society representing clinicians on the front lines of our nation's current opioid epidemic, ASAM recommends the following modifications to the ER/LA REMS Blueprint:

1. Include immediate-release opioids

The current focus of the FDA Blueprint on extended-release/long-acting opioids misses a significant portion of opioid prescribing. While only 42% of CO*RE learners reported having prescribed an ER/LA opioid in the past year, 77% reported having prescribed an immediate-release (IR) opioid. These prescribing patterns suggest that, to be effective in promoting safe opioid prescribing, IR opioids should be included in the curriculum.

Moreover, both ER/LA and IR opioids have significant addictive potential and prescribers should understand the risks associated with both. By omitting IR opioids from the curriculum, the REMS program is missing an opportunity to provide comprehensive education about safe opioid prescribing.

2. Include other clinicians

The current REMS program only counts a subset of learners in its success metrics, a practice which underestimates the program's value and makes it appear as though the program to date has not been a success. While CO*RE can only count 28,857 prescribers in its metrics, we have collectively reached more than 170,000 learners, all of whom play an important role in patient care and medication management. ASAM recommends expanding the REMS program's target audience and prescriber definition to include other clinicians who are critical members of patient care teams, including nurses, pharmacists and other health care providers.

3. Incorporate recommendations from the CDC Guideline

As FDA considers modifications to the ER/LA REMS program, there is an opportunity to streamline federal efforts to promote safe opioid prescribing by incorporating the recommendations included in the recently released CDC Guideline for Prescribing Opioids for Chronic Pain. There is no need for duplicative federal recommendations on opioid prescribing; in fact, duplicative efforts may only confuse prescribers and further clutter an already-crowded educational space on this topic. We recommend reducing the number of free federally funded trainings on opioid prescribing and working with states to consolidate efforts on this issue.

4. Add a module on the identification and treatment of substance use disorders

Given the increasing incidence and growing prevalence of opioid misuse and addiction, as well as the fact that few clinicians receive sufficient education about substance use disorder identification and treatment during their postgraduate education, ASAM recommends the REMS Blueprint be expanded to include an additional module on the identification and treatment of substance use disorders. This



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recommendation accords with the previous one to incorporate the CDC Guideline, as the Guideline recommends providers conduct periodic (at least annual) urine drug testing to assess for prescribed opioids, other controlled substances and illicit drugs as well as offer or arrange for evidence-based treatment for patients with opioid use disorder.

The REMS course offered by ASAM already includes an additional module that covers this important topic area. The ASAM Unit in the CO*RE ASAM REMS Course reviews the vulnerability to opioid use disorder among patients prescribed chronic opioid therapy (COT) for chronic non-cancer pain (CNCP), as well as the challenges of treating chronic pain in patients who have an addictive disorder. The module concludes with a clinical approach to treating opioid use disorder. ASAM recommends that all REMS courses be required to cover this valuable information so that more clinicians are able to identify patients with a potential substance use disorder and offer or connect them with needed treatment.

Thank you again for the opportunity to provide comment on this important process. ASAM looks forward to continuing to work with FDA and our CO*RE collaborators to deliver high-quality and impactful education on safe opioid prescribing to all health care providers.

Sincerely,

Kelly Clark, MD, MBA, DFASAM
President, American Society of Addiction Medicine