American College of Physicians
Leading Internal Medicine, Improving Lives

December 28, 2017

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

RE: Opioid Policy Steering Committee; Establishment of a Public Docket; Request for Comments, FDA-2017-N-5608.

Dear Commissioner Gottlieb:

The American College of Physicians appreciates the opportunity to submit comments regarding the Food and Drug Administration's (FDA) Request for Information Notice. ACP is the largest medical specialty organization and the second largest physician group in the United States, representing 152,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

The Center for Drug Control and Prevention (CDC) has reported that opioids were connected to 33,091 drug overdose deaths in 2015 (1). To help combat this epidemic, ACP believes it is imperative that physicians practice safe, evidence-based pain management. ACP strongly supports efforts to facilitate the integration of behavioral health into primary care and to enable physicians to provide substance use disorder treatment services and referrals for patients in need. We are encouraged by the FDA's continued interest in stopping the opioid epidemic. The College offers the following comments:

II. Steps To Promote Proper Prescribing and Dispensing

1. *Should FDA consider adding a recommended duration of treatment for specific types of patient needs (e.g., for specific types of surgical procedures) to opioid analgesic product labeling? Or, should FDA work with prescriber groups that could, in turn, develop expert guidelines on proper prescribing by indication?*

ACP supports the FDA's proposal to work with prescriber groups on proper prescribing guidelines that are based on the best-available evidence. However, as acknowledged in the current Center for Disease Control and Prevention's (CDC) Guideline for Prescribing Opioids for Chronic Pain, current evidence supporting many aspects of opioid prescribing for chronic pain is weak at best (2). Care should be taken to avoid recommendations that cannot be supported by available evidence. The College has organized a collection of resources under the featured heading "Opioid Epidemic" as part of our Online Learning Center, aimed at helping physicians to better treat patients with pain and/or opioid use disorder. The resources cover opioid therapy, pain management,

behavioral health, and substance use disorder. Since 2015, over 2,000 physicians have attended live seminars provided by ACP at regional and national meetings. ACP's online Safe Opioid Prescribing educational modules have been accessed by over 30,000 unique viewers, and hundreds have viewed our patient education support resources for management of chronic pain and opioids.

ACP's Clinical Guidelines Committee developed a clinical practice guideline on the diagnosis and treatment of low back pain (3). ACP also offered input on the Center for Disease Control and Prevention's (CDC) Guideline for Prescribing Opioids for Chronic Pain (2). The CDC's guideline helps inform physicians of when opioids are appropriate for a typical patient with chronic pain; however, patients have individual care needs that may not reflect the recommendations presented in the guidelines and it is imperative that these and other guidelines not be used to make coverage decisions that may impair access for those with legitimate indications. Further, this and other guidelines should be subject to ongoing systematic evidence review and updated to inform proper pain management.

2. *If opioid product labeling contained recommended duration of treatment for certain common types of patient needs, how should this information be used by FDA, other state and Federal health agencies, providers, and other intermediaries, such as health plans and pharmacy benefit managers, as the basis for making sure that opioid drug dispensing more appropriately and consistently aligns with the type of patient need for which a prescription is being written?*

ACP remains concerned that pain management guidelines or other recommendations will be used by payers and others as prescriptive standards to limit coverage of pain medication. ACP believes that physicians in clinical practice are best suited to determine the proper usage of accepted drugs, and professional judgment should not be restricted by legislative or administrative fiat. The College is concerned by reports that some pharmacy benefit managers are requiring prior authorizations when a prescription exceeds the CDC guideline's day limits or dosage recommendations for opioid therapy (4). At the same time, many payers place substantial restraints on coverage of nonpharmacologic pain management services such as physical therapy and cognitive behavioral therapy. Such restrictions may hinder physicians' ability to adequately manage their patients' pain. ACP underscores that the uniqueness of each patient's clinical situation and circumstances is a paramount consideration in the effective delivery of care and the FDA should emphasize this point should future guidelines be developed.

III. Requirements for Prescriber Education

1. *Are there circumstances under which FDA should require some form of mandatory education for health care professionals to ensure that prescribing professionals are informed about appropriate prescribing and pain management recommendations, understand how to identify the risk of abuse in individual patients, know how to get patients with a substance use disorder into treatment, and know how to prescribe treatment for—and properly manage—patients with substance use disorders, among other educational goals? Are there other steps FDA could take to educate health care professionals to ensure that prescribing professionals are informed about appropriate prescribing and pain management recommendations?*

The ACP Ethics Manual underscores that it is the physician's responsibility to be professionally competent (5). Physicians are obligated by the standards of medical ethics and professionalism to practice evidence-based, conscientious pain management that prevents illness, reduces patient risk, and promotes health. ACP strongly believes that physicians must become familiar with, and follow as appropriate, clinical guidelines related to pain management and controlled substances, such as prescription opioids, as well as nonopioid pharmacologics and nonpharmacologic interventions (6).

Continuing medical education (CME) can broaden awareness and understanding of evidence-based prescribing practices. The Safe and Competent Opioid Prescribing Education (SCOPE of Pain) program can improve prescriber attitudes and knowledge about safe opioid prescribing and increase confidence in assessing pain in a new patient, communicating and collaborating with patients around opioid initiation, and assessing the potential benefit and risk of opioids for chronic pain in a new patient, among other competencies (7). However, a substantial number of physicians report that mandatory education would discourage them from prescribing opioids, potentially limiting access for patients for which opioids are medically necessary (8).

To encourage physicians to participate in CME related to pain management or proper prescribing of opioids, ACP has recommended that the DEA registration fee be waived for those who complete voluntary courses on pain management and substance use disorders (9). This policy will ensure that providers have the flexibility to engage with educational topics and materials that best suit their learning needs, including in-depth courses relating to specific areas of clinical practice. Generally, ACP policy opposes any legislation and/or regulation that mandates CME as a condition of licensure or relicensure to practice medicine, regardless of subject or content. A number of states require prescribers to complete CME related to pain management, controlled substances, and substance use disorders (10,11). ACP encourages the FDA to review the evidence of the effect of such state mandatory education laws on access to pain medication and whether enhancements in prescriber knowledge, awareness, and confidence about safe prescribing have been achieved.

Additionally, the College strongly supports policies designed to better integrate behavioral health, including screening, referral and treatment of substance use disorders, into the primary care setting. ACP policy recommends that training in screening and treatment of substance use disorders be embedded in the continuum of medical education. Continuing medical education providers should offer courses to train physicians in addiction medicine, medication-assisted therapy, evidence-based prescribing, and identification and treatment of substance use disorders. A complete profession-driven and evidence based curricular plan should address training needs across the learning spectrum. To help achieve this goal, federal grants could be provided to support continuing medical educators who create clinically relevant and professionally targeted curricula. Such curricular support should include evidence-based education regarding non-opioid, comprehensive pain management and behavioral health.

ACP supports policies to remove barriers to medication-assisted treatment. ACP recommends that physician support initiatives such as mentor programs, shadowing experienced providers, and telemedicine, can help improve education and support efforts around substance use treatment. Professional support resources, such as Providers' Clinical Support System, and hub-and-spoke programs, such as Project Extension for Community

Healthcare Outcome for Opioid Therapies, can link primary care physicians to health care professionals experienced in substance use disorder treatment and can improve physician confidence in buprenorphine prescribing practices and other areas of substance use disorder treatment (12).

IV. Additional Matters for Consideration

1. *What other steps should FDA take to operationalize the above described goals?*
2. *Are there additional policy steps FDA should consider relating to the OPSC that are not identified in this notice?*

ACP supports expanding the use of nonpharmacologic pain management therapies, particularly among primary care physicians. Federal agencies must conduct research on nonpharmacologic pain management treatment. ACP supports Agency for Healthcare Research and Quality-funded research addressing safety, quality, comparative effectiveness, and cost effectiveness of non-opioid pain management strategies. To ensure validity, large randomized controlled clinical trials should be conducted whenever possible. We encourage the incorporation of patient-centered and patient-reported outcomes in new research to appropriately characterize and assess potential benefits of these therapies.

Thank you for considering these comments. Please contact Ryan Crowley, Senior Associate, Health Policy at rcrowley@acponline.org if you have questions.

Sincerely,

Jack Ende, MD, MACP
President
American College of Physicians

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[1] https://www.cdc.gov/drugoverdose/data/statedeaths.html

[2] https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm

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[5] *Ethics Manual, 6th Edition*. Philadelphia: American College of Physicians, 2012. https://www.acppress-ebooks.org/product/ethics-manual-6th-edition.

[6] Crowley, Ryan, Neil Kirschner, Andrew S. Dunn, and Sue S. Bornstein. "Health and Public Policy to Facilitate Effective Prevention and Treatment of Substance Use Disorders Involving Illicit and Prescription Drugs: An American College of Physicians Position Paper." *Annals of Internal Medicine* 166, no. 10 (2017): 733-736. Accessed at http://annals.org/aim/fullarticle/2613555/health-public-policy-facilitate-effective-prevention-treatment-substance-use-disorders

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[9] https://www.acponline.org/acp_policy/letters/fda_opiod_utilization_2009.pdf

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[11] "Continuing Medical Education Board-by-Board Overview." Federation of State Medical Boards. https://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/GRPOL_CME_Overview_by_State.pdf.

[12] Komaromy, Miriam, Dan Duhigg, Adam Metcalf, Cristina Carlson, Summers Kalishman, Leslie Hayes, Tom Burke, Karla Thornton, and Sanjeev Arora. "Project ECHO (Extension for Community Healthcare Outcomes): a new model for educating primary care providers about treatment of substance use disorders." *Substance abuse* 37, no. 1 (2016): 20-24. Accessed at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4873719/