

September 6, 2016

U.S. Department of Health and Human Services
Office of Civil Rights
Attention: 1557 RFI (RIN 0945-AA02)
Room 509F
200 Independence Avenue SW
Washington, DC 20201

Re: Opioid Analgesic Prescriber Education and Training Opportunities To Prevent Opioid Overdose and Opioid Use Disorder; Request for Information

To Whom It May Concern:

On behalf of our 159,000 members, we are pleased to respond to your request for information about how federal opioid prescriber education and training programs can be improved. We offer these comments in response to your Federal Register notice of July 8, 2016 (81 FR 44640).

Opioid pain relievers—such as hydrocodone (Vicodin® and Lortab®) and oxycodone (OxyContin® and Percocet®)—can be a safe and effective way to help dental patients manage moderate to severe post-operative pain. Unfortunately, the misuse and abuse of these potentially addictive pain medications has become a serious public health problem.

In 2014, over 47,000 people died from drug overdoses, and 40 percent of those (18,893 deaths) involved opioid analgesics.¹ This doesn't count the nearly 2 million Americans who reported abusing or being dependent on prescription pain relievers.²

As the fifth most frequent prescribers of opioid analgesics, dentists are well-positioned to help keep these drugs from becoming a source of harm.³ We can be judicious about the dosage and number of pills we prescribe. When indicated, we can prescribe non-narcotic alternatives. We can screen patients to determine if they might be prone to abuse opioids. And we can counsel patients about how opioids can be addictive and how to safely secure, monitor, and discard them at home.

Enclosed you will find our detailed comments about how federal opioid prescriber education and training programs can be improved. Our main criticism is that the Department's programs and activities have not sufficiently distinguished pain management in dentistry from pain management in medicine.

For example, the Food and Drug Administration's (FDA) risk evaluation and mitigation strategy (REMS) is based on the FDA Blueprint for Prescriber Education for Extended Release and Long-Acting (ER/LA) Opioid Analgesics. The guideline is not particularly helpful to dentists because there is rarely, if ever, a need to prescribe an ER/LA opioid to manage the acute, short-term dental pain most often associated with a one-time outpatient dental procedure (e.g., wisdom tooth extraction).

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The highly touted Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain also does not address the particulars of managing short-term pain in dental settings. In fact, the document expressly states, "Some of the recommendations might be relevant for acute care settings or other specialists, such as emergency physicians or dentists, but use in these settings or by other specialists is not the focus of this guideline."

We urge the Department to give more attention to the nuances of managing acute, short-term pain following a one-time outpatient surgical procedure, particularly in dental settings (e.g., a wisdom tooth extraction). We would be happy to work with you to do so.

We applaud your efforts to help curb the misuse and abuse of opioid pain medications and would welcome the opportunity to discuss this further. If you have any questions, please contact Mr. Robert J. Burns at 202-789-5176 or burnsr@ada.org. Information is also available at ADA.org/opioids.

Sincerely,

/s/

Carol Gomez Summerhays, D.D.S.
President

/s/

Kathleen T. O'Loughlin, D.M.D., M.P.H.
Executive Director

CGS:KTO:rjb
Enclosure

¹ Centers for Disease Control and Prevention, National Center for Health Statistics. Fact Sheet: NCHS Data on Drug-Poisoning Deaths: March 2016.

² Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. (2015). Behavioral health trends in the United States: Results from the 2014 National Survey on Drug Use and Health (HHS Publication No. SMA 15-4927, NSDUH Series H-50): 23.

³ IMS Health, National Prescription Audit, United States, 2012.

Supplemental Comments to the

Department of Health and Human Services

on the

**Opioid Analgesic Prescriber Education and Training Opportunities To
Prevent Opioid Overdose and Opioid Use Disorder; Request for Information**

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On behalf of our 159,000 members, we are pleased to respond to your request for information about how federal opioid prescriber education and training programs can be improved. We offer these comments in response to your Federal Register notice of July 8, 2016 (81 FR 44640).

CENTERS FOR DISEASE CONTROL AND PREVENTION

The highly touted Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain does not address the particulars of managing pain in dentistry. In fact, the document expressly states, "Some of the recommendations might be relevant for acute care settings or other specialists, such as emergency physicians or dentists, but use in these settings or by other specialists is not the focus of this guideline."

To help make the CDC's prescriber education and training content relevant to dentists, we ask the Department to:

- Direct CDC to develop a guideline for prescribing opioids for acute, short-term pain, as is more commonly seen in dental settings.

FOOD AND DRUG ADMINISTRATION

The Food and Drug Administration's (FDA) risk evaluation and mitigation strategy (REMS) is based on the FDA Blueprint for Prescriber Education for Extended Release and Long-Acting (ER/LA) Opioid Analgesics. The guideline is not particularly helpful to dentists because there is rarely, if ever, a need to prescribe an ER/LA opioid to manage acute, short-term dental pain, most often associated with a one-time outpatient dental procedure (e.g., wisdom tooth extraction).

To help make the FDA's prescriber education and training content relevant to dentists, we ask the Department to:

- Direct the FDA to develop a blueprint for educating prescribers of immediate-release and short-acting (IR/SA) opioid analgesics.
- Direct FDA to expand its risk evaluation and mitigation strategy (REMS) to include educating prescribers of immediate-release and short-acting (IR/SA) opioid analgesics.

In the interest of full disclosure, the ADA applied for (and was denied) an FDA REMS training grant in 2012. We did not receive a grant because dentists do not prescribe ER/LA opioids.

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

Thanks, in part, to a grant from the Substance Abuse and Mental Health Services Administration (SAMHSA), the ADA has been offering free, peer-to-peer continuing education webinars covering safe and effective opioid prescribing in dental settings. We have produced 21 webinars since 2012, and will produce four additional webinars in 2017. The webinars are part of SAMHSA's Prescribers' Clinical Support System for Opioid Therapies (PCSS-O) grant program.

The webinars are attractive to dentists because they are free, easy to access, and distinguish pain management in medicine from pain management in dentistry. Above all, they are recognized by the ADA Continuing Education Recognition Program (ADA CERP). The ADA CERP credential provides a sound basis for state regulatory agencies to accept the continuing education (CE) credit for licensure.

To help make the SAMHSA's prescriber education and training content relevant to dentists, we ask the Department to:

- Direct SAMHSA to continue funding PCSS-O webinars on model opioid prescribing in dentistry.

To help federal agencies better decide where to direct their opioid prescriber education and training resources, we also urge the Department to:

- Direct SAMHSA to gather National Survey on Drug Use and Health (NSDUH) data on how many of those who reported abusing or being dependent on prescription pain relievers in the last year initially obtained those drugs directly from a dentist.
- Direct SAMHSA to gather NSDUH data on how many of those who reported abusing or being dependent on prescription pain relievers in the last year are continuing to obtain those drugs directly from a dentist on an ongoing basis.

OTHER DEPARTMENTS

Drug Enforcement Administration (DEA)

The likelihood that a dentist would need to prescribe a Schedule II narcotic varies by the procedures performed in his or her practice. Authority to prescribe opioid analgesics is essential to help patients manage post-operative pain (e.g., root canals, tooth extractions, etc.) when needed. However, some dental specialists (e.g., oral and maxillofacial radiologists) are less likely to prescribe opioid analgesics because they have little (if any) interaction with patients.

To help policy makers decide where federal opioid prescriber education and training funds should be directed, we urge the Department of Justice to:

- Require the DEA to report the number of dentists that have a DEA license to prescribe Schedule II drugs.
- Require the DEA to report how many states already require dentists with Schedule II prescribing authority to complete training in safe and effective opioid prescribing as a condition of licensure.
- Require the DEA to report how many states require dentists with Schedule II prescribing authority to check their state prescription drug monitoring program (where available) before prescribing an opioid analgesic.