

September 28, 2017

Honorable Elizabeth Warren  
317 Hart Senate Office Building  
Washington, DC 20510

Honorable Shelley Moore Capito  
172 Russell Senate Office Building  
Washington, DC 20510

Re: Partial Fills of Schedule II Controlled Substances

Dear Senators Warren and Capito:

On behalf of our 161,000 members, we are pleased to respond to your letter of September 6, regarding implementation of Sec. 702 of the Comprehensive Addiction and Recovery Act of 2016 (CARA).<sup>1</sup>

This provision, which the ADA supported, authorizes pharmacies to partially fill prescriptions for Schedule II controlled substances when requested by the patient or prescriber, and to fill the remaining portions after a specified date without further authorization from the prescriber, subject to state law.

Enclosed you will find our detailed responses to the six questions you posed. We hope you will find these helpful as you continue monitoring the widespread adoption of Sec. 702.

For your consideration, we are also enclosing a copy of a letter we submitted to the Department of Health and Human Services (HHS) last year.<sup>2</sup> It includes a number of recommendations for improving the federal government's opioid prescriber education and training programs. We would welcome the opportunity to talk with you about this further.

Thank you for reaching out to us. We share your commitment to ending this tragic and entirely preventable public health crisis. If you have any questions, please contact Mr. Robert J. Burns at 202-789-5176 or [burnsr@ada.org](mailto:burnsr@ada.org). Information is also available at [ADA.org/opioids](http://ADA.org/opioids).

Sincerely,

/s/

Gary L. Roberts, D.D.S.  
President

/s/

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

GLR:KTO:rjb  
Enclosures (2)

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<sup>1</sup> 21 U.S.C. 289(f)

<sup>2</sup> Carol Gomez Summerhays and Kathleen T. O'Loughlin, American Dental Association, letter to U.S. Department of Health and Human Services Office of Civil Rights, September 6, 2016.

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**Response to Questions Posed by Senators Elizabeth Warren and Shelley Moore Capito**  
September 28, 2017

**1. Have you communicated with your members to alert them to new federal legislation allowing the partial filling of prescriptions in states where such an option is not specifically prohibited by state law?**

We have communicated with our members about Comprehensive Addiction and Recovery Act of 2016 (CARA) and the provisions that are likely to impact them. As with other new laws, we plan to alert our members and share practical resources to help them comply once the final regulations are published.

At present, we are waiting on the Drug Enforcement Administration (DEA) to update its partial fill regulations<sup>3</sup> (or publish some form of interim guidance) so that states, pharmacies, and prescribers will know they are implementing Sec. 702 in a legally acceptable manner.

**2. Have you developed any successful strategies for increasing public awareness of the option to partially fill prescriptions, including working with patient groups and advocacy organizations?**

We have been working with the Partnership for Drug-Free America since 2012 to increase public awareness about ways to keep opioid medications from becoming a source of harm in the household. The Partnership's Medicine Abuse Project campaign encourages parents to talk with their kids about the dangers of abusing prescription and over-the-counter medicines. It also provides educational materials about safeguarding and properly disposing of unused medications at home.

We have also tailored content our consumer website, MouthHealthy.org, to help patients understand the benefits and drawbacks of using opioid pain relievers, including how opioids can be addictive. The current content includes recommendations for using these drugs safely and how to safely secure, monitor, and dispose of them at home.

We would be pleased to add content that urges patients to ask their dentist about a partial fill prescription when an opioid pain reliever is indicated.

**3. Have you developed any successful strategies for increasing your members' awareness of the option to partially fill prescriptions?**

Yes. Thanks, in part, to a grant from the Substance Abuse and Mental Health Services Administration (SAMHSA) and the American Academy of Addiction Psychiatry (AAAP), the ADA has been able to offer free continuing education webinars covering the latest pain management techniques to help prevent opioid abuse. We have included general content on the partial filling of prescriptions in several of these webinars.

- Legal and Ethical Issues of Opioid Prescribing for Acute Dental Pain (6/7/17)
- Pain Management in Dentistry: A Changing and Challenging Landscape (9/2/16)
- Federal and State Policy Efforts to Prevent Prescription Opioid Diversion (2/10/16)

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<sup>3</sup> 21 CFR § 1306.13

The Prescribers' Clinical Support System for Opioid Therapies (PCSS-O) webinars are free, convenient to access, tailored to pain management in dentistry, and available to members and non-members alike. Plus, the ADA CERP credential provides a sound basis for state regulatory agencies to accept the continuing education (CE) credit for licensure.

We also offer educational content on our dental practice website, the ADA Center for Professional Success, to help dentists manage dental pain in patients who are at risk for drug overdose and/or addiction. The current content includes access to the ADA's free continuing education webinars (see above), practical guides for safe prescribing, frequently asked questions, and more. We would be pleased to add general partial fill content on our CPS site.

The ADA is offering free access to this prescribing content as a public service. Most other CPS content is reserved for members only.

**4. Have you encountered any challenges in your efforts to implement federal partial fill legislation that you wish to bring to our attention?**

Yes. Until DEA updates its regulations, we cannot safely assure our members that they are implementing Sec. 702—or any other DEA-related provisions in CARA—in a legally acceptable manner. In fact, a cursory review of the DEA website produced no results that would help states, pharmacies, or prescribers implement the new partial fill provision.

**5. What information or assistance would be helpful on a federal level to support your efforts to encourage your members to utilize partial fill and discuss it with their patients?**

We recommend that the DEA begin the formal rulemaking process to update the federal regulation governing the partial filling of Schedule II controlled substances. In the meantime, we recommend that the agency publish some form of interim guidance so that states, pharmacies, and prescribers will know they are implementing Sec. 702 in a legally acceptable manner.

**6. Are there additional federal efforts your organization believes would be helpful to limit the amount of unused medications in the home?**

For your consideration, we have enclosed a copy of a letter we submitted to the Department of Health and Human Services (HHS) last year.<sup>4</sup> It includes a number of recommendations for improving the federal government's opioid prescriber education and training programs.

Our main criticism is that most federal programs and activities have not sufficiently addressed the nuances of managing *acute* pain versus *chronic* pain.

When indicated, a dentist may prescribe an immediate release and short acting (IR/SA) opioid to help manage *acute* pain following a one-time dental procedure (e.g., wisdom tooth extraction, etc.). But there is rarely, if ever, a need to manage *chronic* pain after dental surgery, much less to prescribe an extended release and long acting (ER/LA) opioid.

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<sup>4</sup> Carol Gomez Summerhays and Kathleen T. O'Loughlin, American Dental Association, letter to U.S. Department of Health and Human Services Office of Civil Rights, September 6, 2016.

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To help make the federal government's prescriber education and training content relevant for dentists, we urge that a greater emphasis be placed on modern techniques for managing acute pain following a one-time surgical procedure.