



Academy of  
Managed Care  
Pharmacy®



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Dear Messrs. Brown and Miller:

Thank you for inviting several associations to meet with you and the Drug Enforcement Administration (DEA) Diversion Control team on June 21, 2019 to discuss issues of mutual interest and concern. We appreciate DEA's efforts to provide information to pharmacists regarding diversion prevention efforts and encourage future meetings.

As DEA is aware, pharmacists play a crucial role in both protecting patients and communities while also providing medications to patients pursuant to legitimate prescriptions. To address the opioid epidemic, several new Federal laws and regulations have passed and/or are being implemented. A crucial component of implementation is creating awareness and providing clarity regarding compliance by effected parties. As expressed at the June 21 meeting, pharmacists and pharmacy associations are concerned that DEA has provided insufficient information to help the pharmacy community understand these changes, including changes to partial fill laws.

To help address this need, we urge DEA to issue a revised Pharmacist Manual and routinely update the manual in the future.<sup>1</sup> As noted in the “Message from the Administrator”, the manual “will answer questions you may encounter in the practice of pharmacy and provide guidance in complying with the CSA regulations.” Since the last update of the Pharmacist’s Manual occurred in 2010, there is not a comprehensive resource available to pharmacists from DEA that addresses many changes in the law, including those more recently passed in the Comprehensive Addiction and Recovery Act of 2016<sup>2</sup> and the SUPPORT for Patients and Communities Act of 2018.<sup>3</sup>

Such an update would also be consistent with the Government Accountability Office’s 2016 recommendation that DEA “solicit input from pharmacists, or associations representing pharmacists, about updated and additions needed to existing guidance for pharmacists, and revise or issue guidance accordingly.”<sup>4</sup> In April 2016, DEA indicated that it was still working to update that Pharmacist’s Manual regarding changes to rescheduling of hydrocodone and new drug disposal regulations<sup>5</sup> and at the June 21 meeting, DEA indicated it would prioritize releasing an updated Pharmacist’s Manual. Yet, no additional guidance or updates have been released. We are concerned DEA is not prioritizing the importance of answering pharmacists’ questions and providing information to help guide compliance with the Controlled Substances Act.

Thank you for your attention to this issue. We look forward to DEA’s response to this request and encourage the DEA to work with pharmacists and pharmacy associations to make available on ongoing updates to the Pharmacist Manual.

Sincerely,

American Pharmacists Association  
Academy of Managed Care Pharmacy  
American Society of Consultant Pharmacists  
American Society of Health-System Pharmacists  
National Alliance of State Pharmacy Associations  
National Association of Chain Drug Stores  
National Community Pharmacists Association

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<sup>1</sup> See Drug Enforcement Administration, (2010) Pharmacist’s Manual, An Informational Outline of the Controlled Substances Act, available at: <https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/index.html>, last accessed: August 28, 2019.

<sup>2</sup> P.L. 114-198

<sup>3</sup> P.L. 115-271

<sup>4</sup> United States Government Accountability Office, (June 2016). Drug Enforcement Administration: Additional Actions Needed to Address Prior GAO Recommendations, available at: <https://www.gao.gov/assets/680/678005.pdf>, last accessed: August 28, 2019.

<sup>5</sup> See United States Government Accountability Office, (June 2016). Drug Enforcement Administration: Additional Actions Needed to Address Prior GAO Recommendations, at 20, available at: <https://www.gao.gov/assets/680/678005.pdf>, last accessed: August 28, 2019.