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Association of  
American Medical Colleges  
655 K Street, N.W., Suite 100, Washington, D.C. 20001-2399  
T 202 828 0400  
www.aamc.org

May 4, 2018

Mr. Robert W. Patterson  
Acting Administrator  
Drug Enforcement Administration  
Attention: DEA Federal Register Representative / DRW  
8701 Morrissette Drive  
Springfield, VA 22152

**Re: *Controlled Substances Quotas (Docket Number: DEA – 480)***

Dear Mr. Patterson:

The Association of American Medical Colleges (AAMC) welcomes this opportunity to submit comments on the Drug Enforcement Administration's (DEA's) proposed rule on Controlled Substances Quota (83 *Fed. Reg.* 17329).

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members are all 151 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

Teaching hospitals and their associated physicians are on the front lines of the deadly opioid epidemic. Every day, AAMC member hospitals and physicians see the devastating effects of opioid addiction on their patients and communities and are actively working to prevent and address the impact. Over half of AAMC-member teaching hospitals offer outpatient substance use services, and over three-quarters operate crisis prevention programs. AAMC-member hospitals also account for 19 percent of the nation's alcohol unit beds and 22 percent of inpatient psychiatric unit beds. The vast majority of our member teaching hospitals provide child psychiatry services or outpatient psychiatric care. These institutions serve on the front lines of the country's safety net, investing in a wide scope of mental and behavioral health services, including treatment and recovery support for substance use disorders.

AAMC agrees that addressing this crisis takes a multi-pronged approach to decrease drug abuse and diversion, and setting quotas for the production of opioid medicines can be an effective part of that strategy. However, we urge the DEA to remember that opioids are also an important part of treatment regimens for controlling acute and chronic pain in a variety of patients – including trauma, post-operative and patients with advanced stage cancer – and any limits on quotas should not negatively impact access for patients that have a legitimate and critical need for these medications.

Mr. Robert W. Patterson

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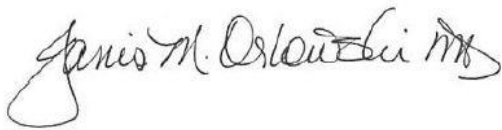
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Hospitals and health systems continue to experience critical shortages of a number of injectable opioid medications due to a slowdown in production and a component problem at a major manufacturing facility. Severe shortages of injectable opioids may threaten patient care in hospitals. Injectable opioids remain a crucial component of patient management during and immediately after many operations. With limited availability of some opioids, operations may have to be postponed or cancelled. In some cases, this could prove life-threatening to the patient.

AAMC appreciates the DEA's temporary adjustment of the individual quotas for three manufacturers to help fill the gap as a result of the shortage. However, the shortage of injectable opioid products is not expected to fully resolve until mid-2019. As the DEA considers limits on production quotas, the DEA should take steps to ensure current drug shortages are alleviated as appropriate to guarantee a sufficient supply of opioid medications for legitimate needs.

Thank you for the opportunity to comment on the Controlled Substances Quotas proposed rule. We would be happy to work with DEA on any of the issues discussed above or other topics that involve the academic health center community. If you have questions regarding our comments, please feel free to contact Mary Mullaney at 202.909.2084 or [mmullaney@aamc.org](mailto:mmullaney@aamc.org).

Sincerely,

A handwritten signature in black ink that reads "Janis M. Orlowski M.D.". The signature is written in a cursive, flowing style.

Janis M. Orlowski, M.D., M.A.C.P.  
Chief, Health Care Officer, AAMC

cc: Ivy Baer, J.D., M.P.H, AAMC  
Mary Mullaney, AAMC