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American Association for the Treatment of Opioid Dependence, Inc.

*Expanding Access to Quality Opioid Addiction Treatment Services*

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February 13, 2013

John W. Partridge
Executive Assistant to the Associate
Deputy Assistant Administrator
Liaison and Policy Section
Office of Diversion Control
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

RE: Docket # DEA-316
RIN 1117-AB18
Disposal of Controlled Substances

Dear Mr. Partridge,

I am writing in response to the above referenced proposed rule, which was published in the Federal Register on December 21, 2012. We appreciate the DEA's interest in developing new categories with regard to the safe return and disposal of previously dispensed controlled substances.

We particularly appreciate the sensitivity of providing such guidance to the country at a time of increasing prescription opioid abuse and addiction. "These proposed regulations expand the entities to which ultimate users may transfer unused, unwanted, or expired controlled substances for the purpose of disposal, as well as the methods by which such controlled substances may be collected."

As you know, AATOD represents over 900 Opioid Treatment Programs (OTPs) throughout the United States and Mexico. We have worked with the Drug Enforcement Administration and all federal regulatory agencies, which have jurisdiction in this area of regulatory oversight for OTPs. OTPs are unique, and in our collective judgment, require their own designation within the proposed rule. OTPs do not operate like retail pharmacies or registered hospitals, but do have a long history of administering controlled substances, primarily methadone and buprenorphine, to patients through on-site administration and in the dispensing of take home medication. The DEA proposed rule makes reference to such entities. "Unlike retail pharmacies, registered hospitals do not dispense controlled substances to ultimate users pursuant to legitimate prescriptions. Rather, registered hospitals administer controlled substances to inpatients dose by dose, and the controlled substances remain within the possession and control of the registered dispenser, the hospital. As such, registered hospitals may not dispose of controlled substances in collection receptacles, but must follow the revised regulations for registered destruction, and keep records of such destruction."

OTPs also fall under the federal regulatory guidance of the Department of Health and Human Services through the Substance Abuse and Mental Health Services Administration. SAMHSA published a Federal Register Notice with regard to oversight of OTPs throughout the United States on January 17, 2001, which took effect on May 18, 2001. There is a specific reference in the SAMHSA regulatory requirements for OTP operations concerning Diversion Control Plans. "An OTP must maintain a current Diversion Control Plan or "DCP" as part of its quality assurance program that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use and that assigns a specific responsibility to the medical and

administrative staff of the OTP for carrying out the diversion control measures and functions described in the DCP."

SAMHSA also published "Guidelines for the Accreditation of Opioid Treatment Programs" on July 20, 2007. We understand that SAMHSA is revising these Guidelines at the present time and expects to have a draft released very shortly. The Guidelines provide additional information about how OTPs should be compliant with the SAMHSA regulation, as referenced above. "The clinic should examine its dosing and take home dispensing practices to ensure that there are no potential weaknesses in the dispensing of medication that could lead to diversion problems." The Guidelines also makes a reference to the fact "OTPs should have a plan in place to address identified diversion problems." OTPs in the United States have developed different Diversion Control Plans as a means of being in compliance with the SAMHSA regulations. Some OTPs have conducted randomized "Call Back Programs" where patients are asked to return to the program with the medication previously dispensed. Nurses or other designated medical personnel within the OTP evaluate the medication as it is returned to the OTP by the patient to determine if there has been any tampering with the medication or if the medication has been improperly used.

In our judgment, the proposed rule should provide a specific category for the Opioid Treatment Program as one of DEA's registrants to be a certified collector for the return of such medications, in order to be in compliance with the SAMHSA regulations as well. "DEA proposes to authorize as collectors those persons already registered as manufacturers, distributors, reverse distributors, and retail pharmacies because, as registrants, these persons are accountable, have experience handling large volumes of controlled substances on a routine basis, and they are subject to controls related to their DEA registration. These pre-existing controls also protect against the diversion of controlled substances in the process of ultimate user collection."

Opioid Treatment Programs have existed in the United States since the mid 1960s. They have been regulated by both the DEA under the authority of the Department of Justice and the Department of Health, providing authority initially through the FDA and subsequently through SAMHSA, to provide oversight on how to conduct clinical and security operations in OTPs.

From our point of view, OTPs constitute one of the categories as referenced immediately above but not currently included in the proposed rule. OTPs have long experience in administering and dispensing controlled substances, primarily methadone, for more than 45 years. According to SAMHSA data, there are approximately 1,250 OTPs in the United States treating approximately 310,000 patients on any given day. The majority of these patients (300,000) use methadone, with the remaining number utilizing buprenorphine products. We also anticipate that a greater number of programs will be using Vivitrol/naltrexone products very shortly.

The OTPs are highly regulated entities, especially when one includes the State Opioid Treatment Authority regulations into the equation. OTPs and their personnel have extraordinary and well documented experience in carefully handling controlled substances throughout the past five decades.

In summary, we believe it would be important to have the DEA include OTPs as a specific category as collector of such controlled substances.

In this way, the OTPs will continue to be in compliance with SAMHSA's Diversion Control Plan requirement in addition to being in compliance with these newly wrought regulations as administered by the Drug Enforcement Administration. Thank you for taking this perspective into consideration as you review comments in response to the proposed rule.

Sincerely yours,

Mark W. Parrino, MPA
President

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