AATOD
American Association for the Treatment of Opioid Dependence, Inc.

Expanding Access to Quality Addiction Treatment Services

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Memorandum

To: AATOD Board of Directors
OTPs/State Opioid Treatment Authorities/Patient Advocacy Groups/Interested Parties

From: Mark W. Parrino, MPA
President

Date: December 27, 2012

RE: Department of Health and Human Services Final Rule - Modification of Dispensing Restrictions of Buprenorphine and Buprenorphine Combination as Used in Approved Opioid Treatment Medications

I am writing as a follow up to the December 6, 2012 Federal Register Notice/Vol. 77, No. 235. AATOD has been encouraging SAMHSA and the related federal agencies to publish this final rule for a number of years and are extremely pleased that this has finally occurred.

The summary of the rule is extremely clear. "This final rule amends the federal opioid treatment program regulations by modifying the dispensing requirements for buprenorphine and buprenorphine combination products approved by the Food and Drug Administration (FDA) for opioid dependence and used in federally certified and registered opioid treatment programs. In particular, this rule would allow opioid treatment programs more flexibility in dispensing take-home supplies of buprenorphine - removing restrictions on the time a patient needs to be in treatment in order to receive take-home supplies – after the assessment and documentation of a patient's responsibility and stability to receive opioid addiction treatment medication. Opioid treatment programs that use these products in the treatment of opioid dependence will continue to adhere to all other federal treatment standards established for methadone." The rule is effective January 7, 2013.

The importance of this rule is to provide OTPs with greater flexibility in providing take-home medication of buprenorphine or buprenorphine combination products in a way that is not connected to the existing standards related to methadone products. The rule is clear in making the point. "The added flexibility will also benefit patients, who should be able to report to the OTP less frequently, while still benefitting from the counseling, medical, recovery, and other services OTPs provide." The rule also makes clear on page 72755 that OTPs still need to assess and document "each patient's responsibility and stability to handle opioid drug products, including buprenorphine products for unsupervised use set forth under 42 CFR 8.12(i)(2) and 8.12(i)(3)." OTPS have a history of providing "wrap around services" to patients, including counseling

and other medical services in addition to the administration and dispensing of medication. NIDA-funded research has consistently supported the benefit to the patients when such services are offered to patients in conjunction with effective and evidence-based medications.

The rule also makes the differentiation of how such medications are prescribed through DATA 2000-waived physician practices and administered/dispensed in OTPs on page 72754. "Under this section, SAMHSA certifies and DEA registers "narcotic treatment programs" (not individual physicians) to dispense and administer (but not prescribe) approved opioid treatment medications for dependence or addiction treatment."

The rule also underscores the fact that OTPs are not limited on how many patients may be treated with buprenorphine or methadone, which is a clear distinction from the DATA waived physicians, who have initial patient restrictions for thirty patients in the first year of providing treatment and then may increase to 100 patients if the physician has demonstrated a desire to do so with established experience. The restrictions on the number of patients in OTPs may be subject to separate state law and that is an issue to be discussed among providers in individual states and the appropriate state regulatory authorities. OTPs should also review individual State regulations to determine if there are stricter dispensary requirements in place for buprenorphine products.

AATOD recommends that all medical practitioners in OTPs receive the special training provided to better understand the unique pharmacology of buprenorphine and buprenorphine combination products. The attached Federal Register Notice makes this point on page 72754. "There is no requirement that the OTP physicians, who are part of the treatment team, complete special training on methadone or buprenorphine treatment, or obtain waivers under DATA 2000." In spite of this, AATOD recommends that all medical practitioners receive this training prior to the use of these medications in the OTP setting. From our point of view, it is important to understand the pharmacological differences between buprenorphine and methadone in addition to the transition of patients from one medication to the other.

The final rule also notes that a significant number of physicians in OTPs have DATA waivers (on page 72757). "Moreover, SAMHSA has analyzed its OTP Medical Director database and cross referenced it to the database of physicians with DATA waivers. This analysis indicates that as of October 2012, at least 80% of the Medical Directors in OTPs have sought and obtained DATA 2000 waivers to prescribe buprenorphine products in office-based or other settings. As stated elsewhere in this notice, SAMHSA will send a formal guidance letter to all OTP Medical Directors, encouraging them to complete buprenorphine training and obtain a waiver."

We completely agree with this recommendation for a number of safety reasons. It is important that medical staff and other clinical personnel understand the important aspects of administering buprenorphine products in the OTPs. The Federal Register Notice also references two TIPs for OTPs. "TIP 40: Clinical Guidance for the Use of Buprenorphine in the Treatment of Opioid Addiction". "TIP 43: Medication Assisted Treatment for Opioid Addiction in Opioid Treatment Programs". These are two benchmark references for all OTPs in the United States and should be read by all clinical personnel. In addition to these TIPs, OTP medical personnel should read the Product Information (PI) and Important Safety Information in the FDA approved Product Insert. There are specific references to dosage ranges and therapeutic maximum dosage levels, which will provide additional guidance to OTP medical personnel.

AATOD is also working with the American Academy of Addiction Psychiatry (AAAP) in its Buprenorphine and Opioid Mentoring Programs. AAAP is planning to host a special buprenorphine training session at our next conference in Philadelphia, Pennsylvania, on November 9, 2013. AATOD will also feature a special section on using buprenorphine and buprenorphine combination products in OTPs during the Clinician's Course on Sunday, November 10, 2013.

There are online training courses available through some of the established medical societies, including AAAP and the American Society of Addiction Medicine. I suspect that SAMHSA will provide guidance to all of these established online training courses in their guidance to Medical Directors, which should be forthcoming.

In spite of this Federal Register Notice being published, we recognize that there are other impediments to the full implementation for the use of these medications in the OTP setting. We are urging all of the State Opioid Treatment Authorities (SOTAs) to work with their respective state insurance groups/regulatory authorities to remove any reimbursement barriers to the full use of this medication in the OTP setting. A number of states have already moved to develop differentiated Medicaid reimbursement rates to compensate for the higher price of buprenorphine products when compared to methadone. There are also a number of states with limitations on the number of patients in treatment at an OTP, and once again, this should be discussed with treatment providers depending on where these states' statutes/regulations affect such outcomes.

As stated at the beginning of this memorandum, AATOD has long supported the publication of this final rule, expanding the use of buprenorphine and buprenorphine combination products in the OTP setting. We have always taken the view that OTPs are uniquely qualified to treat opioid addicted patients given the available "wrap around services", which are provided to patients in addition to the use of federally approved medications.

We are grateful to SAMHSA for its work with other federal agencies in clearing the way for this Federal Register Notice and encouraging all OTPs to plan to provide access to this medication as patients will benefit from such care.