DEPARTMENT OF HE

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Treatment 1 Choke Cherry Road Rockville, MD 20857

Dear Colleague:

This is in response to requests for clarification regarding a physician's authority, while employed by an Opioid Treatment Program (OTP) certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) and registered with the Drug Enforcement Administration (DEA) as an Narcotic Treatment Program (NTP), (hereinafter OTP) to prescribe, write orders for, or dispense Suboxone® or Subutex® to patients for addiction/dependence treatment under the provisions of the Drug Addiction Treatment Act of 2000 (DATA 2000). This letter sets forth the current Federal regulations.

Currently, qualified physicians registered with DEA, in their name, not a program's name, and authorized with a waiver as required under the DATA 2000, can administer and dispense or prescribe Suboxone® or Subutex® for addiction/dependence treatment for up to 30 or 100 patients based on their qualifications. These physicians can issue prescriptions for Suboxone® or Subutex® from any practice location in compliance with DATA 2000, including an appropriately licensed and SAMHSA certified OTP. A physician appropriately authorized by DEA and the respective state authority may prescribe controlled substances from any practice location within the jurisdiction where he/she is authorized. A separate DEA registration is required at location(s) where a physician dispenses controlled substances to his or her patients.

In the case where a DATA 2000 qualified physician employed by an OTP issues Suboxone® or Subutex® prescriptions to patients enrolled in the OTP, the physician is subject to the 30-patient limit for the first year and the 100-patient limit thereafter. Further, as the Suboxone® or Subutex ® has been dispensed by the pharmacy to the ultimate user (the patient), Federal law prohibits transfer of these medications to any person other than the patient for whom it was prescribed.

OTP's may also admit patients and administer or dispense (but not prescribe) methadone, Suboxone® or Subutex®. In these cases, the OTP administers or dispenses the methadone, Suboxone® or Subutex®, from the OTP inventory directly to the patient as directed by the physician. In this instance, the 30 or 100-patient limit, discussed above, does not apply.

For additional information or questions regarding requirements for the administration of Suboxone® or Subutex®, please visit the Substance Abuse and Mental Health Services Administration (SAMHSA) webpage for the "Frequently Asked Questions about Buprenorphine and the Drug Addiction Treatment Act of 2000 (DATA 2000)" at www.buprenorphine.samhsa.gov/faq.html and the DEA webpage at www.buprenorphine.samhsa.gov/faq.html and <a hr

Sincerely,

H. Westley Clark, M.D., J.D., M.P.H.

Director

Center for Substance Abuse Treatment

Joseph Rannazzisi, J.D., R.Ph.

Deputy Assistant Administrator

Office of Diversion Control
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