The Determinations Report:

A Report On the Physician Waiver Program Established by the Drug Addiction Treatment Act of 2000 ("DATA")

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U.S. Department of Health and Human Services

March 30, 2006

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Purpose of this Report:

This report presents and discusses findings on a physician Waiver program established by the Drug Addiction Treatment Act of 2000 ("DATA"), which allows qualified physicians to dispense or prescribe Schedule III, IV, and V narcotic medications approved by the Food and Drug Administration (FDA) for detoxification and maintenance treatment. Buprenorphine, the first and only medication eligible for use under the DATA Waiver program, was approved by the FDA for use in the treatment of opioid dependence[†] on October 8, 2002, and became available early in 2003.

This Determinations Report summarizes key findings and recommendations from a 3-year, national SAMHSA evaluation conducted from 2002 through November 2005, as well as an additional literature review commissioned to ascertain consistency of the evaluation's findings with more recent literature. The evaluation was also useful in identifying and validating special issues emerging from implementation of the DATA program, which this report also discusses. Included with this report are a copy of the legislation (Tab A); the Final Summary Report from the SAMHSA Evaluation of the Impact of the Buprenorphine Waiver Program (Tab C); and a recent literature review commissioned by SAMHSA (Tab D).

Background:

The Problem. Since 1992, the number of persons reporting the abuse of opioids to the National Survey on Drug Use and Health (NSDUH), formerly called the National Household Survey on Drug Abuse (NHSDA) has increased significantly. Even more importantly, past-month abuse of prescription opioid painkillers has for many years surpassed the abuse of heroin.[1,2] There is no evidence that the number of admissions to treatment has risen proportionally, however. Also, although heroin abuse is estimated to be less than one-quarter of the level of prescription opioid abuse, the number of treatment admissions to public facilities for heroin dependence was (currently) twice that of other opioids in 2002.[3, 4] Together, these findings suggest that there are a significant number of people abusing prescription opioids who did not obtain treatment, at least not from facilities reporting to SAMHSA's Treatment Episode Data Set (TEDS) system, which tracks the vast majority of U.S. substance abuse admissions.

[†] In this and related documents, as in general practice, the terms "addiction" and "dependence" are often used inter-changeably. "Dependence" is the term used for medical diagnosis, while "addiction" encompasses behavioral aspects. FDA documents and product labeling refer to "dependence" as is consistent with medical diagnostic and coding standards. DATA, and the section of the Controlled Substances Act (CSA) on which it was based, refer to maintenance and detoxification treatment without, however, specifying whether the treatment is for dependence, addiction or both. More recent regulations specific to opioid treatment programs define detoxification treatment for dependence and maintenance treatment for addiction and therefore both terms are used in the discussion here.

Until very recently, treatment options were limited. Essentially, medication-assisted treatment (MAT) for opioid dependence was restricted to methadone and levo-alpha-acetyl-methadol (LAAM), which were available only through Federally regulated and unevenly distributed opioid treatment programs (OTPs, commonly called methadone clinics); in August 2003, Roxane Laboratories, announced the discontinuation of its distribution of ORLAAM®, due in large measure to reports of severe cardiac-related adverse events, including slowing of cardiac induction (QT interval prolongation) and cardiac arrest.

At present, some 1,150 OTPs exist, serving approximately 250,000 patients, but growth of the overall system of OTPs has remained limited. Also, geographic distribution of OTPs is uneven throughout the United States and for this reason, availability of medication-assisted treatment options was quite limited in many areas, prior to 2002. In many areas of the country, particularly non-urban areas, patients must drive considerable distances, sometimes daily, to obtain the necessary treatment at an OTP.

"DATA" and Buprenorphine. On October 17, 2000, President Clinton signed into law the Drug Addiction Treatment Act of 2000 ("DATA"), Title XXXV, Section 3502 of the Children's Health Act of 2000 (Tab A), in order to address the growing gap between the persons needing treatment for opioid dependence and the services available. DATA established a program of Waivers that enable physicians who already have, or who obtain, specific qualifications and who provide certain assurances, to prescribe or dispense Schedule III, IV and V medications as approved by the FDA for the detoxification and maintenance treatment of opioid dependence. The program's purpose is to increase availability of effective detoxification and maintenance treatment for the growing number of persons dependent on opioids, particularly prescription analgesics. Also, it is expected that success of the Waiver program will further SAMHSA's continuing efforts to ensure that these issues are addressed not only by specialists in addictions treatment but by physicians in primary care or other specialties.

On October 8, 2002, buprenorphine (available in two formulations, Subutex® and Suboxone®), was approved by the FDA for treatment of opioid dependence, becoming the first medication eligible for use under the DATA Waiver program. Although new medications are on the horizon, to date buprenorphine remains the only medication eligible for use under DATA. SAMHSA, which was delegated oversight responsibility for regulation of OTPs in 2001, was delegated oversight of the new Waiver program as well.

To date, some 10,000 physicians have obtained Waiver training, which as specified by DATA may be provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, and the American Psychiatric Association. Of these, 7,000 physicians have obtained Waivers. Based on estimates from the SAMHSA evaluation, as of early 2005, approximately 67 percent of physicians with Waivers were providing buprenorphine treatment. Significantly, these physicians are drawn from primary care and a range of other specialties and include physicians who have previously had minimal

or no involvement with treatment of substance use disorders. Between 2003, when buprenorphine became available under the Waiver program and spring 2005, an estimated 104,640 patients received treatment, also based on estimates from the SAMHA evaluation. Many of these patients were new to addiction treatment of any kind. This last is important given initial concerns that existing patients would simply be shifted from treatment with methadone to treatment with buprenorphine.

The SAMHSA Evaluation of the Impact of the Waiver Program. In 2002, SAMHSA initiated a national, 3-year evaluation. The SAMHSA evaluation was designed specifically to inform certain determinations to be made by the Secretary as outlined in DATA, namely, whether maintenance treatment and detoxification provided under the program of Waivers have been *effective* forms of treatment in clinical settings; whether such Waivers have significantly increased (relative to the beginning of such period) the *availability* of maintenance treatment and detoxification treatment; and whether such Waivers have adverse consequences for the public health (e.g., diversion for abuse).

Other objectives of the SAMHSA Evaluation were to assess the impact of Waiver-based treatment on the existing opioid treatment system; to identify any early, significant problems with the Waiver Program; to provide useful information to guide data systems being developed and maintained by SAMHSA; and to provide baseline data to inform future research and policy analyses.

The evaluation was conducted by Westat on behalf of SAMSHA's Center for Substance Abuse Treatment (CSAT), working in tandem with numerous other agencies and stakeholders, and was completed in November 2005 (see Final Summary Report at Tab C).

The SAMHSA evaluation combined quantitative and qualitative methodologies and involved analysis of both primary and secondary data. Three surveys were conducted in the course of the evaluation, including: (a) a survey of 959 addiction specialists in fall 2003, within a year after introduction of buprenorphine, focusing on this group as the most likely adopters of this new innovation; (b) a longitudinal survey of over 433 patients recruited through a sample of 132 prescribing physicians and clinics, which involved telephone interviews within the first week of treatment and then one month and six months after, to assess patient response to and satisfaction with buprenorphine treatment; and (c) a survey of 1,837 of 3,498 Waivered physicians in CSAT's Buprenorphine Waiver Notification System (BWNS), *not* limited to addiction specialists, which was conducted in spring 2005. Response rates for all surveys were high. Other primary data collection methods included a community forum, telephone interviews, and the Buprenorphine Reimbursement and Availability Tracking Study, a quarterly series of telephone interviews with key informants, intended to monitor trends related to the dissemination and adoption of buprenorphine both as a medication and as a new medication-assisted treatment.

Overall Findings:

Overall, findings from the SAMHSA Evaluation reflect positively on the impact of the Waiver program. In terms of the determinations, findings indicate that treatments provided under the Waiver program have been effective forms of detoxification and maintenance treatment in clinical settings and have significantly increased the availability of maintenance and detoxification treatment. Minimal adverse public health consequences, such as diversion for abuse, or severe adverse reactions, were reported and in fact positive consequences were reported, including less risky behaviors involving use of needles or risky sexual practices. Strikingly, availability of treatment sites has more than doubled nationally under the Waiver program, and buprenorphine patients appear to include a large number who are new to treatment. [It should be noted that findings available at this point reflect the situation fairly early in the introduction of a new innovation.]

The Final Summary report from the SAMHSA evaluation incorporates comments provided by the FDA, the Drug Enforcement Administration of the Department of Justice (DEA/DOJ), and the National Institute on Drug Abuse (NIDA). It should be noted that the current literature (Tab D) supports these findings albeit with mention of some potentially emerging, localized diversion, which SAMHSA is monitoring.

Special Issues:

The SAMHSA evaluation was also useful in identifying a few special issues emerging from implementation of the DATA program.

Access and Availability of Treatment. Importantly, access to treatment has expanded under the Waiver program, both geographically and in terms of the populations served. However, the SAMHSA evaluation also revealed opportunities remaining to increase access and with it, capacity, yet further. During the evaluation period, which ranged from the approval of buprenorphine on October 8, 2002, through the conclusion of the evaluation in November 2005, the availability of treatment sites for persons addicted to opiates increased substantially, largely traceable to the Waiver program. In addition, patients appear to have included a large proportion of patients who are new to treatment. This is important, in that this means existing patients were not simply being shifted from an old to a new modality (i.e., methadone to buprenorphine).

However, while the program of Waivers has shown great promise of increasing access to treatment−particularly for the growing number of persons addicted to prescription analgesics−the evaluation identified two issues that would seem to dampen the Waiver program's potential impact: First, high cost of the medication coupled with the lack of insurance coverage was an issue for patients and practitioners. Patients, physicians, and public sector purchasers alike consistently noted high cost—of the medication and office visits and procedures—as posing a significant barrier to obtaining and continuing buprenorphine treatment. There is concern that this may disproportionately limit access to buprenorphine treatment to those opioid-dependent persons who are able to pay

out-of-pocket. Demographics of the patients in this evaluation differed from those of patients seen in traditional opioid treatment programs, in part related to the higher proportion of buprenorphine patients being treated for misuse of prescription analgesics as opposed to heroin. Some 92 percent of patients in the buprenorphine evaluation were white, and generally of higher socio-economic status, education, etc. than those treated in OTPs. More recently, surveillance data from *DAWN Live!* for the years 2003-2006 indicated that most (75%) patients who made emergency room visits involving buprenorphine were white, with 6% black, 3% Hispanic, and 17% not indicating race or ethnicity. (*DAWN Live!* 3/21/2006, SAMHSA's Office of Applied Studies). These findings seem to suggest that persons who are minorities and/or of lower socio-economic status are not accessing this treatment, at least for the present. However, this was not unexpected, as buprenorphine is new in the United States, more expensive than methadone, and insurance companies and State Medicaid programs have been slow to adopt it into their formularies, at least at this early point in the dissemination of this new medication.

A second limiting circumstance which in terms of the overall system, impacts overall treatment capacity, and for the patient, geographical access, has involved a 30-patient limit imposed by DATA 2000 on both individual and group practitioners. Both limits received considerable attention from study respondents, many of whom voiced concerns that the limits may inadvertently contribute to negative consequences in terms of treatment access and dissemination but also, clinical decision-making. It should be noted that the SAMHSA Evaluation did not survey policymakers or law enforcement, who may have had a different perspective on the 30-patient limit. The physician group practice limit was eliminated by Public Law 109-56, effective August 2, 2005 (after data collection for this evaluation had concluded).

Public Health Consequences. The 3-year national SAMHSA evaluation indicated evidence of little diversion or abuse in the beginning years of buprenorphine dissemination; this is supported by the recent literature, reports issued by the National Drug Intelligence Center of the Department of Justice and from other sources including the Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS™) System, a research-based initiative to study the prevalence of abuse and diversion of controlled prescription medications and the surveillance study being conducted on behalf of the drug's manufacturer. Nonetheless, as with any opioid, the *potential* for abuse or diversion is always a concern. A few as yet uncorroborated anecdotal reports of possible diversion of buprenorphine in certain localities (all locations where abuse of prescription opioids has been reported as a significant problem) have emerged subsequent to completion of the evaluation and are being investigated by SAMHSA as part of its ongoing responsibilities.

Recommendations and SAMHSA Actions:

Specific modifications to the Waiver program are not recommended at this time. SAMHSA plans to continue to administer the DATA Waiver program and will continue to monitor the effectiveness, availability and effects on public health of treatments

provided under the Waiver Program. The SAMHSA Evaluation indicates a level of concern among many physicians about the 30-patient limit still in place for individual practitioners. SAMHSA intends to convene a meeting of stakeholders to discuss this and other issues raised by the final evaluation report, including, for instance, the high cost of the medication and lack of insurance coverage. Stakeholders will be asked to provide information to help guide SAMHSA in determining next steps. Based on their input and further examination of the evidence supporting or not supporting changes in the 30-patient limit, SAMHSA will determine whether a regulatory approach is recommended and will solicit public comment to ensure any changes continue to balance two public health concerns: one, being the desire to safeguard against the potential development of 'pill-mills' (the original intent of the 30-patient limit), the other being to allow the full realization of the Waiver program's potential to increase access to treatment to the many persons still in need of treatment.

As appropriate, SAMHSA will then propose regulatory actions, in accordance with the statute. In addition, and also toward further enhancing access through the Waiver program and the OTP certification program, SAMHSA intends to prepare a notice of proposed rulemaking directed to revising regulations on the dispensing of buprenorphine by opioid treatment programs, which must currently provide the medication under regulations intended for Schedule II medications. Also, although our report finds little evidence of diversion, SAMHSA will continue to monitor the use of these products and to intervene as necessary. Cost concerns will be somewhat mitigated in the future. For one, we understand the manufacturer will soon be launching an indigent program to broaden access to their product. Also, as expected, as time has passed and familiarity with buprenorphine and the Waiver program have grown, more public and private formularies have begun to include buprenorphine. In the future, as the medication's marketing exclusivity expires, it is also possible that other, less costly, generic products may become available.

SAMHSA does not plan to make significant changes to the administration of the Waiver program at this time. However, the agency is concerned about findings that suggest a two-tiered system of opiate addiction treatment could be developing and we will continue to monitor this situation. It is anticipated that enhanced educational efforts, increases in the number of prescribing practitioners, expanded coverage by both public and private third party payers, as well as rulemaking to expand access to treatment, may help increase access to under-served populations. Also, while the agency cannot directly address the issue of expense, it is expected that medication cost concerns may be somewhat mitigated in the future. For one, we understand the manufacturer will soon be launching an indigent program to broaden access to their product. Also, as expected, as time has passed and familiarity with buprenorphine and the Waiver program have grown, more public and private formularies have begun to include buprenorphine. In the future, as the medication's marketing exclusivity expires, it is also possible that other, less costly, generic products may become available.

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