

**States' Perspectives on Buprenorphine and Office Based  
Medication Assisted Opioid Dependency Treatment**

**Prepared by:  
The National Association of State Alcohol and Drug Abuse Directors  
(NASADAD)**

**For:  
The Center for Substance Abuse Treatment (CSAT)**

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Medication Assisted Opioid Dependency Treatment**

**TABLE OF CONTENTS**

Background .....1

Method .....2

Findings.....3

Discussion.....10

References.....13

**APPENDIX**

Appendix A: NASADAD Fax-Back/E-mail Back Membership Inquiry: States’  
Perspectives on Buprenorphine and Office Based Medication Assisted Opioid  
Dependency .....A-1

# **States' Perspectives on Buprenorphine and Office Based Medication Assisted Opioid Dependency Treatment**

## **Background**

The October 8, 2003 FDA approval of buprenorphine for use in the treatment of narcotic dependency has sparked considerable interest within the substance abuse community, particularly among those who are invested in the delivery of opioid dependency treatment. Buprenorphine is an opioid agonist medication used for the detoxification and maintenance treatment of opioid addiction and in the management of pain.

Buprenorphine is now available through the offices of physicians who have been granted a waiver under the provisions of the Drug Abuse Treatment Act of 2000 (DATA). A waiver under DATA permits qualified physicians to prescribe and dispense certain scheduled narcotics for the treatment of drug addiction.

It is hoped that the office-based availability of buprenorphine will enhance treatment accessibility as well as provide opioid dependent clients with an alternative to the existing methadone clinics and drug free treatment modalities. Methadone clinics and drug-free treatment will continue to function as key forms of treatment for opioid addiction, although they are currently only able to treat about one-fifth of the estimated 1 million Americans who are addicted to opioids (Schottenfeld et. al., 2000). Methadone clinics are sparse to non-existent in many rural areas of the country. In most urban areas, there are extensive waiting lists to be admitted to an opioid treatment program. Therefore, regardless of geographic location, methadone clinics are only able to treat a small portion of those addicted to opioids. It is hoped that the availability of buprenorphine, through qualified physicians, will provide a necessary increase in treatment capacity and accessibility.

DATA permits physicians who meet certain qualifications to apply for and receive a waiver from the special registration requirements of the Controlled Substances Act which permits them to prescribe specific FDA approved Schedule III, IV, and V narcotic medications for the treatment of opioid addiction. "DATA-waived" physicians (and group practices) may treat no more than 30 patients at any given time and have the capacity to refer patients for counseling and other appropriate ancillary services. A "qualifying" physician under DATA must be licensed under State law and meet one or more of the following criteria: hold a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties, hold an addiction certification from the American Society of Addiction Medicine, hold a subspecialty board certification in addiction medicine from the American Osteopathic Association, have participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, and/or receive other training and experience that demonstrates the ability to treat and manage opiate-dependent patients.

Waiver applications are made to the Substance Abuse and Mental Health Services Administration which administers a waiver process designed in consultation with the Drug Enforcement Administration, the National Institute on Drug Abuse, and the Food and Drug Administration.

It should be noted that under an amended provision of DATA (Section 303 (g) (2) (I)) a State may not, for a three year period (beginning from the FDA approval date of October 8, 2002) preclude a qualified practitioner from dispensing or prescribing schedule III, IV, or V drugs for maintenance or detoxification treatment unless, before the expiration of that period, the State enacts a law prohibiting such practice.

This new treatment option, while welcomed, raises many questions for the State Alcohol and Other Drug (AOD) Agencies now responsible for the planning, administration, and delivery of publicly supported treatment services. The National Association of State Alcohol and Drug Abuse Directors (NASADAD) is the membership association representing those agencies. With support from the Center for Substance Abuse Treatment (CSAT), NASADAD sought to identify, compile, and disseminate our members' concerns and the preliminary actions taken by the State AOD Agencies regarding office-based opioid addiction treatment. Specifically, NASADAD saw value for its members and relevant federal agencies in seeking basic information and perceptions on how the availability of buprenorphine may impact State treatment capacity, outreach efforts, information dissemination, clinical practices, regulatory provisions, abuse and diversion potential, client-level data collection, planning, and third-party reimbursement issues. In addition, this project was undertaken, in part, to aid CSAT in refining and implementing a plan for the provision of technical assistance to the States as the public treatment system reacts and adapts to this significant change in opioid treatment.

### **Method**

NASADAD staff, in concert with members of its Research and Treatment Committees, constructed a membership consultation document regarding the availability of buprenorphine (See Attachment A). The consultation document contained 26 questions consisting primarily of dichotomous items, although several Likert-scale and open-ended questions were also included. The items solicited views and expectations concerning the rollout of buprenorphine in the States, across a wide range of subject areas.

The Directors of all AOD Agencies, as well as the AOD Directors of the District of Columbia and five Territories, were targeted as potential respondents. In the spring of 2003, each AOD Director received a copy of the focused membership consultation document on buprenorphine through both regular and electronic mail. The consultation document was also available to download from the NASADAD Web site. Follow-up phone calls and e-mails were initiated to those States/Territories that had not responded by the original deadline. Selected findings were previously presented through a poster session during the 2003 American Association for the Treatment of Opioid Dependency.

## Findings

Ninety-four percent of the State AOD Directors participated in this consultation (N = 47) and 33% (N = 2) of the U.S. Territorial AOD Agencies were included in the analyses. A total of 49 States and U.S Territories responded to the consultation document. Responses are summarized, shown in various formats and organized by the topics below:

- Licensure, credentialing, and training
- Treatment capacity concerns
- Regulatory issues
- Abuse, diversion, and other clinical concerns about Suboxone and Subutex
- State's plans on developing clinical and/or administrative protocols
- Data collection and treatment outcome monitoring
- State/Federal financing
- Desired Federal information initiatives and technical assistance needs
- Top buprenorphine-related State technical assistance needs
- Top ATTC activities the States reported would be helpful

### Licensure, Credentialing, and Training Requirements

1. Do States anticipate that physicians who have met the qualifications to prescribe specific FDA approved Schedule III, IV, and V narcotic medications for the treatment of opioid addiction, and applied for and obtained a "DATA" waiver from SAMHSA/CSAT will also be required to secure State AOD treatment licensure?

12% of respondents answered:	Yes
86% of respondents answered:	No
2 % of respondents answered:	Undecided

2. Do States anticipate that "DATA-waived" physicians will be required to attain other credentialing, either instead of or in addition to State AOD treatment licensure?

8% of respondents answered:	Yes
88% of respondents answered:	No
4% of respondents answered:	Undecided

3. Have States requested or plan to request information on those physicians who have been granted a DATA waiver but who chose not to be listed on the on-line Physician Locator Web site established by SAMHSA/CSAT?

82% of respondents answered:	Yes
18% of respondents answered:	No
0% of respondents answered:	Undecided

4. Have States had discussions with their regional Addiction Technology Transfer Centers (ATTC) about the development and delivery of training and educational materials related to the availability of buprenorphine through office-based settings?

30% of respondents answered: Yes  
70% of respondents answered: No  
0% of respondents answered: Undecided

#### Treatment Capacity Concerns

1. Do States' AOD treatment systems have sufficient treatment capacity to meet the anticipated "counseling and other appropriate ancillary services" needs of "DATA-waived" physicians?

61% of respondents answered: Yes  
31% of respondents answered: No  
8% of respondents answered: Undecided

2. Do State AOD Directors believe that a significant portion of referring physicians' "counseling and other appropriate ancillary services" needs will be met by private practitioners who are not currently affiliated with State AOD treatment system programs?

45% of respondents answered: Yes  
33% of respondents answered: No  
22% of respondents answered: Undecided

3. Do States anticipate a significant level of participation among AOD treatment program medical directors and other "DATA-waived" physicians affiliated with AOD treatment programs (not including opioid treatment programs)?

39% of respondents answered: Yes  
51% of respondents answered: No  
10% of respondents answered: Undecided

4. Do States anticipate significant participation among program medical directors and other "DATA-waived" physicians currently affiliated with opioid treatment programs?

71% of respondents answered: Yes  
25% of respondents answered: No  
4% of respondents answered: Undecided

5. Have States been contacted by physicians who have received a "DATA" waiver (or are interested in obtaining one) regarding the use of buprenorphine?

37% of respondents answered: Yes  
63% of respondents answered: No

6. Do States anticipate that the 30-patient limit for “DATA-waived” physicians (and group practices) will restrict access to treatment?

31% of respondents answered: Yes  
67% of respondents answered: No  
2% of respondents answered: Undecided

#### Regulatory Issues

1. Do States anticipate that a State law prohibiting a practitioner from dispensing or prescribing Schedule III, IV, or V drugs for maintenance or detoxification treatment will be enacted before the end of the three year period (starting from the FDA approval date of October 8, 2002) provided for under Data in which States may not preclude such treatment in the absence of specific State legislation?

98% of respondents answered: No  
2% of respondents answered: Undecided

2. Do States anticipate the promulgation of regulations surrounding prescribing and dispensing buprenorphine for detoxification and/or treatment purposes?

10% of respondents answered: Yes  
86% of respondents answered: No  
4% of respondents answered: Undecided

3. Would States support the development of Health Insurance Portability and Accountability Act (HIPAA) transaction codes for office-based buprenorphine treatment?

80% of respondents answered: Yes  
12% of respondents answered: No  
8% of respondents answered: Undecided

#### Abuse, Diversion, and other Clinical Concerns

1. Buprenorphine is available as Subutex, one of the two FDA approved products. It contains only buprenorphine in two strengths. To what extent do you think Subutex represents an abuse threat in your State?

16% of respondents answered: No threat  
47% of respondents answered: Neutral  
33% of respondents answered: Significant threat  
4% of respondents answered: Not sure

2. To what extent do you think Subutex represents a diversion threat in your State?

21% of respondents answered:	No threat
41% of respondents answered:	Neutral
33% of respondents answered:	Significant threat
5% of respondents answered:	Not sure

3. Buprenorphine is also available in Suboxone, another FDA approved product. It contains both buprenorphine and naloxone, in two strengths. (Naloxone is a narcotic antagonist which has the potential to precipitate withdrawal in individuals dependent on heroin, morphine, or other full opiate agonists.) To what extent do you think Suboxone represents an abuse threat in your State?

62% of respondents answered:	No threat
29% of respondents answered:	Neutral
6% of respondents answered:	Significant threat
3% of respondents answered:	Not sure

4. To what extent do you think Suboxone represents a diversion threat in your State?

64% of respondents answered:	No threat
25% of respondents answered:	Neutral
8% of respondents answered:	Significant threat
3% of respondents answered:	Not sure

5. Do States plan to encourage Opioid Treatment Programs (OTP's) to advise existing methadone maintenance patients and/or new admissions of the availability of buprenorphine?

65% of respondents answered:	Yes
31% of respondents answered:	No
4% of respondents answered:	Undecided

#### Clinical and/or Administrative Protocols

1. Do States have or plan to develop protocols addressing dosing adjustments and other actions preparatory to the transfer of methadone maintenance patients to a "DATA-waived" physician who will initiate Subutex or Suboxone therapy?

35% of respondents answered:	Yes
59% of respondents answered:	No
6% of respondents answered:	Undecided

2. Do States have or plan to develop protocols addressing dosing adjustments and other actions preparatory to the transfer of patients receiving buprenorphine treatment to an Opioid Treatment Program and methadone treatment?

35% of respondents answered: Yes  
59% of respondents answered: No  
6% of respondents answered: Undecided

3. Do States have or plan to develop informed consent procedures and forms to permit the disclosure of patient information between Opioid Treatment Programs and "DATA-waived" physicians?

57% of respondents answered: Yes  
39% of respondents answered: No  
4% of respondents answered: Undecided

#### Data Collection and Treatment Outcomes Monitoring

1. To what extent do States anticipate that patients receiving buprenorphine from an office-based setting will be included in your State's client-level data system (CLDS)?

74% of respondents answered: 0-20%  
10% of respondents answered: 21-40%  
4% of respondents answered: 41-60%  
0% of respondents answered: 61-80%  
4% of respondents answered: 81-100%  
8% of respondents answered: Not sure

2. Would States' current CLDS allow them to distinguish buprenorphine patients from other patients?

21% of respondents answered: Yes  
75% of respondents answered: No  
4% of respondents answered: Undecided

3. Do States plan to evaluate treatment outcomes for buprenorphine patients?

20% of respondents answered: Yes  
76% of respondents answered: No  
4% of respondents answered: Undecided

## State/Federal Financing

1. Do States plan to expend Substance Abuse Prevention and Treatment (SAPT) Block Grant monies or other monies controlled by the State AOD Agency in support of appropriate services for buprenorphine patients?

45% of respondents answered: Yes  
49% of respondents answered: No  
6% of respondents answered: Undecided

2. Do States plan to expend SAPT Block Grant monies or other monies controlled by the State AOD Agency to cover the cost of buprenorphine for patients in the public AOD system receiving buprenorphine?

33% of respondents answered: Yes  
59% of respondents answered: No  
8% of respondents answered: Undecided

4. Do States anticipate that Subutex and Suboxone will be included in their States' Medicaid formulary?

43% of respondents answered: Yes  
49% of respondents answered: No  
8% of respondents answered: Undecided

5. Will States' Medicaid benefits cover physician and medication costs associated with office-based buprenorphine treatment for eligible clients?

47% of respondents answered: Yes  
29% of respondents answered: No  
24% of respondents answered: Undecided

## Relative Importance of Desired Federal Information and Technical Assistance Initiatives

1. How important is it that the Federal government immediately implement processes or studies to provide information on changes in treatment access attributable to the availability of buprenorphine?

80% of respondents answered: Important  
10% of respondents answered: Neutral  
10% of respondents answered: Not important

2. How important is it that the Federal government immediately implement processes or studies to provide information on buprenorphine treatment outcomes?

86% of respondents answered: Important  
12% of respondents answered: Neutral  
2% of respondents answered: Not important

3. How important is it that the Federal government immediately implement processes or studies to provide information on the incidence and nature of buprenorphine abuse?

88% of respondents answered: Important  
12% of respondents answered: Neutral

4. How important is it that the Federal government immediately implement processes or studies to provide information on the incidence and nature of buprenorphine diversion?

86% of respondents answered: Important  
14% of respondents answered: Neutral

5. How important is it that the Federal government immediately implement processes or studies to provide information on evidence-based or consensus driven "best" practices for participating physicians?

91% of respondents answered: Important  
9% of respondents answered: Neutral

6. How important is it that the Federal government immediately implement processes or studies to provide information on evidence-based or consensus driven "best" practices for providers of counseling and ancillary services for patients receiving buprenorphine?

86% of respondents answered: Important  
9% of respondents answered: Neutral  
5% of respondents answered: Not important

#### Top Buprenorphine-Related State Technical Assistance Needs

1. Education and training materials appropriate for physicians, treatment providers, and private practice professionals
2. Best practice updates for physicians, counselors, and other professionals involved in treatment
3. Incidence and nature of abuse/diversion and efficient ways to monitor it
4. Development of a statewide data collection system to measure buprenorphine outcomes/Conduct buprenorphine treatment outcome studies
5. Dissemination of information to patients and regarding buprenorphine, its pharmacology and effectiveness

6. Strategies and materials to facilitate collaboration with existing Opioid Treatment Programs (OTP's), prescribing physicians, and other providers
7. Cross training for all health care professionals involved in buprenorphine treatment
8. Assistance on regulatory issues, policies, and guidelines
9. Development of an informational Web-site for physicians, treatment providers, and consumers
10. Provide publications/research papers supporting the effectiveness of buprenorphine to increase physician interest

#### Top ATTC Activities the States Reported would be Helpful

1. Provide professional training and education for physicians, counselors, and other professionals providing ancillary services to individuals treated with buprenorphine
2. Develop best practices guidelines
3. Development and dissemination of information packets to treatment programs and physicians to increase participation and public awareness
4. Strategies and materials to facilitate the formation of partnerships with private physicians

#### **Discussion**

Based on the results of the membership inquiry, very few states anticipate that additional AOD licensure or other credentialing will be required for "DATA-waived" physicians. Most of the states reported that the training requirements established for eligibility to receive a waiver under DATA would serve as adequate verification of appropriate addiction training. Unless the physician would be establishing a formal treatment facility within his or her practice, it is not anticipated that there would be any additional requirement for certification as a substance abuse treatment program.

On the other hand, some jurisdictions anticipate requiring other training in addition to that necessary to qualify for a "DATA" waiver. For example, the New York State Office of Alcoholism and Substance Abuse Services (OASAS) is mandating 10 continuing medical education credits over a 2 year period related to AOD issues and an attestation that the physician has established linkage agreements with AOD providers for ancillary services. In Iowa, opioid substitution treatment programs must be approved and licensed by the Commission on Substance Abuse and there are current discussions as to whether this requirement will be extended to private practitioners.

Historically, State legislation is passed as a response to problems or concerns that arise at the State or local level. Relatively few of the States foresee any type of legislation being enacted that might preclude a practitioner from prescribing or dispensing buprenorphine during the period in which DATA provisions prohibit such actions in the absence of the enactment of a state law to the contrary. It is difficult to forecast legislative action, however, and the enactment of constraining state legislation cannot be ruled out if problems become apparent in the future.

Legislation was drafted in North Carolina that would require all qualified practitioners to register under the NC Controlled Substances Act, be subject to an annual fee, directly provide or refer to appropriate counseling, and provide the State AOD Agency with periodic statistical reports on persons treated for drug dependency.

A large majority of the State AOD Agencies indicated that they intend to request identifying information on those physicians who have opted out of participation in the CSAT online physician locator. Presently, without physician approval, identifying information can only be disclosed to regulatory officials, such as State Methadone Authorities for specific types of uses. The States expressed a need for access to this information to ensure an overall prospective on the availability of buprenorphine, plan outreach activities to the medical community, and for regulatory purposes.

Although it is expected that the availability of buprenorphine in office-based settings will increase the number of admissions into AOD facilities, over half of the States believe that their treatment system has sufficient capacity to meet the ancillary service needs of clients referred by "DATA-waived" physicians. Two-thirds of the States were of the opinion that the 30-patient cap would not restrict access to treatment services. Many States reported that they have already provided physicians with information about addiction treatment in general and the availability of appropriate ancillary treatment services in their area. The use of credentialed substance abuse counselors and case management professionals with specific training in addiction treatment has also been encouraged. Yet, most states do not anticipate an influx of clients from prescribing physicians as a result of the anticipated costs associated with purchasing buprenorphine and paying for private physician services. Those costs, in the estimation of many States, suggest that the majority of clients receiving buprenorphine may be insured or otherwise not typical of the medically indigent most frequently served through publicly supported services. Such individuals may seek ancillary services external to the publicly supported treatment system. The ability of physicians to opt out of the physician's locator may also complicate the States' ability to estimate the number of additional clients state systems can anticipate serving as a consequence of the introduction of buprenorphine from office-based settings.

If the European experience is any guide, buprenorphine will, to some degree, be subject to abuse or diversion as are other opioid substitute medications. Subutex contains only buprenorphine and is intended for use in the beginning of treatment under physician supervision. Suboxone, a combination of buprenorphine and naloxone, is less susceptible to abuse due to the antagonistic properties of naloxone. It was the consensus of the States that Subutex poses a much greater threat of abuse and diversion than Suboxone. In fact, one-third of the States were concerned that Subutex would pose a significant threat of abuse and diversion, whereas less than ten percent shared similar concerns about Suboxone.

In certain circumstances, it may be clinically appropriate for a methadone maintenance patient to be switched to buprenorphine or from buprenorphine to methadone. Therefore, it is essential that a strong relationship exist between OTP's and "DATA-waived"

physicians. In fact, slightly more than half of the States intend to develop administrative protocols that will provide clarity to the informed consent process which would permit the exchange of patient identifying information between OTP's and "DATA-waived" physicians.

Two thirds of the States indicated that they plan to encourage OTP's to advise methadone maintenance patients of the availability of buprenorphine. Switching methadone patients to buprenorphine may not only be clinically appropriate for some individuals, but it has its other advantages as well. For instance, it may help narrow the treatment gap by opening space in existing methadone treatment programs for new patients who might otherwise be placed on a waiting list.

Although States believe that it is important for OTP clients to be aware of buprenorphine to ensure that clients are informed of all treatment options, most do not intend to develop clinical protocols surrounding the transfer from methadone to buprenorphine or vice versa. It was the consensus of the States that this is a medical decision to be made on a case-by-case basis by clinicians.

While it is critical to evaluate buprenorphine treatment outcomes to document its effectiveness in the states, a large majority of States will not be formally implementing outcome studies. There are numerous factors that limit the States' ability to conduct statewide buprenorphine treatment outcome studies. First and foremost, individual practitioners are typically not a part of State client level data systems and have no real incentive to participate. While it may be possible to capture outcome information on patients receiving buprenorphine through publicly supported treatment providers, it is anticipated that the number of such clients would be too small to yield generalizable results or justify the associated costs. Lack of funding and data collection resources also poses a significant problem for the State AOD Agencies.

As previously noted the cost of buprenorphine and physician services may prevent many individuals from receiving this form of treatment. Whether or not SAPT Block Grant or other funds controlled by AOD Agencies will be used to pay for counseling or ancillary services for clients referred to publicly supported facilities varies by State. Only a third of the States plan to expend funds they control to cover the actual cost of buprenorphine. However, approximately half of the States expect to expend SAPT monies in support of counseling and case management services for clients treated with buprenorphine.

There was not unanimity among States as to whether buprenorphine will be included in the State's Medicaid formulary. Some states find it very unlikely considering that State Medicaid programs are already under significant financial pressures. The States suggested that negotiations be entered into at the Federal level with the manufacturer/distributor of buprenorphine to permit it to be available to State Medicaid programs at a discounted price, which would increase the likelihood of it being included in the formularies.

In conclusion, the advent of buprenorphine is a welcomed treatment option among the states. Clearly, the more treatment options available for those addicted to opioids, the better.

### **References**

Shottenfeld, R.S.; Pakes, J.; O'Conner, P.; Chewarski, M.; Oliveto, A.; and Kosten, T.R. Thrice-weekly versus daily buprenorphine maintenance. *Biological Psychiatry*, 47(12):1072-1079, 2000.

**Appendix A: NASADAD Fax-Back/E-Mail Back Membership Inquiry:  
States' Perspectives on Buprenorphine and Office Based Medication  
Assisted Opioid Dependency**



Name: _____
Phone: _____
State _____ E-mail _____

**FAX BACK to NASADAD at 202-293-1250, ATTN: LAURA TRAVEA**

Dear NASADAD Member:

Under the SAMHSA/CSAT (Substance Abuse and Mental Health Services Administration/Center for Substance Abuse Treatment) / NASADAD Cooperative Agreement (5 UDI TI13490-2), NASADAD has agreed to identify, record, and disseminate concerns and actions undertaken by the State AOD Agencies regarding office-based opioid addiction treatment. This project has been undertaken in order to inform potential SAMHSA technical assistance initiatives targeted to assisting the States in implementing the use of buprenorphine and other medications for the treatment of addiction.

In the anticipation of FDA approval of buprenorphine, NASADAD conducted a focus group (July 8, 2002) with NASADAD members and SAMHSA/CSAT/DPT (Division of Pharmacological Therapy) representatives to identify and synthesize State concerns and provide input on the issues surrounding the approval of buprenorphine and its rollout in the States. This effort resulted in a report that has provided general guidance to CSAT regarding the nature of the technical assistance that would be required by the States.

With the FDA approval of buprenorphine (October 8, 2003) and the recent arrival of buprenorphine in area pharmacies, SAMHSA/CSAT/DPT is seeking more in-depth information concerning how the availability of buprenorphine may impact State treatment capacity, outreach efforts, information dissemination, clinical practice, regulatory changes, enforcement activities, client-level data collection planning, and third-party reimbursement issues.

This membership inquiry is designed to allow NASADAD to collect the information that we believe will be helpful to SAMHSA/CSAT/DPT efforts to refine and implement a comprehensive plan for the provision of technical assistance as the public treatment system reacts and adapts to this significant change in opioid addiction treatment alternatives. NASADAD believes that the information collected will be useful to its membership in shaping its responses to office-based opioid treatment. All members will, of course, receive a final copy of the report for their use. We hope that you will provide the needed information by responding to this membership inquiry by Friday, **March 21, 2003**. We also hope that, where applicable, you will feel free to consult with your State Regulatory Coordinator (State Methadone Authority) as you complete the instrument.

The membership inquiry begins on the next page, and consists of 26 questions that can usually be answered by checking off yes or no, or by indicating an area on a scale. You also have opportunities to provide brief comments. For your convenience, we have enclosed a self-addressed, postage-paid envelope to return this inquiry. You may also fax your response or send it via email to [ltravea@nasadad.org](mailto:ltravea@nasadad.org).

You may direct any questions or concerns to Bob Anderson at NASADAD (202-293-0090 X104).

1) The Drug Addiction Treatment Act of 2000 (DATA 2000) permits physicians who meet certain qualifications to prescribe specific FDA approved Schedule III, IV, and V narcotic medications for the treatment of opioid addiction. Once the qualifications are met, the physician then applies for and receives a "DATA waiver" from SAMHSA/CSAT. Do you anticipate that physicians who have obtained this waiver will also be required to secure State AOD treatment licensure?

Yes       No

Comment:

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2) Do you anticipate that "DATA-waived" physicians will be required to attain other credentialing, either instead of or in addition to State AOD treatment licensure?

Yes       No

Comment:

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3) SAMHSA/CSAT has established a Physician Locator on their Web site. The Locator is an on-line resource designed to assist the States, medical and addiction treatment communities, potential patients, and/or their families in finding information on locating physicians who can prescribe buprenorphine for treatment of opioid addiction.

The Locator lists physicians authorized to prescribe buprenorphine for opioid (narcotic) addiction treatment. Inclusion in the database for the Physician Locator is voluntary. Approximately 75% of eligible physicians have asked that their contact information be included in this Web-based tool. CSAT has indicated that at the written request of the Single State Agency they will provide identifying information for regulatory or enforcement purposes on physicians within a State that have been granted a DATA

waiver, but who have opted out of participation in the online SAMHSA/CSAT Physician Locator.

- Have you requested this information?

Yes       No

- If no, do you plan to request this information?

Yes       No

If yes to either of the above, what plans do you have for utilizing that information?

Comment: \_\_\_\_\_

\_\_\_\_\_

4) Do you think that your State AOD treatment system currently has sufficient treatment capacity to meet the anticipated “counseling and other appropriate ancillary services” needs of "DATA-waived" physicians?

Yes       No

Comment:

\_\_\_\_\_

\_\_\_\_\_

- Use the space below to briefly describe the training needed and/or planned by the State AOD Agency that will be offered to practitioners, administrators, etc., in the public treatment system:

\_\_\_\_\_

\_\_\_\_\_

5) Do you anticipate that a significant portion of referring physicians “counseling and other appropriate ancillary services” needs will be met by private practitioners (e.g., psychologists, social workers and professional counselors) who are not currently affiliated with State AOD treatment system programs?

Yes       No

Comment:

\_\_\_\_\_

\_\_\_\_\_

- Use the space below to briefly describe the training needed and/or planned by the State AOD Agency that will be offered to those practitioners:

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6) Do you anticipate a significant level of participation among AOD treatment program medical directors and other "DATA-waived" physicians currently affiliated with AOD treatment programs (not including opioid treatment programs) within your State?

Yes       No

**Comment:**

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7) Do you anticipate a significant level of participation among program medical directors and other "DATA-waived" physicians currently affiliated with opioid treatment programs within your State?

Yes       No

**Comment:**

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8) Has your office already been contacted by physicians who have received a DATA waiver (or are interested in obtaining such a waiver) regarding the use of buprenorphine?

Yes       No

- If yes, please characterize the nature of their request, below:

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9) Under a provision of DATA (Section 303 (g) (2) (I)) a State may not, for a three year period, preclude a practitioner from dispensing or prescribing Schedule III, IV, or V drugs for maintenance or detoxification treatment unless, before the expiration of that period, the State enacts a law prohibiting such practice (This section was amended so that the three-year period begins from the date of FDA approval (October 8, 2002)). Do you

anticipate that a law prohibiting such a practice will be enacted within your State, within this three-year period?

\_\_\_ Yes     \_\_\_ No

Comment:

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10) DATA does not prohibit the States from regulating the dispensing and prescribing of Schedule III, IV, and V drugs for detoxification maintenance treatment purposes provided that those regulations do not preclude the practice. Does your State anticipate the promulgation of regulations in this area?

\_\_\_ Yes     \_\_\_ No

- If yes, please characterize the intent of those regulations

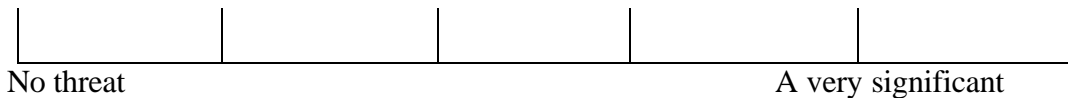
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11) Buprenorphine is available in two FDA approved products: Subutex, which contains only buprenorphine, in two strengths, and Suboxone, which contains both buprenorphine and naloxone, in two strengths. (Naloxone is a narcotic antagonist which has the potential to precipitate withdrawal in individuals dependent on heroin, morphine, or other full opiate agonists. To reduce the possibility of abuse and diversion, it is strongly recommended that Suboxone be used whenever unsupervised administration is planned.

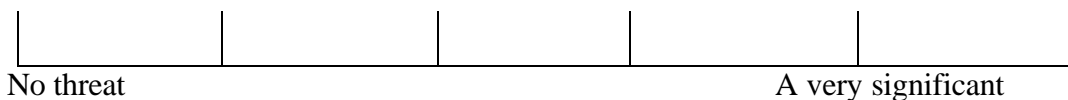
- To what extent do you think each of the formulations represent an abuse threat in your State?

***Subutex***



threat

***Suboxone***



threat

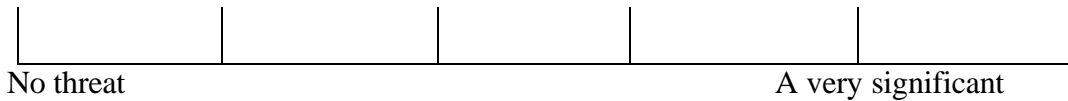
- To what extent do you think each of the formulations represent a diversion threat in your State?

**Subutex**



threat

**Suboxone**



threat

12) It may be clinically appropriate for a patient who is currently engaged in opioid replacement therapy using methadone to transition to using buprenorphine. Do you plan to encourage opioid treatment programs (OTPs) to advise existing methadone maintenance patients and new admissions of the availability of buprenorphine?

Yes       No

**Comment:**

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13) "DATA-waived" physicians (and group practices) may treat no more than 30 patients at any given time. Do you think that the 30- patient cap will restrict access to treatment in your State?

Yes       No

**Comment:**

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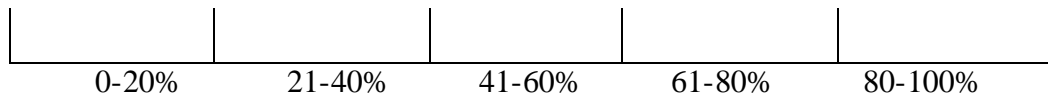


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14) Have you or do you plan to develop clinical and/or administrative protocols in your jurisdiction to cover the following situations:

- Dosing adjustments and other actions preparatory to the transfer of methadone maintenance patients to a “DATA-waived” physician who will initiate Subutex or Suboxone therapy?  
 Yes       No
- Dosing adjustments and other actions preparatory to the transfer of patients receiving buprenorphine treatment to an OTP and methadone treatment?  
 Yes       No
- Informed consent to disclose patient information between OTPs and “DATA-waived” physicians?  
 Yes       No

15) To what extent do you anticipate that patients receiving buprenorphine from an office-based setting will be included in your State’s client-level data system?



16) Would your client-level data system currently allow you to distinguish patients receiving buprenorphine from other clients?

Yes       No

Comment:

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17) Does your jurisdiction have plans to evaluate treatment outcomes for patients receiving buprenorphine?

Yes       No

- If yes, please briefly characterize those plans, below:

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- If no, please briefly characterize your reasons for not attempting to evaluate buprenorphine treatment outcomes, (e.g., lack of funds, inaccessibility of data, limited expectations regarding number of patients).

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18) Please answer the following questions by circling the number indicating the level of importance with one being “not at all important” to five being “very important.”

How important is it to your jurisdiction that the Federal government immediately implements processes or studies to:

- Provide States with information on changes in treatment access attributable to the availability of buprenorphine?

1      2      3      4      5

- Provide States with information on buprenorphine treatment outcomes?

1      2      3      4      5

- Provide States with information on the incidence and nature of buprenorphine abuse?

1      2      3      4      5

- Provide States with information on the incidence and nature of buprenorphine diversion?

1      2      3      4      5

- Provide States with information on evidence-based or consensus driven “best” practices for participating physicians?

1      2      3      4      5

- Provide States with information on evidence-based or consensus driven “best” practices for providers of counseling and ancillary services for patients receiving buprenorphine?

1      2      3      4      5

19) Has your State AOD Agency been in discussion with the Addiction Technology Transfer Center (ATTC) serving your region regarding their plans to develop and deliver training and educational opportunities related to the availability of buprenorphine through office-based settings?

\_\_\_ Yes      \_\_\_ No

- If yes, please briefly characterize the nature of those plans.

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20) Excluding initiatives/actions noted in response to the “if yes” response option in question 20, what ATTC activities/services related to treatment with buprenorphine would be most helpful in your State?

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21) Do you anticipate expending SAPT monies or other funds controlled by the State AOD

Agency (excluding Medicaid) in support of appropriate services for patients receiving buprenorphine?

Yes       No

- If yes, please briefly characterize the nature of those anticipated expenditure, e.g., counseling, case management, or other ancillary services provided by State accredited/licensed treatment facilities?

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22) Do you anticipate expending SAPT or other funds controlled by the State AOD Agency to cover the cost of buprenorphine for patients in the public AOD treatment system receiving buprenorphine?

Yes       No

- If yes, briefly characterize the circumstances in which you would anticipate paying for buprenorphine, e.g., when prescribed for a medically indigent patient by an approved physician in the employ of a State-licensed OTP.

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23) Do you anticipate that Subutex and Suboxone will be included in your jurisdiction’s Medicaid formulary during calendar year 2003?

Yes       No

**Comment:**

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24) Would your State's Medicaid benefits cover physician and medication costs associated with buprenorphine treatment in an office- based setting for eligible clients?

\_\_\_ Yes      \_\_\_No

Comment:

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25) Would you support the development of specific HIPAA transaction codes for office-based buprenorphine treatment?

\_\_\_ Yes              \_\_\_No

Comment:

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26) Please list your top three buprenorphine-related technical assistance needs in order of importance.

Need No.

1 \_\_\_\_\_

Need No.

2 \_\_\_\_\_

Need No.

3 \_\_\_\_\_