DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Substance Abuse and Mental Health Services Administration
Rockville MD 20857

MAR 30 2000

Dear Colleague:

The purpose of this letter is to provide information on methadone medical maintenance. In the past several months, the Center for Substance Abuse Treatment (CSAT) and the Food and Drug Administration (FDA) have received many questions about methadone medical maintenance. These questions indicate some confusion about what medical maintenance means, especially within the context of office-based opioid treatment, or OBOT. In addition, CSAT and FDA have received many questions about the regulatory requirements for medical maintenance and the procedures for authorization. Hopefully, this letter will clarify these terms, and provide additional information to those entities interested in providing medical maintenance treatment.

The 1995 Institute of Medicine report on methadone regulations and the CSAT Treatment Improvement Protocol (TIP) No. 20, Matching Treatment to Patient Needs in Opioid Substitution Therapy, by George E.Woody, M.D., and Janice F. Kauffman, M.P.H., referred to the term methadone medical maintenance as meaning the treatment of stabilized patients with increased amounts of take-home medication for unsupervised use and fewer clinic visits for counseling or other services. As discussed below, a few programs have been providing medical maintenance for several years. It is important to note, however, that virtually all medical maintenance treatment services have been provided to stabilized patients in physician's offices that are affiliated with an opioid treatment program (OTP). CSAT and FDA are not aware of any unaffiliated office-based physicians treating non-stabilized patients with opioid agonist medication.

A recent article in the American Journal on Addictions (vol. 8:293-299, 1999) described the results of a 12-year followup of stabilized patients under the care of a private physician affiliated with a methadone treatment program. That article also references other methadone medical maintenance programs, e.g., Beth Israel Medical Center, New York, New York. In each case, medical maintenance treatment was authorized under an Investigational New Drug Application (IND) pursuant to FDA regulations, 21 CFR § 3 .12.

While the IND process has allowed methadone medical maintenance to proceed in an investigational mode, FDA, among others, has now determined that medical maintenance treatment should be provided in accordance with the program-wide exemption provisions in the current opioid treatment regulations (2 1 CFR § 291.505(d)((11)). Under the exemption procedure, a treatment program may apply to FDA for exemption of specific regulatory requirements, such as the restriction to a maximum 6-day take-home supply. FDA will review the exemption request, consult with the Drug Enforcement Adminstration and State Methadone Authority, then act upon the request. FDA recently approved a medical maintenance exemption from a treatment program in Seattle, Washington (see Enclosure 1). In addition, FDA has authorized several similar exemptions as part of the ongoing CSAT methadone accreditation project.

In 1999, CSAT, together with the State of Connecticut, the Connecticut Counseling Centers, Yale University and the New England Addiction Technology Transfer Center at Brown University, initiated a study of medical maintenance involving the transfer of a cohort of stabilized patients from a traditional OTP to the care of physicians in private practice. This pilot project is being evaluated and will result in a report to the State legislature on the effectiveness of this model in one community in the State. In addition, the project has produced a training curriculum for primary care physicians who will be providing medical maintenance care, in association with a central "hub" program. We anxiously await the results of the study, briefly described in Enclosure 2.

In January of 1999, CSAT established a consensus development panel, cochaired by Joyce Lowinson, M.D., and Mark Publicker, M.D., to develop clinical practice guidelines for OBOT. Vincent Dole, M.D., is serving as emeritus chairman on this project. Andrea Barthwell, M.D., president-elect of the American Society on Addiction Medicine (ASAM), is the executive secretary for the panel. CSAT is grateful that these outstanding individuals have agreed to take the lead in developing these guidelines.

For additional information about these CSAT supported initiatives, contact Mr. Robert Lubran, Acting Director, Office of Pharmacologic and Alternative Therapies (OPAT), CSAT, at (301) 443-7745, or RLubran@samhsa.gov; Alan Trachtenberg, M.D., M.P.H., OPAT Medical Director, is also available for questions about clinical or scientific issues at the same phone number, or Atracht@samhsa.gov. We also direct your attention to CSAT's web site for additional information on the Center and its activities at www.samhsa.gov/csat/csat.htm.

FDA will evaluate exemption requests in accordance with its ongoing authority to enforce regulations set forth under 21 CFR § 291.505(d)(11). OTPs interested in exemptions for methadone medical maintenance should contact Mr. Elsworth Dory, Center for Drug Evaluation and Research, FDA, at (301)827-7264.

Sincerely,

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Enclosures:

Description of Medical Maintenance Exemption for a Treatment Program in Seattle, Washington
Description of Connecticut Methadone Medical Maintenance Pilot Project

Methadone Maintenance in Primary Care Program

Background and Purpose:

The Methadone Maintenance Primary Care Program (MMPCP) is a joint effort between the University of Washington, Harborview Medical Center, Evergreen Treatment Services and the Washington State Division of Alcohol and Substance Abuse Services. The purpose of MMPCP is to examine the policy issues, physician training challenges, and patient safety and acceptability concerns of expanding access to medical treatment for heroin addiction through primary care physicians and pharmacies. These issues must be resolved before medical maintenance programs can be widely adopted as part of a continuum of care for substance abusers.

Multiple Federal, State and local agencies have been involved in the approval of the MMPCP, though the evaluation of the program is a private initiative funded by the Substance Abuse Policy Research Program (SAPRP) of the Robert Wood Johnson Foundation. The first patients began receiving primary care services and methadone at Harborview on February 1, 2000. For additional information on this project, call Joseph Merrill, M.D., at (206)731-4605, or send e-mail requests to joem@u.washington.edu.

Program Structure

The Methadone Maintenance in Primary Care Program is structured as a satellite site of Evergreen Treatment Services, an existing methadone treatment program (MTP). This facilitates close linkages between the primary care physicians at Harborview and Evergreen, and allows for easy return of patients for more intensive treatment, should the need arise. The "medication unit," as defined by FDA regulations, is the basis for the MMPCP structure, with physicians registered on Evergreen's FDA license. The primary care physicians are responsible for methadone dosing and dispensing schedule, with orders filled at the Harborview hospital pharmacy.

Patient Selection

Central to the program is selection of a representative group of stabilized methadone patients who have been successful in stopping the use of drugs and becoming established in the recovery process. This group has been selected from among those patients who: (1) have demonstrated the responsible use of take-home doses of methadone and currently visit their treatment program no more than three times per week; (2) have exhibited 12 months of clinical stability; and (3) have been recommended for participation by their hub MTP. The hub program utilizes a multi-disciplinary team approach to screen patients for participation.

The first "wave" of approximately 10 patients has been selected and admitted from among those patients with maximum take-home privileges. The remaining, approximately 20, patients are selected from the more representative population of stabilized MTP patients defined above. Participation in the MMPCP is entirely voluntary.

Physician Selection and Training

The MMPCP involves interested attending physicians from Harborview Medical Center's Adult Medical Clinic. These physicians participated in a training program before accepting patients, and receive ongoing clinical support.

Counseling Services

Patients who are stable enough to qualify for this program are not required to continue counseling. Their physicians will provide ongoing support. In addition patients can opt to continue seeing their home MTP counselor. Psychiatric services are also available for patients at the primary care site, should they have ongoing needs.

Methadone Dispensing

Methadone is ordered and dispensed through Harborview Medical Center's pharmacy, which has been licensed as a DEA Narcotic Treatment Program. The methadone is stored in the pharmacy, a high security restricted area. Separate detailed records are kept of the amount of methadone received and dispensed. A satellite office of the Harborview pharmacy, in the adult medicine clinic, functions as the primary methadone pick-up site. Ingestion of one dose is observed at the time of dispensing.

Take-Home Dosages

Two months prior to transferring to Harborview, participating patients who attend their MTP three times per week and satisfy stability criteria, change to a two-visit per week schedule. All patients selected for the primary care program enter with the same number of take-home doses they had at the hub MTP. Patients who remain stable at the primary care site will become eligible to increase their dosages gradually up to a maximum one-month supply.

Monitoring

Urinalysis is conducted monthly at the primary care site, either during the patient's physician visit or when methadone is dispensed. A general screen for methadone and metabolites and for drugs of abuse is performed for these stable patients. Any positive screen triggers a comprehensive screen (GC/mass spec.) on the same sample. In addition, should more intensive monitoring be required, comprehensive screens would be used.

To address concerns regarding methadone diversion, patients who extend their take-home doses beyond one week are scheduled to participate in a callback program. They are required to be available to bring in all unused methadone within 24 hours, and to provide a urine sample for analysis.

Specification of Treatment Plan

Patients who transfer to the MMPCP are required to consent to an initial treatment plan that includes the following information:

- assignment of the primary care physician
- consent for the primary care physician to exchange records and communicate with the hub MTP
- location of methadone dispensing, urinalysis, and, if desired, counseling
- initial methadone dose and number of take-home dosages
- expected response to a positive urinalysis, relapse, or risk of relapse, and clinic to which the patient will return should the need arise.
- assigned responsibility for formulating changes in the treatment plan, including the decision to return a patient to the hub MTP

Patients have also given consent to research protocols. The treatment plan will be reviewed every six months. Patients will have input into any treatment plan changes. Any changes in the treatment plan will be communicated to the hub MTP.

Format and Timing of Primary Care Visits

During the initial primary care visit, physicians:

- verify continued stability
- review treatment plan
- conduct primary care assessment

Routine methadone visits occur monthly. They are brief, provided that no medical issues or changes in methadone treatment status need to be addressed. These appointments are made as convenient for the patient as possible. Visits are documented in the methadone chart. If issues requiring further evaluation arise, appointments are scheduled conveniently for both patient and provider.

Protocol for Assessing Threats to Stability

A variety of events may prompt reassessment of continued stability for patients in the MMPCP. These could range from a new life stress, to new or recurrent psychiatric illness, to objective evidence of possible relapse, such as non adherence to the treatment plan, family report of lost stability, or positive urinalysis. These events will trigger a prompt evaluation that includes:

- comprehensive evaluation (H&P)
- repeat urinalysis (with comprehensive screen if responding to positive urinalysis)
- for objective evidence of lapse or relapse: consultation with clinical support program
- increase intensity of monitoring, either in the primary care setting or via return of the patient to the hub MTP
- a treatment plan that reflects an appropriate response to the threat to stability

In general, life stresses or new psychiatric illness not associated with drug use, while triggering increased monitoring for patient safety, may not require involvement of the hub MTP. Consultation with the clinical support program is encouraged. Any evidence of drug use, even if assessed as a single lapse, requires consultation with the clinical support program and

notification of the hub MTP. This will serve to protect patient safety and to ensure that patients who subsequently cannot be maintained in the MMPCP can access intensive services quickly. Significant episodes of relapse to drug use will require return of the patient to the hub MTP. Decisions concerning this transfer will be made collaboratively, and will reflect both (a) the primary care physician's level of comfort assessing and treating the patient, and (b) the opinion of the clinical support staff.

Information Transfer

Close coordination between the home treatment program, the primary care physicians, and the Harborview pharmacy is essential to the success of this program. This is complicated by the Federal confidentiality requirements for drug and alcohol treatment programs. Thus the MMPCP will require a record keeping system that is distinct from the medical record. This parallel record keeping will apply to the pharmacy as well.

Information sharing will include: (1) initial transfer of medical and drug treatment information to the primary care site, from the home MTP; 2) ongoing transfer of medical progress notes, methadone dosage orders, urinalysis results, and reports of missed medical, counseling, urinalysis and pharmacy appointments; and (3) direct telephone consultation in the event of missed appointments or positive urinalysis.

Enclosure 2

Connecticut Methadone Medical Maintenance Pilot Project

The State of Connecticut passed into law Public Act 97-248 which, in part, calls for a research pilot program to investigate the efficacy of managing methadone treatment by private physicians outside of a methadone clinic setting. The project implementation began in February 1999, and is being monitored by the Connecticut Department of Mental Health and Addiction Services (DMHAS). DMHAS convened an advisory group to assist with the design of the pilot project and evaluation. A leading researcher, Richard Schottenfeld, M.D., from Yale University, was selected to conduct the evaluation of the project and to train physicians in private practice. David Lewis, M.D., Director of the CSAT-funded Center for Alcohol and Addiction Studies at Brown University, guided the development of a training curriculum for physicians who are participating in the pilot project. In addition, CSAT provided technical assistance and support for the project design and evaluation. The American Methadone Treatment Association was also involved in planning the pilot project.

One town in Connecticut was selected by the State for the implementation of the pilot project. About 60 patients who met the specific eligibility criteria established by DMHAS, and who were stabilized in methadone treatment, were identified. Physicians from primary care settings, who met eligibility criteria set by DMHAS, were recruited from the community and were provided a considerable amount of training before participating in the project. The physicians entered into a contractual relationship with the sponsoring methadone program and are functioning as satellite clinics. The methadone program provides emergency back-up if a patient deteriorates or needs other ancillary services. The program provides the methadone to the physicians' offices where it is dispensed and continues to manage the accounting for the medication as required by the Drug Enforcement Administration.

Patients were randomly assigned to either a community physician for maintenance treatment or to continued treatment in the methadone program for a 6-month period. Patients assigned to a community physician are seen by the physician in a private office setting at least once a month and usually receive a one-week supply of take-home methadone doses. The evaluation of the level of functioning of the two groups of patients will be conducted through monthly urine toxicology and self-reported drug use and other symptoms as measured by the Addiction Severity Index. A qualitative evaluation will be conducted assessing both patient and physician satisfaction with this type of treatment. In addition, a cost analysis will be performed in an attempt to assess the cost differential between the two treatment modalities.