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October 27, 1999

Dockets Management Branch
(HFA – 305)
Food and Drug Administration
5630 Fishers Lane (Room 1061)
Rockville, MD 20857

[Docket No. 98N-0617]

To Whom It May Concern:

I am writing in response to the Federal Register Notice of July 22, 1999, setting forth proposed rules to repeal the existing Narcotic Treatment Regulations as enforced by the Food and Drug Administration, in addition to creating a new regulatory system founded on the principles of an accreditation model.

The American Methadone Treatment Association represents 643 methadone programs throughout the United States or 81% of the nation's methadone treatment services for 151,329 patients through the organizing vehicle of State Methadone Provider Associations. The Association has continually demonstrated its commitment to improve treatment practices through the development of national conferences, regionalized symposia and the publication of treatment standards and guidelines.

The Association has convened regional conferences since 1984, which evolved into national events during 1990. Regional symposia have focused on managed care interventions, management training practices and physician education seminars. The physician training opportunities have been offered in conjunction with the American Society of Addiction Medicine and more recently with the American Academy of Addiction Psychiatry. Future training opportunities will also include the American Osteopathic Academy of Addiction Medicine.

The American Methadone Treatment Association developed State Methadone Treatment Guidelines for the Center for Substance Abuse

98N-0617

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Treatment in 1992 in conjunction with the Methadone Treatment Committee of the American Society of Addiction Medicine.

The Association has been working with the Drug Enforcement Administration to produce a series of guidelines, which will improve the accountability and tracking of methadone hydrochloride products at the program setting. All of these endeavors work to enhance the quality of care in the nation's treatment system.

Support for an Accreditation Based System

The Association's support for the development of standardized outcome measures in evaluating the efficacy of methadone treatment can be traced back to the development of the State Methadone Treatment Guidelines. These Guidelines were developed following the publication of several critical reports on the effectiveness of methadone treatment in the United States.

The final report of the White House Conference for A Drug Free America, which was published in June, 1988, indicated that "measuring the success of a treatment program is complicated because drug addiction is a chronic disorder that may require numerous treatment episodes and relapse can be one step back on the road to long term recovery. Despite the difficulties, standardized, objective measures that recognize the differences inherent in each type of treatment modality must be developed."

The introduction to the State Methadone Treatment Guidelines provided the illustration of a patient embarking on a cross country trip, receiving varying degrees of medical care depending on the program or state he or she happened to be traveling through during the journey. "This traveling patient might find himself or herself in a 'low dose' state or a state that ties the amount of take home methadone medication to the dosage level. Treatment providers and policy officials should be careful to avoid dysfunctional practices in treating opioid dependent individuals if they want treatment to be effective."

The Association's support for accreditation in evaluating the effectiveness of methadone treatment is rooted in the fact that a major segment of the healthcare system in the United States is being reviewed through such accreditation standards. We believe that accrediting methadone treatment will offer the potential of embracing methadone treatment as part of mainstream medicine in the United States. We understand that the elements of such accreditation standards will draw upon the principles of the aforementioned State Methadone Treatment Guidelines, fulfilling the promise of ensuring that patients will be able to access a reliable standard

of care, regardless of the size and location of a particular program or state policy.

The Association supported the implementation of the accreditation pilot project to incorporate 180 programs in the study, which is taking place in fifteen states. We are hopeful that the pilot will yield valuable information to guide federal agencies in developing a Final Rule, which will lead to the broad implementation of an accreditation system for methadone treatment throughout the United States.

It is critical that credible data are used to develop a blueprint to execute such a major transition in regulatory oversight. We anticipate that this transition will be more costly than the federal agencies have anticipated, based on the data contained in the federal register notice of July 22, 1999. We have attached reports from methadone program administrators in different states, underscoring such concerns, especially as they relate to the indirect costs of implementing accreditation standards in their respective treatment programs.

The Association is also concerned about the duplication of regulatory oversight, which creates conflict and incurs significant expense. It is hoped that one uniform standard will be adopted and implemented in accordance with recommendations from the Institute of Medicine and federal agencies. The following comments detail the Association's response to the Notice for Proposed Rule Making.

Analysis of Impacts

Section VIII (C) of the NPRM provides a baseline description of the treatment system. It indicates that the FDA has approved 869 methadone treatment programs as of early 1997, which encompass outpatient maintenance programs exclusively. Our Association recently conducted a survey of methadone treatment programs in the 42 states and the District of Columbia and found that 785 treatment programs were in existence. We realize that this number did not incorporate a number of VA methadone treatment programs, which would have increased the total.

The NPRM also indicated that the Secretary "estimates the total census of patients in opioid treatment to be approximately 125,000." The Association's 1998 survey data indicated that approximately 179,000 people were in treatment throughout the United States.

The Association has reviewed federal agency reports, indicating that more than 800,000 individuals are dependent on opiates throughout the United States (ONDCP – March, 1999). We understand that the intent of the

Proposed Rule is also to increase access to care through the vehicle of accreditation.

It is certainly possible, that treatment will be made more available to people in need of care through the vehicle of accreditation, however, without an infusion of significant funds at the federal level, meaningful treatment expansion will not occur. Accreditation alone cannot be expected to increase access to care unless there is a commitment of funds to educate the public about the value of methadone treatment and to increase access to new treatment sites.

Costs of the Proposed Regulation

Section VIII (E) discusses the cost of the proposed regulations. It presents information about the direct costs of becoming accredited in addition to indirect costs of improving program procedures to meet accreditation standards.

This section also amortizes the one time cost of accreditation over a three year period of time. This represents a contrivance since the program will incur accreditation costs immediately, which cannot be amortized over three years. The Rule assumes that the majority of programs will only be accredited at three year intervals, in spite of the fact that the Secretary does not have supporting data to substantiate this perspective.

It appears that the direct cost of accrediting a methadone treatment program ranges from $7,500.00 - $11,000.00 (refer to Appendix A, which provides additional information).

The NPRM also indicates: "the most costly compliance activities would be for OTPs that currently do not offer one of the identified services. In order to continue operations, these facilities would be required to offer these services, and incur costs of $150.00 per patient or $21,000.00." Once again, these figures are based on the average census numbers for the program within the scope of the NPRM's paradigm. A review of Appendix A indicates that a number of currently accredited methadone programs have incurred significant staff costs in preparing for accreditation surveys and implementing post survey improvements to be in compliance with accreditation standards. Unfortunately, all of the reporting programs were not able to accurately capture the indirect staff costs, which were incurred in preparing for accreditation surveys.

Three of the reporting states, which were listed in Appendix A, indicate significant indirect costs. Illustratively, the Missouri based methadone program reported a $35,000.00 expenditure for staff time, computer upgrade and physical plant improvement. The Rhode Island program

incurred expenses in the amount of $26,916.00, including the development of an infectious control manual and the hiring of a mental health consultant. The Texas based program reported an indirect cost in the amount of $45,000.00, which is related to the retention of a full time psychologist.

It is hoped that the fiscal data, which will result from the accreditation pilot study, will yield accurate information prior to the full-scale implementation of accreditation in methadone maintenance treatment.

Recommendation to Establish a Federal Fund

Our Association is urging the federal government to develop a multiyear, multipurpose fund to ensure that methadone treatment programs and patients will not be adversely affected by the implementation of accreditation standards, ultimately, decreasing access to care through program closure.

This fund may be developed on a needs based model, which would pay for the cost of submitting the accreditation application (CARF only) in addition to the cost of the survey. The fund would also provide financial and technical support in implementing improvements as a result of the accreditation survey, which would include training of personnel, implementing new information management systems and executing physical plant improvements. The Association recommends that the results of the pilot project be used as a basis in developing such a federal fund. If such a fund is not established, access to care will be affected as programs close under the weight of excessive fiscal burdens. Appendix A indicates that the indirect costs of implementing accreditation are considerable.

The Role of the FDA and the States

Section II (B) of the Rules discusses current oversight of the methadone treatment system. It indicates that "the frequency with which FDA conducts routine inspections has been steadily decreasing as FDA continues to focus on its other core priorities." The FDA was criticized for lack of regulatory vigilance in the General Accounting Office Report of 1990. Many treatment programs in a number of states have not been inspected by the FDA for more than ten years. The concept of regulatory triage has been cited at different times in how the FDA has approached its inspection schedule. Unfortunately, the only method of conducting true regulatory triage, as it has been conceived, is to have an overview of program deficiencies. The FDA is not in such a position.

The Association conducted a survey of the State Methadone Authorities following the release of the Proposed Rule. The results of this survey are summarized in Appendix B. Six states have indicated that twenty-one treatment programs are currently in violation of FDA regulations. Ten states have reported that forty-five programs are in violation of current state regulations. Five states have indicated that five programs are in danger of closing. Twenty-nine states have indicated that 155 programs need programmatic technical assistance. Sixteen states have indicated that twenty-five programs need physical plant improvements. Twenty-one states rated 172 programs as excellent. Thirty states rated 209 programs as good. Twenty-five states have rated 145 programs as fair and eleven states rated 36 programs as poor.

The findings from the states are significant in providing direction to the federal government concerning the challenges of changing to accreditation based outcome oriented oversight. The federal agencies, which will be responsible for implementing accreditation standards, must be mindful of the challenges to the treatment system in executing such sweeping changes.

The role of the FDA must be clearly communicated to the states and to treatment programs during the accreditation pilot, providing guidance leading to the full-scale implementation of accreditation, once the results of the pilot have been fully evaluated.

Will the FDA continue to be involved in conducting "for cause" inspections of methadone treatment programs? If the FDA is expected to conduct such "for cause" inspections, has the Secretary developed a realistic budget to implement such a policy? How will the FDA determine if such "for cause" inspections are needed? How will the FDA work in conjunction with CSAT in conducting "for cause" inspections? How will the FDA work in conjunction with State Methadone Authorities in conducting such inspections? Clearly, such questions are beyond the scope of our Association and have not been incorporated in the Notice for Proposed Rule Making.

Role of the States

Individual states have promulgated regulations, governing the practices of methadone programs in their respective jurisdictions. In certain states, such regulatory oversight has been executed to compensate for the dearth of FDA oversight. In other states, the specific interests of elected and appointed officials have been taken into account. Eight states still do not have any methadone maintenance treatment programs, with Wyoming being the most recent state to close its small treatment program (serving three patients) during February, 1999 and New Hampshire as the most

recent state to open a 180 day outpatient methadone to abstinence program.

Section II (C) (3) discusses the role of the State Authority. "State Authorities may choose to apply to act as accreditation bodies for programs in their jurisdiction and, if approved, would consolidate inspections and minimize burdens. Alternatively, State Authorities could adopt accreditation body findings."

Recommendations to Work with the States in Developing a Uniform Accreditation System

The Association recommends that the federal agencies, which are responsible for implementing accreditation, work in conjunction with the State Authorities to maximize the use of one accreditation standard. We realize that several entities may be involved in conducting such accreditation reviews. We urge the federal government not to approve an excessive number of entities to be involved in conducting such accreditation, since it would run counter to the intent of developing a stable oversight mechanism. The greater number of entities, which would be involved in conducting accreditation surveys, will also produce greater variation in the standards of care.

The Association is hopeful that states will adopt accreditation body findings once it is determined that the accreditation surveys are responding to the needs of the states in ensuring that good quality care is being provided within the methadone treatment programs. We have been informed by a number of State Authorities that they would not be willing to adopt accreditation body findings in lieu of their own state inspections.

Recommendations for Office Based Methadone Treatment Practice

Section III (A) (1) discusses an interest in how federal opioid treatment standards might be "modified to accommodate office based treatment." The Rule asks if a separate set of treatment standards should be included in the Rule for office based treatment.

The Association has recommended that methadone treatment be offered in office based medical practices through the vehicle of expanding access to "medical maintenance treatment". These recommendations have been listed in Appendix C. These recommendations include criteria for participating treatment programs, office based practitioners and patient referrals.

The Association believes that stable patients should be given treatment options, including a referral from the hub methadone treatment program to

an office-based practice. It is recognized that some patients many not choose such an option, however, we believe that such options should be made available. Medical maintenance programs currently operate in New York State and Maryland. Research indicates that approximately seven percent (12,530) of the existing patient population (179,000) would be eligible for such medical maintenance treatment.

If the federal government agrees with the concept of expanding access to medical maintenance treatment, the Rule should be modified to allow such office based practitioners, which have established referral linkages from hub methadone treatment program sites, to keep such stable patients without meeting the burden of accreditation standards. Under this scenario, methadone treatment programs would meet the accreditation standards and the individual office based practice would not be required to offer the full range of comprehensive services, which are available at the OTP.

We understand that there is interest in providing access to treatment in office based practices with physicians treating a number of patients, who would be newly admitted without a referral from an existing OTP. Current regulations allow for physicians to be involved in such practices in areas where patients cannot get ready access to care. Our Association is not opposed to providing access to people in need of care under such circumstances.

Our Association does not support the policy of having physicians involved in treating newly admitted patients, which have not been referred through a hub referral site, where treatment is available at an OTP.

A number of critics have indicated that our Association's Medical Maintenance Criteria are rigid, citing international research and clinical practices. Our Association has received conflicting information about the success of such initiatives in Europe and Australia. Drs. John Caplehorn and Olaf Drummer published an article in the February 1, 1999 edition of the *Medical Journal of Australia*, titled "Mortality Associated with New South Wales Methadone Programs in 1994: Lives Lost and Saved". The article discussed how lives were saved in preventing heroin overdose deaths and also presented findings about methadone related deaths caused by accidental toxicity. (The article has been attached - Appendix D.)

"Methadone was detected in postmortem material from eighty-nine New South Wales coronial cases in 1994. These cases comprised forty-one methadone maintenance patients (thirty-eight registered with the New South Wales Health Department). . . .Of the thirty-eight New South Wales maintenance patients, thirteen died in the first two weeks after admission and twenty-five died later in treatment. We and the official pathologists

concluded that twelve of the thirteen fatalities in the first two weeks of maintenance and six of the twenty-five deaths later in treatment were caused by accidental toxicity."

The authors cited two recent British studies, from Sheffield and Manchester, which "similarly identified significant numbers of deaths from iatrogenic methadone toxicity early in maintenance treatment. These problems also arose after the relaxation of admission criteria and during a period of rapid increase in the numbers of maintenance patients and the involvement of new, inexperienced prescribers."

If the federal government were to certify individual physicians to provide treatment to newly admitted opiate dependent patients and develop a separate standard of care, a two tiered system would inevitably emerge. If the federal government has a plan to encourage physicians to treat newly admitted opiate dependent patients, independent of the existing OTP, then the same standard of care should be applied. Such individual program practitioners should be subject to the same accreditation standards as the existing OTP.

Recommendations for Accrediting Small OTPs

Section VIII (L) (1) indicates that " all small programs would be required to be accredited by an accreditation body approved by SAMHSA. Each OTP, regardless of size would be expected to maintain this accreditation in order to continue to treat patients."

Section VIII (L) (2) discusses alternatives to requiring all small programs to be accredited. "The feasibility of exempting small facilities from some requirements will be examined." The Association has received a number of inquiries from small treatment programs in different states. They have expressed great concern about discontinuing their operations since they treat fewer than seventy-five patients at the program setting.

One of the reasons that the Association encouraged a large sample to be included in the accreditation pilot (180 OTPs) was to incorporate a number of such small OTPs. It is hoped that the pilot will yield meaningful fiscal data about the needs of such programs in meeting accreditation standards. It is certainly possible that such small operations will be able to affiliate with other currently accredited community based operations, however the development of a federal fund would assist such programs in pursuit of accreditation.

The Association recommends that the federal agencies, which have responsibilities for implementing accreditation, develop a series of technical assistance documents, which will be able to assist programs with

different patient census sizes throughout the country. Such technical assistance publications would serve as "how to" documents, including model policy and procedure manuals, model diversion management plans, model quality assurance packages in addition to other elements of the accreditation system. Such models would be provided in a clear and concise format, which could be specific to programs of different sizes. In this regard, programs would not be "reinventing the wheel" many times over throughout the United States.

Specific Recommendations in Response to the NPRM

Quality Assurance Plans

The Association supports the intent to have OTPs develop quality assurance plans to pursue continued improvement of patient care. Section 8.12 (C) requires such quality assurance plans and we believe that they will improve the quality of care in the nation's treatment programs.

Diversion Control Plans

The Association also supports the proposal of 8.12 (C) (2), "that treatment programs include a Diversion Control Plan as part of the quality assurance plan." The Association's work with the Drug Enforcement Administration in producing a series of guidelines for improving the accountability of methadone hydrochloride products indicates our interest in ensuring that programs do all that they can to protect the health of the patients and the public.

Preventing Multiple Patient Enrollment

Section 8.12 (D) indicates that OTPs ensure that patients are not enrolled in any other OTP upon admission. The Association recognizes that this proposed rule retains the existing regulation. It is interesting to note that very few states have a comprehensive computer based patient registry to prevent such multiple enrollments. How does the Secretary propose to implement this system where multiple patient enrollments would be prevented?

Lifting Prohibition on LAAM Take-Home Doses

The Rule recommends that "the Secretary has tentatively decided to remove the prohibition on the unsupervised use of LAAM." The Association understands that LAAM is provided in 279 treatment programs throughout the United States, based on the Association's 1998 survey. LAAM has been used for a number of years in OTPs. The Association supports removing the prohibition on the unsupervised use of LAAM in programs since we believe that it would be of enormous help to

the patients. Take home use of LAAM should follow the same criteria as proposed in option 2 for methadone take home doses.

Recommendations for Greater Clinical Flexibility for Methadone Take-Home Doses

The NPRM presents several options for modifying current take home medication requirements. The Association supports the intent of providing greater clinical flexibility in determining take home dosages for patients, who have met the criteria of current federal law, which are retained under the proposed rule in guiding the prescribing and dispensing of take home medication.

The Association urges the federal government to adopt a variation within option 2 following the Institute of Medicine recommendation. This variation would allow individual OTPs to dispense take home supply of medication for up to fourteen days following one year of treatment and up to a thirty-one day supply following two years of treatment, providing the patient has met the criteria as stipulated in the Proposed Rule.

This provision is consistent with recommendations for expanding access to the Association's policy on expanded medical maintenance treatment, however, it is presumed that all such treatment decisions are made on an individual patient basis through an organized treatment team at the program setting and that such patients continue to access comprehensive treatment.

SUMMARY

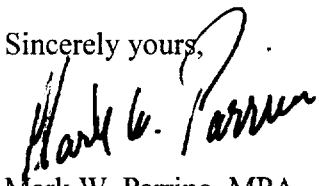
The Association supports the federal government's intent to shift regulatory oversight away from process oriented regulations to outcome oriented accreditation standards of care. We recommend that the federal government develop a fund to assist a treatment program in paying for such a shift in regulatory oversight in order to avoid a decrease in treatment capacity. We urge the federal government not to create a two tiered system of regulatory oversight holding OTPs accountable to accreditation standards and individual practitioners to a different and lesser standard of care. The development of such a two tiered system will create instability throughout the entire system of treatment and will be counter to the intent of the Proposed Rule.

We are hopeful that the individual states will either adopt accreditation standards or accept the results of accreditation surveys in lieu of their own state regulatory inspections as a means of avoiding duplication of effort and cost. This will require extraordinary cooperation among federal agencies and State Methadone Authorities to improve interagency

communication, which has been limited in the past. Fortunately, the Center for Substance Abuse Treatment has been working with the State Methadone Authorities during the past several years to improve such interagency communication.

Our Association views the Proposed Rule as only one piece of a federal strategy to increase access to care, to improve the quality of care currently offered, to expand new opportunities for patients and to educate the public about the value of methadone treatment. It moves the system to a new place in the evolutionary chain in addiction treatment.

Sincerely yours,



Mark W. Parrino, MPA
President

nrpmdraft

Appendix A

Direct/Indirect Costs of Accredited Methadone Treatment Programs

State	Florida	Michigan	Missouri	Pennsylvania	Rhode Island	Texas
Agency/ Date	JCAHO/ 1/99	JCAHO/ 9/98, 3/91, '83	JCAHO/ 4/99	JCAHO/ 9/27-29/99	JCAHO/ 10/96	JCAHO/ 1989
Application Fee	-	-	-	*Mock Survey*	-	-
Number of Surveyors	3	1	4		1	4
On-Site Cost	$33,300.00	$7,400.00	$14,000.00		$12,363.00	$10,000.00
Accredited Services	Inpatient partial hospital, outpatient drug abuse, child/adolescent	Methadone Program and Drug Free	Outpatient methadone, adolescent alcohol/drug abuse program	Methadone, drug free outpatient, prevention, partial hospital, HIV early intervention	All drug free and maintenance	Methadone outpatient, residential, detox, mental health services
Indirect Cost	$17,679.00 consultants and staff time	$10,000.00 staff time/per year	$35,000.00 staff time computer upgrade, physical plant and security upgrade	$7,055.00	$26,916.00 Mental Health Consultant (– infectious control manual) staff time (clinical supervisor & counselor)	$45,000.00 hire FT staff (Community Psychologist) staff time

Note:
These data were compiled through a survey of the state provider associations, which comprise the American Methadone Treatment Association. The information on this chart represents one methadone treatment program within that state.

Appendix A (Continued)

MASSACHUSETTS

City	Fall River	New Bedford
Agency/ Date	JCAHO/ 1999	JCAHO/ 1996/1999
Application Fee	-	-
Number of Surveyors	1	4
On-Site Cost	$3,500 - $5,000.00 based on census of 300 patients	$25,000.00 (multiple site fee)
Accredited Services	Methadone and Outpatient Substance Abuse	Substance Abuse and Mental Health Service, Methadone Program
Indirect Cost	$970.00 Staff time (PI projects)	Hire QI Director - $50k, MIS database Treatment satisfaction surveys, Staff time

NEW YORK

	Albany	Brooklyn	Long Island
Agency/ Date	JCAHO/ 11/98	JCAHO/ 3/98	JCAHO/ 1997
Application Fee	-	-	-
Number of Surveyors	4	1	1
On-site Cost	$15,000.00	$6,000.00	Absorbed by Hospital
Accredited Services	Article 28 Facility	Substance abuse treatment system - family health centers, ambulatory care services	Methadone Treatment
Indirect Cost	Absorbed by Hospital	Staff time, creating manuals, information systems upgrade	Staff time

Appendix B

State Authority Response, September 1999

State	# of Programs	# of Programs Receiving Block Grants	Excel/ Good/Fair /Poor	Violation of FDA Regs	Violation Of State Regs	Danger Of Closing	Technical Assistance (Prog./ Phys. Plant)
AL	15	2	G –13 F - 2	2	0	0	PP - 5
AK	1	1	F – 1	0	0	0	Prog – 1
AZ	-	Did	Not Choose	To	Complete	Inquiry	-
AR	2	1	E – 1 G – 1	0	0	0	PP-1 Both - 1
CA	-	Did	Not Choose	To	Complete	Inquiry	-
CO	9	5	E – 4 G- 5	0	0	0	Prog – 3 Both – 2
CT	18	15	-	0	0	0	Both - 16
DE	2	2	G- 1 F-1	0	0	0	Prog – 1
D.C.	5	2	E- 2 G – 2 F – 1	0	0	0	Prog - 1
FL	25	5	E- 5 F-20	0	0	0	Both 20
GA	19	5	E – 1 G –5 F-8 P- 5	0	5	1	Prog-9 PP-4 Both-4
HI	4	1	G – 3 P – 1	0	0	0	Both - 1
IL	43	30	E- 12 G- 25 F – 6	0	0	0	Both 6
IN	13	2	G- 13	0	0	0	Prog- 13
IA	2	1	G- 1 F- 1	0	0	0	Prog – 2
KS	5	0	G- 5	0	0	0	Prog – 5
KY	6	2	E- 2 F- 4	0	0	0	Prog – 6 PP – 4 Both –4
LA	11	1	G- 6 F- 5	N/A	1	1	0
ME	2	0	P- 2	0	1	1	Prog – 2
MD	35	18	E –10 G-11 F-6 P – 8	0	2	0	Prog –14 PP – 1 Both -1
MA	27	11	-	0	0	0	Both – 27
MI	31	19	-	0	0	0	0
MN	6	5	E – 2 G – 4	0	0	0	0

APPENDIX B (Continued)

State	# of Programs	# of Programs Receiving Block Grants	Excel/ Good/Fair /Poor	Violation of FDA Regs	Violation Of State Regs	Danger Of Closing	Technical Assistance (Prog./ Phys. Plant)
MO	8	4	E – 1 G – 3 F- 3 P – 1	0	1	0	Prog – 4
NE	1	1	G - 1	0	0	0	0
NV	6	N/A	G-6	N/A	N/A	N/A	N/A
NJ	32	22	G-6 F-26	Unkn	Unkn	Unkn	Prog – 26
NM	11	3	E – 1 G –2 F- 8	0	No regs yet	0	Both - 8
NY	124	44	E –88 G-31 F – 5	0	0	0	See note below
NC	13	8	E-1 G –5 F-6 P –1	1	1	0	Prog – 2
OH	9	N/A	N/A	N/A	N/A	N/A	N/A
OK	2	0	G-2	0	0	0	0
OR	13	5	E- 1 G- 5 F-7	0	0	0	Prog - 7
PA	28	22	E –10 G –7 F – 5 P – 6	1	6	0	Prog – 27
RI	8	5	E – 5 F- 3	0	0	0	Both – 3
SC	6	0	G – 2 F- 4	0	0	0	Prog – 5 PP – 3 Both – 3
TN	5	0	G – 4 F- 1	0	0	0	-
TX	70	12	E-17 G –30 F- 17 P-6	12	23	1	Prog – 20 PP – 5 Both- 5
UT	4	2	E – 2 F – 2	N/A	N/A	N/A	N/A
VA	9	9	E-3 G –4 F-1 P - 1	0	0	0	Prog – 1
WA	9	8	E- 2 G- 5 P – 2	2	2	0	Prog –3
WI	9	0	E- 2 G – 1 F-2 P –3	3	3	1	Prog –3 PP- 2 Both 2
	T	O	T	A	L	S	
40/42	648	273	E – 172 G – 209 F – 145 P – 36	21	45	5	Prog-155 PP – 25 Both-103

Note: The NY programs could benefit from TA concerning the development of written comprehensive policies and procedures as well as providing treatment to patients with secondary addictions to other drugs such as cocaine.

Appendix C

Criteria for Stable Patient Referral From Methadone Programs to Office Based Medical Practice Settings "Expanding Access to Medical Maintenance Treatment"

I **Program Involvement**: We recommend the following criteria for choosing the participating agencies:

a) Compliance with federal and state regulatory authorities.
b) Adherence to CSAT's State Methadone Treatment Guidelines and the American Methadone Treatment Association's Ethical Canon.
c) Licensed as a "Narcotic Treatment Program" for a minimum of two years.
d) Demonstrated internal protocols for reviewing patient eligibility, utilizing a multidisciplinary team approach including, at a minimum, the program's Medical Director, Nurse Manager, and the patient's counselor.
e) The program shall contract with the participating physicians.

II **Physician Involvement**: Demonstrated interest in the treatment of opioid dependent patients in his/her medical or psychiatric practices as defined by:

a) Certification by the American Board of Psychiatry and Neurology with subspecialty certification in addiction psychiatry, certification by the American Society of Addiction Medicine or Specialty Board Certification of Physicians of the American Osteopathic Association. It is recommended that physicians with such certification sit for a course on opioid pharmacotherapy as offered by the American Methadone Treatment Association or a recognized medical society.
b) Physicians without such certification, but with a documented two-year involvement in a methadone treatment program, should sit for a course on opioid pharmacotherapy as offered by the American Methadone Treatment Association or a recognized medical society.
c) Knowledge of specific methadone prescribing practices as regulated by state and federal law.
d) Practices consistent with CSAT's State Methadone Treatment Guidelines.
e) Agreement to provide progress reports to the sponsoring "Narcotic Treatment Program".
f) Agreement to work with the patient and program regarding relapses or unstable patients.
g) Provision for urine screens.
h) No pending state licensure actions against the participating physician.
i) Proof of minimum individual professional liability coverage as required by the State Medical Board of Examiners or equivalent thereof.

III **Patient Eligibility**: The patient must meet the following criteria:

a) Patient be physically and emotionally stable for 36 months.
b) The patient should be free of alcohol and drug abuse for 36 months verified by toxicology screening.
c) The patient has not been convicted of any criminal activity for 36 months.
d) The patient has been employed or in a similar capacity (a student, homemaker or disabled) for 36 months as well as a stable living environment.
e) Demonstrated responsible use of take home methadone through a participating licensed "Narcotic Treatment Program".

There may be exceptions granted to the 36 month criteria. Exceptions must be based on the individual's progress in treatment and recommendations made by the treatment team as documented in the clinical record. The process for which this decision can be made must be endorsed and reviewed by the State Regulatory Authority.

IV **Organizational Issues:**

1) **Professional and agency liability**:

   a) A copy of the physician's professional liability insurance would be included in the physician's file, which would be kept at the program site.
   b) Professional liability coverage would be incorporated into the contractual agreement with participating physicians.

2) **Methadone distribution to participating physicians:**

   a) The participating physicians will be registered under the umbrella of the narcotic treatment program license.
   b) A personnel file with resumes, license, registration numbers, personal professional liability insurance carrier, and contract to provide this service would be on file with the program.
   c) The administration and dispensing of methadone hydrochloride in an "off-site" physician based practice will require a change in federal and state laws and regulations.

3) **Discontinuation of off-site services:** Patients will be referred back to the base "Narcotic Treatment Program" for continued services for the following reasons:

   a) Signs and/or symptoms of recurring drug or alcohol misuse.
   b) Negative methadone urine screens or positive for drugs not appropriately prescribed.

c) Significant changes in mental/physical/behavioral status that would require more patient supervision.
d) Noncompliance with medical care.
e) Evidence of criminal activity (drug or other).

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