Bill as Introduced

SB 445-FN – AS AMENDED BY THE SENATE

3/9/00 3582s
3/9/00 3711s

2000 SESSION

00-2748
01/09

SENATE BILL ***445-FN***

AN ACT relative to methadone maintenance treatment.

SPONSORS: Sen. Wheeler, Dist 21; Sen. Squires, Dist 12; Sen. Russman, Dist 19; Rep. Chabot, Hills 48; Rep. Flora, Hills 15; Rep. O'Keefe, Rock 21; Rep. Taylor, Straf 11

COMMITTEE: Public Institutions, Health and Human Services

AMENDED ANALYSIS

This bill requires the commissioner of the department of health and human services to adopt rules relative to methadone maintenance treatment.

Explanation: Matter added to current law appears in ***bold italics.***
Matter removed from current law appears [~~in brackets and struckthrough.~~]
Matter which is either (a) all new or (b) repealed and reenacted appears in regular type.

SB 445-FN – AS AMENDED BY THE SENATE

3/9/00 3582s
3/9/00 3711s

00-2748
01/09

STATE OF NEW HAMPSHIRE

In the Year of Our Lord Two Thousand

AN ACT relative to methadone maintenance treatment.

Be it Enacted by the Senate and House of Representatives in General Court convened:

1 Methadone Maintenance Treatment; Rulemaking. RSA 318-B:10, VIII is repealed and reenacted to read as follows:

VIII. The commissioner of health and human services shall adopt rules, pursuant to RSA 541-A, relative to methadone maintenance treatment. Except as otherwise specified, no methadone maintenance programs may be initiated until the commissioner adopts rules as required under this paragraph or until 2 years after the effective date of this paragraph, whichever is sooner. Notwithstanding the above, nothing in this paragraph shall be construed as prohibiting or limiting the provision of methadone detoxification services or from prohibiting or limiting those already providing methadone detoxification or maintenance services as of January 1, 2000, from providing methadone maintenance services upon the effective date of this paragraph.

2 Repeal. RSA 318-B:10, VII, relative to methadone maintenance.

3 Effective Date. This act shall take effect 60 days after its passage.

LBAO
00-2748
12/16/99

SB 445-FN - FISCAL NOTE

AN ACT establishing a opioid treatment pilot program.

FISCAL IMPACT:

The Department of Health and Human Services indicates this bill will increase state expenditures by $76,000 in FY 2001, by $424,000 in FY 2002, by $224,000 in FY 2003 and FY 2004 and by an indeterminable amount each year thereafter. There will be no fiscal impact on state, county, and local revenues or on county and local expenditures.

METHODOLOGY:

The Department assumes 112 of the estimated 371 heroin users in New Hampshire would seek treatment in the pilot program, and 56 of these users will require state assistance. The average cost per client for existing programs is $4,000 per year. General funds would be required since only five percent of the clients would be Medicaid-eligible. The Department would require a consultant experienced in methadone treatment to develop the program and assist with establishing the rules and the approval of participating providers. To complete the required report on program operation and efficacy the Department proposes a university-based study in FY 2002. Expenditures beyond the pilot program would be necessary to support continued treatment for clients participating in the pilot. Based on the effective date of January 1, 2001, the program would be operational on April 1, 2001.

	FY 2001	FY 2002	FY 2003	FY 2004
Treatment (56 clients $4,000)	$56,000	$224,000	$224,000	$224,000
Evaluation Study				
Personnel and Consultants		129,000		
Supplies, travel , lab fees, etc.		30,000		
University Overhead Costs		41,000		
Program Consultant	20,000			
Totals	$76,000	$424,000	$224,000	$224,000

Amendments

Rep. Christie, Rock. 22
April 13, 2000
2000-4128h
01/09

Amendment to SB 445-FN

Amend the bill by replacing all after the enacting clause with the following:

1 Methadone Maintenance Treatment; Rulemaking. RSA 318-B:10, VII is repealed and reenacted to read as follows:

VII. The department of health and human services is hereby declared to be the state methadone authority. The department of health and human services shall, on or before December 31, 2000, adopt rules pursuant to RSA 541-A, relative to:

(1) Eligibility for the program.

(2) Length of time in the program.

(3) Security measures to prevent diversion of methadone to illegal use.

(4) Any other provisions necessary to implement the purposes of this paragraph.

Once the rules are adopted pursuant to this paragraph, providers may operate a methadone maintenance program in the state of New Hampshire. For the purposes of this paragraph, "methadone maintenance program" means a program designed to substitute the administration of methadone for the illegal use of heroin over a period of time beyond the minimum necessary to resolve physiological addiction to heroin. Nothing in this paragraph shall prohibit a practitioner from administering, prescribing, or dispensing a controlled drug under paragraph I.

2 New Paragraph; Definition Added. Amend RSA 318:1 by inserting after paragraph VII the following new paragraph:

VII-a. "Limited retail drug distributor" means federally funded clinics operated under contract with the department of health and human services and drug abuse treatment centers, where legend and controlled drugs are held, stored or dispensed to patients pursuant to the order of an authorized practitioner.

3 New Section; Licensing of Limited Retail Drug Distributors Required.

318:51-b Licensing of Limited Retail Drug Distributors Required.

I. No person shall operate as a limited retail drug distributor, as defined in RSA 318:1, VII-a, without first having obtained a license to do so from the board. Such license shall expire annually on June 30. An application together with a reasonable fee as established by the board shall be filed annually on or before July 1.

II. No license shall be issued under this section unless the applicant has furnished proof satisfactory to the board that:

(a) The applicant is of good moral character or, if that applicant is an association or

corporation, that the managing officers are of good moral character.

(b) The applicant has sufficient space and security equipment as to properly carry on the business described in the application.

(c) The license granted by this chapter shall at all times be displayed in a conspicuous place in the facility for which it is issued.

(d) The applicant has a written contract with a pharmacist licensed in the state to serve as a consultant on all matters relating to the storage and dispensing of prescription drugs.

III. No license shall be granted to any person who has within 5 years been convicted of a violation of any law of the United States, or of any state, relating to drugs, as defined in this chapter or RSA 318-B, or to any person who is a drug-dependent person.

IV. Any person licensed pursuant to this section is subject to the provisions of RSA 318:29.

4 Licensure Required. RSA 318:42, VII(d) is repealed and reenacted to read as follows:

(d) The clinic, except for clinics operated directly by the department of health and human services, possesses a current limited retail drug distributor's license under RSA 318:51-b.

5 Repeal. RSA 318:42, VII(e), relative to drug wholesaler's license is repealed.

6 Repeal. RSA 318-B:10, VIII, relative to certain methadone maintenance treatment, is repealed.

7 Contingency. Section 6 of this act shall take effect on the date when the rules required under section 1 of this act are adopted.

8 Applicability.

I. Notwithstanding the above, nothing in this act shall be construed as prohibiting or limiting the provision of methadone detoxification services or as prohibiting or limiting treatment for those persons in treatment under RSA 318-B:10, VIII, as of the effective date of this act, until the rules required pursuant to section 1 of this act are adopted. Any methadone detoxification program shall cease to operate on December 31, 2000 if the rules required under section 1 of this act have not been adopted.

II. Any provider under this section may provide treatment as long as the provider meets Commission on Accreditation of Rehabilitation Facilities (CARF) accreditation standards and is licensed by the federal Food and Drug Administration and the federal Drug Enforcement Administration, and otherwise meets all applicable state and federal laws and regulations.

9 Effective Date.

I. Section 6 of this act shall take effect as provided in section 7 of this act.

II. The remainder of this act shall take effect upon its passage.

2000-4128h

AMENDED ANALYSIS

This bill requires the commissioner of the department of health and human services to adopt rules relative to methadone maintenance treatment.

This bill also requires limited retail drug distributors to be licensed by the New Hampshire pharmacy board.

Rep. Christie, Rock. 22
April 18, 2000
2000-4154h
01/09

Amendment to SB 445-FN

Amend the bill by replacing all after the enacting clause with the following:

1 Methadone Maintenance Treatment; Rulemaking. RSA 318-B:10, VII is repealed and reenacted to read as follows:

VII. The department of health and human services is hereby declared to be the state methadone authority. The department of health and human services shall, on or before December 31, 2000, adopt rules pursuant to RSA 541-A, relative to methadone maintenance programs as follows:

(1) Eligibility for the program.

(2) Length of time in the program.

(3) Security measures to prevent diversion of methadone to illegal use.

(4) Any other provisions necessary to implement the purposes of this paragraph.

Once the rules are adopted pursuant to this paragraph, providers may operate a methadone maintenance program in the state of New Hampshire. In implementing this paragraph, the department shall not use the interim rulemaking process specified in RSA 541-A:19. For the purposes of this paragraph, "methadone maintenance program" means a program designed to substitute the administration of methadone for the illegal use of heroin over a period of time beyond the minimum necessary to resolve physiological addiction to heroin. Nothing in this paragraph shall prohibit a practitioner from administering, prescribing, or dispensing a controlled drug under paragraph I.

2 New Paragraph; Definition Added. Amend RSA 318:1 by inserting after paragraph VII the following new paragraph:

VII-a. "Limited retail drug distributor" means federally funded clinics operated under contract with the department of health and human services and drug abuse treatment centers, where legend and controlled drugs are held, stored or dispensed to patients pursuant to the order of an authorized practitioner.

3 New Section; Licensing of Limited Retail Drug Distributors Required.

318:51-b Licensing of Limited Retail Drug Distributors Required.

I. No person shall operate as a limited retail drug distributor, as defined in RSA 318:1, VII-a, without first having obtained a license to do so from the board. Such license shall expire annually on June 30. An application together with a reasonable fee as established by the board shall be filed annually on or before July 1.

II. No license shall be issued under this section unless the applicant has furnished proof satisfactory to the board that:

(a) The applicant is of good moral character or, if that applicant is an association or corporation, that the managing officers are of good moral character.

(b) The applicant has sufficient space and security equipment as to properly carry on the business described in the application.

(c) The license granted by this chapter shall at all times be displayed in a conspicuous place in the facility for which it is issued.

(d) The applicant has a written contract with a pharmacist licensed in the state to serve as a consultant on all matters relating to the storage and dispensing of prescription drugs.

III. No license shall be granted to any person who has within 5 years been convicted of a violation of any law of the United States, or of any state, relating to drugs, as defined in this chapter or RSA 318-B, or to any person who is a drug-dependent person.

IV. Any person licensed pursuant to this section is subject to the provisions of RSA 318:29.

4 Licensure Required. RSA 318:42, VII(d) is repealed and reenacted to read as follows:

(d) The clinic, except for clinics operated directly by the department of health and human services, possesses a current limited retail drug distributor's license under RSA 318:51-b.

5 Repeal. RSA 318:42, VII(e), relative to drug wholesaler's license is repealed.

6 Repeal. RSA 318-B:10, VIII, relative to certain methadone maintenance treatment, is repealed.

7 Contingency. Section 6 of this act shall take effect on the date when the rules required under section 1 of this act are adopted.

8 Applicability.

I. Notwithstanding the above, nothing in this act shall be construed as prohibiting or limiting the provision of methadone detoxification services or as prohibiting or limiting treatment for those persons in treatment under RSA 318-B:10, VIII[~~, as of the effective date of this act, until the rules required pursuant to section 1 of this act are adopted~~]. Except for treatment provided pursuant to RSA 318-B:10, VIII, any methadone detoxification program shall cease to operate on December 31, 2000 if the rules required under section 1 of this act have not been adopted.

II. Any provider under this section may provide treatment as long as the provider meets Commission on Accreditation of Rehabilitation Facilities (CARF) accreditation standards and is licensed by the federal Food and Drug Administration and the federal Drug Enforcement Administration, and otherwise meets all applicable state and federal laws and regulations.

9 Effective Date.

I. Section 6 of this act shall take effect as provided in section 7 of this act.

II. The remainder of this act shall take effect upon its passage.

2000-4154h

AMENDED ANALYSIS

This bill requires the commissioner of the department of health and human services to adopt rules relative to methadone maintenance treatment.

This bill also requires limited retail drug distributors to be licensed by the New Hampshire pharmacy board.

Criminal Justice and Public Safety
May 2, 2000
2000-4325h
01/09

Amendment to SB 445-FN

Amend the bill by replacing all after the enacting clause with the following:

1 Methadone Maintenance Treatment; Rulemaking. RSA 318-B:10, VII is repealed and reenacted to read as follows:

VII.(a) The department of health and human services is hereby declared to be the state methadone authority.

(b) The commissioner of the department of health and human services shall, on or before June 30, 2001, adopt and have in effect rules, pursuant to RSA 541-A, relative to detoxification and methadone maintenance programs as follows:

(1) Application procedure and standards for approval for certification and re-certification of providers to operate detoxification and methadone maintenance programs, including certification period, for each type of certification.

(2) Eligibility of individuals for admission to such programs.

(3) Qualifications of program personnel.

(4) Program content, including, but not limited to, services to be offered by the program.

(5) Mandatory records and reports to the department.

(6) Security measures to prevent diversion of methadone to illegal use.

(7) Confidentiality and disclosure of identifying information, records and reports.

(8) Financial responsibility.

(9) Any other provision necessary to implement the purposes of this paragraph.

(c) Providers may operate a methadone detoxification or methadone maintenance program, or both, in the state of New Hampshire only if the providers are certified to operate pursuant to rules adopted under subparagraph VII(b). In implementing subparagraph VII(b), the commissioner shall not use the interim rulemaking process in RSA 541-A:19.

(d) For the purposes of this paragraph:

(1) "Heroin" means an illegal semi-synthetic drug produced from the morphine contained in sap of the opium poppy, and known to have the potential for devastating addictive properties in vulnerable individuals.

(2) "Methadone" means a legal drug, methadone hydrochloride, which is a synthetic opiod that has been demonstrated to be an effective treatment agent for heroin abuse and dependence.

(3) "Methadone detoxification treatment" means the dispensing of methadone or similar substance in decreasing doses to an individual in order to reduce or eliminate adverse physiological or psychological effects incident to the withdrawal from the sustained use of heroin.

(4) "Methadone maintenance program" means a substance abuse treatment program substituting methadone or any of its derivatives, over time, to relieve withdrawal symptoms of heroin dependence, to reduce craving, and to permit normal functioning and engagement in rehabilitative services.

(e) Nothing in this paragraph shall prohibit a licensed health care practitioner from administering, prescribing, or dispensing a controlled drug under paragraph I.

2 Applicability. Notwithstanding RSA 318-B:10, VII(c) as inserted by section 1 of this act, existing providers of methadone detoxification programs licensed pursuant to federal statute and regulations may continue to operate without certification under paragraph VII for up to 90 days after the effective date of rules adopted under RSA 318-B:10, VII(b) as inserted by section 1 of this act.

3 Applicability.

I. Notwithstanding the above, nothing in this act shall be construed as prohibiting or limiting the provision of methadone detoxification treatment or from prohibiting or limiting treatment for those persons in treatment under RSA 318-B:10, VIII. Any other methadone detoxification treatment shall cease to operate on June 30, 2001 if the rules required under section 1 of this act have not been adopted.

II. Any provider under this section may provide treatment as long as the provider meets Commission on Accreditation of Rehabilitation Facilities (CARF) accreditation standards and is licensed by the federal Food and Drug Administration and the federal Drug Enforcement Administration, and otherwise meets all applicable state and federal laws and regulations.

4 New Paragraph; Definition Added. Amend RSA 318:1 by inserting after paragraph VII the following new paragraph:

VII-a. "Limited retail drug distributor" means federally funded clinics operated under contract with the department of health and human services and drug abuse treatment centers, where legend and controlled drugs are held, stored or dispensed to patients pursuant to the order of an authorized practitioner.

5 New Section; Licensing of Limited Retail Drug Distributors Required.

318:51-b Licensing of Limited Retail Drug Distributors Required.

I. No person shall operate as a limited retail drug distributor, as defined in RSA 318:1, VII-a, without first having obtained a license to do so from the board. Such license shall expire annually on June 30. An application together with a reasonable fee as established by the board shall be filed annually on or before July 1.

II. No license shall be issued under this section unless the applicant has furnished proof

satisfactory to the board that:

(a) The applicant is of good moral character or, if that applicant is an association or corporation, that the managing officers are of good moral character.

(b) The applicant has sufficient space and security equipment as to properly carry on the business described in the application.

(c) The license granted by this chapter shall at all times be displayed in a conspicuous place in the facility for which it is issued.

(d) The applicant has a written contract with a pharmacist licensed in the state to serve as a consultant on all matters relating to the storage and dispensing of prescription drugs.

III. No license shall be granted to any person who has within 5 years been convicted of a violation of any law of the United States, or of any state, relating to drugs, as defined in this chapter or RSA 318-B, or to any person who is a drug-dependent person.

IV. Any person licensed pursuant to this section is subject to the provisions of RSA 318:29.

6 Licensure Required. RSA 318:42, VII(d) is repealed and reenacted to read as follows:

(d) The clinic, except for clinics operated directly by the department of health and human services, possesses a current limited retail drug distributor's license under RSA 318:51-b.

7 Repeal. RSA 318:42, VII(e), relative to drug wholesaler's license is repealed.

8 Effective Date. This act shall take effect upon its passage.

2000-4325h

AMENDED ANALYSIS

This bill requires the commissioner of the department of health and human services to adopt rules relative to methadone maintenance treatment.

This bill also requires limited retail drug distributors to be licensed by the New Hampshire pharmacy board.

Criminal Justice and Public Safety
May 3, 2000
2000-4358h
01/09

Amendment to SB 445-FN

Amend the bill by replacing all after the enacting clause with the following:

1 Methadone Maintenance Treatment; Rulemaking. RSA 318-B:10, VII is repealed and reenacted to read as follows:

VII.(a) The department of health and human services is hereby declared to be the state methadone authority.

(b) The commissioner of the department of health and human services shall, on or before June 30, 2001, adopt and have in effect rules, pursuant to RSA 541-A, relative to detoxification and methadone maintenance programs as follows:

(1) Application procedure and standards for approval for certification and re-certification of providers to operate detoxification and methadone maintenance programs, including certification period, for each type of certification.

(2) Eligibility of individuals for admission to such programs.

(3) Qualifications of program personnel.

(4) Program content, including, but not limited to, services to be offered by the program.

(5) Mandatory records and reports to the department.

(6) Security measures to prevent diversion of methadone to illegal use.

(7) Confidentiality and disclosure of identifying information, records and reports.

(8) Financial responsibility.

(9) Any other provisions necessary to implement the purposes of this paragraph.

(c) Providers may operate a methadone detoxification or methadone maintenance program, or both, in the state of New Hampshire only if the providers are certified to operate pursuant to rules adopted under subparagraph VII(b). In implementing subparagraph VII(b), the commissioner shall not use the interim rulemaking process in RSA 541-A:19.

(d) For the purposes of this paragraph:

(1) "Heroin" means an illegal semi-synthetic drug produced from the morphine contained in sap of the opium poppy, and known to have the potential for devastating addictive properties in vulnerable individuals.

(2) "Methadone" means a legal drug, methadone hydrochloride, which is a synthetic opiod that has been demonstrated to be an effective treatment agent for heroin abuse and dependence.

(3) "Methadone detoxification treatment" means the dispensing of methadone or similar substance in decreasing doses to an individual in order to reduce or eliminate adverse physiological or psychological effects incident to the withdrawal from the sustained use of heroin.

(4) "Methadone maintenance program" means a substance abuse treatment program substituting methadone or any of its derivatives, over time, to relieve withdrawal symptoms of heroin dependence, to reduce craving, and to permit normal functioning and engagement in rehabilitative services.

(e) Nothing in this paragraph shall prohibit a licensed health care practitioner from administering, prescribing, or dispensing a controlled drug under paragraph I.

2 Applicability. Notwithstanding RSA 318-B:10, VII(c) as inserted by section 1 of this act, methadone detoxification programs licensed pursuant to federal statute and regulations may operate without certification under paragraph VII for up to 90 days after the effective date of rules adopted under RSA 318-B:10, VII(b) as inserted by section 1 of this act.

3 Applicability.

I. Notwithstanding the above, nothing in this act shall be construed as prohibiting or limiting the provision of methadone detoxification treatment or from prohibiting or limiting treatment for those persons in treatment under RSA 318-B:10, VIII. Any other methadone detoxification treatment shall cease to operate on June 30, 2001 if the rules required under section 1 of this act have not been adopted.

II. Any provider under this section may provide treatment as long as the provider meets Commission on Accreditation of Rehabilitation Facilities (CARF) accreditation standards and is licensed by the federal Food and Drug Administration and the federal Drug Enforcement Administration, and otherwise meets all applicable state and federal laws and regulations.

4 New Paragraph; Definition Added. Amend RSA 318:1 by inserting after paragraph VII the following new paragraph:

VII-a. "Limited retail drug distributor" means federally funded clinics operated under contract with the department of health and human services and drug abuse treatment centers, where legend and controlled drugs are held, stored or dispensed to patients pursuant to the order of an authorized practitioner.

5 New Section; Licensing of Limited Retail Drug Distributors Required.

318:51-b Licensing of Limited Retail Drug Distributors Required.

I. No person shall operate as a limited retail drug distributor, as defined in RSA 318:1, VII-a, without first having obtained a license to do so from the board. Such license shall expire annually on June 30. An application together with a reasonable fee as established by the board shall be filed annually on or before July 1.

II. No license shall be issued under this section unless the applicant has furnished proof satisfactory to the board that:

(a) The applicant is of good moral character or, if that applicant is an association or corporation, that the managing officers are of good moral character.

(b) The applicant has sufficient space and security equipment as to properly carry on the business described in the application.

(c) The license granted by this chapter shall at all times be displayed in a conspicuous place in the facility for which it is issued.

(d) The applicant has a written contract with a pharmacist licensed in the state to serve as a consultant on all matters relating to the storage and dispensing of prescription drugs.

III. No license shall be granted to any person who has within 5 years been convicted of a violation of any law of the United States, or of any state, relating to drugs, as defined in this chapter or RSA 318-B, or to any person who is a drug-dependent person.

IV. Any person licensed pursuant to this section is subject to the provisions of RSA 318:29.

6 Licensure Required. RSA 318:42, VII(d) is repealed and reenacted to read as follows:

(d) The clinic, except for clinics operated directly by the department of health and human services, possesses a current limited retail drug distributor's license under RSA 318:51-b.

7 Repeal. RSA 318:42, VII(e), relative to drug wholesaler's license is repealed.

8 Effective Date. This act shall take effect upon its passage.

2000-4358h

AMENDED ANALYSIS

This bill requires the commissioner of the department of health and human services to adopt rules relative to methadone maintenance treatment.

This bill also requires limited retail drug distributors to be licensed by the New Hampshire pharmacy board.

Speakers

SIGN UP SHEET

To Register Opinion If Not Speaking

Bill # SB 445 Date APRIL 11, 2000

Committee CJ + PS

**** Please Print All Information ****

Name	Address	Phone	Representing	(check one) Pro	Con
Russell Jones		~~526-2006~~ 225-2983	NHPHA	✓	
Lisa K. Carpenter	New London	526-8899	NHNA/NHNPA (NURSES)	✓	
DENISE DEVLIN, LADC	KINGSTON	642-8719	MYSELF	✓	
Seddon Savage	Newbury	938-2894	NH Med Soc		

SIGN UP SHEET

To Register Opinion If Not Speaking

Bill # SB 444 Date APRIL 11, 2000

Committee CJ + PS

**** Please Print All Information ****

Name	Address	Phone	Representing	(check one) Pro	Con
RUSSELL JONES	MD, MPH	~~526-2983~~ 228-2983	NHPHA	✓	
Lisa LaClair	New London	526-8899	NH Nurses + Nurse Prac. Practitioners	✓	
Eva Scatuzzi	Concord			✓	
DENISE DEVLIN, LADC	Kingston	642-8717	MYSELF		

SIGN UP SHEET

To Register Opinion If Not Speaking

Bill # ______________________ Date ______________________

Committee ____

**** Please Print All Information ****

Name	Address	Phone	Representing	(check one) Pro	Con
Bob CHABOT (REP)	MANCHESTER			✓	
Rep Barbara C. French	Merr 3			✓	
Rep Gloria Seldin	Merr 17			✓	

Hearing Minutes

HOUSE COMMITTEE ON CRIMINAL JUSTICE AND PUBLIC SAFETY

PUBLIC HEARING ON SB 445-FN

BILL TITLE: (New Title) relative to methadone maintenance treatment.

DATE: April 11, 2000

LOB ROOM: 204 **Time Public Hearing Called to Order:** 10:15 am

Time Adjourned: 12:30 pm

(please circle if present)

Committee Members: Reps. Welch, Christie, Hansen, Dunham, Sargent, Pepino, Flora, Mikowleit, Fesh, Weare, Andrews, J. Johnson, Tholl, Knowles, Doucette, Berube, Schanda, O'Keefe, McCarthy, Robertson, Callaghan and Rodd

Bill Sponsors: Sen. Wheeler, Dist 21; Sen. Squires, Dist 12; Sen. Russman, Dist 19; Rep. Chabot, Hills 48; Rep. Flora, Hills 15; Rep. O'Keefe, Rock 21, Rep. Tay.lor, Straf 11

TESTIMONY

* Use asterisk if written testimony and/or amendments are submitted.

See Attached ~~See SB 445~~

New Hampshire House of Representatives
Criminal Justice and Public Safety Committee
Committee Minutes

Bill Number - SB 444 and SB 445 **Date of meeting** - April 11, 2000
Presiding - Rep. David A. Welch, Chairman

Testifying:

*1. Sen. K. Wheeler, Dist. # 21, prime sponsor, in support. Bill is the result of a study committee from a bill Rep. O'Keefe sponsored. Lack of substance abuse treatments in NH. This would repeal ban against Methadone Maintenance Treatment (MMT). Heroin addicts are traveling out of state to get MMT. We only allow now for detoxification, (6 months), and treatment of women while pregnant. Study shows 6 months detox isn't a cure. ***(See copy of letter from N.H. Assn. Of Chiefs of Police, taking no position.)***

In answer to question from Rep. Welch: Fiscal note needs to be removed. Was there initially because there was a pilot program.

2. Rep. D. Lozeau, Hillsborough Dist. #30, Deputy Speaker, in opposition. RSA 318 B:10 VIII is the exception for pregnant women, passed 5 years ago. Philosophy was to take care of the child. Incidence of drug use is cyclical – yes, is on the rise, now. We don't give replacement drug to alcoholics. Don't like to think we're treating with methadone for a lifetime. Used to be only hospitals could dispense methadone. Now there's a for-profit clinic offering it. Asks the committee to please go slowly. Speaker Sytek will submit testimony against the bill. Bad policy to replace an addiction to an illegal substance with an addition to a legal substance. Suggests, if anything, should be a pilot project.

* 3. Dr. Seddon Savage, 171 Pleasant View Rd., Newbury, NH (938-2894), rep. NH Medical Society, in support. He's a specialist in opiod treatment. ***(See data supporting expanding program; testimony; statement from National Institute of Health)***. Do have drugs for alcohol – antabuse, etc. Lots of data supporting the use of methadone. We make insulin available to patients who could control their diabetes without insulin. Heroin use, over time, can change the brain, maybe permanently. If so, person can experience a consistent need. Most people would prefer to be drug free, rather than drive to methadone clinic daily. Other drugs are being used experimentally. Seems there is a stigma attached to name, methadone. People on methadone experience no high, no withdrawal, no cravings. Reduced morbidity, HIV transmission, heroin-related crimes, health problems. Helps people return to work and productive life style. No impairment while on methadone. Psycho-social therapy is required along with the methadone treatment. Some pilots now in US give methadone treatment in physician's office – it used to be usual prior to 1920).

* 4. NH Atty. General Philip McLaughlin, no position indicated. ***(See written testimony.)*** Talked about law enforcement in fight against drugs. We are not winning the war on drugs. Can not arrest or enforce our way out of the problem. Have education efforts, too. Gave mortality figures for several years. We need the 3rd prong to combat drugs – treatment. Need to combat the myth that the addict is not someone like us. Need to listen to the medical community views.

*5. Dr. John C. Dalco, 7 North State St., Concord, NH (224-1909), rep. NH Medical Society, in support. ***(See written testimony.)*** Has worked 17 years in addiction treatment. You're not replacing one high for another. There is no high. Talked about reduction of public health problems as a result of MMT. Sees it as cost effective. Talked about spread of Hepatitis C. Biggest factor is IV drug use.

Rep. Welch: re: clinic in Hudson? Referrals are usually word of mouth. Now the press coverage has also helped people know where it is.

In answer to question from Rep. Doucette: Do use methadone to get off prescription drugs, too.

Continued on page 2

In answer to question from Rep. Knowles: Blue Cross in Mass. Covers MMT for years, even.

* 6. Dr. Russell Jones, 95 North State St., Concord, NH (228-2983), Chairman, NH Public Health Assn., in strong support. ***(See written testimony.)*** Talked of similar issues of benefits of MMT. Abstinence is ideal, but MMT is next best.

7. Rep. J. Piliod, Belmont, in support. Also, a physician. Was astonished at lack of MMT in N.H. We don't deny treatment for most things, but do for this. Every hospital should have a MMT program.

* 8. John Bunker, Huddleston Hall, Durham, NH (862-3706), Executive Director, New Futures, in support. ***(See written testimony.)*** New Futures' mission: work on effective strategies to reduce alcohol, tobacco and other drug problems through criminal justice, education, prevention, public policy and treatment initiatives.

9. George Rosado, Manchester, representing self, in opposition. Was a heroin addict, himself. Buried many relatives. Been clean for 25 years. Now is a pastor in Manchester and runs a clinic with his wife for addicts. He's opposed to methadone, as it's substituting one drug for another. (Several questions from committee about his clinic, coming off 'cold turkey', etc.)

* 10. Timothy Hartnet, NH Dept. of Health and Human Services, Division of Alcohol and Drug Abuse Prevention and Recovery, 105 Pleasant St., Concord, (271-6105), in support. ***(See written testimony and other materials.)***

Rep. Knowles: Why require a one year documented use of the drug? Response: To ensure that there is an addiction.

11. Denise Devlin, LADC, former director of BSAS. Referred to Rep. Lozeau re: the history the methadone ban in NH. In 1992, Concerns about who would control methadone services resulted in the ban, along with concerns about legal repercussions. In 1996, the pregnant woman/child issue with opiate addiction. The Peri-natal Task Force was created and then the pilot program for treatment with methadone for pregnant women was created. Suggests it would not be a 180 degree turn as suggested by Rep. Lozeau. New brain chemistry research and what our neighbors have experienced, (especially Maine), supports this. Has found that many people are still on methadone, while others gave up the methadone after a shorter period of time. This is about giving people treatment options.

Rep. Welch: Should a clinic be operating without rules? Hartnett: We've committed to Sen. Squires that there is a draft of rules already.

12. Sara Miller, R.N., N.H. Nurses Assn., in support. Has spent time at the clinic in Hudson. Did not see any loitering. 90% of clients work full time. About 65 clients are served, subjected to urinalysis. The best outcomes have been shown to couple comprehensive social services with medication.

Rep. Knowles: Is Hudson non-profit. Response: Not to my knowledge.

13. Peter Grasso, N.H. Board of Pharmacy, in support. Regulatory practices are the basis of these bills; to regulate and ensure compliance. NH Board of Pharmacy will be a part of the process. Methadone can only be prescribed for intractable pain at this time.

* 14. Ed Dania-Blonjarz and Norma Reppucci, R.N., Community Substance Abuse Centers, Hudson. They are in total compliance with local, state, federal regulations. Methadone and LAAM are available for a total of 180 days. ***(See letters from clients, describing benefits of methadone treatment.)***

In answer to question from Rep. Christie, Jr. – Total of 76 clients, all from NH.

Continued on page 3

There is a 7 day mandatory waiting period between 180 day treatment periods. (After 180 days, treatment stops.)
Empire, Blue Cross/Blue Shield and Tufts insurances currently pay for methadone services.

Rep. Maxwell D. Sargent - Clerk

April 12 – Executive Session

Further discussion included:
Hudson clinic – stabilize patient in 3 or 4 months; then start slow detox process. 21 people have been discharged; have re-admitted 4. No revolving door intent.
Federal law prohibits doctors from prescribing it in office.
Michael Greene, Habit Management (Mass.): Need maybe 70 – 80 clients to make it worthwhile to begin a free-standing clinic. Or can partnership with an existing drug counseling clinic. Ohio is the only state which limits MMT centers to non-profits, and they have state funding.
Though CARF certification is not yet achievable, can adhere to CARF standards.

A straw poll of committee members showed 12 – 1 that the committee did not want to limit the MMT centers to non-profits, only.

No vote was taken on the bill.

Sub-Committee Minutes

New Hampshire House of Representatives
Criminal Justice and Public Safety Committee
Sub-Committee Minutes

Bill Number - SB 444-FN and SB 445-FN **Date of meeting** - April 18, 2000
Presiding - Rep. David A. Welch, Chairman

(Sub-committee of the whole) Attending: Reps. Welch, Knowles, Flora, O'Keefe, Rodd, Weare, Tholl, Dyer, Sargent. Senator K. Wheeler.

Both bills are supposed to go to the Finance Committee when they leave here.
Sen. Wheeler: Doctors are working on 'opiod substance' definition. Hudson clinic is now operating on Federal rules and CARF. Doesn't think clinic went beyond what the statute implies, (re: treating for opiods other than heroin.) If so, there was nothing deliberate. Questions the date of Dec. 31 as being not enough time for rule making.
Rep. Dyer: End of February is more realistic.
Sen. Wheeler: Would prefer the end of June, 2001.
Page 2, line 29 of Christie amendment 4/18/00 should be left out altogether as that line refers to detox.
Add "methadone maintenance can not begin until rules are promulgated".

There are no state rules for detox. Tim Hartnett, Health and Human Services, agreed to add in detox rules.

Discussion re: there are already legitimate avenues for detoxing off legitimate drugs like codeine, etc., versus no legal methods to get off heroin. Questioning the need to change the word "heroin" to opiods.

Rep. Flora: RSA 318B VIII says rules need to be written for detox for pregnant and post partum women.
Hartnett: No rules exist.

Rep. Dyer: With methadone, you are substituting aless addictive drug for an addictive drug. Maybe should expand it to morphine, too.

Federal regulations for use of methadone say the person has to have been drug dependent for at least a year.

Eva Sartwell spoke: daughter 34 has to go to Lowell, Mass. Every day for methadone treatment. Probably will be on it for the rest of her life. Difficult to do all of that traveling. Counseling is an important part of the treatment, too.

Sub-committee appointed: Rep. Sargent, chair; Reps. Flora, Knowles, O'Keefe, Rodd, Weare and: Reps. M. Goulet, M. Dyer

Rep. Maxwell D. Sargent - Clerk

New Hampshire House of Representatives
Criminal Justice and Public Safety Committee
Sub-Committee Minutes

Bill Number - SB 444-FN and SB 445-FN **Date of meeting** - April 29, 2000 **10:00 a.m.**
Presiding - Rep. Maxwell D. Sargent, Sub-committee chair

Attending: Reps. Knowles, Flora, O'Keefe, Rodd, Weare, Dyer, Goulet, Doucette, Schanda, Sargent. Senator K. Wheeler.

Marie Bailinson went over the areas of agreement. Problem with detox and maintenance issues.

Rep. Flora stated the need for maintenance rules. Do opiod treatment programs for detox require longer treatment?

Rep. Dyer: wants heroin to remain in the bill, due to its addictive nature as opposed to changing the language to opiods.

Rep. Flora: need rules for both detox and maintenance.

Dr. Steven Kassels: heroin crosses the blood barrier quickly which gives the rush. Any opiate taken over a longer period of time will be addictive. Many people who become addicted to pain meds, often seek out heroin on the street. Suggests wording 'all people addicted to heroin or any other opiod' in order to treat all addictions. 30% of their clients are poly-substance abusers. 5% or less were non-heroin abusers.

Mr. Green: Habit management. Federal Government allows treatment for opiod addicts, as does Mass.

Rep. Dyer would like to keep the treatment to just heroin addiction. Federal regulations say that state rules can be more restrictive.

Rep. Goulet: Deal with the methadone/heroin now, and then later the other opiods.

Bob Potter: Policy in place for intake, now. When a urine sample tests positive, they sign a release to contact the doctor which prescribed the legitimate medication.

Arpiar Saunders, lobbyist: issues – separate detox from maintenance and rules timeline estimate. Existing federal regulations cover detox.

Rep. Doucette: should this bill cover other addictive drugs?

A. Saunders: Applicability, page 2, lines 23, 24, 25, 26 – then providers must meet CARF standards.

Tim Hartnett: Suggest that the new amendment may save time.

Rep. Dyer: Should be more specific in the area where rules are drafted and in what areas – then the catch all phrase.

Tim Hartnett: Have drafted rules that cover a lot of ground already.

Rep. Flora: Should add "requirements for participation in detox and maintenance" between line 10 and 11. Add one line 7 "detox" and maintenance.

Rep. Dyer will go through the proposed rules and will meet next Monday with Tim Hartnett to discuss.

Dr. Steven Kassels: If non-heroin addicts don't test for heroin, they sometimes will do a bag to be eligible for the treatment program.

Rep. Patricia O'Keefe, Sub-committee Clerk

Testimony

file

Bangor Daily News
www.bangornews.com

CITY / PENOBSCOT

Thursday
Mar 23, 2000

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Response to proposed methadone clinic varied

Thursday, March, 23, 2000

By Renee Ordway, Of the NEWS Staff

BANGOR — There's little debate that the opiate addiction problem in the Greater Bangor area is increasing, but there is much controversy in the community about how to deal with it.

During a three-hour workshop Wednesday night to discuss a proposed methadone clinic in Bangor, a few things were clear — the U.S. Attorney's Office is adamantly opposed, the Office of Substance Abuse supports it, many city councilors are at least wary, and officials from Acadia Hospital, the only institution that has submitted a proposal to run the clinic, haven't much to say.

''Right now this is between the city and the state,'' said Ali Elhaj, president of Acadia Hospital. ''After the legal issues are worked out between them, then that is when Acadia will come in.''

Though three officials from Acadia were present at the hearing, they chose not to speak publicly about the pros or cons of having a methadone clinic in the city.

Methadone is a drug widely used to treat opiate addicts. Methadone clinics are regulated by the Food and Drug Administration and the Drug Enforcement Administration. Two clinics now operate in Maine, one in Portland and one in Winslow, both run by the private, for-profit organization called the Discovery House.

Just recently, however, the Office of Substance Abuse pulled the license of the Winslow clinic because of licensing and regulatory violations. The clinic remains in operation and is appealing the state's decision.

According to figures of the OSA, 28 of the Winslow clinic's daily clients come from Penobscot County. The office is concerned about how and where those clients will be treated should the Winslow clinic close.

Last November, OSA approached Acadia and asked if it would consider running a methadone clinic in Bangor. Acadia was interested, according to Joanne Augden of OSA, because it saw a huge increase in the number of opiate addicts seeking treatment at the recovery clinic.

Acadia originally planned to operate the clinic at the site of the Acadia Recovery Clinic on the former Dow Air Force Base near the Bangor International Airport. Now, however, it appears the clinic may be located on the campus of the Bangor Mental Health Institute on Hogan Road.

Methadone treatment is supported by the American Psychiatric Association and hailed by many medical groups as the most effective treatment for opiate addicts. The OSA said Wednesday night that those on methadone treatment can live productive lives and get back to work.

At Wednesday night's meeting, U.S. Attorney Jay McCloskey put on an elaborate presentation about the growing opiate addiction problem in the city and the law enforcement and community initiatives under way to deal with the issue.

"We can drive this out of here without [methadone]," McCloskey told city councilors. "By Acadia's own admission 30 to 50 percent of those seeking methadone treatment fail. What happens to those people?"

McCloskey said oversight of clinics was lacking and said Acadia's proposed standards for methadone treatment were "incomplete and inadequate."

McCloskey said he would propose a moratorium on any new methadone clinics.

Dr. Robert Dana, an addictive behavioral specialist at the University of Maine, said methadone was controversial and that many other treatments are available.

"Should Bangor encourage 200 addicts to come to the city each day for treatment when maybe only 5 percent of those addicts are actually from Bangor?," Dana asked the council. "My answer is not here. Not now. Not in Bangor."

Mayor Michael Aube said he thought there was tremendous confusion among those in state government about the law surrounding methadone treatment in the state. There apparently is debate over whether the statute governing methadone treatment programs was meant to be a three-year experimental project or a permanent law.

Aube called Gov. Angus King's office to discuss it on Wednesday and said he was told it was the opinion of that office that the program was experimental and that the methadone treatment was to continue for only three years at which time the Legislature would have to address it again. That time limit would have expired in 1998.

Augden said the State Attorney General's Office had looked at the law and found that the statute did not place a three-year deadline on the treatment law.

A former heroin addict who spent six years in federal prison for trafficking in heroin told councilors that he failed three times at the methadone treatment clinic in Portland. He said he got off heroin through more traditional programs offered at the Hope House in Bangor.

"You bring methadone here and there are people in Portland who will move here. You don't want them here," he said.

The Union Leader Tuesday, 3-14-2000

NH drug officer amazed by heroin use

PORTSMOUTH (AP) — Michael Hambrook wants to get the word out about the heroin flooding into New Hampshire.

A one-dose bag that costs $7 to $10 is enough to keep a first-time user high for a day, Hambrook says. But he says addicts tell him that subsequent highs are never as good, and the amount someone needs escalates to 20 to 30 bags per day.

"It's a cheap high at first, and it lasts you a very long time," he said. "But you start using more and more and more, and it becomes extremely expensive."

Hambrook, a state police sergeant, headed an investigation that resulted in 40 arrests in New Hampshire and Massachusetts this month on heroin charges. But he said he is well-aware that law enforcement alone cannot stem heroin's growing popularity.

"We didn't crack the ring. We're not fooling anybody," he told the Portsmouth Herald. "These people will be replaced as fast as you can snap your fingers, because these people are making money."

In addition to law enforcement, Hambrook wants education to keep people from becoming addicts and treatment for those who are.

"If you fight the battle on all three fronts, we won't ever stop it, but I think we can control it so it's not the epidemic we see now," he said.

Heroin was a major problem in this country in the 1970s. Then it came mainly from Asian and was only about 5 percent pure.

In the 1980s, heroin stayed in the background as cocaine became the drug of choice, especially for the affluent.

In the 1990s, Columbian drug cartels got into the business, selling heroin that is 80 percent to 90 percent pure and relatively cheap. The drug's image also has changed.

"Heroin was that little skinny guy in the corner with a needle in his arm. It was dirty," Hambrook said.

Now, heroin has become chic, even in mainstream society. One reason is the new, purer drug can be snorted, like cocaine, eliminating the stigma of using a needle.

But as their need for the drug grows, addicts soon switch to injecting. Feeding a habit becomes consuming, and addicts can rarely hold full-time jobs, Hambrook said. Many turn to stealing, prostitution or being "mules" — small-time, traveling dealers who feed their habits by buying for several other addicts.

Hambrook said most of the heroin in southern New Hampshire comes from Lawrence and Haverhill, Mass. And he said the drug's availability and popularity are staggering.

"I've been in the drug unit since 1987 and I've never seen anything like it," he said.

Town meetings take a vote on conservation

By PAULA TRACY
Union Leader Staff

It can be counted on each year at this time, along with running sap, pot holes and mud on back roads.

If it is the middle of March, it's town meeting time again.

Voters from Pittsburg to Pelham, Errol to Effingham will head to the polls today to vote on everything from who will be the next fire warden to whether complicated changes will be allowed in the town's zoning ordinance.

For some so-called Senate Bill 2 towns and school districts, the voting will require some staying power because the list of questions may be long. In those communities, the voting also could include whether townspeople want to buy a new fire truck, give teachers a raise or pay for ditch repairs and road repaving eyed by the road agent.

For thousands of other residents who have maintained the traditional deliberative sessions, this week and next also will include the big town gathering of the year, where the town's business will get a public airing.

As different as each town is, many will have the same question put to voters this year.

About 100 towns will be asked whether they support establishing a state conservation program being considered by the Legislature.

Similar to the Land Conservation Investment Program of the late 1980s, which preserved more than 100,000 acres during a building boom, this program would

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MEETINGS

(Continued From Page A1)

broaden the concept to help municipalities protect historic resources.

Many communities voting on the question are in the southern part of the state, which is again facing issues of sprawl and accelerated development in a booming economy, said Brian Hart, coordinator of the Citizens for New Hampshire Land and Community Heritage.

By the time voting is done, he said, 60 to 70 percent of the state's population will have been given an opportunity to vote on the question.

The concept has the support of Gov. Jeanne Shaheen, as well as her predecessors in the office.

The cities of Portsmouth, Concord, Rochester and Claremont already passed the language as city council resolutions to support Senate Bill 401.

The bill seeks to spend $6 million in 2001 through a state bond, with $200,000 from the general fund to pay for staffing the program. It passed the Senate Capital Budget Committee on Friday and now heads to the Senate Finance Committee.

Many supporters are concerned about what will happen to the bill when it reaches the House Resource Recreation and Development Committee, with the key issue being how to pay for it.

"The hope is that with many towns voting support of this, it will encourage the Legislature to act this year," said Hart.

The idea of offering a sort of town meeting resolution to the Legislature has been used on environmental issues since the early 1980s, when towns throughout the state voted to send a message to Concord and beyond about their concern for the dangers of acid rain.

This item, which has been placed on warrants either by town conservation commissions or through petition, states: "To see if the town will vote to send the following resolution to the New Hampshire General Court: Resolved, New Hampshire's natural, cultural and historic resources in this town and throughout the state are worthy of protection and, therefore, the State of New Hampshire should establish and fund a permanent public/private partnership for the voluntary conservation of these important resources."

"New Hampshire is facing a resurgence of growth approaching the scale of the mid-1980s," said Hart.

Already the fastest-growing state in the Northeast, New Hampshire loses about 20,000 acres of land to development each year, according to a recent study funded in part by the Society for the Protection of New Hampshire Forests.

"Communities across the state, and especially in the southern tier, are losing some of their most economically and culturally significant lands and buildings to the new growth," Hart said.

The proposed program would provide matching grants to communities, nonprofit organizations and state agencies to protect farmland, forests, water supplies and wildlife habitat and to restore and preserve historic structures such as mills, town halls and covered bridges. Under the proposal, 70 percent of the funding would go to local projects.

Communities would have to come up with 40 percent of the money needed for a project, and the remaining 60 percent would be matched by the program.

An authority would be created by the bill to decide which projects to fund. It would be composed of six nonvoting officials from state departments and 10 voting members of the public, six selected by the governor, two by the Senate president and two by the House speaker.

The following communities are considering the resolution: Amherst, Andover, Antrim, Ashland, Atkinson, Auburn, Barrington, Bartlett, Boscawen, Bow, Brentwood, Brookline, Candia, Canterbury, Center Harbor, Charlestown, Chester, Chesterfield, Conway, Danbury, Deerfield, Dummer, East Kingston, Effingham, Enfield, Epping, Exeter, Farmington, Fitzwilliam, Francestown, Gilmanton, Greenfield, Greenland, Groton, Hancock, Henniker, Hill, Hillsborough, Hopkinton, Jackson, Kensington, Kingston, Lee, Lebanon, Litchfield, Londonderry, Loudon, Lyme, Madbury, Madison, Marlborough, Middleton, Milford, Milton, Mont Vernon, Nelson, New Durham, New Hampton, New Ipswich, New London, Newbury, Newfields, Newton, Nottingham, Ossipee, Pembroke, Peterborough, Piermont, Pittsfield, Plainfield, Raymond, Sanbornton, Sandown, Sandwich, Sharon, Stoddard, Stratham, Sullivan, Sunapee, Tamworth, Temple, Wakefield, Walpole, Weare, Wilton, Winchester, Windham.

Bedford Town Meeting already passed the measure, Hart said.

Amend SB 444 to read as follows:

1. Methadone Treatment; Rulemaking. RSA 318-B:10, VII is repealed and reenacted to read as follows:

a) VII. The Department of Health and Human Services shall be the methadone authority for the State of New Hampshire. Methadone discontinuance and methadone maintenance services shall be provided only by programs certified by the department. A certified methadone program shall be operated only by the department or a not for profit New Hampshire based organization. The commissioner of health and human services shall adopt rules, pursuant to RSA 541-A, relative to certification of methadone programs which shall provide for accreditation of the program by CARF or other recognized national accrediting body and which shall address the safe and effective administration of the program.

2. New Paragraph; Definition Added. Amend RSA 318:1 by inserting after paragraph VII the following new paragraph:

VII-a. "Limited retail drug distributor" means federally funded clinics operated under contract with the department of health and human services and certified methadone programs, where legend and controlled drugs are held, stored or dispensed to patients pursuant to the order of an authorized practitioner.

3. New Section; Licensing of Limited Retail Drug Distributors Required. Amend RSA 318 by inserting the following new paragraph:

318:51-b Licensing of Limited Retail Drug Distributors Required.

I. No person shall operate as a limited retail drug distributor, as defined in RSA 318:1, VII-a, without first having obtained a license to do so from the board. Such license shall expire annually on June 30. An application together with a reasonable fee as established by the board shall be filed annually on or before July 1.

II. No license shall be issued under this section unless the applicant has furnished proof satisfactory to the board that:

(a) The applicant is of good moral character or, if that applicant is an association or corporation, that the managing officers are of good moral character.

(b) The applicant has sufficient space and security equipment as to properly carry on the business described in the application.

(c) The license granted by this chapter shall at all times be displayed in a conspicuous place in the facility for which it is issued.

(d) The applicant has a written contract with a pharmacist licensed in the state to serve as a consultant on all matters relating to the storage and dispensing prescription drugs.

III. No license shall be granted to any person who has within 5 years been convicted of a violation of any law of the United States, or of any state, relating to drugs, as defined in this chapter or RSA 318-B, or to any person who is a drug-dependent person.

IV. Any person licensed pursuant to this section is subject to the provisions of RSA 318:29.

4. Licensure Required. Repeal and reenact RSA 318:42, VII to read as follows:

VII. The dispensing of noncontrolled prescription drugs by registered nurses in clinics operated by or under contract with the department of health and human services, or by such nurses in clinics of nonprofit family planning agencies under contract with the department of health and human services or by nurses in certified methadone programs, provided that:

(a) The drugs are dispensed under a written protocol established by a licensed physician and approved by the department of health and human services which provides for responsible supervision over the activities in question and mentions the name of each registered nurse for whom the physician is assuming supervisory responsibility. A written copy of the protocol showing the date it was approved by the department of health and human services shall be kept at the clinic or certified methadone program at all times and shall be made available during any inspection conducted under RSA 318:8.

(b) The drugs appear on the current formulary approved pursuant to RSA 326-B:10, II.

(c) The drugs are dispensed only to bona fide clients of the clinic or certified methadone program for their personal needs pursuant to written eligibility criteria established by the department of health and human services.

(d) The clinic or certified methadone program has a written contract with a pharmacist licensed in this state to serve as a consultant on all matters relating to the dispensing of prescription drugs.

(e) The clinic or certified methadone program, except for clinics operated directly by the department of health and human services, possesses a current limited retail drug distributor's license under RSA 318:51-b.

5. Repeal. RSA 318:42, VII(e), relative to drug wholesaler's license, is repealed.

6. Effective Date. This act shall take effect 60 days after passage.

The Senate of the State of New Hampshire

107 N. Main Street, Room 302, Concord, N.H. 03301-4951

KATHERINE WELLS WHEELER
Vice President - Operations
District 21

Office 271-2111

TTY/TDD
1-800-735-2964

Representative David Welch
Criminal Justice and Public Safety
New Hampshire House of Representatives
Legislative Office Building
Concord, NH 03301

April 18, 2000

Dear Chairman Welch,

I have reviewed the proposed amendment to SB-445 distributed by Rep. Christie on April 13 and have some minor concerns that I hope can be addressed during your work session on Tuesday.

It appears that there is still confusion regarding the difference between methadone detoxification and methadone maintenance. Under current law, detoxification is legal in the State and allows providers to give methadone in accordance with strict federal regulations for a period not to exceed 180 days. Methadone maintenance involves the provision of methadone over a period of time beyond the detoxification period. New Hampshire law currently prohibits methadone maintenance by statute with an exception for pregnant women. In bringing forth SB-445, it is the intent of the sponsors to allow methadone maintenance services to be provided.

It is my understanding that your committee is attempting to draft legislation that will maintain the status quo until the Department of Health and Human Services adopts rules. Unfortunately, due to an apparent drafting error, the currently proposed amendment fails to do that and, in fact, places new prohibitions on the provision of methadone detoxification and methadone maintenance for pregnant women. The proposed language reads as follows:

> "8.I. Notwithstanding the above, nothing in this act shall be construed as prohibiting or limiting the provision of methadone detoxification services or as prohibiting or limiting treatment for those persons in treatment under RSA 318-B:10, VIII, as of the effective date of this act until the rules required pursuant to section 1 of this act are adopted. Any methadone detoxification program shall cease to operate on December 31, 2000 if the rules required under section 1 of this act have not been adopted."

The Senate of the State of New Hampshire

107 N. Main Street, Room 302, Concord, N.H. 03301-4951

KATHERINE WELLS WHEELER
Vice President - Operations
District 21

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Though this language attempts to allow for the continued provision of services to pregnant women by including those person in treatment under RSA 318-B:10 VIII, it limits services to those pregnant women who are in treatment as of the effective date of the act, and thus prohibits pregnant women who enter treatment after the effective date of the act from receiving maintenance.

Also the December 31, 2000 date in the last sentence would eliminate all detoxification services if rules are not enacted by year end. This is a new restriction to current law since at this time, providers are able to provide detoxification services under strict federal rules. We are all aware of the unanticipated delays that can occur in the administrative rulemaking process. I'm sure you share my concern that establishing this arbitrary cessation date could endanger those in treatment and those in need of treatment by denying them medical services. Thus, while we strongly support the adoption of stringent rules that would be in place as soon as possible, we do not believe that placing new limitations on the availability of methadone treatment serves the needs of New Hampshire residents in desperate need of this medical treatment.

Finally, the original legislation and testimony was intended to address all opioid addiction rather than only the illegal use of heroin. I have altered the language to reflect this change.

For your consideration, I have attached a copy of a draft amendment based upon the latest work of your Committee that maintains the status quo until rules are adopted without placing any new prohibitions on the provision of services.

Very truly yours,

Katie Wheeler

Senator Katherine Wheeler

Senator Wheeler
April 18, 2000

Amendment to SB 445-FN

Amend the bill by replacing all after the enacting clause with the following:

1 Methadone Maintenance Treatment; Rulemaking. RSA 318-B:10, VII is repealed and reenacted to read as follows:

VII. The department of health and human services is hereby declared to be the state methadone authority. The department of health and human services shall, on or before December 31, 2000, adopt rules pursuant to RSA 541-A, relative to:

(1) Eligibility for the program.

(2) Length of time in the program.

(3) Security measures to prevent diversion of methadone to illegal use.

(4) Any other provisions necessary to implement the purposes of this paragraph.

Once the rules are adopted pursuant to this paragraph , providers may operate a methadone maintenance program in the state of New Hampshire. For the purposes of this paragraph, "methadone maintenance program" means a program designed to substitute the administration of methadone for the addictive use of opioid substances, including heroin, over a period of beyond the minimum necessary to resolve physiological addiction. Nothing in this paragraph shall prohibit a practitioner from administering, prescribing, or dispensing a controlled drug under paragraph I.

2 New Paragraph; Definition Added. Amend RSA 318:1 by inserting after paragraph VII the following new paragraph:

VII-a. "Limited retail drug distributor" means federally funded clinics operated under contract with the department of health and human services and drug abuse treatment centers, where legend and controlled drugs are held, stored or dispensed to patients pursuant to the order of an authorized practitioner.

3 New Section; Licensing of Limited Retail Drug Distributions Required.

318:51-b Licensing of Limited Retail Drug Distributors Required.

I. No person shall operate as a limited retail drug distributor, as defined in RSA 318:1, VII-a, without first having obtained a license to do so from the board.

Such license shall expire annually on June 30. An application together with a reasonable fee as established by the board shall be filed annually on or before July 1.

II. No license shall be issued under this section unless the applicant has furnished proof satisfactory to the board that:

(a) The applicant is of good moral character or, if that applicant is an association or corporation, that the managing officers are of good moral character.

(b) The applicant has sufficient space and security equipment as to properly carry on the business described in the application.

(c) The license granted by this chapter shall at all times be displayed in a conspicuous place in the facility for which it is issued.

(d) The applicant has a written contract with a pharmacist licensed in the state to serve as a consultant on all matters relating to the storage and dispensing of prescription drugs.

III. No license shall be granted to any person who has within 5 years been convicted of a violation of any law of the United States, or of any state, relating to drugs, as defined in this chapter or RSA 318-B, or to any person who is a drug-dependent person.

IV. Any person licensed pursuant to this section is subject to the provisions of RSA 318:29.

4 Licensure Required. RSA 318:42, VII(d) is repealed and reenacted to read as follows:

(d) The clinic, except for clinics operated directly by the department of health and human services, possesses a current limited retail drug distributor's license under RSA 318-51-b.

5 Repeal. RSA 318:42, VI(e), relative to drug wholesaler's license is repealed.

6 Repeal. RSA 318-B:10, VIII, relative to certain methadone maintenance treatment, is repealed.

7 Contingency. Section 6 of this act shall take effect on the date when the rules required under section 1 of this act are adopted.

8 Applicability.

I. Notwithstanding the above, nothing in this act shall be construed as prohibiting or limiting the provision of methadone detoxification services or as prohibiting or limiting treatment for those persons in treatment under RSA 318-B:10, VIII, until the rules required pursuant to section 1 of this act are adopted.

II. Any provider under this section may provide treatment as long as the provider meets Commission on Accreditation of Rehabilitation Facilities (CARF) accreditation standards and is licensed by the federal Food and Drug Administration and the federal Drug Enforcement Administration, and otherwise Meets all applicable state and federal laws and regulations.

9 Effective Date

I. Section 6 of this act shall take effect as provided in section 7 of this act.

II. The remainder of this act shall take effect upon its passage.

Senator Wheeler
April 18, 2000

AMENDED ANALYSIS

This bill requires the commissioner of the department of health and human services to adopt rules relative to methadone maintenance treatment.

This bill also requires limited retail drug distributors to be licensed by the New Hampshire pharmacy board.

NEW HAMPSHIRE MEDICAL SOCIETY

SB445

For the betterment of public health since 1791

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EXECUTIVE VICE PRESIDENT
Palmer P. Jones

TO: The Honorable David A. Welch, Chairman
Criminal Justice & Public Safety Committee

FR: Palmer P. Jones

DT: April 10, 2000

RE: **Methadone Maintenance**

Program Treatment Goals:

1. Cessation of illegal opiod use.
2. Cessation of drug related crime to maintain dependence.
3. Rehabilitation of array of social and psychological problems that are associated with opiod dependence.
4. Treatment of co-existing psychiatric and other medical conditions.
5. Eventual cessation of methadone.

Essential Components of Successful Program:
Methadone maintenance programs have generated the largest scientific database of any biopsychosocial problem. This has resulted in treatment models that have been thoroughly tested and evaluated. Currently this treatment is the single most effective treatment of substance or alcohol abuse with retention and stabilization rates of about 70%.

1. Must be licensed to meet all FDA and DEA regulations.
2. Comprehensive assessment leading to individualized treatment.
3. Dose methadone at 60mg./day or higher to suppress the need for illegal opiods. Lower doses result in relapse and return to previous behaviors.
4. Mandatory random urine testing.
5. Emphasis on rehabilitation leading to recovery of a non-abusing life.
6. Work in small groups that build adaptive coping skills, educate about illness, and have clear cut consequences for non-compliance. Group norms consist of:
    - Get better or get sanctioned or dismissed
    - Failure and manipulations are not condoned
    - "Straight" lifestyle valued as the goal

- Accept responsibility for own actions
- Impulsive behaviors controlled
- No exceptions to rules without everyone (client and staff) being involved
- Anger managed rather than expressed

7. The longer you stay in the program, the more likely the success. Minimal stays in treatment of at least one year are the best.

8. The more co-morbidity (e.g. heroin dependence, major depression, and character disordered) and functional deficit, the more specialized the rehabilitation.

9. Specialized psychosocial rehabilitation including the following:

    - Strength focused case management to provide and coordinate care
    - Basic communication and coping skills building
    - Education and vocational assistance
    - Specialized pre-natal care to pregnant mothers
    - HIV/AIDS prevention and treatment
    - Housing assistance

10. After years of recovery, trial of methadone Withdraw. 40% won't make it on the first try.

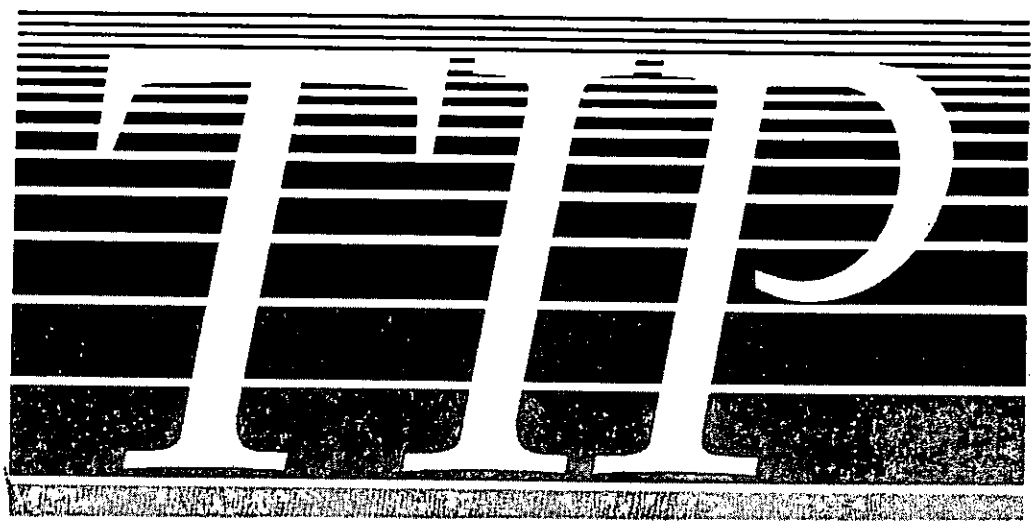
U.S. DEPARTMENT
OF HEALTH AND
HUMAN SERVICES
Public Health Service
Substance Abuse and
Mental Health Services
Administration

Center for Substance Abuse Treatment

State Methadone Treatment Guidelines

Treatment Improvement Protocol (TIP) Series

1



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Appendix A—Drugs Used for Treatment of Narcotic Addicts

Part 291

DRUGS USED FOR TREATMENT OF NARCOTIC ADDICTS

Secs.

291.501

Methadone in the maintenance treatment of narcotic addicts.

291.505

Conditions for the use of narcotic drugs; appropriate methods of professional practice for medical treatment of the narcotic addiction of various classes of narcotic addicts under Section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970.

Authority: Secs. 505, 701 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355, 371); 21 U.S.C. 823; Secs. 301(d), 548 of the Public Health Service Act (42 U.S.C. 241(d), 290ee-3); 42 U.S.C. 257a.

§291.501 Methadone in the maintenance treatment of narcotic addicts

(a) The Food and Drug Administration and the Drug Enforcement Administration recognize that the investigational use of methadone requiring the prolonged maintenance of narcotic dependence as part of a total treatment effort has shown promise in the management and rehabilitation of selected narcotic addicts. It is also recognized that a number of dangers and possible abuses may arise from such efforts if professional services and controls are inadequately applied. It is further felt that additional research is urgently needed so that data may be accumulated which will permit sound determinations of safety, efficacy, and necessary procedural safeguards.

(b) Therefore, the commissioner of Food and Drugs and the Director of the Drug Enforcement Administration Department of Justice, agree that interested professionals, municipalities, and organizations should be allowed to conduct further research in this area within a framework of adequate controls designed to protect the individual patients and the community. To facilitate this purpose, the Food and Drug Administration and the Drug Enforcement Administration, Department of Justice, have jointly agreed upon acceptable criteria and guidelines which are set forth in §291.505. In addition, such other provisions of the Federal narcotic laws and regulations as are applicable must also be observed.

[42 FR 46698, Sept. 16, 1977]

§291.505 Conditions for the use of narcotic drugs; appropriate methods of professional practice for medical treatment of the narcotic addiction of various classes of narcotic addicts under Section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970.

(a) Definitions. As used in this part:

(1) "Detoxification treatment" means the dispensing of a narcotic drug in decreasing doses to an individual to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period. There are two types of detoxification treatment: short-term detoxification treatment and long-term detoxification treatment.

(i) "Short-term detoxification treatment" is for a period not in excess of 30 days.

(ii) "Long-term detoxification treatment" is for a period more than 30 days, but not in excess of 180 days.

(2) "Maintenance treatment" means the dispensing of a narcotic drug in the treatment of an individual for dependence on heroin or other morphine-like drug.

(3) A "medical director" is a physician, licensed to practice medicine in the jurisdiction in which the program is located, who assumes responsibility for the administration of all medical services performed by the narcotic treatment program, including ensuring that the program is in compliance with all Federal, State, and local laws and regulations regarding the medical treatment of narcotic addiction with a narcotic drug.

(4) A "medication unit" is a facility established as part of, but geographically dispersed, i.e., separate from a narcotic treatment program from which licensed private practitioners and community pharmacists-

(i) Are permitted to administer and dispense a narcotic drug, and

(ii) Are authorized to collect samples for drug testing or analysis for narcotic drugs.

(5) "Narcotic dependent" means an individual who physiologically needs heroin or a morphine-like drug to prevent the onset of signs of withdrawal.

(6) A "narcotic treatment program" is an organization (or a person, including a private physician) that administers or dispenses a narcotic drug to a narcotic addict for maintenance or detoxification treatment, provides, when appropriate or necessary, a comprehensive range of medical and rehabilitative services, is approved by the State authority and the Food and Drug Administration, and that is registered with the Drug Enforcement Administration to use a narcotic drug for the treatment of narcotic addiction.

(7) A "program sponsor" is a person (or representative of an organization) who is responsible for the operation of a narcotic treatment program and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing services at the program (including its medication units).

(8) The term "services," as used in this part, includes medical evaluations, counseling, rehabilitative and other social programs (e.g., vocational and educational guidance, employment placement, which will help the patient become a productive member of society.

(9) A "State authority" is the agency designated by the Governor or other appropriate official to exercise the responsibility and authority within the State or Territory for governing the treatment of narcotic addiction with a narcotic drug.

(b) Organizational structure and approval requirements-

(1) Organizational structure

(i) A narcotic treatment program may be an independent organization or part of a centralized organization. For example, if a centralized organizational structure consists of a primary facility and other outpatient facilities, all of which conduct initial evaluation of patients and administer or dispense medication, the primary facility and each outpatient facility are separate programs, even though some services (e.g., the same hospital or rehabilitative services) are shared.

(ii) The program sponsor shall submit to the Food and Drug Administration and the State authority a description of the organizational structure of the program, the name of the persons responsible for the program, the address of the program, and the responsibilities of each facility or medication unit. The sources of funding for each program shall be listed and the name and address of each governmental agency providing funding shall be stated.

(iii) Where two or more programs share a central administration (e.g., a city or State-wide organization), the person responsible for the organization (administrator or program sponsor) is required to be listed as the program sponsor for each separate participating program. An individual program shall indicate its participation in the central organization at the time of its application. The administrator or sponsor may fulfill all recordkeeping and reporting requirements for these programs, but each program must continue to receive separate approval.

(iv) One physician may assume primary medical responsibility for more than one program and be listed as medical director. If a physician assumes medical responsibility for more than one program, a statement documenting the feasibility of the arrangement is required to be attached to the application.

(v) [Reserved]

(2) Program approval

(i) Before a narcotic treatment program may be lawfully operated, the program, whether an outpatient facility or a private practitioner, shall submit the applications specified in this section simultaneously to the Food and Drug Administration and the State authority and must receive the approval of both, except as provided for in Paragraph (h)(5) of this section. Before granting approval, the Food and Drug Administration will consult with the Drug Enforcement Administration, Department of Justice, to ascertain if the program is in compliance with Federal controlled substances laws. Each physical location within any program is required to be identified and listed in the approval application. At the time of application for approval, the program sponsor shall indicate whether medication will be administered or dispensed at the facility. Before medication may be administered or dispensed at a location not previously approved for this purpose, the program is required to obtain approval from FDA and the State agency. However, no approval is necessary, but notification is required when a facility in which medication is administered or dispensed is deleted by a program. In that event, the program shall notify the Food and Drug Administration and the State authority within three weeks of the deletion. Similarly, addition or deletion of facilities which provide services other than administering or dispensing medication is also permitted without approval, but notification must be made within 3 weeks to the Food and Drug Administration and the State authority about the addition and/or deletion.

(ii) Exemption of Federal programs. The provisions of this section requiring approval (or permitting disapproval or revocation of approval) by the State authority, compliance with requirements imposed by State law, or the submission of applications or reports required by the State authority do not apply to programs operated directly by the Veterans' Administration or any other department or agency of the United States. Federal agencies operating narcotic treatment programs have agreed to cooperate voluntarily with State agencies by granting permission on an informal basis for designated State representatives to visit Federal narcotic treatment programs and by furnishing a copy of Federal reports to the State authority, including the reports required under this section.

(iii) Services. Each narcotic treatment program shall provide medical and rehabilitative services and programs. (See Paragraph (d)(4) of this section.) These services should normally be made available at the primary

facility, but the program sponsor may enter into a formal documented agreement with private or public agencies, organizations, or institutions for these services if they are available elsewhere. The program sponsor, in any event, must be able to document that medical and rehabilitative services are fully available to patients.

(iv) Prohibition against unapproved use of narcotic drugs. No prescribing, administering, or dispensing of a narcotic drug for the treatment of narcotic addiction may occur without prior approval by the Food and Drug Administration and the State authority, except as provided for in Paragraph (h)(5) of this section, unless specifically exempted by this section.

(v) Approved narcotic drugs for use in treatment programs. The following narcotic drug has been approved for use in the treatment of narcotic addiction: Methadone.

(3) Medication unit.

(i) A program may establish a medication unit to facilitate the needs of patients who are stabilized on an optimal dosage level. To lawfully operate a medication unit, the program shall, for each separate unit, obtain approval from the Food and Drug Administration, the Drug Enforcement Administration, and the State authority, except as provided for in Paragraph (h)(5) of this section. The Food and Drug Administration, in determining whether to approve a medication unit, will consider the distribution of units within a particular geographic area. Any new medication unit is required to receive approval before it may lawfully commence operation.

(ii) Revocation of approval. If the Food and Drug Administration revokes the primary program's approval, the approval for any medication unit associated with the program is deemed to be automatically revoked. The Food and Drug Administration's revocation of the approval of a particular medication unit, will not, in and of itself, affect the approval of the primary program.

(iii) Narcotic drug supply. A medication unit must receive its supply of the narcotic drug directly from the stocks of the primary facility. Only persons permitted to administer or dispense the drug or security personnel licensed or otherwise authorized by State law to do so may deliver the drug to a medication unit.

(iv) Referral.

(A) The patient shall be stabilized at his or her optimal dosage level before he or she may be referred to a medication unit.

(B) Since the medication unit does not provide a range of services, the program sponsor shall determine that the patient to be referred is not in need of frequent counseling, rehabilitative, and other services which are only available at the primary program facility.

(v) Services. A medication unit is limited to administering or dispensing a narcotic drug and collecting samples for drug testing or analysis for narcotic drugs in accordance with Paragraph (d)(2) of this section. If a private practitioner wishes to provide other services besides administering or dispensing a narcotic drug and collecting samples for drug testing or analysis for narcotic drugs, he or she must submit an application for separate approval.

(vi) Responsibility for patient. After a patient is referred to a medication unit, the program sponsor retains continuing responsibility for the patient's care. The program sponsor shall ensure that the patient receives needed medical and rehabilitative services at the primary facility.

(c) Conditions for approval of the use of a narcotic drug in a treatment program-

(1) Applicants. An individual listed as program sponsor for a treatment program using a narcotic drug need not personally be a licensed practitioner, but shall employ a licensed physician for the position of medical director. Persons responsible for administering or dispensing the narcotic drug shall be practitioners as defined by Section 102(21) of the Controlled Substances Act (21 U.S.C. 802(21)) and licensed to practice by the State in which the program is to be established.

(2) Assent to regulation.

(i) A person who sponsors a narcotic treatment program, and any persons responsible for a particular program, shall agree to adhere to all the rules, directives, and procedures, set forth in this section, and any regulation regarding the use of narcotic drugs in the treatment of narcotic addiction which may be promulgated in the future. The program sponsor has responsibility for all personnel and individuals providing services, who work in the program at the primary facility or at other facilities or medication units. The program sponsors shall agree to inform all personnel

and individuals providing services of the provisions of this section and to monitor their activities to assure compliance with the provisions.

(ii) The Food and Drug Administration and the State authority are required to be notified within 3 weeks of any replacement of the program sponsor or medical director. Activities in violation of this regulation may give rise to the sanctions set forth in paragraph (i) of this section.

(3) Description of facilities. Only program site(s) approved by Federal, State, and local authorities may treat narcotic addicts with a narcotic drug. To obtain program approval, the applicant shall demonstrate that he or she will have access to adequate physical facilities to provide all necessary services. A program must have ready access to a comprehensive range of medical and rehabilitative services so that the services may be provided when necessary. The name, address and description of each hospital, institution, clinical laboratory, or other facility available to provide the necessary services are required to be included in the application submitted to the Food and Drug Administration and the State authority. The application is also required to include the name and address of each medication unit.

(4) Submission of proper applications. The following applications shall be filed simultaneously with both the Food and Drug Administration and the State authority.

(i) Form FDA-2632 "Application for Approval of Use of Methadone in a Treatment Program." This form, required by Paragraph (k) of this section, shall be completed and signed by the program sponsor and submitted in duplicate to the Food and Drug Administration and the State authority.

(ii) Form FDA-2633 "Medical Responsibility Statement for Use of Methadone in a Treatment Program." This form required by Paragraph (k) of this section, shall be completed and signed by each licensed physician authorized to administer or dispense narcotic drugs and submitted in duplicate to the Food and Drug Administration and the State authority. The names of any other persons licensed by law to administer or dispense narcotic drugs working in the program shall be listed even if they are not responsible for administering or dispensing the drug at the time the application is submitted.

(5) State and Federal approval, denial, and revocation of approval of narcotic treatment programs.

(i) The Food and Drug Administration may grant approval to a program only after FDA has received notification from both the State authority and the Drug Enforcement Administration that the program conforms to all pertinent State and Federal requirements.

(ii) The Food and Drug Administration will revoke the approval of a narcotic treatment program if so requested by the State authority or the Drug Enforcement Administration. If approval of a program is denied or revoked, the program shall have a right to appeal to the Commissioner, as provided for in Paragraph (h)(5) of this section.

(iii) No shipment of a narcotic drug may lawfully be made to any program which does not have current approval from the Food and Drug Administration. Within 60 days after receipt of the application from the program sponsor for approval, the Food and Drug Administration will notify the sponsor whether the application is approved or denied.

(d)(1) Minimum standards for admission-

(i) History of addiction and current physiologic dependence.

(A) A person may be admitted as a patient for a maintenance program only if a program physician determines that the person is currently physiologically dependent upon a narcotic drug and became physiologically dependent at least 1 year before admission for maintenance treatment. A 1-year history of addiction means that an applicant for admission to a maintenance program was physiologically addicted to a narcotic at a time at least 1 year before admission to a program and was addicted, continuously or episodically, for most of the year immediately before admission to a program. In the case of a person for whom the exact date on which physiological addiction began cannot be ascertained, the admitting program physician may, in his or her reasonable clinical judgment, admit the person to maintenance treatment, if from the evidence presented, observed, and recorded in the patient's record, it is reasonable to conclude that there was physiologic dependence at a time approximately 1 year before admission.

(B) Although daily use of a narcotic for an entire year could satisfy the regulatory definition of a 1-year history of addiction, operationally one might be physiologically dependent without daily use during the entire 1-year period and still satisfy the definition. The following, although not exhaustive, are examples of applicants who would

meet the minimum standard of a 1-year history of addiction and who, if currently physiologically dependent on the date of application for admission, would be eligible for admission to a maintenance program:

(1) Physiologic addiction began in August 1987 and continued to the date of application for admission in August 1988.

(2) Physiologic addiction began in January 1988 and continued until April 1988. Physiologic addiction began again in July 1988 and continued until the application for admission in January 1989.

(3) Physiologic addiction began in January 1987 and continued until October 1987. The date of application for admission was January 1988, at which time the patient had been readdicted for 1 month preceding his or her admission.

(4) Physiologic addiction consisted of four episodes in the last year, each episode lasting 2½ months.

(C) The program physician or an appropriately trained staff member designated and supervised by the physician shall record in the patient's record the criteria used to determine the patient's current physiologic dependence and history of addiction. In the latter circumstances, the program physician shall review, date, and countersign the supervised staff member's evaluation to demonstrate his or her agreement with the evaluation. The program physician shall make the final determination concerning a patient's physiologic dependence and history of addiction. The program physician shall sign, date, and record a statement that he or she has reviewed all the documented evidence to support a 1-year history of addiction and the current physiologic dependence and that in his or her reasonable clinical judgment the patient fulfills the requirements for admission to maintenance treatment. The program physician shall complete and record the statement before the program administers any methadone to the patient.

(ii) Voluntary participation, informed consent. The person responsible for the program shall ensure that: A patient voluntarily chooses to participate in a program; all relevant facts concerning the use of the narcotic drug used by the program are clearly and adequately explained to the patient; all patients, with full knowledge and understanding of its contents, sign the "Consent to Methadone Treatment" Form FDA-2635 (see Paragraph (k) of this section); a parent, legal guardian, or responsible adult designated by the State authority (e.g., "emancipated minor" laws) sign for patients under the age of 18 the second part of Form FDA-2635 "Consent to Methadone Treatment."

(iii) Exceptions to minimum admission criteria-

(A) Penal or chronic care. A person who has resided in a penal or chronic care institution for 1 month or longer may be admitted to maintenance treatment within 14 days before release or discharge, or within 6 months after release from such an institution without documented evidence to support findings of physiological dependence, provided the person would have been eligible for admission before he or she was incarcerated or institutionalized and, in the reasonable clinical judgment of a program physician, treatment is medically justified. Documented evidence of the prior residence in a penal or chronic care institution and evidence of all other findings and the criteria used to determine the findings are required to be recorded in the patient's record by the admitting program physician, or by program personnel supervised by the admitting program physician. The admitting program physician shall date and sign these recordings or review the health-care professional's recordings before the initial dose is administered to the patient. In the latter case, the admitting program physician shall date and sign the recordings in the patient's record made by the health-care professional within 72 hours of administration of the initial dose to the patient.

(B) Pregnant patients.

(1) Pregnant patients, regardless of age, who have had a documented narcotic dependency in the past and who may return to narcotic dependency, with all its attendant dangers during pregnancy, may be placed on a maintenance regimen. For such patients, evidence of current physiological dependence on narcotic drugs is not needed if a program physician certifies the pregnancy and, in his or her reasonable clinical judgment, finds treatment to be medically justified. Evidence of all findings and the criteria used to determine the findings are required to be recorded in the patient's record by the admitting program physician, or by program personnel supervised by the admitting program physician. The admitting program physician shall date and sign these recordings or review the health-care professional's recordings before the initial methadone dose is administered to the patient. In the latter case, the admitting program physician shall date and sign the recordings in the patient's record made by the health-care professional within 72 hours of administration of the initial methadone dose to the patient. Pregnant patients are required to be given the opportunity for prenatal care either by the program or by referral to appropriate health-care providers.

(2) If a program cannot provide direct prenatal care for pregnant patients in treatment, the program shall establish a system for informing the patients of the publicly or privately funded prenatal care opportunities available. If there are no publicly funded prenatal referral opportunities and the program cannot provide such services or the patient cannot afford them or refuses them, then the treatment program shall, at a minimum, offer her basic prenatal instruction on maternal, physical, and dietary care as part of its counseling service.

(3) Counseling records and/or other appropriate patient records are required to reflect the nature of prenatal support provided by the program. If the patient is referred for prenatal services, the physician to whom she is referred is required to be notified that she is in maintenance treatment, provided that notification is in accordance with the Department of Health and Human Services' confidentiality regulations (42 CFR Part 2). If a pregnant patient refuses direct treatment or appropriate referral for treatment, the treating program physician should consider using informed consent procedures; e.g., to have the patient acknowledge in writing that she had the opportunity for this treatment but refuses it. The program physician, consistent with the confidentiality regulations, shall request the physician or the hospital to which a patient is referred to provide, following birth, a summary of the delivery and treatment outcome for the patient and offspring. If the program physician does not receive a response to the request, he or she shall document in the record that such a request was made.

(4) Within 3 months after termination of pregnancy, the program physician shall enter an evaluation of the patient's treatment state into her record and state whether she should remain in the maintenance program or be detoxified.

(5) Caution should be taken in the maintenance treatment of pregnant patients. Dosage levels should be maintained at the lowest effective dose if treatment is deemed necessary. The program sponsor shall ensure that each female patient is fully informed of the possible risks to her or to her unborn child from continued use of illicit drugs and from the use of or withdrawal from, a narcotic drug administered or dispensed by the program in maintenance or detoxification treatment.

(C) Previously treated patients. Under certain circumstances, a patient who has been treated and later voluntarily detoxified from maintenance treatment may be readmitted to maintenance treatment, without evidence to support findings of current physiologic dependence, up to 2 years after discharge, if the program attended is able to document prior narcotic drug maintenance treatment of 6 months or more, and the admitting program physician, in his or her reasonable clinical judgment, finds readmission to maintenance treatment to be medically justified. For patients meeting these criteria, the quantity of take-home medication will be determined in the reasonable clinical judgment of the program physician, but in no case may the quantity of take-home medication be greater than would have been allowed at the time the patient voluntarily terminated previous treatment. The admitting program physician or a program employee under supervision of the admitting program physician must enter in the patient's record documented evidence of the patient's prior treatment and evidence of all decisions and criteria used relating to the admission of the patient and the quantity of take-home medication permitted. The admitting program physician shall date and sign these entries in the patient's record or review the health-care professional's entries therein before the program administers any medication to the patient. In the latter case, the admitting program physician shall date and sign the entries in the patient's record made by the health-care professional within 72 hours of administration of the initial dose to the patient.

(iv) Special limitation; treatment of patients under 18 years of age. A person under 18 is required to have had two documented attempts at short-term detoxification or drug-free treatment to be eligible for maintenance treatment. A 1-week waiting period is required after such a detoxification attempt, however, before an attempt is repeated. The program physician shall document in the patient's record that the patient continues to be or is again physiologically dependent on narcotic drugs. No person under 18 years of age may be admitted to a maintenance treatment program unless a parent, legal guardian or responsible adult designated by the State authority (e.g., "emancipated minor" laws) completes and signs consent form, Form FDA-2635 "Consent to Methadone Treatment."

(v) Denial of admission. If in the reasonable clinical judgment of the medical director a particular patient would not benefit from treatment with a narcotic drug, the patient may be refused such treatment even if the patient meets the admission standards.

(2) Minimum testing or analysis for drugs: Uses and frequency.

(i) The person(s) responsible for a program shall ensure that: An initial drug-screening test or analysis is completed for each prospective patient; at least eight additional random tests or analyses are performed on each patient during the first year in maintenance treatment; and at least quarterly random tests or analyses are performed on

each patient in maintenance treatment for each subsequent year, except that a random test or analysis is performed monthly on each patient who receives a 6-day supply of take-home medication. When a sample is collected from each patient for such test or analysis, it must be done in a manner that minimizes opportunity for falsification. Each test or analysis must be analyzed for opiates, methadone, amphetamines, cocaine, and barbiturates. In addition, if any other drug or drugs have been determined by a program to be abused in that program's locality, or as otherwise indicated, each test or analysis must be analyzed for any of those drugs as well. Any laboratory that performs the testing required under this regulation shall be in compliance with all applicable Federal proficiency testing and licensing standards and all applicable State standards. If a program proposes to change a laboratory used for such testing or analysis, the program shall have the change approved by the Food and Drug Administration.

(ii) The person responsible for a program shall ensure that test results are not used as the sole criterion to force a patient out of treatment but are used as a guide to change treatment approaches. The person responsible for a program shall also ensure that when test results are used, presumptive laboratory results are distinguished from results that are definitive.

(3) Patient evaluation; minimum admission and periodic requirements-

(i) Minimum contents of medical evaluation. Each patient is required to have a medical evaluation by a program physician or an authorized health-care professional under the supervision of a program physician on admission to a program. At a minimum, this evaluation is required to consist of a medical history which includes the required history of narcotic dependence, evidence of current physiologic dependence unless excepted by the regulations, and a physical examination, and includes the following laboratory examinations: serological test for syphilis, a tuberculin skin test, and a test or analysis for drug determination. If in the reasonable clinical judgment of the program physician, a patient's subcutaneous veins are severely damaged to the extent that a blood specimen cannot be obtained, the serological test for syphilis may be omitted. The physical examination is required to consist of an investigation of the organ systems for possibilities of infectious disease, pulmonary, liver, and cardiac abnormalities, and dermatologic sequelae of addiction. In addition, the physical examination is required to include a determination of the patient's vital signs (temperature, pulse, and blood pressure and respiratory rate); an examination of the patient's general appearance, head, ears, eyes, nose, throat (thyroid), chest (including heart, lungs, and breasts), abdomen, extremities, skin, and neurological assessment; and the program physician's overall impression of the patient.

(ii) Recordings of findings. The admitting program physician or an appropriately trained health care professional supervised by the admitting program physician shall record in the patient's record all findings from the admission medical evaluation. In each case, the admitting program physician shall date and sign these entries, or date, review, and countersign these recordings in the patient's record to signify his or her review of and concurrence with the history and physical findings.

(iii) Admission evaluation.

(A) Each patient seeking admission or readmission for treatment services is required to be interviewed by a well-trained program counselor, qualified by virtue of education, training, or experience to assess the psychological and sociological background of drug abusers, to determine the appropriate treatment plan for the patient. To determine the most appropriate treatment plan for a patient, the interviewer shall obtain and document in the patient's record the patient's history.

(B) A patient's history includes information relating to his or her educational and vocational achievements. If a patient has no such history; i.e., he or she has no formal education or has never had an occupation, this requirement is met by writing this information in the patient's history.

(iv) Initial treatment plan.

(A)(1) The initial treatment plan is required to contain a statement that outlines realistic short-term treatment goals which are mutually acceptable to the patient and the program. The initial treatment plan is also required to spell out the behavioral tasks a patient must perform to complete each short-term goal; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psychosocial, economic, legal, or other supportive services that a patient needs. The plan is also required to identify the frequency with which these services are likely to be provided. Prior to developing a treatment plan, the patient's needs for medical, social, and psychological services; education; vocational rehabilitation; and employment must be assessed, and the needs reflected, when clinically appropriate, in the treatment plan.

(2) A primary counselor is one who is assigned by the program to develop, implement, and evaluate the patient's initial and periodic treatment plan and to monitor a patient's progress in treatment. The primary counselor shall enter in the patient's record the counselor's name, the contents of a patient's initial assessment, and the initial treatment plan. The primary counselor shall make these entries immediately after the patient is stabilized on a dose or within 4 weeks after admission, whichever is sooner.

(B) It is recognized that patients need varying degrees of treatment and rehabilitative services which are often dependent on or limited by a number of variables; e.g., patient resources, available program, and community services. It is not the intent of this regulation to prescribe a particular treatment and rehabilitative service or the frequency at which a service should be offered.

(C) The program supervisory counselor or other appropriate program personnel so designated by the program physician shall review and countersign all the information and findings required to be recorded in each patient's record under Paragraph (d)(3)(iv) of this section.

(v) Periodic treatment plan evaluation.

(A) The program physician or the primary counselor shall review, reevaluate, and alter where necessary each patient's treatment plan at least once each 90 days during the first year of treatment, and then at least twice a year after the first year of continuous treatment.

(B) The program physician shall ensure that the periodic treatment plan becomes part of each patient's record and that it is signed and dated in the patient's record by the primary counselor and is countersigned and dated by the supervisory counselor.

(C) At least once a year, the program physician shall date, review, and countersign the treatment plan recorded in each patient's record and ensure that each patient's progress or lack of progress in achieving the treatment goals is entered in the patient's record by the primary counselor. When appropriate, the treatment plan and progress notes should deal with the patient's mental and physical problems, apart from drug abuse. The treatment plan is required to include the name of and the reasons for prescribing any medication for emotional or physical problems.

(D) The requirement for annual physician review and signature by the program physician in Paragraph (d)(3)(v)(C) of this section is discretionary, however, as it applies to a patient, who has satisfactorily adhered to program rules for at least 3 consecutive years from his or her entrance into the maintenance treatment program and who has made substantial progress in rehabilitation.

(4) Minimum program services-

(i)(A) Access to a range of services. A treatment program shall provide a comprehensive range of medical and rehabilitative services to its patients, especially during the first 3 years of treatment.

(B) Pregnant patients

(1) For pregnant patients in a treatment program who were not admitted under Paragraph (d)(1)(iii)(B) of this section, a treatment program shall give them the opportunity for prenatal care either by the narcotic treatment program or by referral to appropriate health care providers. If a program cannot provide direct prenatal care for pregnant patients in treatment, it shall establish a system of referring them for prenatal care which may be either publicly or privately funded. If there is no publicly funded prenatal care available to which a patient may be referred, and the program cannot provide such services, or the patient cannot afford or refuses prenatal care services, then the treatment program shall, at a minimum, offer her basic prenatal instruction on maternal, physical, and dietary care as a part of its counseling service.

(2) Counseling records and other appropriate patient records are required to reflect the nature of prenatal support provided by the program. If the program refers a patient for prenatal services, it shall inform the physician to whom she is referred that the patient is in maintenance treatment, provided such notification is in accordance with the Department of Health and Human Services' confidentiality regulations (42 CFR Part 2). If a pregnant patient refuses direct prenatal services or appropriate referral for prenatal services, the treating program physician should consider using informed consent procedures; i.e., to have the patient acknowledge in writing that she has the opportunity for this treatment but refuses it. The program physician shall request the physician or the hospital to which a patient is referred to provide, following birth, a summary of the delivery and treatment outcome for the patient and offspring. The information should be obtained in accordance with the Department of Health and Human

Services' confidentiality regulations (42 CFR Part 2). If no response is received, the program physician shall document in the record that such a request was made and no response was received.

(3) Caution should be taken in the maintenance treatment of pregnant patients. Dosage levels should be maintained at the lowest effective dose if continued treatment is deemed necessary. It is the responsibility of the program sponsor to ensure that each female patient is fully informed of the possible risks to a pregnant woman and her unborn child from continued use of illicit drugs and from the use of, or withdrawal from, a narcotic drug administered or dispensed by the program in maintenance or detoxification treatment.

(C) [Reserved]

(D) Off-site services. Any service not furnished at the primary facility is required to be listed in any application for approval submitted to the Food and Drug Administration or to the State authority. The addition, modification, or deletion of any program service is required to be reported immediately to the Food and Drug Administration.

(ii) Minimum medical services; designation of medical director and responsibilities. Each program shall have a designated medical director who assumes responsibility for administering all medical services performed by the program. The medical director and other authorized program physicians are required to be licensed to practice medicine in the jurisdiction in which the program is located. The medical director is responsible for ensuring that the program is in compliance with all Federal, State, and local laws and regulations regarding medical treatment of narcotic addiction. In addition, the medical director or other authorized physicians shall:

(A) Ensure that evidence of current physiologic dependence, length of history of addiction, or exceptions to criteria for admission are documented in the patient's record before the patient receives the initial dose.

(B) Ensure that a medical evaluation, including a medical history has been taken, and physical examination has been done before the patient receives the initial dose (except that in an emergency situation, the initial dose may be given before the physical examination).

(C) Ensure that appropriate laboratory studies have been performed and reviewed.

(D) Sign or countersign all medical orders as required by Federal or State law. (Such medical orders include but are not limited to the initial medication orders and all subsequent medication order changes, all changes in the frequency of take-home medication and prescribing additional take-home medication for an emergency situation.)

(E) Review and countersign treatment plans at least annually as qualified by Paragraph (d)(3)(v)(D) of this section.

(F) Ensure that justification is recorded in the patient's record for reducing the frequency of clinic visits for observed drug ingesting, providing additional take-home medication under exceptional circumstances or when there is physical disability, or prescribing any medication for physical or emotional problems.

(iii) Use of health-care professionals. Although the final decision to accept a patient for treatment may be made only by the medical director or other designated program physician, it is recognized that physicians can train program personnel to detect and document narcotic abstinence symptoms and that some jurisdictions allow State-licensed or certified health-care professionals; e.g., physician's assistants, nurse practitioners, to perform certain functions — record medical histories, perform physical examinations, and prescribe, administer, or dispense certain medications — that are ordinarily performed by a licensed physician. These regulations do not prohibit licensed or certified health-care professionals from performing those functions in narcotic treatment programs if it is authorized by Federal, State, and local laws and regulations, and if those functions are delegated to them by the medical director, and records are properly countersigned by the medical director or a licensed physician.

(iv) Vocational rehabilitation, education, and employment. Each program shall provide opportunities directly, or through referral to community resources, for patients who either desire or have been deemed by the program staff to be ready to participate in educational job training programs or to obtain gainful employment as soon as possible.

(5) Staffing patterns-

(i) Program personnel. The person(s) responsible for a program shall determine program personnel requirements after considering the number of patients who are vocationally and educationally impaired; the number of patients with significant psychopathology; the number of patients who are also non-narcotic drug or alcohol

abusers; the number of patients with behavioral problems in the program; and the number of patients with serious medical problems.

(ii) Supportive services. The person(s) responsible for the program shall take notice, when considering the staffing pattern, that maintenance treatment programs need to establish supportive services in accordance with the varying characteristics and needs of their patient populations. The person(s) responsible for a program shall also take notice of the availability of existing community resources which may complement or enhance the program's delivery of supportive services and then establish a staffing pattern based on a combination of patient needs and available, accessible community resources.

(6) Frequency of attendance; quantity of take-home medication; dosage of methadone; initial and stabilization-

(i) Dosage and responsibility for administration.

(A) The person(s) responsible for the program shall ensure that the initial dose of methadone does not exceed 30 milligrams and that the total dose for the first day does not exceed 40 milligrams, unless the program medical director documents in the patient's record that 40 milligrams did not suppress opiate abstinence symptoms.

(B) A licensed physician shall assume responsibility for the amount of the narcotic drug administered or dispensed and shall record, date, and sign in each patient's record each change in dosage schedule.

(C) The administering licensed physician shall ensure that a daily dose greater than 100 milligrams is justified in the patient's record.

(ii) Authorized dispensers of narcotic drugs; responsibility. A narcotic drug may be administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to order narcotic drugs for patients, or by an agent of such a practitioner, supervised by and under the order of the practitioner. This agent is required to be a pharmacist, registered nurse, or licensed practical nurse, or any other health-care professional authorized by Federal and State law to administer or dispense narcotic drugs. The licensed practitioner assumes responsibility for the amounts of narcotic drugs administered or dispensed and shall record and countersign all changes in dosage schedule.

(iii) Form. Methadone may be administered or dispensed in oral form only when used in a treatment program. Hospitalized patients under care for a medical or surgical condition are permitted to receive methadone in parenteral form when the attending physician judges it advisable. Although tablet, syrup concentrate, or other formulations may be distributed to the program, all oral medication is required to be administered or dispensed in a liquid formulation. The oral dosage form is required to be formulated in such a way as to reduce its potential for parenteral abuse. Take-home medication is required to be labeled with the treatment center's name, address, and telephone number and must be packaged in special packaging as required by 16 CFR 1700.14 in accordance with the Poison Prevention Packaging Act (Pub. L. 91-601, 15 U.S.C. 1471 et seq.) to reduce the chances of accidental ingestion. Exceptions may be granted when these provisions conflict with State law with regard to the administering or dispensing of drugs.

(iv) Take-home medication

(A) Take-home medication may be given only to a patient who, in the reasonable clinical judgment of the program physician, is responsible in handling narcotic drugs. Before the program physician reduces the frequency of a patient's clinical visits, she or he or a designated staff member shall record the rationale for the decision in the patient's clinical record. If this is done by a designated staff member, a program physician shall review, countersign, and date the patient's record where this information is recorded.

(B) The program physician shall consider the following in determining whether, in his or her reasonable clinical judgment, a patient is responsible in handling narcotic drugs:

(1) Absence of recent abuse of drugs (narcotic or non-narcotic), including alcohol;

(2) Regularity of clinic attendance;

(3) Absence of serious behavioral problems at the clinic;

(4) Absence of known recent criminal activity, e.g., drug dealing;

(5) Stability of the patient's home environment and social relationships;

(6) Length of time in maintenance treatment;

(7) Assurance that take-home medication can be safely stored within the patient's home; and

(8) Whether the rehabilitative benefit to the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.

(v) Take-home requirements. The requirement of time in treatment is a minimum reference point after which a patient may be eligible for take-home privileges. The time reference is not intended to mean that a patient in treatment for a particular time has a specific right to take-home medication. Thus, regardless of time in treatment, a program physician may, in his or her reasonable judgment, deny or rescind the take-home medication privileges of a patient.

(A)(1) In maintenance treatment, it is required that a patient come to the clinic for observation daily or at least 6 days a week. If, in the reasonable clinical judgment of the program physician, a patient demonstrates that he or she has satisfactorily adhered to program rules for at least 3 months, has made substantial progress in rehabilitation and responsibility in handling narcotic drugs (see Paragraphs (d)(6)(iv)(B) (1) through (8) of this section, and would improve his or her rehabilitative progress by decreasing the frequency of attendance at the clinic for observation, the patient may be permitted to reduce his or her attendance at the clinic for observation to three times weekly. The patient may receive no more than a 2-day take-home supply of medication.

(2) If, in the reasonable clinical judgment of the program physician, a patient demonstrates that he or she has satisfactorily adhered to program rules for at least 2 years from his or her entrance into the program, has made substantial progress in rehabilitation and responsibility in handling narcotic drugs (see Paragraphs (d)(6)(iv)(B) (1) through (8) of this section), and would improve his or her rehabilitative progress by decreasing the frequency of attendance at the clinic for observation, the patient may be permitted to reduce his or her clinic attendance at the clinic for observation to twice weekly. Such a patient may receive no more than a 3-day take-home supply of medication.

(3) If, in the reasonable clinical judgment of the program physician, a patient demonstrates that he or she has satisfactorily adhered to program rules for at least 3 consecutive years from his or her entrance into the maintenance treatment program, has made substantial progress in rehabilitation, has no major behavioral problems, is responsible in handling narcotic drugs (see Paragraphs (d)(6)(iv)(B) (1) through (8) of this section), and would improve his or her rehabilitative progress by decreasing the frequency of his or her clinic attendance for observation, the patient may be permitted to reduce clinic attendance for observation to once weekly, provided that the following additional criteria are met:

The program physician has written into the patient's record an evaluation that the patient is responsible in handling narcotic drugs (Paragraphs (d)(6)(iv)(B) (1) through (8) of this section); the patient is employed (or actively seeking employment), attends school, is a homemaker, or is considered unemployable for mental or physical reasons by a program physician; the patient is not known to have abused drugs, including alcohol in the last year; and the patient is not known to have engaged in criminal activity; e.g., drug dealing in the last year. A patient is permitted to reduce clinic attendance for observation to once weekly may receive no more than a 6-day take-home supply of medication.

(B)(1) If a patient, after receiving a supply of take-home medication, is inexcusably absent from or misses a scheduled appointment with a treatment program without authorization from the program staff, the program physician shall increase the frequency of the patient's clinic attendance for drug ingestion under observation. For such a patient, the program physician shall not reduce the frequency of the patient's clinic attendance for drug ingestion under observation until she or he has had at least three consecutive monthly tests or analyses that are neither positive for morphine-like drugs (except from the narcotic drug administered or dispensed by the program) or other drugs of abuse, nor negative for the narcotic drug administered or dispensed by the program, and until she or he is again determined by a program physician to be responsible in handling narcotic drugs (see Paragraphs (d)(6)(iv)(B) (1) through (8) of this section) and to meet criteria in Paragraph (d)(6)(v)(A) of this section.

(2) If a patient, after receiving a 6-day supply of take-home medication, has a test or analysis which is confirmed to be positive for morphine-like drugs (except for the narcotic drug administered or dispensed by

the program) or other drugs of abuse, or negative for the narcotic drug administered or dispensed by the program, the program physician shall place the patient on probation for 3 months. If, during this probation, the patient has a test or analysis either positive for morphine-like drugs (except for the narcotic drug administered or dispensed by the program) or other drugs of abuse, or negative for the narcotic drug administered or dispensed by the program, the program physician shall increase the frequency of the patient's clinic attendance for observation to at least twice weekly. Such a patient may receive no more than a 3-day take-home supply of medication until she or he has had at least three consecutive monthly tests or analyses which are neither positive for morphine-like drugs (except for the narcotic drug administered or dispensed by the program) or other drugs of abuse, nor negative for the narcotic drug administered or dispensed by the program, and the program physician again determines that the patient is responsible in handling narcotic drugs (see Paragraphs (d)(6)(iv)(B) (1) through (8) of this section) and meets the criteria contained in Paragraph (d)(6)(v)(A) of this section.

(C) In calculating the number of years of maintenance treatment, the period is considered to begin on the first day the medication is administered, or on readmission if a patient has had a continuous absence of 90 days or more. Cumulative time spent by the patient in more than one program is counted toward the number of years of treatment, provided there has not been a continuous absence of 90 days or more.

(D) Each patient whose daily dose is above 100 milligrams is required to be under observation while ingesting the drug at least 6 days per week irrespective of the length of time in treatment, unless the program has received prior approval from the Food and Drug Administration with the concurrence of the State authority.

(vi) Exceptions to take-home requirements. If, in the reasonable clinical judgment of the program physician:

(A) A patient is found to have a physical disability which interferes with his or her ability to conform to the applicable mandatory schedule, she or he may be permitted a temporarily or permanently reduced schedule, provided she or he is also found to be responsible in handling narcotic drugs.

(B) A patient, because of exceptional circumstances such as illness, personal or family crises, travel, or other hardship, is unable to conform to the applicable mandatory schedule, she or he may be permitted a temporarily reduced schedule, provided she or he is also found to be responsible in handling narcotic drugs. The rationale for an exception to a mandatory schedule is to be based on the reasonable clinical judgment of the program physician and shall be recorded in the patient's record by the program physician or by program personnel supervised by the program physician. In the latter situation, the physician shall review, countersign, and date the patient's record where this rationale is recorded. In any event, a patient may not be given more than a 2 week supply of narcotic drugs at one time.

(vii) Official State holidays. If a treatment center program is not in operation due to the observance of an official State holiday, patients may be permitted one extra take-home dose per visit and one fewer clinic visit per week to allow patients not to have to attend the clinic on an official State holiday. An official State holiday is a holiday on which most State offices are usually closed and routine State government business is not conducted.

(7) [Reserved]

(8) Minimum standards for short-term detoxification treatment.

(i) For short-term detoxification from narcotic drugs, the narcotic drug is required to be administered by the program physician or by an authorized agent of the physician, supervised by and under the order of the physician. The narcotic drug is required to be administered daily, under close observation, in reducing dosages over a period not to exceed 30 days. All requirements for maintenance treatment apply to short-term detoxification treatment with the following exceptions:

(A) Take-home medication is not allowed during short-term detoxification.

(B) A history of 1 year physiologic dependence is not required for admission to short-term detoxification.

(C) Patients who have been determined by the program physician to be currently physiologically narcotic dependent may be placed in short-term detoxification treatment, regardless of age.

(D) No test or analysis is required except for the initial drug screening test or analysis.

(E) The initial treatment plan and periodic treatment plan evaluation required for maintenance patients are not necessary for short-term detoxification patients. However, a primary counselor must be assigned by the program to monitor a patient's progress toward the goal of short-term detoxification and possible drug-free treatment referral.

(F) The requirements of Paragraph (d)(4) of this section, except Paragraphs (d)(4)(ii) (A) through (D) and (d)(4)(iii) of this section, do not apply to short-term detoxification treatment.

(ii) A patient is required to wait at least 7 days between concluding a short-term detoxification treatment episode and beginning another. Before a short-term detoxification attempt is repeated, the program physician shall document in the patient's record that the patient continues to be, or is again, physiologically dependent on narcotic drugs. The provisions of these requirements, except as noted in Paragraph (d)(8)(i) of this section, apply to both inpatient and ambulatory short-term detoxification treatment.

(iii) Short-term detoxification treatment is not recommended for a pregnant patient.

(9) Minimum standards for long-term detoxification treatment.

(i) For long-term detoxification from narcotic drugs, the narcotic drug is required to be administered by the program physician or by an authorized agent of the physician, supervised by and under the order of the physician. The narcotic drug is required to be administered on a regimen designed to reach a drug-free state and to make progress in rehabilitation in 180 days or less. All requirements for maintenance treatment apply to long-term detoxification treatment with the following exception.

(A) In long-term detoxification treatment, it is required that the patient be under observation while ingesting the drug daily or at least 6 days a week, for the duration of the long-term detoxification treatment.

(B) A history of 1 year physiologic dependence is not required for admission to long-term detoxification.

(C) The program physician shall document in the patient's record that short-term detoxification is not a sufficiently long enough treatment course to provide the patient with the additional program services he or she deems necessary for the patient's rehabilitation. The program physician shall document this information in the patient's record before long-term detoxification may begin.

(D) Patients who have been determined by the program physician to be currently physiologically dependent on narcotics may be placed in long-term detoxification treatment, regardless of age.

(E) An initial drug screening test or analysis is required for each patient. And at least one additional random test or analysis must be performed monthly on each patient during long-term detoxification.

(F) The initial treatment plan and periodic treatment plan evaluation required for maintenance patients are also required for long-term detoxification patients, except that the required periodic treatment plan evaluation is required to occur monthly.

(ii) A patient is required to wait at least 7 days between concluding a long-term treatment episode and beginning another. Before a long-term detoxification attempt is repeated, the program physician shall document in the patient's record that the patient continues to be or is again physiologically dependent on narcotic drugs. The provisions of these requirements apply to both inpatient and ambulatory long-term detoxification treatment.

(iii) Long-term detoxification is not recommended for a pregnant patient.

(10) Inspections of programs; patient confidentiality. A program shall allow inspections by duly authorized employees of the State authority, and in accordance with Federal controlled substances law and Federal confidentiality laws, by duly authorized employees of the Food and Drug Administration, the Drug Enforcement Administration of the Department of Justice, and the National Institute on Drug Abuse.

(11) Exemptions from specific program standards.

(i) A program is permitted, at the time of application or any time thereafter, to request exemption from specific program standards. The rationale for an exemption shall be thoroughly documented in an appendix to be submitted with the application or at some later time. The Food and Drug Administration will approve such exemptions of program standards at the time of application, or any time thereafter, with the concurrence of the State authority. An example of a case in which an exemption might be granted would be for a private practitioner who wishes to treat a limited number of patients in a nonmetropolitan area with few physicians and no rehabilitative services geographically accessible and requests exemption from some of the staffing and service standards.

(ii) The Food and Drug Administration has the right to withhold the granting of an exemption requested at the time of application until a program is in actual operation in order to assess if the exemption is necessary. If periodic inspections of the program reveal that discrepancies or adverse conditions exist, the Food and Drug Administration shall reserve the right to revoke any or all exemptions previously granted.

(12) Research. When a program conducts research on human subjects or provides subjects for research, there must be written policies and written review to assure the rights of the patients involved. Appropriate informed consent forms are required to be signed by the patient and to be retained in his or her patient record at the program. All research, development, and related activities which involve human subjects and which are funded by grants from or contracts with the Department of Health and Human Services are required to comply with the Department of Health and Human Services' regulations on the protection of human subjects, 45 CFR Part 46, and confidentiality of information, 42 CFR Part 2. All investigational research involving human subjects conducted for submission to the Food and Drug Administration must be conducted in compliance with Part 312 of this chapter.

(13) Patient record system-

(i) Patient care. The person(s) responsible for a program shall establish a record system to document and monitor patient care. This system is required to comply with all Federal and State reporting requirements relevant to methadone. All records are required to be kept confidential and in accordance with all applicable Federal and State regulations regarding confidentiality.

(ii) Drug dispensing. The person(s) responsible for a program shall ensure that accurate records traceable to specific patients are maintained showing dates, quantity, and batch or code marks of the drug dispensed. These records must be retained for a period of 3 years from the date of dispensing.

(iii) Patient's record. An adequate record must be maintained for each patient. The record is required to contain a copy of the signed consent form(s), the date of each visit, the amount of drug administered or dispensed, the results of each test or analysis for drugs, any significant physical or psychological disability, the type of rehabilitative and counseling efforts employed, an account of the patient's progress, and other relevant aspects of the treatment program. For recordkeeping purposes, if a patient misses appointments for 2 weeks or more without notifying the program, the episode of care is considered terminated and is to be so noted in the patient's record. This does not mean that the patient cannot return for care. If the patient does return for care and is accepted into the program, this is considered a readmission and is to be so noted in the patient's record. This method of recordkeeping helps assure the easy detection of sporadic attendance and decreases the possibility of administering inappropriate doses of narcotic drugs (e.g., the patient who has received no medication for several days or more and upon return receives the usual stabilization dose). An annual evaluation of the patient's progress must be entered in the patient's record.

(14) Security of drug stocks. Adequate security is required to be maintained over drug stocks, over the manner in which it is administered or dispensed, over the manner in which it is distributed to medication units, and over the manner in which it is stored to guard against theft and diversion of the drug. The program is required to meet the security standards for the distribution and storage of controlled substances as required by the Drug Enforcement Administration, Department of Justice (21 CFR 1301.72-1301.76).

(e) Multiple enrollments-

(1) Administering or dispensing to patients enrolled in other programs. There is a danger of drug dependent persons attempting to enroll in more than one narcotic treatment program to obtain quantities of drugs for the purpose of self-administration or illicit marketing. Therefore, except in an emergency situation, drugs shall not be provided to a patient who is known to be currently receiving drugs from another treatment program.

(2) Patient attendance requirements. The patient shall always report to the same treatment facility unless prior approval is obtained from the program sponsor for treatment at another program. Permission to

report for treatment at the facility of another program shall be granted only in exceptional circumstances and shall be noted on the patient's clinical record.

(f) Conditions for use of narcotic drugs in hospitals for detoxification treatment-

(1) Form. The drug may be administered or dispensed in either oral or parenteral form. (See Paragraph (d)(6)(iii) of this section.)

(2) Use of narcotic drugs in hospitals-

(1) Approved uses. For hospitalized patients, the use of a narcotic drug for narcotic addict treatment may be administered or dispensed only for detoxification treatment. If a narcotic drug is administered for treatment of narcotic dependence for more than 180 days, the procedure is no longer considered detoxification but is, rather, considered maintenance treatment. Only approved narcotic treatment programs may undertake maintenance treatment. This does not preclude the maintenance treatment of a patient who is hospitalized for treatment of medical conditions other than addiction and who requires temporary maintenance treatment during the critical period of his or her stay or whose enrollment in a program which has approval for maintenance treatment using narcotic drugs has been verified. (See 21 CFR 1306.07(c).) Any hospital which already has received approval under this paragraph (f) may serve as a temporary narcotic treatment program when an approved treatment program has been terminated, and there is no other facility immediately available in the area to provide narcotic drug treatment for the patients. The Food and Drug Administration may give this approval upon the request of the State authority or the hospital, when no State authority has been established.

(ii) [sic] Individuals responsible for supplies. Hospitals shall submit to the Food and Drug Administration and the State authority the name of the individual (e.g., pharmacist) responsible for receiving and securing supplies of narcotic drugs for the treatment of narcotic addicts. The individual responsible for supplies shall ensure that the only persons who receive supplies of narcotic drugs are those who are authorized to do so by Federal or State law.

(iii) General description. The hospital shall submit to the Food and Drug Administration and the State authority a general description of the hospital, including the number of beds, specialized treatment facilities for drug dependence, and nature of patient care undertaken.

(iv) Anticipated quantity of drug needed. The hospital shall submit to the Food and Drug Administration and the State authority the anticipated quantity of narcotic drugs for narcotic addict treatment needed per year.

(v) Records. The hospital shall maintain accurate records showing dates, quantity, and batch or code marks of the drug used for inpatient treatment. The hospital shall retain the records for at least a period of 3 years.

(vi) Inspection. The hospital shall permit the Food and Drug Administration and the State authority to inspect supplies of the drug at the hospital and evaluate the uses to which the drug is being put. The Food and Drug Administration and the State authority will keep the identity of the patients confidential in accordance with confidentiality requirements of 42 CFR Part 2. Records on the receipt, storage, and distribution of narcotic medication are subject to inspection under Federal controlled substances law; but use or disclosure of records identifying patients will, in any case, be limited to actions involving the program or its personnel.

(vii) Approval of hospital pharmacy. Application for a hospital pharmacy to provide narcotic drugs for detoxification treatment must be submitted to the Food and Drug Administration and the State authority and approval from both is required, except as provided for in Paragraph (h)(5) of this section. Within 60 days after the Food and Drug Administration receives the application, it will notify the applicant of approval or denial or will request additional information, when necessary.

(viii) Approval of shipments to hospital pharmacies. Before a hospital pharmacy may lawfully receive shipments of narcotic drugs for detoxification treatment, a responsible official shall complete, sign, and file in duplicate with the Food and Drug Administration and the State authority Form FDA-2636 "Hospital Request for Methadone Detoxification Treatment" (see Paragraph (k) of this section) and must have received from the Food and Drug Administration a notice that the request has been approved.

(ix) Sanctions. Failure to abide by the requirements described in this section may result in revocation of approval to receive shipments of narcotic drugs for narcotic addict treatment, seizure of the drug supply on hand, injunction, and criminal prosecution.

(g) Confidentiality of patient records.

(1) Except as provided in Paragraph (g)(2) of this section, disclosure of patient records maintained by any program is governed by the provisions of 42 CFR Part 2, and every program must comply with that part. Records on the receipt, storage, and distribution of narcotic medication are also subject to inspection under Federal controlled substances laws: But use or disclosure of records identifying patients will, in any case, be limited to actions involving the program or its personnel.

(2) A treatment program or medication unit or any part thereof, including any facility or any individual, shall permit a duly authorized employee of the Food and Drug Administration to have access to and to copy all records on the use of narcotic drugs in accordance with the provisions of 42 CFR Part 2. A treatment program may reveal such records only when necessary in a related administrative or court proceeding.

(h) Denial or revocation of approval.

(1) Complete or partial denial or revocation of approval of an application to receive shipments of narcotic drugs (Forms FDA-2632 "Application for Approval of Use of Methadone in a Treatment Program" and FDA-2636 "Hospital Request for Methadone Detoxification Treatment") may be proposed to the Commissioner of Food and Drugs by the Director of the Food and Drug Administration's Center for Drug Evaluation and Research, on his or her own initiative or at the request of representatives of the Drug Enforcement Administration, Department of Justice, National Institute of Drug Abuse, the State authority, or any other interested person.

(2) Before presenting such a proposal to the Commissioner, the Director of the Center for Drug Evaluation and Research, or his or her representative, will notify the applicant in writing of the proposed action and the reasons therefor and will offer the applicant an opportunity to explain the matters in question in an informal conference and/or in writing within 10 days after receipt of such notification. The applicant shall have the right to hear and to question the information on which the proposal to deny or revoke approval is based, and may present any oral or written information and views.

(3) If the explanation offered by the applicant is not accepted by the Center for Drug Evaluation and Research as sufficient to justify approval of the application, and denial or revocation of approval is therefore proposed, the Commissioner will evaluate information obtained in the informal conference and/or in writing before the Director of the Center for Drug Evaluation and Research. If the Commissioner finds that the applicant has failed to submit adequate assurance justifying approval of the application, the Commissioner shall issue a notice of opportunity for hearing with respect to the matter pursuant to §314.200 of this chapter and the matter shall thereafter be handled in accordance with established procedures for denial or revocation of approval of a new drug application. If the Secretary determines that there is an imminent hazard to health, revocation of approval will become effective immediately and any administrative procedure will be expedited. Upon revocation of approval of an application, the Commissioner will notify the applicant, the State authority, the Drug Enforcement Administration, Department of Justice, and all other appropriate persons that the applicant may no longer receive shipments of narcotic drugs, and will require the recall of all of the drugs from the applicant. Revocation of approval may also result in criminal prosecution.

(4) Denial or revocation of approval may be reversed when the Commissioner determines that the applicant has justified approval of the application.

(5) A treatment program or medication unit or any part thereof, including any facility or any individual, may appeal to the Food and Drug Administration a complete or partial denial or revocation of approval by the State authority unless the denial or revocation is based upon a State law or regulation. The appeal shall first be made to the Director of the Center for Drug Evaluation and Research, who shall hold an informal conference on the matter in accordance with Paragraph (h)(2) of this section. The State authority may participate in the conference. The appellant or the State authority may appeal the Director's decision to the Commissioner, who shall decide the matter in accordance with Paragraph (h)(3) of this section. If the Commissioner denies or revokes approval, such action shall be handled in accordance with Paragraph (h)(3) of this section. The Commissioner may not grant or retain Food and Drug Administration approval if the Commissioner finds that the appellant is not in compliance with all applicable State laws and regulations and with this section.

(i) Sanctions-

(1) Program sponsor or individual responsible for a particular program. If the program sponsor or the person responsible for a particular program fails to abide by all the requirements set forth in this regulation, or fails to adequately monitor the activities of those employed in the program, he or she may have the approval of his or her application revoked, his or her narcotic drug supply seized, an injunction granted precluding operation of his or her program, and criminal prosecution instituted against him or her.

(2) Persons responsible for administering or dispensing narcotic drugs. If a person responsible for administering or dispensing narcotic drugs for narcotic addict treatment fails to abide by all the requirements set forth in this regulation, criminal prosecution may be instituted against him or her, his or her drug supply may be seized, the approval of the program may be revoked, and an injunction may be granted precluding operation of the program.

(j) Requirements for distribution by manufacturers of narcotic drugs for narcotic addict treatment-

(1) Distribution requirements. Shipments of narcotic drugs for narcotic addict treatment are restricted to direct shipments by manufacturers of the drugs to approved treatment programs using the narcotic drugs and to approved hospital pharmacies. If requested by a manufacturer or State authority, wholesale pharmacy outlets in some regions or States may be authorized to stock narcotic drugs for narcotic addict treatment for that area and then transship the drug to approved narcotic treatment programs and approved hospital pharmacies. Alternative methods of distribution will be permitted if they are approved by the Food and Drug Administration and the State authority. Prior to any approval of an alternative method of distribution, there will be consultation with the Drug Enforcement Administration, Department of Justice, to assure compliance with its regulations regarding controlled substance distribution.

(2) Information regarding approved programs and hospitals. The Food and Drug Administration will provide manufacturer and the public with names and locations of programs and hospitals that have been approved to receive shipments of narcotic drugs for narcotic addiction treatment. All information contained in the forms required by Paragraph (k) of this section is available for public disclosure, except the names or other identifying information.

(3) Acceptance of delivery. Delivery shall only be made to a licensed practitioner or a licensed pharmacist employed at the facility. At the time of delivery, the licensed practitioner or licensed pharmacist shall sign for the drugs and place his or her specific title and identification number on any invoice. Copies of these signed invoices shall be kept by the manufacturer.

(k) Program forms. The program sponsor must ensure that the following forms are completed by the proper program staff and submitted to the appropriate State authority and the Division of Scientific Investigations, Regulatory Management Branch (HFD-342), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Forms are available upon request from the Regulatory Management Branch (HFD-352) at the same address.

FORM

FDA-2632	Application for Approval of Use of Methadone in a Treatment Program
FDA-2633	Medical Responsibility Statement for Use of Methadone in a Treatment Program
FDA-2635	Consent to Methadone Treatment
FDA-2636	Hospital Request for Methadone Detoxification Treatment

(Approved by the Office of Management and Budget under Number 0910-0140)

[54 FR 8960, Mar. 2, 1989; 54 FR 12531, Mar. 27, 1989]

Appendix B—Guidance on the Use of Methadone in Maintenance and Detoxification Treatment of Narcotic Addicts

March 1989

Center for Drug Evaluation and Research
Food and Drug Administration
Department of Health and Human Services

National Institute on Drug Abuse
Alcohol, Drug Abuse, and Mental Health Administration
Department of Health and Human Services

For further information regarding the guidance document, please contact

Food and Drug Administration
Center for Drug Evaluation and Research
Regulatory Management Branch (HFD-342)
5600 Fishers Lane
Rockville, MD 20857
301-295-8029

Introduction

FDA and NIDA regulation of the medical use of methadone began with Congress' passage of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Pub. L. 91-513). Section 4 of this act instructed the Secretary of Health, Education, and Welfare to determine "appropriate methods of professional practice in the medical treatment of * * * narcotic addiction."

The legislative history of the act recognized that, historically, practitioners ran a significant risk of criminal prosecution under the Harrison Act of 1914 if they used a narcotic drug in the treatment of drug addiction. Congress referred to the Supreme Court's holding in *Linder* v. *United States*, 268 U.S. 5, 45 S.Ct. 446, 69 L.Ed. 819 (1925) that prescribing "in the ordinary course and in good faith, [a quantity of a narcotic drug] for relief of conditions incident to addiction" was not violative of Federal law. Congress also pointed out that the Bureau of Narcotics' (a predecessor of the Drug Enforcement Administration (DEA)) regulations were, apparently, not in accord with the Court's language. In 1970, the Bureau's regulations stated:

> An order purporting to be a prescription issued to an addict or habitual user of narcotics, not in the course of professional treatment but for the purpose of providing the user with narcotics sufficient to keep him comfortable by maintaining his customary use, is not a prescription within the meaning and intent of the [Harrison] Act; and the person filling such an order, as well as the person issuing it, may be charged with violation of the law.

26 CFR 151.392 (1970)

Congress passed the Comprehensive Drug Abuse Prevention and Control Act of 1970 to clarify this confusing situation. Congressional intent was clear that practitioners who complied with the standards prescribed under section 4 would be assured that their action would not lead to prosecution under the Controlled Substances Act (21 U.S.C. 801 et seq.).

In the early 1970's, diversion of methadone from legitimate commerce into the illegal marketplace was becoming a serious problem. Congress wished neither to ignore this diversion nor to eliminate methadone as a treatment for narcotic drug addiction. Therefore, Congress passed the Narcotic Addict Treatment Act of 1974 (Pub. L. 93-281, 88 Stat. 124), which allowed methadone to be dispensed for detoxification and maintenance only by practitioners who held a registration with DEA to do so. In order for a practitioner to obtain the registration, FDA had to determine that the practitioner was complying with the standards that were established under section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970. Over the intervening years, FDA and NIDA have issued a regulation setting forth the conditions under which narcotic drugs could be dispensed for the treatment of drug addiction, and establishing methadone as the only narcotic drug approved for such a use.

Over the years, the regulation accumulated language that recommended certain practices in addition to requiring other practices. In order to clarify matters, the agencies have issued this guidance document. Most of the provisions are "recommended practices" originally contained in the former regulation, while other provisions were formerly mandatory provisions that are being reissued as recommendations. Certain recommendations in this guidance document are new.

This guidance document is intended to provide recommendations for providing medical and other services in addition to the regulation under 21 CFR 291.505. Following these recommendations should facilitate treatment for narcotic addicts. This guidance document does not represent the formal legal opinion of either FDA or NIDA.

This guidance document and the regulation contained in 21 CFR 291.505 are not meant to preclude States from regulating the practice of medicine in the treatment of narcotic drug addicts. States are free to provide additional requirements for practitioners dispensing methadone for treatment of narcotic addicts. The recommendations of the agencies follow:

Services

Required medical services and counseling, rehabilitative, and other social services (e.g., vocational and educational guidance, employment placement) should normally be made available directly by the sponsor at the primary outpatient facility, but the program sponsor may enter into a formal agreement, which must be documented (see 21 CFR 291.505(b)(2)(iii)), with private or public agencies, organizations, or institutions for these services to be provided on site or elsewhere. Such facilities should be easily accessible to the patient. The patient's progress at the referral agency should be periodically updated.

Hospital Affiliation

If a program is not physically located within a hospital that has agreed to provide any needed medical care for drug-related problems for the program's patients, there should be a formal, documented agreement between the program sponsor and a responsible official of a licensed and accredited hospital demonstrating that hospital care, including emergency, inpatient, and ambulatory care, is fully available to any patient who may need it for such problems. It is suggested that the program sponsor enter into an agreement with the hospital official to provide general medical care for patients. Neither the program sponsor nor the hospital is required to assume financial responsibility for the patient's medical care.

Medication Units

Medication units should normally be located at some distance from the program's primary facility and other medication units so as to serve a separate and distinct geographic area. The enrollment in a medication unit should be of reasonable size in relation to the space available for treatment.

Current Physiological Dependence

In determining current physiologic dependence, the physician should consider signs and symptoms of intoxication, a positive urine specimen for a narcotic drug, and old or fresh needle marks. Other evidence of current physiologic dependence may be obtained by noting early signs of withdrawal (lacrimation, rhinorrhea, pupilary [sic] dilation, and piloerection) during the initial period of abstinence. Withdrawal signs may be observed during the initial period of hospitalization or while the person is an outpatient undergoing diagnostic evaluation (e.g., medical and personal history, physical examination, and laboratory studies). Increased body temperature, pulse rate, blood pressure, and respiratory rate are also signs of withdrawal, but their detection may require inpatient observation. It is unlikely but possible that a person could be currently dependent on narcotic drugs without having a positive urine test for narcotics. Conversely, it is possible that a person could have a positive urine test for narcotics and not be currently physiologically dependent. Thus, a urine sample that is positive for narcotics is not a requirement for admission to detoxification or maintenance treatment.

Drug Screening Urinalysis

The person(s) responsible for the program who uses the results of presumptive urinalysis for patient management should show evidence of reasonable access to confirmatory laboratory analysis for use on occasions when this is necessary, e.g., for intake urine testing on all prospective methadone patients, for any loss of patient privileges based on urinalysis, and for indicating frequency of use of other drugs not detectable by a screening method.

After the initial drug screening urinalysis, urine specimens for each patient should be collected and analyzed on a randomly scheduled basis at least monthly. More frequent testing for a specific drug(s) and for a specific person should occur when clinically indicated as determined by the reasonable clinical judgment of the medical director. Results of urine testing should be used as one clinical tool for the purposes of diagnosis, and in the determination of treatment plans, as well as used as one technique for overall program evaluation by monitoring patient drug-using patterns before and during treatment.

Contents of Medical Evaluation

The following laboratory examinations should be conducted for each patient on admission to a program in addition to the required examinations stated in § 291.505(d)(3)(i):

(1) Complete blood count and differential;

(2) Routine and microscopic urinalysis;

(3) Liver functions profile, e.g., SGOT and SGPT.

(4) When the tuberculin skin test is positive, a chest X-ray or other appropriate tests;

(5) Hepatitis B surface antigen (HBsAg) testing;

(6) When clinically indicated, an EKG;

(7) When appropriate, pregnancy test and a Pap test; and

(8) Other tests when clinically indicated.

When a person is readmitted to a program, it is recommended that the decision determining the appropriate laboratory tests to be conducted be based on the intervening medical history and a physical examination.

Admission Evaluation

A patient's history should include information relating to his or her psychosocial, economic, and family background, and any other information deemed necessary by the program that is relevant to the application or that may be helpful in assessing the resources, e.g., psychological, economic, educational, and vocational strengths and weaknesses, that a patient brings to the treatment setting. Each program should establish its own methods for measuring those strengths and weaknesses to assess the severity of the patient's problem, establish realistic treatment goals, and develop an appropriate treatment plan to achieve these goals. Such assessments should be made on admission or as soon as the patient is stable enough for appropriate interviewing. Treatment plans should reflect individualization geared to the patient's needs.

Initial Treatment Plan

The short-term goals contained in the initial treatment plan should be designed to expect completion within a finite time period, e.g., 90 to 180 days.

The information contained in the initial treatment plan should be in sufficient detail to demonstrate that each patient has been assessed and that the services provided are based on the patient assessment findings and the available program and community services.

Patients need varying degrees of treatment and rehabilitative services which are often dependent on or limited by a number of variables, e.g., patient resources, available program, and community services. It is not the intent of 21 CFR 291.505 or this guidance document to prescribe a particular treatment and rehabilitative service or the frequency at which a service should be offered.

Periodic Treatment Plan Evaluation

Changes made to a treatment plan should be fully explained to the patient.

Pregnant Patients

If a pregnant patient refuses direct prenatal services or appropriate referral for prenatal services, the treating program physician should consider using informed consent procedures, i.e., to have the patient acknowledge in writing that she had the opportunity for this treatment but refuses it.

Caution should be taken in the maintenance treatment of pregnant patients. Dosage levels should be maintained at the lowest effective dose if continued methadone treatment is deemed necessary. Detoxification treatment is not recommended for a pregnant patient.

Staffing Level

Programs that are not treating a large number of patients in maintenance treatment with a once weekly clinic visit schedule should maintain a staffing level ratio of at least 1 counselor to 50 patients.

Initial Dose

The initial dose of methadone should be given in an amount considered sufficient to control or mitigate abstinence symptoms concomitant to withdrawal of narcotic drugs. Currently, there is no absolutely reliable method available to determine narcotic tolerance levels. Thus, determination of the optimum initial dose is made on a case-by-case basis. Methadone dosages that are lower than the patient's current level of narcotic tolerance may result in the patient's experiencing withdrawal symptoms. Dosages sufficiently greater than the current level of narcotic tolerance can result in central nervous system depression, coma, and death. Therefore, it is important that the initial dose be adjusted individually to the narcotic tolerance of the patient. If the patient has been a heavy user of heroin up to the day of admission, he or she may require an initial dose of 15 to 30 milligrams with additional smaller increments 4 to 8 hours later. It is recommended practice that if the patient enters treatment with little or no narcotic tolerance (e.g., recently released from jail or using poor quality heroin), the initial dose be one-half these quantities. If there is any doubt, the smaller dose should be used initially and the patient kept under observation; if the symptoms of abstinence are distressing, an additional 5- to 10-milligram dose should be administered as needed. Subsequently, the dosage should be adjusted individually as tolerated and required. The stabilization dose frequently, but not necessarily, is higher than

the dose needed to reduce withdrawal severity. The usual range of methadone maintenance dosages in the country today is between 40 and 100 milligrams daily.

Maintenance Dosage

The physician should regularly review each patient's dosage level, carefully considering either increasing or decreasing the dosage as indicated. It should be noted that according to the official approved labeling, therapeutic doses of meperidine have precipitated severe reactions in patients currently receiving monoamine oxidase inhibitors or those who have received such agents within 14 days. Similar reactions have not yet been reported with methadone, but if the use of methadone is necessary in such patients, it is recommended that a sensitivity test be performed in which repeated small incremental doses are administered over the course of several hours while the patient's condition and vital signs are under careful observation. Likewise, physicians should also be aware that according to the official approved labeling, concurrent administration of rifampin may possibly reduce the blood concentration of methadone to a degree sufficient to produce withdrawal symptoms. The mechanism by which rifampin may decrease blood concentrations of methadone is not fully understood, although enhanced microsomal drug-metabolized enzymes may influence drug disposition.

Methadone Formulation

The liquid for methadone vehicle should be nonsweetened and should contain a preservative so that the program may instruct patients to keep take-home methadone out of the refrigerator to try to minimize the likelihood of accidental overdoses by children or fermentation of the vehicle.

Take-Home Dose

When considering patient responsibility in handling methadone, the program physician should either consult with, or consider the recommendations of, the staff members most familiar with the relevant facts about the patient involved.

Initial Detoxification Dose

The recommended initial dose in detoxification treatment is 15 to 20 milligrams.

Discontinuation of Methadone Use

Involuntary termination from treatment. The person(s) responsible for a program should develop and post prominently about the program premises at least one copy of a written policy establishing criteria for involuntary termination from treatment. This policy should describe patients' rights as well as the responsibilities and rights of the program staff. At the time a patient enters treatment, an appropriate program staff member designated by the person(s) responsible for the program should inform the patient where the copy of the policy is posted and should inform him or her of the reasons which he or she might be terminated from treatment, his or her right under the involuntary termination procedure, and the fact that information about him or her shall be kept confidential in accordance with 42 CFR Part 2.

Voluntary withdrawal from methadone use. As with most types of medical treatment that require chronic daily administration of medication, patients in methadone treatment should be evaluated periodically regarding the risks and benefits of continuing the medication. For some, the eventual withdrawal from methadone is a realistic goal. However, years of experience demonstrate that for others this goal is not yet realistic, even though these patients show vocational, educational, and psychosocial improvement, and are productive members of society. Research and clinical experience have not yet identified all the critical variables that determine when a patient can be successfully withdraw from methadone and remain drug free. Thus, the determination to withdraw voluntarily from methadone maintenance is empirical and is left to the patient and the reasonable clinical judgment of the physician. Upon reaching a drug-free state, the patient should be encouraged to remain in the program for as long as the program considers it necessary to ensure stability in the drug-free state. The frequency of required program visits for patients for drug-free state may be adjusted at the discretion of the medical director.

Appendix C—List of DEA Regulations Governing Narcotic Treatment Programs

Note to reader: Only those Parts 1301-1307 that apply specifically to methadone maintenance treatment programs are provided in this section. However, the reader is advised to review the DEA regulations in their entirety, as other parts may impact on compliance issues.

§ 1301.22 (a)(6),(11)	Separate registration for medication units and compounders
§ 1301.29	Provisional registration
§ 1301.71 through 1301.74	Security requirements and physical security controls
§ 1304.03 (a),(c),(d)	Records requirements
§ 1304.04 (a),(c),(f)	Maintenance of records and inventories
§ 1304.11 through 1304.14	Requirements for inventories
§ 1304.17	Inventories
§ 1304.21	Continuing records requirements
§ 1304.28	Patient records
§ 1305.08 through 1305.09	Order forms
§ 1307.21	Disposal of controlled substance

CHAPTER II -- DRUG ENFORCEMENT ADMINISTRATION DEPARTMENT OF JUSTICE

PART 1301--REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

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1301.02 Definitions.
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1301.11 Fee amounts.
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1301.21 Persons required to register.
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1301.29 Provisional registration of narcotic treatment programs; compounders.

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1301.31 Time for application for registration; expiration date.
1301.32 Application forms; contents; signature.
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1301.71 Security requirements generally.
1301.72 Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.
1301.73 Physical security controls for non-practitioners; compounders for narcotic treatment programs; manufacturing and compounding areas.
1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.
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1301.76 Other security controls for practitioners.

EMPLOYEE SCREENING—NON-PRACTITIONERS

1301.90 Employee screening procedures.
1301.91 Employee responsibility to report drug diversion.
1301.92 Illicit activities by employees.
1301.93 Sources of information for employee checks.

AUTHORITY: 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877.

SOURCE: 36 FR 7778 Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

Note to reader: Only those paragraphs in this Part that apply specifically to methadone maintenance treatment programs are provided.

§ 1301.22 Separate registration for independent activities.

(a) The following groups of activities are deemed to be independent of each other:

(1) Manufacturing controlled substances;

(2) Distributing controlled substances;

(3) Dispensing controlled substances listed in Schedules II through V;

(4) Conducting research with controlled substances listed in Schedules II through V;

(5) Conducting instructional activities with controlled substances listed in schedules II through V;

(6) Conducting a narcotic treatment program using any narcotic drug listed in Schedules II, III, IV or V, however, pursuant to § 1301.24, employees, agents, or affiliated practitioners, in programs, need not register separately. Each program site located away from the principal location and at which place narcotic drugs are stored or dispensed must be separately registered and obtain narcotic drugs by use of order forms pursuant to § 1305.03;

(7) Conducting research and instructional activities with controlled substances listed in Schedule I;

(8) Conducting chemical analysis with controlled substances listed in any schedule;

(9) Importing controlled substances;

(10) Exporting controlled substances; and

(11) A compounder as defined by § 1301.02(d).

(b) Every person who engages in more than one group of independent activities shall obtain a separate registration for each group of activities, except as provided in this paragraph. Any person, when registered to engage in the group of activities described in each subparagraph in this paragraph, shall be authorized to engage in the coincident activities described in that subparagraph without obtaining a registration to engage in such coincident activities, provided that, unless specifically exempted, he complies with all requirements and duties prescribed by law for persons registered to engage in such coincident activities:

(1) A person registered to manufacture or import any controlled substance or basic class of controlled substance shall be authorized to distribute that substance or class, but no other substance or class which he is not registered to manufacture or import;

(2) A person registered to manufacture any controlled substance listed in Schedules II through V shall be authorized to conduct chemical analysis and preclinical research (including quality control analysis) with narcotic and non-narcotic controlled substances listed in those schedules in which he is authorized to manufacture;

(3) A person registered to conduct research with a basic class of controlled substance listed in Schedule I shall be authorized to manufacture or import such class if and to the extent that such manufacture or importation is set forth in the research protocol described in § 1301.33 and to distribute such class to other persons registered or authorized to conduct research with such class or registered or authorized to conduct chemical analysis with controlled substances;

(4) A person registered or authorized to conduct chemical analysis with controlled substances shall be authorized to manufacture and import such substances for analytical or instructional purposes, to distribute such substances to other persons registered or authorized to conduct chemical analysis or instructional activities or research with such substances and to persons exempted from registration pursuant to § 1301.26, to export such substances to persons in other countries performing chemical analysis or enforcing laws relating to controlled substances or drugs in those countries, and to conduct instructional activities with controlled substances; and

(5) A person registered or authorized to conduct research with controlled substances listed in Schedules II through V shall be authorized to conduct chemical analysis with controlled substances listed in those schedules in which he is authorized to conduct research, to manufacture such substances if and to the extent that such manufacture is set forth in a statement filed with the application for registration, to import such substances for research purposes, to distribute such substances to other persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances and to persons exempted from registration pursuant to § 1301.26, and to conduct instructional activities with controlled substances;

(6) A person registered to dispense controlled substances listed in Schedules II through V shall be authorized to conduct research and to conduct instructional activities with those substances.

(c) A single registration to engage in any group of independent activities may include one or more controlled substances listed in the schedules authorized in that group of independent activities. A person registered to conduct research with controlled substances listed in Schedule I may conduct research with any substance listed in Schedule I for which he has filed and had approved a research protocol.

[36 FR 7778, Apr. 24, 1971, as amended at 36 FR 18728, Sept. 21, 1971; 37 FR 15918, Aug. 8, 1972; 38 FR 756, Jan. 4, 1973. Redesignated at 38 FR 26609, Sept. 24, 1973.

EDITORIAL NOTE: For FR Citations affecting § 1301.22, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 1301.29 Provisional registration of narcotic treatment programs; compounders.

(a) All persons currently approved by the Food and Drug Administration under § 310.505 (formerly § 130.44) of this title to conduct a methadone treatment program and who are registered by the Drug Enforcement Administration under this section will be granted a Provisional Narcotic Treatment Program Registration.

(b) The provisions of § 1301.45–1301.57 relating to revocation and suspension of registration, shall apply to a provisional registration.

(c) Unless sooner revoked or suspended under paragraph (b) of this section, a provisional registration shall remain in effect until (1) the date on which such person has registered under this section or has had his registration denied, or (2) such date as may be prescribed by written notification to the person from the Drug Enforcement Administration for the person to become registered to conduct a narcotic treatment program, whichever occurs first.

[39 FR 37984, Oct. 25, 1974]

SECURITY REQUIREMENTS

§ 1301.71 Security requirements generally.

(a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72–1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. Materials and construction which will provide a structural equivalent to the physical security controls set forth in §§ 1301.72, 1301.73 and 1301.75 may be used in lieu of the materials and construction described in those sections.

(b) Substantial compliance with the standards set forth in §§ 1301.72–1301.76 may be deemed sufficient by the Administrator after evaluation of the overall security system and needs of the applicant or registrant. In evaluating the overall security system of a registrant or applicant, the Administrator may consider any of the following factors as he may deem relevant to the need for strict compliance with security requirements:

(1) The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);

(2) The type and form of controlled substances handled (e.g., bulk liquids or dosage units, usable powders or nonusable powders);

(3) The quantity of controlled substances handled;

(4) The location of the premises and the relationship such location bears on security needs;

(5) The type of building construction comprising the facility and the general characteristics of the building or buildings;

(6) The type of vault, safe, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used;

(7) The type of closures on vaults, safes, and secure enclosures;

(8) The adequacy of key control systems and/or combination lock control systems;

(9) The adequacy of electric detection and alarm systems, if any including use of supervised transmittal lines and standby power sources;

(10) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;

(11) The adequacy of supervision over employees having access to manufacturing and storage areas;

(12) The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;

(13) The availability of local police protection or of the registrant's or applicant's security personnel, and;

(14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.

(c) When physical security controls become inadequate as a result of a controlled substance being transferred to a different schedule, or as a result of a noncontrolled substance being listed on any schedule, or as a result of a significant increase in the quantity of controlled substances in the possession of the registrant during normal business operations, the physical security controls shall be expanded and extended accordingly. A registrant may adjust physical security controls within the requirements set forth in §§ 1301.72–1301.76 when the need for such controls decreases as a result of a controlled substance being transferred to a different schedule, or a result of a controlled substance being removed from control, or as a result of a significant decrease in the quantity of controlled substances in the possession of the registrant during normal business operations.

(d) Any registrant or applicant desiring to determine whether a proposed security system substantially complies with, or is the structural equivalent of, the requirements set forth in §§ 1301.72–1301.76 may submit any plans, blueprints, sketches or other materials regarding the proposed security system either to the Special Agent in Charge in the region in which the system will be used, or to the Diversion Operations Section, Drug Enforcement Administration, Department of Justice, Washington, DC 20537.

(e) Physical security controls of locations registered under the Harrison Narcotic Act or the Narcotics Manufacturing Act of 1960 on April 30, 1971, shall be deemed to comply substantially with the standards set forth in §§ 1301.72, 1301.73 and 1301.75. Any new facilities or work or storage areas constructed or utilized for controlled substances, which facilities or work or storage areas have not been previously approved by the Administration, shall not necessarily be deemed to comply substantially with the standards set forth in §§ 1301.72, 1301.73 and 1301.75, notwithstanding that such facilities or work or storage areas have physical security controls similar to those previously approved by the Administration.

[36 FR 18729, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973 [sic], and amended at 46 FR 28841, May 29, 1981; 47 FR 41735, Sept. 22, 1982; 51 FR 5319, Feb. 13, 1986]

§ 1301.72 Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.

(a) *Schedules I and II.* Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedule I or II shall be stored in one of the following secure storage areas:

(1) Where small quantities permit, a safe or steel cabinet;

(i) Which safe or steel cabinet shall have the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;

(ii) Which safe or steel cabinet, if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way that it cannot be readily removed; and

(iii) Which safe or steel cabinet if necessary, depending upon the quantities and type of controlled substances stored, is equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or State police agency which has a legal duty to respond or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve.

(2) A vault constructed before, or under construction on, September 1, 1971, which is of substantial construction with a steel door, combination or key lock, and an alarm system; or

(3) A vault constructed after September 1, 1971:

(i) The walls, floors, and ceilings of which vault are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with 1/2- inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings;

(ii) The door and frame unit of which vault shall conform to the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;

(iii) Which vault, if operations require it to remain open for frequent access, is equipped with a "day-gate" which is self-closing and self-locking, or the equivalent, for use during the hours of operation in which the vault door is open;

(iv) The walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central station protection company, or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve, and, if necessary, holdup buttons at strategic points of entry to the perimeter area of the vault;

(v) The door of which vault is equipped with contact switches; and

(vi) Which vault has one of the following: Complete electrical lacing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the Administration.

(b) *Schedules III, IV and V.* Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedules III, IV and V shall be stored in the following secure storage areas:

(1) A safe or steel cabinet as described in paragraph (a)(1) of this section;

(2) A vault as described in paragraph (a)(2) or (3) of this section equipped with an alarm system as described in paragraph (b)(4)(v) of this section;

(3) A building used for storage of Schedules III through V controlled substances with perimeter security which limits access during working hours and provides security after working hours and meets the following specifications:

(i) Has an electronic alarm system as described in paragraph (b)(4)(v) of this section,

(ii) Is equipped with self-closing, self-locking doors constructed of substantial material commensurate with the type of building construction, provided, however, a door which is kept closed and locked at all times when not in use and when in use is kept under direct observation of a responsible employee or agent of the registrant is permitted in lieu of a self-closing, self-locking door. Doors may be sliding or hinged. Regarding hinged doors, where hinges are mounted on the outside, such hinges shall be sealed, welded or otherwise constructed to inhibit removal. Locking devices for such doors shall be either of the multiple-position combination or key lock type and:

(a) In the case of key locks, shall require key control which limits access to a limited number of employees, or;

(b) In the case of combination locks, the combination shall be limited to a minimum number of employees and can be changed upon termination of employment of an employee having knowledge of the combination;

(4) A cage, located within a building on the premises, meeting the following specifications:

(i) Having walls constructed of not less than No. 10 gauge steel fabric mounted on steel posts, which posts are:

(a) At least one inch in diameter;

(b) Set in concrete or installed with lay bolts that are pinned or brazed; and

(c) Which are placed no more than ten feet apart with horizontal one and one-half inch reinforcements every sixty inches;

(ii) Having a mesh construction with openings of not more than two and one-half inches across the square,

(iii) Having a ceiling constructed of the same material, or in the alternative, a cage shall be erected which reaches and is securely attached to the structural ceiling of the building. A lighter gauge mesh may be used for the ceilings of large enclosed areas if walls are at least 14 feet in height,

(iv) Is equipped with a door constructed of No. 10 gauge steel fabric on a metal door frame in a metal door flange, and in all other respects conforms to all the requirements of 21 CFR 1301.72(b)(3)(ii), and

(v) Is equipped with an alarm system which upon unauthorized entry shall transmit a signal directly to a central station protection agency or a local or state police agency, each having a legal duty to respond, or to a 24-hour control station operated by the registrant, or to such other source of protection as the Administrator may approve;

(5) An enclosure of masonry or other material, approved in writing by the Administrator as providing security comparable to a cage;

(6) A building or enclosure within a building which has been inspected and approved by DEA or its predecessor agency, BNDD, and continues to provide adequate security against the diversion of Schedule III through V controlled substances, of which fact written acknowledgment has been made by the Special Agent in Charge of DEA for the area in which such building or enclosure is situated;

(7) Such other secure storage areas as may be approved by the Administrator after considering the factors listed in
§ 1301.71(b), (1) through (14);

(8) (i) Schedule III through V controlled substances may be stored with Schedules I and II controlled substances under security measures provided by 21 CFR 1301.72(a);

(ii) Non-controlled drugs, substances and other materials may be stored with Schedule III through V controlled substances in any of the secure storage areas required by 21 CFR 1301.72(b), provided that permission for such storage of non-controlled items is obtained in advance, in writing, from the Special Agent in Charge of DEA for the area in which such storage area is situated. Any such permission tendered must be upon the Special Agent in Charge's written

determination that such non-segregated storage does not diminish security effectiveness for Schedules III through V controlled substances.

(c) *Multiple storage areas.* Where several types or classes of controlled substances are handled separately by the registrant or applicant for different purposes (e.g., returned goods, or goods in process), the controlled substances may be stored separately, provided that each storage area complies with the requirements set forth in this section.

(d) *Accessibility to storage areas.* The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass through controlled substances storage areas, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

[36 FR 18730, Sept. 21, 1971, as amended at 37 FR 15919, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973 [sic]].

EDITORIAL NOTE: For Federal Register citations affecting § 1301.72, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 1301.73 Physical security controls for non-practitioners; compounders for narcotic treatment programs; manufacturing and compounding areas.

All manufacturing activities (including processing, packaging and labeling) involving controlled substances listed in any schedule and all activities of compounders shall be conducted in accordance with the following:

(a) All in-process substances shall be returned to the controlled substances storage area at the termination of the process. If the process is not terminated at the end of a workday (except where a continuous process or other normal manufacturing operation should not be interrupted), the processing area or tanks, vessels, bins or bulk containers containing such substances shall be securely locked, with adequate security for the area or building. If such security requires an alarm, such alarm, upon unauthorized entry, shall transmit a signal directly to a central station protection company, or local or state police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant.

(b) Manufacturing activities with controlled substances shall be conducted in an area or areas of clearly defined limited access which is under surveillance by an employee or employees designated in writing as responsible for the area. "Limited access" may be provided, in the absence of physical dividers such as walls or partitions, by traffic control lines or restricted space designation. The employee designated as responsible for the area may be engaged in the particular manufacturing operation being conducted: *Provided*, That he is able to provide continuous surveillance of the area in order that unauthorized persons may not enter or leave the area without his knowledge.

(c) During the production of controlled substances, the manufacturing areas shall be accessible to only those employees required for efficient operation. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass through manufacturing areas during production of controlled substances, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

36 FR 18731, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973 [sic] and amended at 39 FR 37984, Oct. 25, 1974]

§ 1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

(a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

(c) The registrant shall notify the Field Division Office of the Administration in his area of any theft or significant loss of any controlled substances upon discovery of such theft or loss. The supplier shall be responsible for reporting in-transit losses of controlled substances by the common or contract carrier selected pursuant to § 1301.74(e),

upon discovery of such theft or loss. The registrant shall also complete DEA Form 106 regarding such theft or loss. Thefts must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them.

(d) The registrant shall not distribute any controlled substance listed in Schedules II through V as a complimentary sample to any potential or current customer (1) without the prior written request of the customer, (2) to be used only for satisfying the legitimate medical needs of patients of the customer, and (3) only in reasonable quantities. Such request must contain the name, address, and registration number of the customer and the name and quantity of the specific controlled substance desired. The request shall be preserved by the registrant with other records of distribution of controlled substances. In addition, the requirements of part 1305 of the chapter shall be complied with for any distribution of a controlled substance listed in Schedule II. For purposes of this paragraph, the term "customer" includes a person to whom a complimentary sample of a substance is given in order to encourage the prescribing or recommending of the substance by the person.

(e) When shipping controlled substances, a registrant is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses. When storing controlled substances in a public warehouse, a registrant is responsible for selecting a warehouseman which will provide adequate security to guard against storage losses; wherever possible, the registrant shall store controlled substances in a public warehouse which complies with the requirements set forth in § 1301.72. In addition, the registrant shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or in-transit losses.

(f) When distributing controlled substances through agents (e.g., detailmen), a registrant is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

(g) Before the initial distribution of carfentanil etorphine hydrochloride and/or diprenorphine to any person, the registrant must verify that the person is authorized to handle the substances(s) [sic] by contacting the Drug Enforcement Administration.

(h) The acceptance of delivery of narcotic substances by a narcotic treatment program shall be made only by a licensed practitioner employed at the facility or other authorized individuals designated in writing. At the time of delivery, the licensed practitioner or other authorized individual designated in writing (excluding persons currently or previously dependent on narcotic drugs), shall sign for the narcotics and place his specific title (if any) on any invoice. Copies of these signed invoices shall be kept by the distributor.

(i) Narcotics dispensed or administered at a narcotic treatment program will be dispensed or administered directly to the patient by either (1) the licensed practitioner, (2) a registered nurse under the direction of the licensed practitioner, (3) a licensed practical nurse under the direction of the licensed practitioner, or (4) a pharmacist under the direction of the licensed practitioner.

(j) Persons enrolled in a narcotic treatment program will be required to wait in an area physically separated from the narcotic storage and dispensing area. This requirement will be enforced by the program physician and employees.

(k) All narcotic treatment programs must comply with standards established by the Secretary of Health and Human Services (after consultation with the Administration) respecting the quantities of narcotic drugs which may be provided to persons enrolled in a narcotic treatment program for unsupervised use.

(l) DEA may exercise discretion regarding the degree of security required in narcotic treatment programs based on such factors as the location of a program, the number of patients enrolled in a program and the number of physicians, staff members and security guards. Similarly, such factors will be taken into consideration when evaluating existing security or requiring new security at a narcotic treatment program.

[36 FR 7778, Apr. 24, 1971; 36 FR 13386, July 21, 1971, as amended at 36 FR 18731, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973 [sic]]

EDITORIAL NOTE: For Federal Register citations affecting § 1301.74, see the List of CFR Sections Affected in the Finding Aids section of this volume.

PART 1304—RECORDS AND REPORTS OF REGISTRANTS

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AUTHORITY: 21 U.S.C. 821, 827, 871(b), 958(d), 965, unless otherwise noted.

Note to reader: Only those paragraphs in this Part that apply specifically to methadone maintenance treatment programs are provided.

§ 1304.03 Persons required to keep records and file reports.

(a) Each registrant shall maintain the records and inventories and shall file the reports required by this part, except as exempted by this section. Any registrant who is authorized to conduct other activities without being registered to conduct those activities, either pursuant to § 1301.22(b) of this chapter or pursuant to § 1307.11-1307.15 of this chapter, shall maintain the records and inventories and shall file the reports required by this part for persons registered to conduct such activities. This latter requirement should not be construed as requiring stocks of controlled substances being used in various activities under one registration to be stored separately nor that separate records are required for each activity. The intent of the Administration is to permit the registrant to keep one set of records which are adapted by the registrant to account for controlled substances used in any activity. Also, the Administration does not wish to acquire separate stocks of the same substance to be purchased and stored for separate activities. Otherwise, there is no advantage gained by permitting several activities under one registration. Thus, when a researcher manufactures a controlled item, he must keep a record of the quantity manufactured; when he distributes a quantity of the item, he must use and keep invoices or order forms to document the transfer; when he imports a substance, he keeps as part of his records the documentation required of an importer; and when substances are used in chemical analysis, he need not keep a record of this because such a record would not be required of him under a registration to do chemical analysis. All of these records may be maintained in one consolidated record system. Similarly, the researcher may store all of his controlled items in one place, and every two years take inventory of all items on hand, regardless of whether the substances were manufactured by him, imported by him, or purchased domestically by him, of whether the substances will be administered to subjects, distributed to other researchers, or destroyed during chemical analysis.

(b) A registered individual practitioner is required to keep records, as described in § 1304.04, of controlled substances in Schedules II, III, IV, and V which are dispensed, other than by prescribing or administering in the lawful course of professional practice.

(c) A registered individual practitioner is not required to keep records of controlled substances in Schedules II, III, IV, and V which are prescribed in the lawful course of professional practice, unless such substances are prescribed in the course of maintenance or detoxification treatment of an individual.

(d) A registered individual practitioner is not required to keep records of controlled substances listed in Schedules II, III, IV and V which are administered in the lawful course of professional practice unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges patients, either separately or together with charges for other professional services, for substances so dispensed or administered. Records are required to be kept for controlled substances administered in the course of maintenance or detoxification treatment of an individual.

(e) A registered person using any controlled substance in research conducted in conformity with an exemption granted under section 505(i) or 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i) or 360b(j)) at a registered establishment which maintains records in accordance with either of those sections is not required to keep records if he notifies the Administration of the name, address, and registration number of the establishment maintaining such records.

(f) A registered person using any controlled substance in preclinical research or in teaching at a registered establishment which maintains records with respect to such substances is not required to keep records if he notifies the Administration of the name, address, and registration number of the establishment maintaining such records.

(g) Notice required by paragraphs (e) and (f) of this section shall be given at the time the person applies for registration or reregistration and shall be made in the form of an attachment to the application, which shall be filed with the application.

[36 FR 7790, Apr. 24, 1971, as amended at 36 FR 18731, Sept. 21, 1971; 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 50 FR 40523, Oct. 4, 1985; 51 FR 5320, Feb. 13, 1986; 51 FR 26154, July 21, 1986]

§ 1304.04 Maintenance of records and inventories.

(a) Every inventory and other records required to be kept under this part shall be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration, except that financial and shipping records (such as invoices and packing slips but not excuted [sic] order forms subject to § 1305.13 of this chapter) may be kept at a central location, rather than at the registered location, if the registrant has notified the Administration of his intention to keep central records. Written notification must be submitted by registered or certified mail, return receipt requested, in triplicate, to the Special Agent in

Charge of the Administration in the area in which the registrant is located. Unless the registrant is informed by the Special Agent in Charge that permission to keep central records is denied, the registrant may maintain central records commencing 14 days after receipt of his notification by the Special Agent in Charge.
All notifications must include:

(1) The nature of the records to be kept centrally.

(2) The exact location where the records will be kept.

(3) The name, address, DEA registration number and type of DEA registration of the registrant whose records are being maintained centrally.

(4) Whether central records will be maintained in a manual, or computed readable form.

(b) All registrants that are authorized to maintain a central recordkeeping system shall be subject to the following conditions:

(1) The records to be maintained at the central record location shall not include executed order forms, prescriptions and/or inventories which shall be maintained at each registered location.

(2) If the records are kept on microfilm, computer media or in any form requiring special equipment to render the records easily readable, the registrant shall provide access to such equipment with the records. If any code system is used (other than pricing information), a key to the code shall be provided to make the records understandable.

(3) The registrant agrees to deliver all or any part of such records to the registered location within two business days upon receipt of a written request from the Administration for such records, and if the Administration chooses to do so in lieu of requiring delivery of such records to the registered location, to allow authorized employees of the Administration to inspect such records at the central location upon request by such employees without a warrant of any kind.

(4) In the event that a registrant fails to comply with these conditions, the Special Agent in Charge may cancel such central recordkeeping authorization, and all other central recordkeeping authorizations held by the registrant without a hearing or other procedures. In the event of a cancellation of central recordkeeping authorizations under this paragraph the registrant shall, within the time specified by the Special Agent in Charge, comply with the requirements of this section that all records be kept at the registered location.

(c) Registrants need not notify the Special Agent in Charge or obtain central recordkeeping approval in order to maintain records on an in-house computer system.

(d) ARCOS participants who desire authorization to report from other than their registered locations must obtain a separate central reporting identifier. Request for central reporting identifiers will be submitted to: ARCOS Unit, P.O. Box 28293, Central Station, Washington, DC 20005.

(e) All central recordkeeping permits previously issued by the Administration will expire on September 30, 1980. Registrants who desire to continue maintaining central records will make notification to the local Special Agent in Charge as provided in paragraph (a) of this section.

(f) Each registered manufacturer, distributor, importer, exporter, narcotic treatment program and compounder for narcotic treatment program shall maintain inventories and records of controlled substances as follows:

(1) Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and

(2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.

(g) Each registered individual practitioner required to keep records and institutional practitioner shall maintain inventories and records of controlled substances in the manner prescribed in paragraph (f) of this section.

(h) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file; and

(2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy, and prescriptions for such substances shall be maintained either in separate prescription file for controlled substances listed in Schedules III, IV, and V only or in such form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner

with the letter "C" no less than 1-inch high and filed either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for non-controlled substances.

(21 U.S.C. 821 and 871(b); 28 CFR 0.100)

[36 FR 7790, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973 [sic], and amended at 39 PR 37985, Oct. 25, 1974; 45 FR 44266, July 1, 1980; 47 FR 41735, Sept. 22, 1982; 51 FR 5320, Feb. 13, 1986]

INVENTORY REQUIREMENTS

§ 1304.11 General requirements for inventories.

(a) Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, substances ordered by a customer but not yet invoiced, substances stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples.

(b) A separate inventory shall be made by a registrant for each registered location. In the event controlled substances in [sic] the possession or under the control of the registrant at a location for which he is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. Each inventory for a registered location shall be kept at the registered location.

(c) A separate inventory shall be made by a registrant for each independent activity for which he is registered, except as provided in § 1304.18.

(d) A registrant may take an inventory on a date that is within 4 days of his biennial inventory date pursuant to § 1304.13 if he notifies in advance the Special Agent in Charge of the Administration in his area of the date on which he will take the inventory. A registrant may take an inventory either as of the opening of business or as of the close of business on the inventory date. The registrant shall indicate on the inventory records whether the inventory is taken as of the opening or as of the close of business and the date the inventory is taken.

(e) An inventory must be maintained in a written, typewritten or printed form. An inventory taken by use of an oral recording device must be promptly transcribed.

[36 FR 7790, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973 [sic], and amended at 47 FR 41735, Sept. 22, 1982]

§ 1304.12 Initial inventory date.

(a) Every person required to keep records who is provisionally registered on May 1, 1971, shall take an inventory of all stocks of controlled substances on hand on that date in accordance with §§ 1304.15-1304.19, as applicable.

(b) Every person required to keep records who is registered after May 1, 1971, and who was not provisionally registered on that date, shall take an inventory of all stocks of controlled substances on hand on the date he first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with §§ 1304.15-1304.19, as applicable. In the event a person commences business with no controlled substances on hand, he shall record this fact as his initial inventory.

[36 FR 7791, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971; 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1304.13 Biennial inventory date.

Every 2 years following the date on which the initial inventory is taken by a registrant pursuant to § 1304.12, the registrant shall take a new inventory of all stocks of controlled substances on hand. The biennial inventory may be taken (a) on the day of the year on which the initial inventory was taken or (b) on the registrant's regular general physical inventory date, if any, which is nearest to and does not vary by more than 6 months from the biennial date that would otherwise apply or (c) on any other fixed date which does not vary by more than 6 months from the biennial date that would otherwise apply. If the registrant elects to take the biennial inventory on his regular general physical inventory

date or another fixed date, he shall notify the Administration of this election and of the date on which the biennial inventory will be taken.

[36 FR 7791, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1304.14 Inventory date for newly controlled substances.

On the effective date of a rule by the Administrator pursuant to §§ 1308.48-1308.49, or § 1308.50 of this chapter adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter such substance shall be included in each inventory made by the registrant pursuant to § 1304.13.

[36 FR 7791, Apr. 24, 1971, as amended at 36 FR 18732, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1304.17 Inventories of dispensers and researchers.

Each person registered or authorized (by § 1301.22(b) of this chapter) to dispense or conduct research with controlled substances and required to keep records pursuant to § 1304.03 shall include in his inventory the same information required of manufacturers pursuant to § 1304.15 (c) and (d). In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser shall do as follows:

(a) If the substance is listed in Schedule I or II, he shall make an exact count or measure of the contents; and

(b) If the substance is listed in Schedule III, IV, or V, he shall make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he must make an exact count of the contents.

[36 FR 7791, Apr. 24, 1971, as amended at 36 FR 18732, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

CONTINUING RECORDS

§ 1304.21 General requirements for continuing records.

(a) On and after May 1, 1971, every registrant required to keep records pursuant to § 1304.03 shall maintain on a current basis a complete and accurate record of each such substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him, except that no registrant shall be required to maintain a perpetual inventory.

(b) Separate records shall be maintained by a registrant for each registered location except as provided in § 1304.04 (a). In the event controlled substances are in the possession or under the control of a registrant at a location for which he is not registered, the substances shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible.

(c) Separate records shall be maintained by a registrant for each independent activity for which he is registered, except as provided in §§ 1304.25 and 1304.26.

(d) In recording dates of receipt, importation, distribution, exportation, or other transfers, the date on which the controlled substances are actually received, imported, distributed, exported, or otherwise transferred shall be used as the date of receipt or distribution of any documents of transfer (e.g., invoices or packing slips).

[36 FR 7792, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1304.28 Records for maintenance treatment programs and detoxification treatment programs.

(a) Each person registered or authorized (by § 1301.22 of this chapter) to maintain and/or detoxify controlled substance users in a narcotic treatment program shall maintain records with the following information for each narcotic controlled substance:

(1) Name of substance;
(2) Strength of substance;
(3) Dosage form;
(4) Date dispensed;
(5) Adequate identification of patient (consumer);

(6) Amount consumed;
(7) Amount and dosage form taken home by patient; and
(8) Dispenser's initials.

(b) The records required by paragraph (a) of this section will be maintained in a dispensing log at the narcotic treatment program site and will be maintained in compliance with § 1304.24 without reference to § 1304.03.

(c) All sites which compound a bulk narcotic solution from bulk narcotic powder to liquid for on-site use must keep a separate batch record of the compounding.

(d) Records of identity, diagnosis, prognosis, or treatment of any patients which are maintained in connection with the performance of a narcotic treatment program shall be confidential, except that such records may be disclosed for purposes and under the circumstances authorized by part 310 and part 1401 of this title.
[39 FR 37985, Oct. 25, 1974]

PART 1305—ORDER FORMS

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1305.04 Persons entitled to obtain and execute order forms.
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1305.13 Preservation of order forms.
1305.14 Return of unused order forms.
1305.15 Cancellation and voiding of order forms.
1305.16 Special procedure for filling certain order forms.

AUTHORITY: 21 U.S.C. 821, 828, 871(b), unless otherwise noted.
SOURCE: 36 FR 7796, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

Note to reader: Only those paragraphs in this Part that apply specifically to methadone maintenance treatment programs are provided.

§ 1305.08 Persons entitled to fill order forms.

An order form may be filled only by a person registered as a manufacturer or distributor of controlled substances listed in Schedule I or II under section 303 of the Act (21 U.S.C. 823) or as an importer of such substances under section 1008 of the Act (21 U.S.C. 958), except for the following:

(a) A person registered to dispense such substances under section 303 of the Act, or to export such substances under section 1008 of the Act, if he is discontinuing business or if his registration is expiring without reregistration, may dispose of any controlled substances listed in Schedule I or II in his possession pursuant to order forms in accordance with § 1307.14 of this chapter;

(b) A person who has obtained any controlled substance in Schedule I or II by order form may return such substance, or portion thereof, to the person from whom he obtained the substance or the manufacturer of the substance pursuant to the order form of the latter person;

(c) A person registered to dispense such substances may distribute such substances to another dispenser pursuant to, and only in the circumstances described in, § 1307.11 of this chapter; and

(d) A person registered or authorized to conduct chemical analysis or research with controlled substances may distribute a controlled substance listed in Schedule I or II to another person registered or authorized to conduct

chemical analysis, instructional activities, or research with such substances pursuant to the order form of the latter person, if such distribution is for the purpose of furthering such chemical analysis, instructional activities, or research.

(e) A person registered as a compounder of narcotic substances for use at off-site locations in conjunction with a narcotic treatment program at the compounding location, who is authorized to handle Schedule II narcotics, is authorized to fill order forms for distribution of narcotic drugs to offsite narcotic treatment programs only.

[36 FR 7796, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971; 36 FR 18732, Sept. 21, 1971; 37 FR 15921, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

EDITORIAL NOTE: For FR citations affecting § 1305.08, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 1305.09 Procedure for filling order forms.

(a) The purchaser shall submit Copy 1 and Copy 2 of the order form to the supplier, and retain Copy 3 in his own files.

(b) The supplier shall fill the order, if possible and if he desires to do so, and record on Copies 1 and 2 the number of commercial or bulk containers furnished on each item and the date on which such containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the order form. No order form shall be valid more than 60 days after its execution by the purchaser, except as specified in paragraph (f) of this section.

(c) The controlled substances shall only be shipped to the purchaser and at the location printed by the Administration on the order form, except as specified in paragraph (f) of this section.

(d) The supplier shall retain Copy 1 of the order form for his own files and forward Copy 2 to the Special Agent in Charge of the Drug Enforcement Administration in the area in which the supplier is located. Copy 2 shall be forwarded at the close of the month during which the order is filled; if an order is filled by partial shipments, Copy 2 shall be forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.

(e) The purchaser shall record on Copy 3 of the order form the number of commercial or bulk containers furnished on each item and the dates on which such containers are received by the purchaser.

(f) Order forms submitted by registered procurement officers of the Defense Personnel Support Center of Defense Supply Agency for delivery to armed services establishments within the United States may be shipped to locations other than the location printed on the order form, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

[36 FR 7796, Apr. 24, 1971, as amended at 36 FR 18732, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 47 FR 41735, Sept. 22, 1982]

PART 1307—MISCELLANEOUS

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1307.21 Procedure for disposing of controlled substances.
1307.22 Disposal of controlled substances by the Administration.

SPECIAL EXEMPT PERSONS

1307.31 Native American Church.

AUTHORITY: 21 U.S.C. 821, 822(d), 871(b), unless otherwise noted.

SOURCE: 36 FR 7801, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

Note to reader: Only those paragraphs in this Part that apply specifically to methadone maintenance treatment programs are provided.

DISPOSAL OF CONTROLLED SUBSTANCES

§ 1307.21 Procedure for disposing of controlled substances.

(a) Any person in possession of any controlled substance and desiring or required to dispose of such substance may request the Special Agent in Charge of the Administration in the area in which the person is located for authority and instructions to dispose of such substance. The request should be made as follows:

(1) If the person is a registrant required to make reports pursuant to part 1304 of this chapter, he shall list the controlled substance or substances which he desires to dispose of on the "b" subpart of the report normally filed by him, and submit three copies of that subpart to the Special Agent in Charge of the Administration in his area.

(2) If the person is a registrant not required to make reports pursuant to part 1304 of this chapter, he shall list the controlled substance or substances which he desires to dispose of on DEA Form 41, and submit three copies of that form to the Special Agent in Charge in his area; and

(3) If the person is not a registrant, he shall submit to the Special Agent in Charge a letter stating:

(i) The name and address of the person;

(ii) The name and quantity of each controlled substance to be disposed of;

(iii) How the applicant obtained the substance, if known; and

(iv) The name, address, and registration number, if known, of the person who possessed the controlled substances prior to the applicant, if known.

(b) The Special Agent in Charge shall authorize and instruct the applicant to dispose of the controlled substance in one of the following manners:

(1) By transfer to person registered under the Act and authorized to possess the substance;

(2) By delivery to an agent of the Administration or to the nearest office of the Administration;

(3) By destruction in the presence of an agent of the Administration or other authorized person; or

(4) By such other means as the Special Agent in Charge may determine to assure that the substance does not become available to unauthorized persons.

(c) In the event that a registrant is required regularly to dispose of controlled substances, the Special Agent in Charge may authorize the registrant to dispose of such substances, in accordance with paragraph (b) of this section, without prior approval of the Administration in each instance, on the condition that the registrant keep records of such disposals and file periodic reports with the Special Agent in Charge summarizing the disposals made by the registrant. In granting such authority, the Special Agent in Charge may place such conditions as he deems proper on the disposal of controlled substances, including the method of disposal and the frequency and detail of reports.

(d) This section shall not be construed as affecting or altering in any way the disposal of controlled substances through procedures provided in laws and regulations adopted by the State.

[36 FR 7801, Apr. 24, 1971, as amended at 37 FR 15922, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 47 FR 41735, Sept. 22, 1982]

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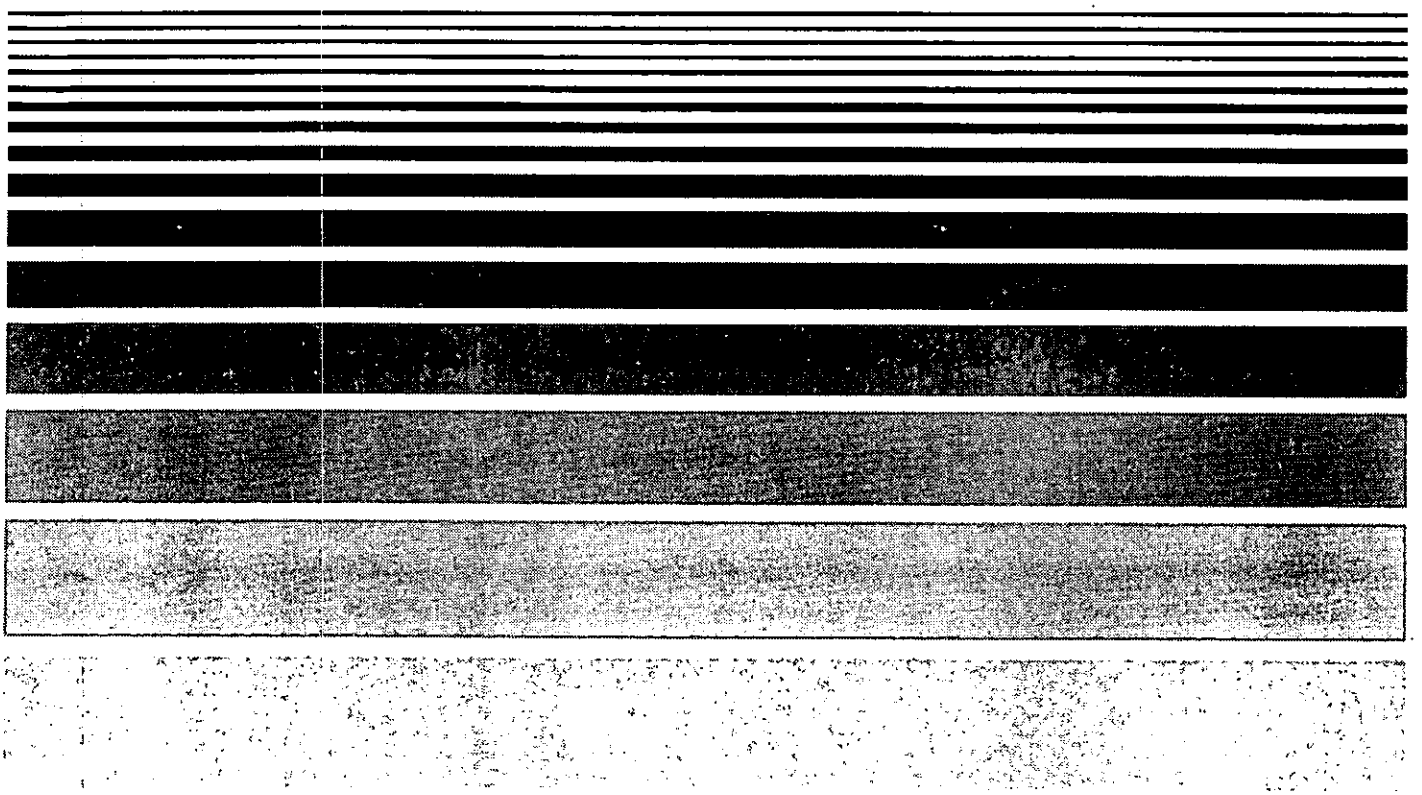
Center for Substance Abuse Treatment

Approval and Monitoring of Narcotic Treatment Programs

A Guide on the Roles of Federal and State Agencies

Technical Assistance Publication Series

12



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Part 291

DRUGS USED FOR TREATMENT OF NARCOTIC ADDICTS

Secs.

291.501

Methadone in the maintenance treatment of narcotic addicts.

291.505

Conditions for the use of narcotic drugs; appropriate methods of professional practice for medical treatment of the narcotic addiction of various classes of narcotic addicts under Section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970.

Authority: Secs. 505, 701 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355, 371); 21 U.S.C. 823; Secs. 301(d), 548 of the Public Health Service Act (42 U.S.C. 241(d), 290ee-3); 42 U.S.C. 257a.

§291.501 Methadone in the maintenance treatment of narcotic addicts

(a) The Food and Drug Administration and the Drug Enforcement Administration recognize that the investigational use of methadone requiring the prolonged maintenance of narcotic dependence as part of a total treatment effort has shown promise in the management and rehabilitation of selected narcotic addicts. It is also recognized that a number of dangers and possible abuses may arise from such efforts if professional services and controls are inadequately applied. It is further felt that additional research is urgently needed so that data may be accumulated which will permit sound determinations of safety, efficacy, and necessary procedural safeguards.

(b) Therefore, the commissioner of Food and Drugs and the Director of the Drug Enforcement Administration Department of Justice, agree that interested professionals, municipalities, and organizations should be allowed to conduct further research in this area within a framework of adequate controls designed to protect the individual patients and the community. To facilitate this purpose, the Food and Drug Administration and the Drug Enforcement Administration, Department of Justice, have jointly agreed upon acceptable criteria and guidelines which are set forth in §291.505. In addition, such other provisions of the Federal narcotic laws and regulations as are applicable must also be observed.

[42 FR 46698, Sept. 16, 1977]

§291.505 Conditions for the use of narcotic drugs; appropriate methods of professional practice for medical treatment of the narcotic addiction of various classes of narcotic addicts under Section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970.

(a) Definitions. As used in this part:

(1) "Detoxification treatment" means the dispensing of a narcotic drug in decreasing doses to an individual to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period. There are two types of detoxification treatment: short-term detoxification treatment and long-term detoxification treatment.

(i) "Short-term detoxification treatment" is for a period not in excess of 30 days.

(ii) "Long-term detoxification treatment" is for a period more than 30 days, but not in excess of 180 days.

(2) "Maintenance treatment" means the dispensing of a narcotic drug in the treatment of an individual for dependence on heroin or other morphine-like drug.

(3) A "medical director" is a physician, licensed to practice medicine in the jurisdiction in which the program is located, who assumes responsibility for the administration of all medical services performed by the narcotic treatment program, including ensuring that the program is in compliance with all Federal, State, and local laws and regulations regarding the medical treatment of narcotic addiction with a narcotic drug.

(4) A "medication unit" is a facility established as part of, but geographically dispersed, i.e., separate from a narcotic treatment program from which licensed private practitioners and community pharmacists-

(i) Are permitted to administer and dispense a narcotic drug, and

(ii) Are authorized to collect samples for drug testing or analysis for narcotic drugs.

(5) "Narcotic dependent" means an individual who physiologically needs heroin or a morphine-like drug to prevent the onset of signs of withdrawal.

(6) A "narcotic treatment program" is an organization (or a person, including a private physician) that administers or dispenses a narcotic drug to a narcotic addict for maintenance or detoxification treatment, provides, when appropriate or necessary, a comprehensive range of medical and rehabilitative services, is approved by the State authority and the Food and Drug Administration, and that is registered with the Drug Enforcement Administration to use a narcotic drug for the treatment of narcotic addiction.

(7) A "program sponsor" is a person (or representative of an organization) who is responsible for the operation of a narcotic treatment program and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing services at the program (including its medication units).

(8) The term "services," as used in this part, includes medical evaluations, counseling, rehabilitative and other social programs (e.g., vocational and educational guidance, employment placement, which will help the patient become a productive member of society.

(9) A "State authority" is the agency designated by the Governor or other appropriate official to exercise the responsibility and authority within the State or Territory for governing the treatment of narcotic addiction with a narcotic drug.

(b) Organizational structure and approval requirements-

(1) Organizational structure

(i) A narcotic treatment program may be an independent organization or part of a centralized organization. For example, if a centralized organizational structure consists of a primary facility and other outpatient facilities, all of which conduct initial evaluation of patients and administer or dispense medication, the primary facility and each outpatient facility are separate programs, even though some services (e.g., the same hospital or rehabilitative services) are shared.

(ii) The program sponsor shall submit to the Food and Drug Administration and the State authority a description of the organizational structure of the program, the name of the persons responsible for the program, the address of the program, and the responsibilities of each facility or medication unit. The sources of funding for each program shall be listed and the name and address of each governmental agency providing funding shall be stated.

(iii) Where two or more programs share a central administration (e.g., a city or State-wide organization), the person responsible for the organization (administrator or program sponsor) is required to be listed as the program sponsor for each separate participating program. An individual program shall indicate its participation in the central organization at the time of its application. The administrator or sponsor may fulfill all recordkeeping and reporting requirements for these programs, but each program must continue to receive separate approval.

(iv) One physician may assume primary medical responsibility for more than one program and be listed as medical director. If a physician assumes medical responsibility for more than one program, a statement documenting the feasibility of the arrangement is required to be attached to the application.

(v) [Reserved]

(2) Program approval

(i) Before a narcotic treatment program may be lawfully operated, the program, whether an outpatient facility or a private practitioner, shall submit the applications specified in this section simultaneously to the Food and Drug Administration and the State authority and must receive the approval of both, except as provided for in Paragraph (h)(5) of this section. Before granting approval, the Food and Drug Administration will consult with the Drug Enforcement Administration, Department of Justice, to ascertain if the program is in compliance with Federal controlled substances laws. Each physical location within any program is required to be identified and listed in the approval application. At the time of application for approval, the program sponsor shall indicate whether medication will be administered or dispensed at the facility. Before medication may be administered or dispensed at a location not previously approved for this purpose, the program is required to obtain approval from FDA and the State agency.

However, no approval is necessary, but notification is required when a facility in which medication is administered or dispensed is deleted by a program. In that event, the program shall notify the Food and Drug Administration and the State authority within three weeks of the deletion. Similarly, addition or deletion of facilities which provide services other than administering or dispensing medication is also permitted without approval, but notification must be made within 3 weeks to the Food and Drug Administration and the State authority about the addition and/or deletion.

(ii) Exemption of Federal programs. The provisions of this section requiring approval (or permitting disapproval or revocation of approval) by the State authority, compliance with requirements imposed by State law, or the submission of applications or reports required by the State authority do not apply to programs operated directly by the Veterans' Administration or any other department or agency of the United States. Federal agencies operating narcotic treatment programs have agreed to cooperate voluntarily with State agencies by granting permission on an informal basis for designated State representatives to visit Federal narcotic treatment programs and by furnishing a copy of Federal reports to the State authority, including the reports required under this section.

(iii) Services. Each narcotic treatment program shall provide medical and rehabilitative services and programs. (See Paragraph (d)(4) of this section.) These services should normally be made available at the primary facility, but the program sponsor may enter into a formal documented agreement with private or public agencies, organizations, or institutions for these services if they are available elsewhere. The program sponsor, in any event, must be able to document that medical and rehabilitative services are fully available to patients.

(iv) Prohibition against unapproved use of narcotic drugs. No prescribing, administering, or dispensing of a narcotic drug for the treatment of narcotic addiction may occur without prior approval by the Food and Drug Administration and the State authority, except as provided for in Paragraph (h)(5) of this section, unless specifically exempted by this section.

(v) Approved narcotic drugs for use in treatment programs. The following narcotic drug has been approved for use in the treatment of narcotic addiction: Methadone.

(3) Medication unit.

(i) A program may establish a medication unit to facilitate the needs of patients who are stabilized on an optimal dosage level. To lawfully operate a medication unit, the program shall, for each separate unit, obtain approval from the Food and Drug Administration, the Drug Enforcement Administration, and the State authority, except as provided for in Paragraph (h)(5) of this section. The Food and Drug Administration, in determining whether to approve a medication unit, will consider the distribution of units within a particular geographic area. Any new medication unit is required to receive approval before it may lawfully commence operation.

(ii) Revocation of approval. If the Food and Drug Administration revokes the primary program's approval, the approval for any medication unit associated with the program is deemed to be automatically revoked. The Food and Drug Administration's revocation of the approval of a particular medication unit, will not, in and of itself, affect the approval of the primary program.

(iii) Narcotic drug supply. A medication unit must receive its supply of the narcotic drug directly from the stocks of the primary facility. Only persons permitted to administer or dispense the drug or security personnel licensed or otherwise authorized by State law to do so may deliver the drug to a medication unit.

(iv) Referral.

(A) The patient shall be stabilized at his or her optimal dosage level before he or she may be referred to a medication unit.

(B) Since the medication unit does not provide a range of services, the program sponsor shall determine that the patient to be referred is not in need of frequent counseling, rehabilitative, and other services which are only available at the primary program facility.

(v) Services. A medication unit is limited to administering or dispensing a narcotic drug and collecting samples for drug testing or analysis for narcotic drugs in accordance with Paragraph (d)(2) of this section. If a private practitioner wishes to provide other services besides administering or dispensing a narcotic drug and collecting samples for drug testing or analysis for narcotic drugs, he or she must submit an application for separate approval.

(vi) Responsibility for patient. After a patient is referred to a medication unit, the program sponsor retains continuing responsibility for the patient's care. The program sponsor shall ensure that the patient receives needed medical and rehabilitative services at the primary facility.

(c) Conditions for approval of the use of a narcotic drug in a treatment program-

(1) Applicants. An individual listed as program sponsor for a treatment program using a narcotic drug need not personally be a licensed practitioner, but shall employ a licensed physician for the position of medical director. Persons responsible for administering or dispensing the narcotic drug shall be practitioners as defined by Section 102(21) of the Controlled Substances Act (21 U.S.C. 802(21)) and licensed to practice by the State in which the program is to be established.

(2) Assent to regulation.

(i) A person who sponsors a narcotic treatment program, and any persons responsible for a particular program, shall agree to adhere to all the rules, directives, and procedures, set forth in this section, and any regulation regarding the use of narcotic drugs in the treatment of narcotic addiction which may be promulgated in the future. The program sponsor has responsibility for all personnel and individuals providing services, who work in the program at the primary facility or at other facilities or medication units. The program sponsors shall agree to inform all personnel and individuals providing services of the provisions of this section and to monitor their activities to assure compliance with the provisions.

(ii) The Food and Drug Administration and the State authority are required to be notified within 3 weeks of any replacement of the program sponsor or medical director. Activities in violation of this regulation may give rise to the sanctions set forth in paragraph (i) of this section.

(3) Description of facilities. Only program site(s) approved by Federal, State, and local authorities may treat narcotic addicts with a narcotic drug. To obtain program approval, the applicant shall demonstrate that he or she will have access to adequate physical facilities to provide all necessary services. A program must have ready access to a comprehensive range of medical and rehabilitative services so that the services may be provided when necessary. The name, address and description of each hospital, institution, clinical laboratory, or other facility available to provide the necessary services are required to be included in the application submitted to the Food and Drug Administration and the State authority. The application is also required to include the name and address of each medication unit.

(4) Submission of proper applications. The following applications shall be filed simultaneously with both the Food and Drug Administration and the State authority.

(i) Form FDA-2632 "Application for Approval of Use of Methadone in a Treatment Program." This form, required by Paragraph (k) of this section, shall be completed and signed by the program sponsor and submitted in duplicate to the Food and Drug Administration and the State authority.

(ii) Form FDA-2633 "Medical Responsibility Statement for Use of Methadone in a Treatment Program." This form required by Paragraph (k) of this section, shall be completed and signed by each licensed physician authorized to administer or dispense narcotic drugs and submitted in duplicate to the Food and Drug Administration and the State authority. The names of any other persons licensed by law to administer or dispense narcotic drugs working in the program shall be listed even if they are not responsible for administering or dispensing the drug at the time the application is submitted.

(5) State and Federal approval, denial, and revocation of approval of narcotic treatment programs.

(i) The Food and Drug Administration may grant approval to a program only after FDA has received notification from both the State authority and the Drug Enforcement Administration that the program conforms to all pertinent State and Federal requirements.

(ii) The Food and Drug Administration will revoke the approval of a narcotic treatment program if so requested by the State authority or the Drug Enforcement Administration. If approval of a program is denied or revoked, the program shall have a right to appeal to the Commissioner, as provided for in Paragraph (h)(5) of this section.

(iii) No shipment of a narcotic drug may lawfully be made to any program which does not have current approval from the Food and Drug Administration. Within 60 days after receipt of the application from the

program sponsor for approval, the Food and Drug Administration will notify the sponsor whether the application is approved or denied.

(d)(1) Minimum standards for admission-

(i) History of addiction and current physiologic dependence.

(A) A person may be admitted as a patient for a maintenance program only if a program physician determines that the person is currently physiologically dependent upon a narcotic drug and became physiologically dependent at least 1 year before admission for maintenance treatment. A 1-year history of addiction means that an applicant for admission to a maintenance program was physiologically addicted to a narcotic at a time at least 1 year before admission to a program and was addicted, continuously or episodically, for most of the year immediately before admission to a program. In the case of a person for whom the exact date on which physiological addiction began cannot be ascertained, the admitting program physician may, in his or her reasonable clinical judgment, admit the person to maintenance treatment, if from the evidence presented, observed, and recorded in the patient's record, it is reasonable to conclude that there was physiologic dependence at a time approximately 1 year before admission.

(B) Although daily use of a narcotic for an entire year could satisfy the regulatory definition of a 1-year history of addiction, operationally one might be physiologically dependent without daily use during the entire 1-year period and still satisfy the definition. The following, although not exhaustive, are examples of applicants who would meet the minimum standard of a 1-year history of addiction and who, if currently physiologically dependent on the date of application for admission, would be eligible for admission to a maintenance program:

(1) Physiologic addiction began in August 1987 and continued to the date of application for admission in August 1988.

(2) Physiologic addiction began in January 1988 and continued until April 1988. Physiologic addiction began again in July 1988 and continued until the application for admission in January 1989.

(3) Physiologic addiction began in January 1987 and continued until October 1987. The date of application for admission was January 1988, at which time the patient had been readdicted for 1 month preceding his or her admission.

(4) Physiologic addiction consisted of four episodes in the last year, each episode lasting 2½ months.

(C) The program physician or an appropriately trained staff member designated and supervised by the physician shall record in the patient's record the criteria used to determine the patient's current physiologic dependence and history of addiction. In the latter circumstances, the program physician shall review, date, and countersign the supervised staff member's evaluation to demonstrate his or her agreement with the evaluation. The program physician shall make the final determination concerning a patient's physiologic dependence and history of addiction. The program physician shall sign, date, and record a statement that he or she has reviewed all the documented evidence to support a 1-year history of addiction and the current physiologic dependence and that in his or her reasonable clinical judgment the patient fulfills the requirements for admission to maintenance treatment. The program physician shall complete and record the statement before the program administers any methadone to the patient.

(ii) Voluntary participation, informed consent. The person responsible for the program shall ensure that: A patient voluntarily chooses to participate in a program; all relevant facts concerning the use of the narcotic drug used by the program are clearly and adequately explained to the patient; all patients, with full knowledge and understanding of its contents, sign the "Consent to Methadone Treatment" Form FDA-2635 (see Paragraph (k) of this section); a parent, legal guardian, or responsible adult designated by the State authority (e.g., "emancipated minor" laws) sign for patients under the age of 18 the second part of Form FDA-2635 "Consent to Methadone Treatment."

(iii) Exceptions to minimum admission criteria-

(A) Penal or chronic care. A person who has resided in a penal or chronic care institution for 1 month or longer may be admitted to maintenance treatment within 14 days before release or discharge, or within 6 months after release from such an institution without documented evidence to support findings of physiological dependence, provided the person would have been eligible for admission before he or she was incarcerated or institutionalized and, in the reasonable clinical judgment of a program physician, treatment is medically justified. Documented evidence of the prior residence in a penal or chronic care institution and evidence of all other findings and the criteria used to determine the findings are required to be recorded in the patient's record by the admitting program physician, or by

program personnel supervised by the admitting program physician. The admitting program physician shall date and sign these recordings or review the health-care professional's recordings before the initial dose is administered to the patient. In the latter case, the admitting program physician shall date and sign the recordings in the patient's record made by the health-care professional within 72 hours of administration of the initial dose to the patient.

(B) Pregnant patients.

(1) Pregnant patients, regardless of age, who have had a documented narcotic dependency in the past and who may return to narcotic dependency, with all its attendant dangers during pregnancy, may be placed on a maintenance regimen. For such patients, evidence of current physiological dependence on narcotic drugs is not needed if a program physician certifies the pregnancy and, in his or her reasonable clinical judgment, finds treatment to be medically justified. Evidence of all findings and the criteria used to determine the findings are required to be recorded in the patient's record by the admitting program physician, or by program personnel supervised by the admitting program physician. The admitting program physician shall date and sign these recordings or review the health-care professional's recordings before the initial methadone dose is administered to the patient. In the latter case, the admitting program physician shall date and sign the recordings in the patient's record made by the health-care professional within 72 hours of administration of the initial methadone dose to the patient. Pregnant patients are required to be given the opportunity for prenatal care either by the program or by referral to appropriate health-care providers.

(2) If a program cannot provide direct prenatal care for pregnant patients in treatment, the program shall establish a system for informing the patients of the publicly or privately funded prenatal care opportunities available. If there are no publicly funded prenatal referral opportunities and the program cannot provide such services or the patient cannot afford them or refuses them, then the treatment program shall, at a minimum, offer her basic prenatal instruction on maternal, physical, and dietary care as part of its counseling service.

(3) Counseling records and/or other appropriate patient records are required to reflect the nature of prenatal support provided by the program. If the patient is referred for prenatal services, the physician to whom she is referred is required to be notified that she is in maintenance treatment, provided that notification is in accordance with the Department of Health and Human Services' confidentiality regulations (42 CFR Part 2). If a pregnant patient refuses direct treatment or appropriate referral for treatment, the treating program physician should consider using informed consent procedures; e.g., to have the patient acknowledge in writing that she had the opportunity for this treatment but refuses it. The program physician, consistent with the confidentiality regulations, shall request the physician or the hospital to which a patient is referred to provide, following birth, a summary of the delivery and treatment outcome for the patient and offspring. If the program physician does not receive a response to the request, he or she shall document in the record that such a request was made.

(4) Within 3 months after termination of pregnancy, the program physician shall enter an evaluation of the patient's treatment state into her record and state whether she should remain in the maintenance program or be detoxified.

(5) Caution should be taken in the maintenance treatment of pregnant patients. Dosage levels should be maintained at the lowest effective dose if treatment is deemed necessary. The program sponsor shall ensure that each female patient is fully informed of the possible risks to her or to her unborn child from continued use of illicit drugs and from the use of or withdrawal from, a narcotic drug administered or dispensed by the program in maintenance or detoxification treatment.

(C) Previously treated patients. Under certain circumstances, a patient who has been treated and later voluntarily detoxified from maintenance treatment may be readmitted to maintenance treatment, without evidence to support findings of current physiologic dependence, up to 2 years after discharge, if the program attended is able to document prior narcotic drug maintenance treatment of 6 months or more, and the admitting program physician, in his or her reasonable clinical judgment, finds readmission to maintenance treatment to be medically justified. For patients meeting these criteria, the quantity of take-home medication will be determined in the reasonable clinical judgment of the program physician, but in no case may the quantity of take-home medication be greater than would have been allowed at the time the patient voluntarily terminated previous treatment. The admitting program physician or a program employee under supervision of the admitting program physician must enter in the patient's record documented evidence of the patient's prior treatment and evidence of all decisions and criteria used relating to the admission of the patient and the quantity of take-home medication permitted. The admitting program physician shall date and sign these entries in the patient's record or review the health-care professional's entries therein before the

program administers any medication to the patient. In the latter case, the admitting program physician shall date and sign the entries in the patient's record made by the health-care professional within 72 hours of administration of the initial dose to the patient.

(iv) Special limitation; treatment of patients under 18 years of age. A person under 18 is required to have had two documented attempts at short-term detoxification or drug-free treatment to be eligible for maintenance treatment. A 1-week waiting period is required after such a detoxification attempt, however, before an attempt is repeated. The program physician shall document in the patient's record that the patient continues to be or is again physiologically dependent on narcotic drugs. No person under 18 years of age may be admitted to a maintenance treatment program unless a parent, legal guardian or responsible adult designated by the State authority (e.g., "emancipated minor" laws) completes and signs consent form, Form FDA-2635 "Consent to Methadone Treatment."

(v) Denial of admission. If in the reasonable clinical judgment of the medical director a particular patient would not benefit from treatment with a narcotic drug, the patient may be refused such treatment even if the patient meets the admission standards.

(2) Minimum testing or analysis for drugs: Uses and frequency.

(i) The person(s) responsible for a program shall ensure that: An initial drug-screening test or analysis is completed for each prospective patient; at least eight additional random tests or analyses are performed on each patient during the first year in maintenance treatment; and at least quarterly random tests or analyses are performed on each patient in maintenance treatment for each subsequent year, except that a random test or analysis is performed monthly on each patient who receives a 6-day supply of take-home medication. When a sample is collected from each patient for such test or analysis, it must be done in a manner that minimizes opportunity for falsification. Each test or analysis must be analyzed for opiates, methadone, amphetamines, cocaine, and barbiturates. In addition, if any other drug or drugs have been determined by a program to be abused in that program's locality, or as otherwise indicated, each test or analysis must be analyzed for any of those drugs as well. Any laboratory that performs the testing required under this regulation shall be in compliance with all applicable Federal proficiency testing and licensing standards and all applicable State standards. If a program proposes to change a laboratory used for such testing or analysis, the program shall have the change approved by the Food and Drug Administration.

(ii) The person responsible for a program shall ensure that test results are not used as the sole criterion to force a patient out of treatment but are used as a guide to change treatment approaches. The person responsible for a program shall also ensure that when test results are used, presumptive laboratory results are distinguished from results that are definitive.

(3) Patient evaluation; minimum admission and periodic requirements-

(i) Minimum contents of medical evaluation. Each patient is required to have a medical evaluation by a program physician or an authorized health-care professional under the supervision of a program physician on admission to a program. At a minimum, this evaluation is required to consist of a medical history which includes the required history of narcotic dependence, evidence of current physiologic dependence unless excepted by the regulations, and a physical examination, and includes the following laboratory examinations: serological test for syphilis, a tuberculin skin test, and a test or analysis for drug determination. If in the reasonable clinical judgment of the program physician, a patient's subcutaneous veins are severely damaged to the extent that a blood specimen cannot be obtained, the serological test for syphilis may be omitted. The physical examination is required to consist of an investigation of the organ systems for possibilities of infectious disease, pulmonary, liver, and cardiac abnormalities, and dermatologic sequelae of addiction. In addition, the physical examination is required to include a determination of the patient's vital signs (temperature, pulse, and blood pressure and respiratory rate); an examination of the patient's general appearance, head, ears, eyes, nose, throat (thyroid), chest (including heart, lungs, and breasts), abdomen, extremities, skin, and neurological assessment; and the program physician's overall impression of the patient.

(ii) Recordings of findings. The admitting program physician or an appropriately trained health care professional supervised by the admitting program physician shall record in the patient's record all findings from the admission medical evaluation. In each case, the admitting program physician shall date and sign these entries, or date, review, and countersign these recordings in the patient's record to signify his or her review of and concurrence with the history and physical findings.

(iii) Admission evaluation.

(A) Each patient seeking admission or readmission for treatment services is required to be interviewed by a well-trained program counselor, qualified by virtue of education, training, or experience to assess the psychological and sociological background of drug abusers, to determine the appropriate treatment plan for the patient. To determine the most appropriate treatment plan for a patient, the interviewer shall obtain and document in the patient's record the patient's history.

(B) A patient's history includes information relating to his or her educational and vocational achievements. If a patient has no such history; i.e., he or she has no formal education or has never had an occupation, this requirement is met by writing this information in the patient's history.

(iv) Initial treatment plan.

(A)(*1*) The initial treatment plan is required to contain a statement that outlines realistic short-term treatment goals which are mutually acceptable to the patient and the program. The initial treatment plan is also required to spell out the behavioral tasks a patient must perform to complete each short-term goal; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psychosocial, economic, legal, or other supportive services that a patient needs. The plan is also required to identify the frequency with which these services are likely to be provided. Prior to developing a treatment plan, the patient's needs for medical, social, and psychological services; education; vocational rehabilitation; and employment must be assessed, and the needs reflected, when clinically appropriate, in the treatment plan.

(2) A primary counselor is one who is assigned by the program to develop, implement, and evaluate the patient's initial and periodic treatment plan and to monitor a patient's progress in treatment. The primary counselor shall enter in the patient's record the counselor's name, the contents of a patient's initial assessment, and the initial treatment plan. The primary counselor shall make these entries immediately after the patient is stabilized on a dose or within 4 weeks after admission, whichever is sooner.

(B) It is recognized that patients need varying degrees of treatment and rehabilitative services which are often dependent on or limited by a number of variables; e.g., patient resources, available program, and community services. It is not the intent of this regulation to prescribe a particular treatment and rehabilitative service or the frequency at which a service should be offered.

(C) The program supervisory counselor or other appropriate program personnel so designated by the program physician shall review and countersign all the information and findings required to be recorded in each patient's record under Paragraph (d)(3)(iv) of this section.

(v) Periodic treatment plan evaluation.

(A) The program physician or the primary counselor shall review, reevaluate, and alter where necessary each patient's treatment plan at least once each 90 days during the first year of treatment, and then at least twice a year after the first year of continuous treatment.

(B) The program physician shall ensure that the periodic treatment plan becomes part of each patient's record and that it is signed and dated in the patient's record by the primary counselor and is countersigned and dated by the supervisory counselor.

(C) At least once a year, the program physician shall date, review, and countersign the treatment plan recorded in each patient's record and ensure that each patient's progress or lack of progress in achieving the treatment goals is entered in the patient's record by the primary counselor. When appropriate, the treatment plan and progress notes should deal with the patient's mental and physical problems, apart from drug abuse. The treatment plan is required to include the name of and the reasons for prescribing any medication for emotional or physical problems.

(D) The requirement for annual physician review and signature by the program physician in Paragraph (d)(3)(v)(C) of this section is discretionary, however, as it applies to a patient, who has satisfactorily adhered to program rules for at least 3 consecutive years from his or her entrance into the maintenance treatment program and who has made substantial progress in rehabilitation.

(4) Minimum program services-

(i)(A) Access to a range of services. A treatment program shall provide a comprehensive range of medical and rehabilitative services to its patients, especially during the first 3 years of treatment.

(B) Pregnant patients

(1) For pregnant patients in a treatment program who were not admitted under Paragraph (d)(1)(iii)(B) of this section, a treatment program shall give them the opportunity for prenatal care either by the narcotic treatment program or by referral to appropriate health care providers. If a program cannot provide direct prenatal care for pregnant patients in treatment, it shall establish a system of referring them for prenatal care which may be either publicly or privately funded. If there is no publicly funded prenatal care available to which a patient may be referred, and the program cannot provide such services, or the patient cannot afford or refuses prenatal care services, then the treatment program shall, at a minimum, offer her basic prenatal instruction on maternal, physical, and dietary care as a part of its counseling service.

(2) Counseling records and other appropriate patient records are required to reflect the nature of prenatal support provided by the program. If the program refers a patient for prenatal services, it shall inform the physician to whom she is referred that the patient is in maintenance treatment, provided such notification is in accordance with the Department of Health and Human Services' confidentiality regulations (42 CFR Part 2). If a pregnant patient refuses direct prenatal services or appropriate referral for prenatal services, the treating program physician should consider using informed consent procedures; i.e., to have the patient acknowledge in writing that she has the opportunity for this treatment but refuses it. The program physician shall request the physician or the hospital to which a patient is referred to provide, following birth, a summary of the delivery and treatment outcome for the patient and offspring. The information should be obtained in accordance with the Department of Health and Human Services' confidentiality regulations (42 CFR Part 2). If no response is received, the program physician shall document in the record that such a request was made and no response was received.

(3) Caution should be taken in the maintenance treatment of pregnant patients. Dosage levels should be maintained at the lowest effective dose if continued treatment is deemed necessary. It is the responsibility of the program sponsor to ensure that each female patient is fully informed of the possible risks to a pregnant woman and her unborn child from continued use of illicit drugs and from the use of, or withdrawal from, a narcotic drug administered or dispensed by the program in maintenance or detoxification treatment.

(C) [Reserved]

(D) Off-site services. Any service not furnished at the primary facility is required to be listed in any application for approval submitted to the Food and Drug Administration or to the State authority. The addition, modification, or deletion of any program service is required to be reported immediately to the Food and Drug Administration.

(ii) Minimum medical services; designation of medical director and responsibilities. Each program shall have a designated medical director who assumes responsibility for administering all medical services performed by the program. The medical director and other authorized program physicians are required to be licensed to practice medicine in the jurisdiction in which the program is located. The medical director is responsible for ensuring that the program is in compliance with all Federal, State, and local laws and regulations regarding medical treatment of narcotic addiction. In addition, the medical director or other authorized physicians shall:

(A) Ensure that evidence of current physiologic dependence, length of history of addiction, or exceptions to criteria for admission are documented in the patient's record before the patient receives the initial dose.

(B) Ensure that a medical evaluation, including a medical history has been taken, and physical examination has been done before the patient receives the initial dose (except that in an emergency situation, the initial dose may be given before the physical examination).

(C) Ensure that appropriate laboratory studies have been performed and reviewed.

(D) Sign or countersign all medical orders as required by Federal or State law. (Such medical orders include but are not limited to the initial medication orders and all subsequent medication order changes, all changes in the frequency of take-home medication and prescribing additional take-home medication for an emergency situation.)

(E) Review and countersign treatment plans at least annually as qualified by Paragraph (d)(3)(v)(D) of this section.

(F) Ensure that justification is recorded in the patient's record for reducing the frequency of clinic visits for observed drug ingesting, providing additional take-home medication under exceptional circumstances or when there is physical disability, or prescribing any medication for physical or emotional problems.

(iii) Use of health-care professionals. Although the final decision to accept a patient for treatment may be made only by the medical director or other designated program physician, it is recognized that physicians can train program personnel to detect and document narcotic abstinence symptoms and that some jurisdictions allow State-licensed or certified health-care professionals; e.g., physician's assistants, nurse practitioners, to perform certain functions — record medical histories, perform physical examinations, and prescribe, administer, or dispense certain medications — that are ordinarily performed by a licensed physician. These regulations do not prohibit licensed or certified health-care professionals from performing those functions in narcotic treatment programs if it is authorized by Federal, State, and local laws and regulations, and if those functions are delegated to them by the medical director, and records are properly countersigned by the medical director or a licensed physician.

(iv) Vocational rehabilitation, education, and employment. Each program shall provide opportunities directly, or through referral to community resources, for patients who either desire or have been deemed by the program staff to be ready to participate in educational job training programs or to obtain gainful employment as soon as possible.

(5) Staffing patterns-

(i) Program personnel. The person(s) responsible for a program shall determine program personnel requirements after considering the number of patients who are vocationally and educationally impaired; the number of patients with significant psychopathology; the number of patients who are also non-narcotic drug or alcohol abusers; the number of patients with behavioral problems in the program; and the number of patients with serious medical problems.

(ii) Supportive services. The person(s) responsible for the program shall take notice, when considering the staffing pattern, that maintenance treatment programs need to establish supportive services in accordance with the varying characteristics and needs of their patient populations. The person(s) responsible for a program shall also take notice of the availability of existing community resources which may complement or enhance the program's delivery of supportive services and then establish a staffing pattern based on a combination of patient needs and available, accessible community resources.

(6) Frequency of attendance; quantity of take-home medication; dosage of methadone; initial and stabilization-

(i) Dosage and responsibility for administration.

(A) The person(s) responsible for the program shall ensure that the initial dose of methadone does not exceed 30 milligrams and that the total dose for the first day does not exceed 40 milligrams, unless the program medical director documents in the patient's record that 40 milligrams did not suppress opiate abstinence symptoms.

(B) A licensed physician shall assume responsibility for the amount of the narcotic drug administered or dispensed and shall record, date, and sign in each patient's record each change in dosage schedule.

(C) The administering licensed physician shall ensure that a daily dose greater than 100 milligrams is justified in the patient's record.

(ii) Authorized dispensers of narcotic drugs; responsibility. A narcotic drug may be administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to order narcotic drugs for patients, or by an agent of such a practitioner, supervised by and under the order of the practitioner. This agent is required to be a pharmacist, registered nurse, or licensed practical nurse, or any other health-care professional authorized by Federal and State law to administer or dispense narcotic drugs. The licensed practitioner assumes responsibility for the amounts of narcotic drugs administered or dispensed and shall record and countersign all changes in dosage schedule.

(iii) Form. Methadone may be administered or dispensed in oral form only when used in a treatment program. Hospitalized patients under care for a medical or surgical condition are permitted to receive methadone in parenteral form when the attending physician judges it advisable. Although tablet, syrup concentrate, or other formulations may be distributed to the program, all oral medication is required to be administered or dispensed in a liquid formulation. The oral dosage form is required to be formulated in such a way as to reduce its potential for parenteral abuse. Take-home medication is required to be labeled with the treatment center's name, address, and telephone number and must be packaged in special packaging as required by 16 CFR 1700.14 in accordance with the Poison Prevention Packaging Act (Pub. L. 91-601, 15 U.S.C. 1471 et seq.) to reduce the chances of accidental ingestion.

Exceptions may be granted when these provisions conflict with State law with regard to the administering or dispensing of drugs.

(iv) Take-home medication

(A) Take-home medication may be given only to a patient who, in the reasonable clinical judgment of the program physician, is responsible in handling narcotic drugs. Before the program physician reduces the frequency of a patient's clinical visits, she or he or a designated staff member shall record the rationale for the decision in the patient's clinical record. If this is done by a designated staff member, a program physician shall review, countersign, and date the patient's record where this information is recorded.

(B) The program physician shall consider the following in determining whether, in his or her reasonable clinical judgment, a patient is responsible in handling narcotic drugs:

(*1*) Absence of recent abuse of drugs (narcotic or non-narcotic), including alcohol;

(2) Regularity of clinic attendance;

(*3*) Absence of serious behavioral problems at the clinic;

(*4*) Absence of known recent criminal activity, e.g., drug dealing;

(*5*) Stability of the patient's home environment and social relationships;

(*6*) Length of time in maintenance treatment;

(*7*) Assurance that take-home medication can be safely stored within the patient's home; and

(*8*) Whether the rehabilitative benefit to the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.

(v) Take-home requirements. The requirement of time in treatment is a minimum reference point after which a patient may be eligible for take-home privileges. The time reference is not intended to mean that a patient in treatment for a particular time has a specific right to take-home medication. Thus, regardless of time in treatment, a program physician may, in his or her reasonable judgment, deny or rescind the take-home medication privileges of a patient.

(A)(*1*) In maintenance treatment, it is required that a patient come to the clinic for observation daily or at least 6 days a week. If, in the reasonable clinical judgment of the program physician, a patient demonstrates that he or she has satisfactorily adhered to program rules for at least 3 months, has made substantial progress in rehabilitation and responsibility in handling narcotic drugs (see Paragraphs (d)(6)(iv)(B) (1) through (8) of this section, and would improve his or her rehabilitative progress by decreasing the frequency of attendance at the clinic for observation, the patient may be permitted to reduce his or her attendance at the clinic for observation to three times weekly. The patient may receive no more than a 2-day take-home supply of medication.

(2) If, in the reasonable clinical judgment of the program physician, a patient demonstrates that he or she has satisfactorily adhered to program rules for at least 2 years from his or her entrance into the program, has made substantial progress in rehabilitation and responsibility in handling narcotic drugs (see Paragraphs (d)(6)(iv)(B) (1) through (8) of this section), and would improve his or her rehabilitative progress by decreasing the frequency of attendance at the clinic for observation, the patient may be permitted to reduce his or her clinic attendance at the clinic for observation to twice weekly. Such a patient may receive no more than a 3-day take-home supply of medication.

(*3*) If, in the reasonable clinical judgment of the program physician, a patient demonstrates that he or she has satisfactorily adhered to program rules for at least 3 consecutive years from his or her entrance into the maintenance treatment program, has made substantial progress in rehabilitation, has no major behavioral problems, is responsible in handling narcotic drugs (see Paragraphs (d)(6)(iv)(B) (1) through (8) of this section), and would improve his or her rehabilitative progress by decreasing the frequency of his or her clinic attendance for observation, the patient may be permitted to reduce clinic attendance for observation to once weekly, provided that the following additional criteria are met:

The program physician has written into the patient's record an evaluation that the patient is responsible in handling narcotic drugs (Paragraphs (d)(6)(iv)(B) (1) through (8) of this section); the patient is employed (or actively seeking employment), attends school, is a homemaker, or is considered unemployable for mental or physical reasons by a program physician; the patient is not known to have abused drugs, including alcohol in the last year; and the patient is not known to have engaged in criminal activity; e.g., drug dealing in the last year. A patient is permitted to reduce clinic attendance for observation to once weekly may receive no more than a 6-day take-home supply of medication.

(B)(1) If a patient, after receiving a supply of take-home medication, is inexcusably absent from or misses a scheduled appointment with a treatment program without authorization from the program staff, the program physician shall increase the frequency of the patient's clinic attendance for drug ingestion under observation. For such a patient, the program physician shall not reduce the frequency of the patient's clinic attendance for drug ingestion under observation until she or he has had at least three consecutive monthly tests or analyses that are neither positive for morphine-like drugs (except from the narcotic drug administered or dispensed by the program) or other drugs of abuse, nor negative for the narcotic drug administered or dispensed by the program, and until she or he is again determined by a program physician to be responsible in handling narcotic drugs (see Paragraphs (d)(6)(iv)(B) (1) through (8) of this section) and to meet criteria in Paragraph (d)(6)(v)(A) of this section.

(2) If a patient, after receiving a 6-day supply of take-home medication, has a test or analysis which is confirmed to be positive for morphine-like drugs (except for the narcotic drug administered or dispensed by the program) or other drugs of abuse, or negative for the narcotic drug administered or dispensed by the program, the program physician shall place the patient on probation for 3 months. If, during this probation, the patient has a test or analysis either positive for morphine-like drugs (except for the narcotic drug administered or dispensed by the program) or other drugs of abuse, or negative for the narcotic drug administered or dispensed by the program, the program physician shall increase the frequency of the patient's clinic attendance for observation to at least twice weekly. Such a patient may receive no more than a 3-day take-home supply of medication until she or he has had at least three consecutive monthly tests or analyses which are neither positive for morphine-like drugs (except for the narcotic drug administered or dispensed by the program) or other drugs of abuse, nor negative for the narcotic drug administered or dispensed by the program, and the program physician again determines that the patient is responsible in handling narcotic drugs (see Paragraphs (d)(6)(iv)(B) (1) through (8) of this section) and meets the criteria contained in Paragraph (d)(6)(v)(A) of this section.

(C) In calculating the number of years of maintenance treatment, the period is considered to begin on the first day the medication is administered, or on readmission if a patient has had a continuous absence of 90 days or more. Cumulative time spent by the patient in more than one program is counted toward the number of years of treatment, provided there has not been a continuous absence of 90 days or more.

(D) Each patient whose daily dose is above 100 milligrams is required to be under observation while ingesting the drug at least 6 days per week irrespective of the length of time in treatment, unless the program has received prior approval from the Food and Drug Administration with the concurrence of the State authority.

(vi) Exceptions to take-home requirements. If, in the reasonable clinical judgment of the program physician:

(A) A patient is found to have a physical disability which interferes with his or her ability to conform to the applicable mandatory schedule, she or he may be permitted a temporarily or permanently reduced schedule, provided she or he is also found to be responsible in handling narcotic drugs.

(B) A patient, because of exceptional circumstances such as illness, personal or family crises, travel, or other hardship, is unable to conform to the applicable mandatory schedule, she or he may be permitted a temporarily reduced schedule, provided she or he is also found to be responsible in handling narcotic drugs. The rationale for an exception to a mandatory schedule is to be based on the reasonable clinical judgment of the program physician and shall be recorded in the patient's record by the program physician or by program personnel supervised by the program physician. In the latter situation, the physician shall review, countersign, and date the patient's record where this rationale is recorded. In any event, a patient may not be given more than a 2 week supply of narcotic drugs at one time.

(vii) Official State holidays. If a treatment center program is not in operation due to the observance of an official State holiday, patients may be permitted one extra take-home dose per visit and one fewer clinic visit per week to allow patients not to have to attend the clinic on an official State holiday. An official State holiday is a holiday on which most State offices are usually closed and routine State government business is not conducted.

(7) [Reserved]

(8) Minimum standards for short-term detoxification treatment.

(i) For short-term detoxification from narcotic drugs, the narcotic drug is required to be administered by the program physician or by an authorized agent of the physician, supervised by and under the order of the physician. The narcotic drug is required to be administered daily, under close observation, in reducing dosages over a period not to exceed 30 days. All requirements for maintenance treatment apply to short-term detoxification treatment with the following exceptions:

(A) Take-home medication is not allowed during short-term detoxification.

(B) A history of 1 year physiologic dependence is not required for admission to short-term detoxification.

(C) Patients who have been determined by the program physician to be currently physiologically narcotic dependent may be placed in short-term detoxification treatment, regardless of age.

(D) No test or analysis is required except for the initial drug screening test or analysis.

(E) The initial treatment plan and periodic treatment plan evaluation required for maintenance patients are not necessary for short-term detoxification patients. However, a primary counselor must be assigned by the program to monitor a patient's progress toward the goal of short-term detoxification and possible drug-free treatment referral.

(F) The requirements of Paragraph (d)(4) of this section, except Paragraphs (d)(4)(ii) (A) through (D) and (d)(4)(iii) of this section, do not apply to short-term detoxification treatment.

(ii) A patient is required to wait at least 7 days between concluding a short-term detoxification treatment episode and beginning another. Before a short-term detoxification attempt is repeated, the program physician shall document in the patient's record that the patient continues to be, or is again, physiologically dependent on narcotic drugs. The provisions of these requirements, except as noted in Paragraph (d)(8)(i) of this section, apply to both inpatient and ambulatory short-term detoxification treatment.

(iii) Short-term detoxification treatment is not recommended for a pregnant patient.

(9) Minimum standards for long-term detoxification treatment.

(i) For long-term detoxification from narcotic drugs, the narcotic drug is required to be administered by the program physician or by an authorized agent of the physician, supervised by and under the order of the physician. The narcotic drug is required to be administered on a regimen designed to reach a drug-free state and to make progress in rehabilitation in 180 days or less. All requirements for maintenance treatment apply to long-term detoxification treatment with the following exception.

(A) In long-term detoxification treatment, it is required that the patient be under observation while ingesting the drug daily or at least 6 days a week, for the duration of the long-term detoxification treatment.

(B) A history of 1 year physiologic dependence is not required for admission to long-term detoxification.

(C) The program physician shall document in the patient's record that short-term detoxification is not a sufficiently long enough treatment course to provide the patient with the additional program services he or she deems necessary for the patient's rehabilitation. The program physician shall document this information in the patient's record before long-term detoxification may begin.

(D) Patients who have been determined by the program physician to be currently physiologically dependent on narcotics may be placed in long-term detoxification treatment, regardless of age.

(E) An initial drug screening test or analysis is required for each patient. And at least one additional random test or analysis must be performed monthly on each patient during long-term detoxification.

(F) The initial treatment plan and periodic treatment plan evaluation required for maintenance patients are also required for long-term detoxification patients, except that the required periodic treatment plan evaluation is required to occur monthly.

(ii) A patient is required to wait at least 7 days between concluding a long-term treatment episode and beginning another. Before a long-term detoxification attempt is repeated, the program physician shall document in the patient's record that the patient continues to be or is again physiologically dependent on narcotic drugs. The provisions of these requirements apply to both inpatient and ambulatory long-term detoxification treatment.

(iii) Long-term detoxification is not recommended for a pregnant patient.

(10) Inspections of programs; patient confidentiality. A program shall allow inspections by duly authorized employees of the State authority, and in accordance with Federal controlled substances law and Federal confidentiality laws, by duly authorized employees of the Food and Drug Administration, the Drug Enforcement Administration of the Department of Justice, and the National Institute on Drug Abuse.

(11) Exemptions from specific program standards.

(i) A program is permitted, at the time of application or any time thereafter, to request exemption from specific program standards. The rationale for an exemption shall be thoroughly documented in an appendix to be submitted with the application or at some later time. The Food and Drug Administration will approve such exemptions of program standards at the time of application, or any time thereafter, with the concurrence of the State authority. An example of a case in which an exemption might be granted would be for a private practitioner who wishes to treat a limited number of patients in a nonmetropolitan area with few physicians and no rehabilitative services geographically accessible and requests exemption from some of the staffing and service standards.

(ii) The Food and Drug Administration has the right to withhold the granting of an exemption requested at the time of application until a program is in actual operation in order to assess if the exemption is necessary. If periodic inspections of the program reveal that discrepancies or adverse conditions exist, the Food and Drug Administration shall reserve the right to revoke any or all exemptions previously granted.

(12) Research. When a program conducts research on human subjects or provides subjects for research, there must be written policies and written review to assure the rights of the patients involved. Appropriate informed consent forms are required to be signed by the patient and to be retained in his or her patient record at the program. All research, development, and related activities which involve human subjects and which are funded by grants from or contracts with the Department of Health and Human Services are required to comply with the Department of Health and Human Services' regulations on the protection of human subjects, 45 CFR Part 46, and confidentiality of information, 42 CFR Part 2. All investigational research involving human subjects conducted for submission to the Food and Drug Administration must be conducted in compliance with Part 312 of this chapter.

(13) Patient record system-

(i) Patient care. The person(s) responsible for a program shall establish a record system to document and monitor patient care. This system is required to comply with all Federal and State reporting requirements relevant to methadone. All records are required to be kept confidential and in accordance with all applicable Federal and State regulations regarding confidentiality.

(ii) Drug dispensing. The person(s) responsible for a program shall ensure that accurate records traceable to specific patients are maintained showing dates, quantity, and batch or code marks of the drug dispensed. These records must be retained for a period of 3 years from the date of dispensing.

(iii) Patient's record. An adequate record must be maintained for each patient. The record is required to contain a copy of the signed consent form(s), the date of each visit, the amount of drug administered or dispensed, the results of each test or analysis for drugs, any significant physical or psychological disability, the type of rehabilitative and counseling efforts employed, an account of the patient's progress, and other relevant aspects of the treatment program. For recordkeeping purposes, if a patient misses appointments for 2 weeks or more without notifying the program, the episode of care is considered terminated and is to be so noted in the patient's record. This does not mean that the patient cannot return for care. If the patient does return for care and is accepted into the program, this is considered a readmission and is to be so noted in the patient's record. This method of recordkeeping helps assure the easy detection of sporadic attendance and decreases the possibility of administering inappropriate doses of narcotic drugs (e.g., the patient who has received no medication for several days or more and upon return receives the usual stabilization dose). An annual evaluation of the patient's progress must be entered in the patient's record.

(14) Security of drug stocks. Adequate security is required to be maintained over drug stocks, over the manner in which it is administered or dispensed, over the manner in which it is distributed to medication units, and over the manner in which it is stored to guard against theft and diversion of the drug. The program is required to meet the security standards for the distribution and storage of controlled substances as required by the Drug Enforcement Administration, Department of Justice (21 CFR 1301.72-1301.76).

(e) Multiple enrollments-

(1) Administering or dispensing to patients enrolled in other programs. There is a danger of drug dependent persons attempting to enroll in more than one narcotic treatment program to obtain quantities of drugs for the purpose of self-administration or illicit marketing. Therefore, except in an emergency situation, drugs shall not be provided to a patient who is known to be currently receiving drugs from another treatment program.

(2) Patient attendance requirements. The patient shall always report to the same treatment facility unless prior approval is obtained from the program sponsor for treatment at another program. Permission to report for treatment at the facility of another program shall be granted only in exceptional circumstances and shall be noted on the patient's clinical record.

(f) Conditions for use of narcotic drugs in hospitals for detoxification treatment-

(1) Form. The drug may be administered or dispensed in either oral or parenteral form. (See Paragraph (d)(6)(iii) of this section.)

(2) Use of narcotic drugs in hospitals-

(1) [sic] Approved uses. For hospitalized patients, the use of a narcotic drug for narcotic addict treatment may be administered or dispensed only for detoxification treatment. If a narcotic drug is administered for treatment of narcotic dependence for more than 180 days, the procedure is no longer considered detoxification but is, rather, considered maintenance treatment. Only approved narcotic treatment programs may undertake maintenance treatment. This does not preclude the maintenance treatment of a patient who is hospitalized for treatment of medical conditions other than addiction and who requires temporary maintenance treatment during the critical period of his or her stay or whose enrollment in a program which has approval for maintenance treatment using narcotic drugs has been verified. (See 21 CFR 1306.07(c).) Any hospital which already has received approval under this paragraph (f) may serve as a temporary narcotic treatment program when an approved treatment program has been terminated, and there is no other facility immediately available in the area to provide narcotic drug treatment for the patients. The Food and Drug Administration may give this approval upon the request of the State authority or the hospital, when no State authority has been established.

(ii) Individuals responsible for supplies. Hospitals shall submit to the Food and Drug Administration and the State authority the name of the individual (e.g., pharmacist) responsible for receiving and securing supplies of narcotic drugs for the treatment of narcotic addicts. The individual responsible for supplies shall ensure that the only persons who receive supplies of narcotic drugs are those who are authorized to do so by Federal or State law.

(iii) General description. The hospital shall submit to the Food and Drug Administration and the State authority a general description of the hospital, including the number of beds, specialized treatment facilities for drug dependence, and nature of patient care undertaken.

(iv) Anticipated quantity of drug needed. The hospital shall submit to the Food and Drug Administration and the State authority the anticipated quantity of narcotic drugs for narcotic addict treatment needed per year.

(v) Records. The hospital shall maintain accurate records showing dates, quantity, and batch or code marks of the drug used for inpatient treatment. The hospital shall retain the records for at least a period of 3 years.

(vi) Inspection. The hospital shall permit the Food and Drug Administration and the State authority to inspect supplies of the drug at the hospital and evaluate the uses to which the drug is being put. The Food and Drug Administration and the State authority will keep the identity of the patients confidential in accordance with confidentiality requirements of 42 CFR Part 2. Records on the receipt, storage, and distribution of narcotic medication are subject to inspection under Federal controlled substances law; but use or disclosure of records identifying patients will, in any case, be limited to actions involving the program or its personnel.

(vii) Approval of hospital pharmacy. Application for a hospital pharmacy to provide narcotic drugs for detoxification treatment must be submitted to the Food and Drug Administration and the State authority and approval from both is required, except as provided for in Paragraph (h)(5) of this section. Within 60 days after the Food and Drug Administration receives the application, it will notify the applicant of approval or denial or will request additional information, when necessary.

(viii) Approval of shipments to hospital pharmacies. Before a hospital pharmacy may lawfully receive shipments of narcotic drugs for detoxification treatment, a responsible official shall complete, sign, and file in duplicate with the Food and Drug Administration and the State authority Form FDA-2636 "Hospital Request for Methadone Detoxification Treatment" (see Paragraph (k) of this section) and must have received from the Food and Drug Administration a notice that the request has been approved.

(ix) Sanctions. Failure to abide by the requirements described in this section may result in revocation of approval to receive shipments of narcotic drugs for narcotic addict treatment, seizure of the drug supply on hand, injunction, and criminal prosecution.

(g) Confidentiality of patient records.

(1) Except as provided in Paragraph (g)(2) of this section, disclosure of patient records maintained by any program is governed by the provisions of 42 CFR Part 2, and every program must comply with that part. Records on the receipt, storage, and distribution of narcotic medication are also subject to inspection under Federal controlled substances laws. But use or disclosure of records identifying patients will, in any case, be limited to actions involving the program or its personnel.

(2) A treatment program or medication unit or any part thereof, including any facility or any individual, shall permit a duly authorized employee of the Food and Drug Administration to have access to and to copy all records on the use of narcotic drugs in accordance with the provisions of 42 CFR Part 2. A treatment program may reveal such records only when necessary in a related administrative or court proceeding.

(h) Denial or revocation of approval.

(1) Complete or partial denial or revocation of approval of an application to receive shipments of narcotic drugs (Forms FDA-2632 "Application for Approval of Use of Methadone in a Treatment Program" and FDA-2636 "Hospital Request for Methadone Detoxification Treatment") may be proposed to the Commissioner of Food and Drugs by the Director of the Food and Drug Administration's Center for Drug Evaluation and Research, on his or her own initiative or at the request of representatives of the Drug Enforcement Administration, Department of Justice, National Institute of Drug Abuse, the State authority, or any other interested person.

(2) Before presenting such a proposal to the Commissioner, the Director of the Center for Drug Evaluation and Research, or his or her representative, will notify the applicant in writing of the proposed action and the reasons therefor and will offer the applicant an opportunity to explain the matters in question in an informal conference and/or in writing within 10 days after receipt of such notification. The applicant shall have the right to hear and to question the information on which the proposal to deny or revoke approval is based, and may present any oral or written information and views.

(3) If the explanation offered by the applicant is not accepted by the Center for Drug Evaluation and Research as sufficient to justify approval of the application, and denial or revocation of approval is therefore proposed, the Commissioner will evaluate information obtained in the informal conference and/or in writing before the Director of the Center for Drug Evaluation and Research. If the Commissioner finds that the applicant has failed to submit adequate assurance justifying approval of the application, the Commissioner shall issue a notice of opportunity for hearing with respect to the matter pursuant to §314.200 of this chapter and the matter shall thereafter be handled in accordance with established procedures for denial or revocation of approval of a new drug application. If the Secretary determines that there is an imminent hazard to health, revocation of approval will become effective immediately and any administrative procedure will be expedited. Upon revocation of approval of an application, the Commissioner will notify the applicant, the State authority, the Drug Enforcement Administration, Department of Justice, and all other appropriate persons that the applicant may no longer receive shipments of narcotic drugs, and will require the recall of all of the drugs from the applicant. Revocation of approval may also result in criminal prosecution.

(4) Denial or revocation of approval may be reversed when the Commissioner determines that the applicant has justified approval of the application.

(5) A treatment program or medication unit or any part thereof, including any facility or any individual, may appeal to the Food and Drug Administration a complete or partial denial or revocation of approval by the State authority unless the denial or revocation is based upon a State law or regulation. The appeal shall first be made to the Director of the Center for Drug Evaluation and Research, who shall hold an informal conference on the matter in accordance with Paragraph (h)(2) of this section. The State authority may participate in the conference. The appellant or the State authority may appeal the Director's decision to the Commissioner, who shall decide the matter in accordance with Paragraph (h)(3) of this section. If the Commissioner denies or revokes approval, such action shall be handled in accordance with Paragraph (h)(3) of this section. The Commissioner may not grant or retain Food and Drug Administration approval if the Commissioner finds that the appellant is not in compliance with all applicable State laws and regulations and with this section.

(i) Sanctions-

(1) Program sponsor or individual responsible for a particular program. If the program sponsor or the person responsible for a particular program fails to abide by all the requirements set forth in this regulation, or fails to adequately monitor the activities of those employed in the program, he or she may have the approval of his or her application revoked, his or her narcotic drug supply seized, an injunction granted precluding operation of his or her program, and criminal prosecution instituted against him or her.

(2) Persons responsible for administering or dispensing narcotic drugs. If a person responsible for administering or dispensing narcotic drugs for narcotic addict treatment fails to abide by all the requirements set forth in this regulation, criminal prosecution may be instituted against him or her, his or her drug supply may be seized, the approval of the program may be revoked, and an injunction may be granted precluding operation of the program.

(j) Requirements for distribution by manufacturers of narcotic drugs for narcotic addict treatment-

(1) Distribution requirements. Shipments of narcotic drugs for narcotic addict treatment are restricted to direct shipments by manufacturers of the drugs to approved treatment programs using the narcotic drugs and to approved hospital pharmacies. If requested by a manufacturer or State authority, wholesale pharmacy outlets in some regions or States may be authorized to stock narcotic drugs for narcotic addict treatment for that area and then transship the drug to approved narcotic treatment programs and approved hospital pharmacies. Alternative methods of distribution will be permitted if they are approved by the Food and Drug Administration and the State authority. Prior to any approval of an alternative method of distribution, there will be consultation with the Drug Enforcement Administration, Department of Justice, to assure compliance with its regulations regarding controlled substance distribution.

(2) Information regarding approved programs and hospitals. The Food and Drug Administration will provide manufacturer and the public with names and locations of programs and hospitals that have been approved to receive shipments of narcotic drugs for narcotic addiction treatment. All information contained in the forms required by Paragraph (k) of this section is available for public disclosure, except the names or other identifying information.

(3) Acceptance of delivery. Delivery shall only be made to a licensed practitioner or a licensed pharmacist employed at the facility. At the time of delivery, the licensed practitioner or licensed pharmacist shall sign for the drugs and place his or her specific title and identification number on any invoice. Copies of these signed invoices shall be kept by the manufacturer.

(k) Program forms. The program sponsor must ensure that the following forms are completed by the proper program staff and submitted to the appropriate State authority and the Division of Scientific Investigations, Regulatory Management Branch (HFD-342), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Forms are available upon request from the Regulatory Management Branch (HFD-352) at the same address.

FORM

FDA-2632	Application for Approval of Use of Methadone in a Treatment Program
FDA-2633	Medical Responsibility Statement for Use of Methadone in a Treatment Program
FDA-2635	Consent to Methadone Treatment
FDA-2636	Hospital Request for Methadone Detoxification Treatment

(Approved by the Office of Management and Budget under Number 0910-0140)

[54 FR 8960, Mar. 2, 1989; 54 FR 12531, Mar. 27, 1989]

PART 291

DRUGS USED FOR TREATMENT OF NARCOTIC ADDICTS [Revisions]

1. The authority citation for 21 CFR part 291 is revised to read as follows:

AUTHORITY: Secs. 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 371); 21 U.S.C. 823; secs. 301(d), 548, 1976 of the Public Health Service Act (42 U.S.C. 241(d), 290ee-3, 300y-11); 42 U.S.C. 257a.

2. Section 291.505 is amended by inserting the word "comprehensive" before the word "maintenance" everywhere it appears in paragraphs (d)(1)(i), (d)(1)(iii), (d)(1)(iv), (d)(2)(i), (d)(3)(v)(D), (d)(4)(i)(B)(2), (d)(5)(ii), (d)(6)(iv)(B)(6), (d)(6)(v)(A)(1) and (d)(6)(v)(A)(3), (d)(6)(v)(C), (d)(8)(i) introductory text and (d)(8)(i)(E), (d)(9)(i) introductory text and (d)(9)(i)(F), and by revising paragraph (a)(2), by adding paragraphs (a)(10), (b)(1)(v), (b)(2)(vi), (d)(4)(i)(C), and (d)(7), and by revising paragraph (d)(8)(i)(F) to read as follows:

Sec. 291.505 Conditions for the use of narcotic drugs; appropriate methods of professional practice for medical treatment of the narcotic addiction of various classes of narcotic addicts under section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970.

(a) * * *

(2) Maintenance treatment means the dispensing of a narcotic drug, at relatively stable dosage levels, in the treatment of an individual for dependence on heroin or other morphine-like drug. There are two types of maintenance treatment: comprehensive maintenance treatment and interim maintenance treatment.

(i) Comprehensive maintenance treatment is maintenance treatment provided in conjunction with a comprehensive range of appropriate medical and rehabilitative services.

(ii) Interim maintenance treatment is maintenance treatment provided in conjunction with appropriate medical services while a patient is awaiting transfer to comprehensive maintenance treatment.

* * * * *

(10) The term HIV disease means infection with the etiologic agent for acquired immunodeficiency syndrome.

* * * * *

(b) * * *

(1) * * *

(v) Interim maintenance treatment. A public or nonprofit private narcotic treatment program may provide interim maintenance treatment only if the program also provides comprehensive maintenance treatment to which interim maintenance treatment patients may be transferred.

(2) * * *

(vi) Interim maintenance treatment program approval. Before a public or nonprofit private narcotic treatment program may provide interim maintenance treatment, the program must receive approval of both the Food and Drug Administration and the chief public health officer of the State. Before such approval is granted, the program must provide the Food and Drug Administration with certification from the chief public officer of the State that:

(A) Such officer does not object to the authorization of programs providing interim maintenance treatment in the State and that programs seeking such authorization are unable to place patients in a public or nonprofit private comprehensive treatment program within a reasonable geographic area within 14 days of the time patients seek admission to such programs;

(B) The authorization of programs providing interim maintenance treatment in the State will not reduce the capacity of comprehensive programs in the State to admit individuals to these programs (relative to the date on which such officer so certifies);

(C) The State guarantees that individuals enrolled in interim maintenance treatment will be transferred to comprehensive programs not later than 120 days, as provided by section 1923 of the Public Health Service Act (the PHS Act) and applicable regulations; and

(D) Requests for authorization should be submitted to the address specified in Sec. 291.505(k).

* * * * *

(d) * * *

(4) * * *

(i) * * *

(C) Counseling on HIV disease. A narcotic treatment program shall provide counseling on preventing exposure to, and the transmission of, HIV disease for each patient admitted or readmitted to maintenance or detoxification treatment. Although HIV testing is not required, an interim program shall inform patients of the availability of HIV testing. The program sponsor shall also ensure that HIV testing is accessible to patients who request such testing either on site or by the programs entering into agreements with HIV testing facilities to make HIV testing accessible to those patients who request it.

* * * * *

(7) Minimum standards for interim maintenance treatment. The person(s) responsible for a program may place an individual, who is eligible for admission to comprehensive maintenance treatment, in interim maintenance treatment if the individual cannot be placed in a public or nonprofit private comprehensive program within a reasonable geographic area and within 14 days of the individual's application for admission. An initial and at least two other urine screens shall be taken from interim patients during the maximum of 120 days permitted for such treatment. A program shall establish and follow reasonable criteria for establishing priorities for transferring patients from interim maintenance to comprehensive maintenance treatment. These transfer criteria shall be in writing and available for inspection and shall include, at a minimum, a preference for pregnant women in admitting patients to interim maintenance and in transferring patients from interim maintenance to comprehensive maintenance treatment. Interim maintenance shall be provided in a manner consistent with all applicable Federal and State laws including sections 1923 (mandatory transfer) and 1927(a) (pregnant patients) of the PHS Act. The program shall notify the State health officer when a patient begins interim treatment, when a patient leaves interim treatment, and before the date of mandatory transfer to a comprehensive program, and shall document such notifications. Programs in States not in compliance with provisions of this regulation risk loss of authorization for interim maintenance. All requirements for comprehensive maintenance treatment apply to interim maintenance treatment with the following exceptions:

(i) The narcotic drug is required to be administered daily under observation;

(ii) Take-home medication is not allowed;

(iii) The initial treatment plan and periodic treatment plan evaluation are,not [sic] required;

(iv) A primary counselor is not required to be assigned to a patient;

(v) Interim maintenance cannot be provided for longer than 120 days in any 12 month-period [sic]; and

(vi) The requirements and exceptions in paragraphs (b)(2)(iii) (as apply to rehabilitative services), in paragraphs (b)(3)(iv)(B) and (d)(4)(i)(A) (as apply to rehabilitative services), and in paragraphs (d)(4)(ii)(E), (d)(4)(ii)(F), (d)(4)(iv), (d)(6)(iv), (d)(6)(v), (d)(6)(vi), and (d)(6)(vii) of this section do not apply.

* * * * *

(8) * * *

(i) * * *

(F) The requirements of paragraph (d)(4) of this section, except paragraphs (d)(4)(i)(C), (d)(4)(ii)(A) through (d)(4)(ii)(D), and (d)(4)(iii) of this section, do not apply to short-term detoxification treatment.

PART 291

DRUGS USED FOR TREATMENT OF NARCOTIC ADDICTS [INTERIM RULE]

1. The authority citation for 21 CFR part 291 continues to read as follows:

AUTHORITY: Secs. 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 371); 21 U.S.C. 823; secs. 301(d), 548, 1976 of the Public Health Services Act (42 U.S.C. 241(d), 290ee-3, 300y-11); 42 U.S.C. 257a.

2. Section 291.501 is revised to read as follows:

§ 291.501 Narcotic drugs in the maintenance treatment of narcotic addicts.

(a) The Food and Drug Administration, the National Institute of Drug Abuse, and the Drug Enforcement Administration, Department of Justice, recognize that the use of narcotic drugs in the prolonged maintenance of narcotic dependence has been shown to be an effective part of a total treatment effort in the management and rehabilitation of selected narcotic addicts. It is also recognized that a number of dangers and possible abuses may arise from such efforts if professional services and controls are inadequately applied.

(b) Therefore, the Commissioner of Food and Drugs, the Director of the National Institute on Drug Abuse, and the Administrator of the Drug Enforcement Administration, Department of Justice, agree that interested professionals, municipalities, and organizations should be allowed to use narcotic drugs in the medical treatment of narcotic addiction within a framework of adequate controls designed to protect the individual patients and the community. Narcotic drugs that are to be used as part of the treatment of narcotic addiction must have an approved new drug application for use. To facilitate this purpose, the Food and Drug Administration, the National Institute on Drug Abuse, and the Drug Enforcement Administration, Department of Justice, have jointly agreed upon acceptable conditions for the use of narcotic drugs in a treatment program, which are set forth in § 291.505. In addition, such other provisions of the Federal narcotic laws and regulations as are applicable must also be observed.

3. Section 291.505 is amended by revising paragraphs (b)(2)(v), (b)(2)(vi)(D), (c)(4)(i), (c)(4)(ii), the last sentence in paragraph (d)(1)(i)(C), paragraph (d)(1)(ii), the first sentence in paragraph (d)(1)(iii)(B)(1) and by removing the word "methadone" in the two places it appears in paragraph (d)(1)(iii)(B)(1), by adding new paragraph (d)(1)(iii)(B)(6), by revising the second sentence in paragraph (d)(1)(iii)(C), paragraph (d)(1)(iv), by adding a new sentence after the second sentence in paragraph (d)(3)(i), by adding new paragraph (d)(4)(v), by revising the paragraph headings of paragraphs (d)(6) and (d)(6)(i), by removing paragraph (d)(6)(ii) and reserving it, by revising the second sentence in paragraph (d)(13)(i), in paragraph (f)(2)(viii) by removing the phrase "paragraph (k) of this section" and adding in in its place "paragraph (l) of this section", [sic] by revising paragraph (h)(1), by redesignating paragraph (k) as paragraph (l) and revising it, and by adding new paragraph (k) to read as follows:

§ 291.505 Conditions for the use of narcotic drugs; appropriate methods of professional practice for medical treatment of the narcotic addiction of various classes of narcotic addicts under section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970.

* * * * *

(b) * * *

(2) * * *

(v) *Approved narcotic drugs for use in treatment programs.* The following narcotic drugs have been approved for use in the treatment of narcotic addiction: Methadone and Levo-*Alpha*-Acetyl-Methadol (LAAM).

(vi)* * *

(D) Requests for authorization should be submitted to the address specified in paragraph (l) of this section.

* * * * *

(c) * * *

(4) * * *

(i) Form FDA-2632 "Application for Approval of Use of Narcotic Drugs in a Treatment Program." This form, required by paragraph (l) of this section, shall be completed and signed by the program sponsor and submitted in duplicate to the Food and Drug Administration and the State authority.

(ii) Form FDA-2633 "Medical Responsibility Statement for Use of Narcotic Drugs in a Treatment Program." This form, required by paragraph (l) of this section, shall be completed and signed by each licensed physician authorized to administer or dispense narcotic drugs and submitted in duplicate to the Food and Drug Administration and the State authority. The names of any other persons licensed by law to administer or dispense narcotic drugs working in the program shall be listed even if they are not responsible for administering or dispensing the drug at the time the application is submitted.

* * * * *

(d)(1) * * * (i) * * *

(C) * * * The program physician shall complete and record the statement before the program administers any narcotic drug to the patient.

(ii) *Voluntary participation, informed consent.* The person responsible for the program shall ensure that: A patient voluntarily chooses to participate in a program; all relevant facts concerning the use of the narcotic drug used by the program are clearly and adequately explained to the patient; all patients, with full knowledge and understanding of its contents, sign the "Consent to Treatment with an Approved Narcotic Drug" Form FDA-2635 (see paragraph (l) of this section); a parent, legal guardian, or responsible adult designated by the State authority (e.g., "emancipated minor" laws) sign for patients under the age of 18 the second part of Form FDA-2635 "Consent to Treatment with an Approved Narcotic Drug."

(iii) * * *

(B) *Pregnant patients.* (1) Pregnant patients, regardless of age, who have had a documented narcotic dependency in the past and who may return to narcotic dependency, with all its attendant dangers during pregnancy, may be placed on a comprehensive maintenance regimen, except as provided in paragraph (d)(1)(iii)(B)(6) of this section. * * *

* * * * *

(6) Patients who are or become pregnant shall not be started or continued on LAAM, except by the written order of a physician who determines this to be the best choice of therapy for that patient. Clinics providing treatment with LAAM must advise all patients of childbearing potential of the risks of LAAM and make a medical evaluation available to all patients who become pregnant while taking the drug. An initial pregnancy test shall be performed for each prospective female patient of childbearing potential before admission to LAAM comprehensive maintenance treatment and monthly pregnancy tests performed thereafter on such female patients in LAAM comprehensive maintenance treatment. Analysis of such tests shall be performed in a laboratory approved under the Clinical Laboratory Improvement Amendments of 1988 or in a laboratory certified by a State or private accrediting body approved by the Health Care Financing Administration.

(C) * * * For patients meeting these criteria, the quantity of take-home medication, if take-home medication is permitted for the narcotic drug, will be determined in the reasonable clinical judgment of the program physician, but in no case may the quantity of take-home medication be greater than would have been allowed at the time the patient voluntarily terminated previous treatment. * * *

(iv) *Special limitation; treatment of patients under 18 years of age.* (A) A person under 18 years of age is required to have had two documented attempts at short-term detoxification or drug-free treatment to be eligible for maintenance treatment, except as provided in paragraph (d)(1)(iv)(B) of this section. A 1-week waiting period is required after such a detoxification attempt, however, before an attempt is repeated. The program physician shall document in the patient's record that the patient continues to be or is again physiologically dependent on narcotic drugs. No person under 18 years of age may be admitted to a maintenance treatment program unless a parent, legal guardian, or responsible adult designed by the State authority (e.g., "emancipated minor" laws) completes and signs consent form, Form FDA-2635 "Consent to Treatment with an Approved Narcotic Drug."

(B) A person under 18 years of age shall not be admitted to LAAM maintenance treatment.

* * * * *

(3) * * * (i) * * * A pregnancy test is required for any woman of childbearing potential before she may be administered LAAM as directed in paragraph (d)(1)(iii)(B)(1) of this section. * * *

* * * * *

(4) * * *

(v) *Authorized dispensers of narcotic drugs; responsibility.* A narcotic drug nay be administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to order narcotic drugs for patients, or by an agent of such a practitioner, supervised by and under the order of the practitioner. This agent is required to be a pharmacist, registered nurse, or licensed practical nurse, or any other health care professional authorized by Federal and State law to administer or dispense narcotic drugs. The

licensed practitioner assumes responsibility for the amounts of narcotic drugs administered or dispensed and shall record and countersign all changes in dosage schedule.

* * * * *

(6) *Use of methadone in a treatment program; frequency of attendance; quantity of take-home medication; dosage of methadone; initial and stabilization—(i) Dosage and responsibility.* * * *

(ii) [Reserved]

* * * * *

(13) * * *

(i) * * * This system is required to comply with all Federal and State reporting requirements relevant to narcotic drugs approved for use in treatment of narcotic addiction. * * *

* * * * *

(h) *Denial or revocation of approval.* (1) Complete or partial denial or revocation of approval of an application to receive shipments of narcotic drugs (Forms FDA-2632 "Application for Approval of Use of Narcotic Drugs in a Treatment Program" and FDA-2636 "Hospital Request for Methadone Detoxification Treatment") may be proposed to the Commissioner of Food and Drugs by the Director of the Food and Drugs Administration's Center for Drug Evaluation and Research, on his or her own initiative or at the request of representatives of the Drug Enforcement Administration, Department of Justice, National Institute of Drug Abuse, the State authority, or any other interested person.

* * * * *

(k) *Use of narcotics other than methadone in a treatment program.* Narcotic drug products other than methadone that have been approved for treatment of narcotic addiction are listed in paragraph (b)(2)(v) of this section. Detailed information on the conditions for use of narcotic drug products other than methadone, with the exception of take-home and dosage form requirements, can be found in the respective approved product labeling. Treatment programs shall review the most recent approved product labeling for up-to-date information on important treatment parameters for each drug. Deviation from doses, frequencies, and conditions of usage described in the approved labeling shall be justified in the patient's record. Treatment programs that dispense narcotics other than methadone shall conform with the requirements set forth under paragraphs (a), (b), (c), (d)(1) through (d)(5), (d)(8) through (d)(14), and (e) through (l) of this section. Specifics regarding take-home and dosage form requirements along with any additional requirements are set forth in this paragraph.

(1) *LAAM*—(i) *Dosage and responsibility for administration.* After a patient's tolerance to LAAM is established, LAAM shall be administered no more frequently than every other day. Dosage of LAAM shall be individualized at doses, frequencies, and under conditions of usage described in approved labeling and as follows:

(A) *New Patients.* The persons responsible for the program shall ensure that the initial dose of LAAM to a patient whose tolerance for the drug is unknown does not exceed 40 milligrams.

(B) *Stabilized methadone maintenance patient.* The persons responsible for the program shall ensure that the initial dose of LAAM for a previously stabilized methadone maintenance patient is less than or equal to 1.3 times the patient's daily methadone dose, not to exceed 120 milligrams.

(C) A licensed physician shall assume responsibility for the amount of the narcotic drug administered or dispensed and shall record, date, and sign or countersign in each patient's record each change in dosage schedule.

(D) The administering licensed physician shall ensure that a single dose of LAAM greater than 140 milligrams is justified in the patient's record.

(ii) *Dosage form.* LAAM may be administered in oral form when used in a maintenance treatment program. Hospitalized patients under care for a medical or surgical condition are permitted to receive LAAM in oral form when the attending physician judges it advisable. Although syrup concentrate or other formulations may be distributed to the program, all oral medication is required to be administered in a liquid formulation. Clinics that administer both LAAM and methadone shall take appropriate measures, including contrasting color and taste, to ensure that dosage forms of LAAM and methadone are easily distinguished.

(iii) *Take-home medication.* Take-home doses of LAAM are not permitted. A Patient who is eligible for one or more take-home doses of methadone under paragraph (d)(6) of this section and who is unable to conform to the applicable mandatory LAAM dosing schedule because of exceptional circumstances such as illness, personal or family crises, travel, or other hardship, or official State holidays, may be temporarily transferred to methadone. Take home doses of methadone for a patient eligible for a planned temporary discontinuation of treatment with

LAAM shall be individualized at doses, frequencies, and under conditions of usage described in the approved labeling and the applicable provisions for take-home methadone medication under paragraph (d)(6) of this section. The maximum number of take-home doses of methadone shall be determined in accordance with the provisions of 21 CFR 291.505(d)(6)(v) and (d)(6)(vi).

(2) [Reserved]

(l) *Program forms.* The program sponsor must ensure that the following forms are completed by the proper program staff and submitted to the appropriate State authority and the Division of Scientific Investigations, Regulatory Management Branch (HFD-342), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855. The sponsor will indicate on the appropriate form which treatment drug is being utilized. Forms are available upon request from the Regulatory Management Branch (HFD-342) at the same address.

FORMS

FDA–2632 Application for Approval of Use of Narcotic Drugs in a Treatment Program.
FDA–2633 Medical Responsibility Statement for Use of Narcotic Drugs in a Treatment Program.
FDA–2635 Consent to Treatment with an Approved Narcotic Drug.
FDA–2636 Hospital Request for Methadone Detoxification Treatment.

(Approved by the Office of Management and Budget under number 0910–0140.)

Michael R. Taylor,
Deputy Commissioner for Policy.
Dated: April 8, 1993.
Richard A. Millstein,
Acting Director, National Institute on Drug Abuse.
[FR Doc. 93-17134 Filed 7-19-93; 8:45 am]
BILLING CODE 4160-01-P

Appendix D—DEA Regulations

Note to reader: Only those Parts 1301–1307 that apply specifically to narcotic treatment programs are provided in this section. However, the reader is advised to review the DEA regulations in their entirety, as other parts may impact on compliance issues.

§ 1301.11 (f)	Fee amounts
§ 1301.22 (a)(6),(11)	Separate registration for independent activities
§ 1301.23 (a),(b)	Separate registrations for separate locations
§ 1301.32 (a)(4)-(6),(9),(b)(9)	Application forms; contents; signature
§ 1301.41	Administrative review generally
§ 1301.48	Order to show cause
§ 1301.55	Burden of proof
§ 1301.61	Modification in registration
§ 1301.71 through 1301.74	Security requirements and physical security controls
§ 1301.90 through 1301.93	Employee screening—responsibility, illicit activities, employee checks
§ 1304.03	Persons required to keep records and file reports
§ 1304.04	Maintenance of records and inventories
§ 1304.11 through 1304.13	Inventory requirements
§ 1304.17	Inventories of dispensers and researchers
§ 1304.21	General requirements for continuing records
§ 1304.28 through 1304.29	Patient records

§ 1305.08, 1305.09, 1305.11 through 1305.13	Order forms
§ 1307.14, 1307.21	Disposal of controlled substance
§ 1316.03	Authority to make inspections
§ 1316.06	Notice of inspection
§ 1316.31–34	Enforcement proceedings

CHAPTER II — DRUG ENFORCEMENT ADMINISTRATION DEPARTMENT OF JUSTICE

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

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1301.03 Information; special instructions.

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1301.12 Time and method of payment; refund.
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1301.72 Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.
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EMPLOYEE SCREENING—NON-PRACTITIONERS

1301.90 Employee screening procedures.
1301.91 Employee responsibility to report drug diversion.
1301.92 Illicit activities by employees.
1301.93 Sources of information for employee checks.

AUTHORITY: 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877.

SOURCE: 36 FR 7778 Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

Note to reader: Only those paragraphs in this Part that apply specifically to methadone maintenance treatment programs are provided.

FEES FOR REGISTRATION AND REREGISTRATION

§1301.11 **Fee amounts.**

(f) For each registration or reregistration to engage in a narcotic treatment program, including a compounder, the registrant shall pay an application fee of $20.

[48 FR 56043, Dec. 19, 1983, as amended at 52 FR 20598, June 2, 1987; 53 FR 4963, Feb. 19, 1988]

§ 1301.22 Separate registration for independent activities.

(a) The following groups of activities are deemed to be independent of each other:

(1) Manufacturing controlled substances;

(2) Distributing controlled substances;

(3) Dispensing controlled substances listed in Schedules II through V;

(4) Conducting research with controlled substances listed in Schedules II through V;

(5) Conducting instructional activities with controlled substances listed in schedules II through V;

(6) Conducting a narcotic treatment program using any narcotic drug listed in Schedules II, III, IV or V, however, pursuant to § 1301.24, employees, agents, or affiliated practitioners, in programs, need not register separately. Each program site located away from the principal location and at which place narcotic drugs are stored or dispensed must be separately registered and obtain narcotic drugs by use of order forms pursuant to § 1305.03;

(7) Conducting research and instructional activities with controlled substances listed in Schedule I;

(8) Conducting chemical analysis with controlled substances listed in any schedule;

(9) Importing controlled substances;

(10) Exporting controlled substances; and

(11) A compounder as defined by § 1301.02(d).

(b) Every person who engages in more than one group of independent activities shall obtain a separate registration for each group of activities, except as provided in this paragraph. Any person, when registered to engage in the group of activities described in each subparagraph in this paragraph, shall be authorized to engage in the coincident activities described in that subparagraph without obtaining a registration to engage in such coincident activities, provided that, unless specifically exempted, he complies with all requirements and duties prescribed by law for persons registered to engage in such coincident activities:

(1) A person registered to manufacture or import any controlled substance or basic class of controlled substance shall be authorized to distribute that substance or class, but no other substance or class which he is not registered to manufacture or import;

(2) A person registered to manufacture any controlled substance listed in Schedules II through V shall be authorized to conduct chemical analysis and preclinical research (including quality control analysis) with narcotic and non-narcotic controlled substances listed in those schedules in which he is authorized to manufacture;

(3) A person registered to conduct research with a basic class of controlled substance listed in Schedule I shall be authorized to manufacture or import such class if and to the extent that such manufacture or importation is set forth in the research protocol described in § 1301.33 and to distribute such class to other persons registered or authorized to conduct research with such class or registered or authorized to conduct chemical analysis with controlled substances;

(4) A person registered or authorized to conduct chemical analysis with controlled substances shall be authorized to manufacture and import such substances for analytical or instructional purposes, to distribute such substances to other persons registered or authorized to conduct chemical analysis or instructional activities or research with such substances and to persons exempted from registration pursuant to § 1301.26, to export such substances to persons in other countries performing chemical analysis or enforcing laws relating to controlled substances or drugs in those countries, and to conduct instructional activities with controlled substances; and

(5) A person registered or authorized to conduct research with controlled substances listed in Schedules II through V shall be authorized to conduct chemical analysis with controlled substances listed in those schedules in which he is authorized to conduct research, to manufacture such substances if and to the extent that such manufacture is set forth in a statement filed with the application for registration, to import such substances for research purposes, to distribute such substances to other persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances and to persons exempted from registration pursuant to § 1301.26, and to conduct instructional activities with controlled substances;

(6) A person registered to dispense controlled substances listed in Schedules II through V shall be authorized to conduct research and to conduct instructional activities with those substances.

(c) A single registration to engage in any group of independent activities may include one or more controlled substances listed in the schedules authorized in that group of independent activities. A person registered to conduct research with controlled substances listed in Schedule I may conduct research with any substance listed in Schedule I for which he has filed and had approved a research protocol.

[36 FR 7778, Apr. 24, 1971, as amended at 36 FR 18728, Sept. 21, 1971; 37 FR 15918, Aug. 8, 1972; 38 FR 756, Jan. 4, 1973. Redesignated at 38 FR 26609, Sept. 24, 1973.

EDITORIAL NOTE: For FR Citations affecting § 1301.22, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§1301.23 Separate registrations for separate locations.

(a) A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, or dispensed by a person.

(b) The following locations shall be deemed not to be places where controlled substances are manufactured, distributed, or dispensed:

(1) A warehouse where controlled substances are stored by or on behalf of a registered person, unless such substances are distributed directly from such warehouse to registered locations other than the registered location from which the substances were delivered or to persons not required to register by virtue of subsection 302(c)(2) of the Act (21 U.S.C. 822(c)(2));

(2) An office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised but which neither contains such substances (other than substances for display purposes or lawful distribution as samples only) nor serves as a distribution point for filling sales orders; and

(3) An office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained.

[36 FR 7778, Apr. 24, 1971, as amended at 36 FR 18728, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

APPLICATIONS FOR REGISTRATION

§1301.32 Application forms; contents; signature.

(a) If any person is required to be registered, and is not so registered and is applying for registration:

(4) To conduct research with controlled substances listed in Schedules II through V (other than research described in §§1301.22(a)(6), he shall apply on DEA Form 225;

(5) To conduct research with narcotic drugs listed in Schedules II through V, as described in §1301.22(a)(6), he shall apply on DEA Form 225;

(6) To conduct research with controlled substances listed in Schedule I, he shall apply on DEA Form 225, with three copies of a research protocol as described in §[1]301.33(a) attached to the form, or, in the case of a clinical investigation, with three copies of a certificate of submission of an IND as described in §1301.33(b) attached to the form (the researcher also submitting to the Food and Drug Administration three copies of a Notice of Claimed Investigational Exemption for a New Drug as required in §1301.33(b));

(9) To conduct a narcotic treatment program, including a compounder, shall apply on DEA Form 363.

(b) If any person is registered and is applying for reregistration:

(9) To conduct a narcotic treatment program, including a compounder, shall apply on DEA Form 363a (Renewal Form).

ACTION ON APPLICATIONS FOR REGISTRATION; REVOCATION OR SUSPENSION OF REGISTRATION

§1301.41 Administrative review generally.

The Administrator may inspect, or cause to be inspected, the establishment of an applicant or registrant, pursuant to subpart A of part 1316 of this chapter. The Administrator shall review, [sic] the application for registration and other information gathered by the Administrator regarding an applicant in order to determine whether the applicable standards of section 1303 of the Act (21 U.S.C. 823) have been met by the applicant.

§1301.48 Order to show cause.

(a) If, upon examination of the application for registration from any applicant and other information gathered by the Administration regarding the applicant, the Administrator is unable to make the determinations required by the applicable provisions of section 303 of the Act (21 U.S.C. 823) to register the applicant, the Administrator shall serve upon the applicant an order to show cause why the registration should not be denied.

(b) If, upon information gathered by the Administration regarding any registrant, the Administrator determines that the registration of such registrant is subject to suspension or revocation pursuant to section 304 of the Act (21 U.S.C. 824), the Administrator shall serve upon the registrant an order to show cause why the registration should not be revoked or suspended.

(c) The order to show cause shall call upon the applicant or registrant to appear before the Administrator at a time and place stated in the order, which shall not be less than 30 days after the date of receipt of the order. The order to show cause shall also contain a statement of the legal basis for such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted.

(d) Upon receipt of an order to show cause, the applicant or registrant must, if he desires a hearing, file a request for a hearing pursuant to §1301.54. If a hearing is requested, the Administrator shall hold a hearing at the time and place stated in the order, pursuant to §1301.51.

(e) When authorized by the Administrator, any agent of the Administration may serve the order to show cause.

[36 FR 7778, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

HEARINGS

§1301.55 Burden of proof.

(a) At any hearing on an application to manufacture any controlled substance listed in Schedule I or II, the applicant shall have the burden of proving that the requirements for such registration pursuant to section 303(a) of the Act (21 U.S.C. 823(a)) are satisfied. Any other person participating in the hearing pursuant to §1301.43 shall have the burden of proving any propositions of fact or law asserted by him in the hearing.

(b) At any hearing on the granting or denial of an applicant to be registered to conduct a narcotic treatment program or as a compounder, the applicant shall have the burden of proving that the requirements for each registration pursuant to section 303(g) of the Act (21 U.S.C. 823(g)) are satisfied.

(c) At any other hearing for the denial of a registration, the Administration shall have the burden of proving that the requirements for such registration pursuant to section 303 of the Act (21 U.S.C. 823) are not satisfied.

(d) At any hearing for the revocation or suspension of a registration, the Administration shall have the burden of proving that the requirements for such revocation or suspension to section 304(a) of the Act (21 U.S.C. 824(a)) are satisfied.

[36 FR 7778, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 41 FR 21448, May 26, 1976]

MODIFICATION, TRANSFER, AND TERMINATION OF REGISTRATION

§1301.61 Modification in registration.

Any registrant may apply to modify his registration to authorize the handling of additional controlled substances or to change his name or address, by submitting a letter of request to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005. The letter shall contain the registrant's name, address, and registration number as printud [sic] on the certificate of registration, and the substances and/or schedules to be added to his registration of the new name or address and shall be signed in accordance with §1301.32(f). If the registrant is seeking to handle additional controlled substances listed in Schedule I for the purpose of research or instructional activities, he shall attach three copies of a research protocol describing each research project involving the additional substances, or two copies of a statement describing the nature, extent, and duration of such instructional activities, as appropriate.

No fee shall be required to be paid for the modification. The request for modification shall be handled in the same manner as an application for registration. If the modification in registration is approved, the Administrator shall issue a new certificate of registration (DEA Form 223) to the registrant, who shall maintain it with the old certificate of registration until expiration.

[36 FR 18729, Sept. 21, 1971, as amended at 37 FR 15919, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 51 FR 5319, Feb. 13, 1986; 53 FR 4963, Feb. 19, 1988]

SECURITY REQUIREMENTS

§ 1301.71 Security requirements generally.

(a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72–1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. Materials and construction which will provide a structural equivalent to the physical security controls set forth in §§ 1301.72, 1301.73 and 1301.75 may be used in lieu of the materials and construction described in those sections.

(b) Substantial compliance with the standards set forth in §§ 1301.72–1301.76 may be deemed sufficient by the Administrator after evaluation of the overall security system and needs of the applicant or registrant. In evaluating the overall security system of a registrant or applicant, the Administrator may consider any of the following factors as he may deem relevant to the need for strict compliance with security requirements:

(1) The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);

(2) The type and form of controlled substances handled (e.g., bulk liquids or dosage units, usable powders or nonusable powders);

(3) The quantity of controlled substances handled;

(4) The location of the premises and the relationship such location bears on security needs;

(5) The type of building construction comprising the facility and the general characteristics of the building or buildings;

(6) The type of vault, safe, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used;

(7) The type of closures on vaults, safes, and secure enclosures;

(8) The adequacy of key control systems and/or combination lock control systems;

(9) The adequacy of electric detection and alarm systems, if any including use of supervised transmittal lines and standby power sources;

(10) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;

(11) The adequacy of supervision over employees having access to manufacturing and storage areas;

(12) The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;

(13) The availability of local police protection or of the registrant's or applicant's security personnel, and;

(14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.

(c) When physical security controls become inadequate as a result of a controlled substance being transferred to a different schedule, or as a result of a noncontrolled substance being listed on any schedule, or as a result of a significant increase in the quantity of controlled substances in the possession of the registrant during normal business operations, the physical security controls shall be expanded and extended accordingly. A registrant may adjust physical security controls within the requirements set forth in §§ 1301.72–1301.76 when the need for such controls decreases as a result of a controlled substance being transferred to a different schedule, or a result of a controlled substance being removed from control, or as a result of a significant decrease in the quantity of controlled substances in the possession of the registrant during normal business operations.

(d) Any registrant or applicant desiring to determine whether a proposed security system substantially complies with, or is the structural equivalent of, the requirements set forth in §§ 1301.72–1301.76 may submit

any plans, blueprints, sketches or other materials regarding the proposed security system either to the Special Agent in Charge in the region in which the system will be used, or to the Diversion Operations Section, Drug Enforcement Administration, Department of Justice, Washington, DC 20537.

(e) Physical security controls of locations registered under the Harrison Narcotic Act or the Narcotics Manufacturing Act of 1960 on April 30, 1971, shall be deemed to comply substantially with the standards set forth in §§ 1301.72, 1301.73 and 1301.75. Any new facilities or work or storage areas constructed or utilized for controlled substances, which facilities or work or storage areas have not been previously approved by the Administration, shall not necessarily be deemed to comply substantially with the standards set forth in §§ 1301.72, 1301.73 and 1301.75, notwithstanding that such facilities or work or storage areas have physical security controls similar to those previously approved by the Administration.

[36 FR 18729, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973 [sic], and amended at 46 FR 28841, May 29, 1981; 47 FR 41735, Sept. 22, 1982; 51 FR 5319, Feb. 13, 1986]

§ 1301.72 Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.

(a) *Schedules I and II.* Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedule I or II shall be stored in one of the following secure storage areas:

(1) Where small quantities permit, a safe or steel cabinet;

(i) Which safe or steel cabinet shall have the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;

(ii) Which safe or steel cabinet, if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way that it cannot be readily removed; and

(iii) Which safe or steel cabinet if necessary, depending upon the quantities and type of controlled substances stored, is equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or State police agency which has a legal duty to respond or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve.

(2) A vault constructed before, or under construction on, September 1, 1971, which is of substantial construction with a steel door, combination or key lock, and an alarm system; or

(3) A vault constructed after September 1, 1971:

(i) The walls, floors, and ceilings of which vault are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with 1/2- inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings;

(ii) The door and frame unit of which vault shall conform to the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;

(iii) Which vault, if operations require it to remain open for frequent access, is equipped with a "day-gate" which is self-closing and self-locking, or the equivalent, for use during the hours of operation in which the vault door is open;

(iv) The walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central station protection company, or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve, and, if necessary, holdup buttons at strategic points of entry to the perimeter area of the vault;

(v) The door of which vault is equipped with contact switches; and

(vi) Which vault has one of the following: Complete electrical lacing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the Administration.

(b) *Schedules III, IV and V.* Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedules III, IV and V shall be stored in the following secure storage areas:

(1) A safe or steel cabinet as described in paragraph (a)(1) of this section;

(2) A vault as described in paragraph (a)(2) or (3) of this section equipped with an alarm system as described in paragraph (b)(4)(v) of this section;

(3) A building used for storage of Schedules III through V controlled substances with perimeter security which limits access during working hours and provides security after working hours and meets the following specifications:

(i) Has an electronic alarm system as described in paragraph (b)(4)(v) of this section,

(ii) Is equipped with self-closing, self-locking doors constructed of substantial material commensurate with the type of building construction, provided, however, a door which is kept closed and locked at all times when not in use and when in use is kept under direct observation of a responsible employee or agent of the registrant is permitted in lieu of a self-closing, self-locking door. Doors may be sliding or hinged. Regarding hinged doors, where hinges are mounted on the outside, such hinges shall be sealed, welded or otherwise constructed to inhibit removal. Locking devices for such doors shall be either of the multiple-position combination or key lock type and:

(a) In the case of key locks, shall require key control which limits access to a limited number of employees, or;

(b) In the case of combination locks, the combination shall be limited to a minimum number of employees and can be changed upon termination of employment of an employee having knowledge of the combination;

(4) A cage, located within a building on the premises, meeting the following specifications:

(i) Having walls constructed of not less than No. 10 gauge steel fabric mounted on steel posts, which posts are:

(a) At least one inch in diameter;

(b) Set in concrete or installed with lay bolts that are pinned or brazed; and

(c) Which are placed no more than ten feet apart with horizontal one and one-half inch reinforcements every sixty inches;

(ii) Having a mesh construction with openings of not more than two and one-half inches across the square,

(iii) Having a ceiling constructed of the same material, or in the alternative, a cage shall be erected which reaches and is securely attached to the structural ceiling of the building. A lighter gauge mesh may be used for the ceilings of large enclosed areas if walls are at least 14 feet in height,

(iv) Is equipped with a door constructed of No. 10 gauge steel fabric on a metal door frame in a metal door flange, and in all other respects conforms to all the requirements of 21 CFR 1301.72(b)(3)(ii), and

(v) Is equipped with an alarm system which upon unauthorized entry shall transmit a signal directly to a central station protection agency or a local or state police agency, each having a legal duty to respond, or to a 24-hour control station operated by the registrant, or to such other source of protection as the Administrator may approve;

(5) An enclosure of masonry or other material, approved in writing by the Administrator as providing security comparable to a cage;

(6) A building or enclosure within a building which has been inspected and approved by DEA or its predecessor agency, BNDD, and continues to provide adequate security against the diversion of Schedule III through V controlled substances, of which fact written acknowledgment has been made by the Special Agent in Charge of DEA for the area in which such building or enclosure is situated;

(7) Such other secure storage areas as may be approved by the Administrator after considering the factors listed in
§ 1301.71(b), (1) through (14);

(8) (i) Schedule III through V controlled substances may be stored with Schedules I and II controlled substances under security measures provided by 21 CFR 1301.72(a);

(ii) Non-controlled drugs, substances and other materials may be stored with Schedule III through V controlled substances in any of the secure storage areas required by 21 CFR 1301.72(b), provided that permission for such storage of non-controlled items is obtained in advance, in writing, from the Special Agent in Charge of DEA for the area in which such storage area is situated. Any such permission tendered must be upon the Special Agent in Charge's written determination that such non-segregated storage does not diminish security effectiveness for Schedules III through V controlled substances.

(c) *Multiple storage areas.* Where several types or classes of controlled substances are handled separately by the registrant or applicant for different purposes (e.g., returned goods, or goods in process), the controlled substances may be stored separately, provided that each storage area complies with the requirements set forth in this section.

(d) *Accessibility to storage areas.* The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass through controlled substances storage areas, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

[36 FR 18730, Sept. 21, 1971, as amended at 37 FR 15919, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973 [sic]].

EDITORIAL NOTE: For Federal Register citations affecting § 1301.72, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 1301.73 Physical security controls for non-practitioners; compounders for narcotic treatment programs; manufacturing and compounding areas.

All manufacturing activities (including processing, packaging and labeling) involving controlled substances listed in any schedule and all activities of compounders shall be conducted in accordance with the following:

(a) All in-process substances shall be returned to the controlled substances storage area at the termination of the process. If the process is not terminated at the end of a workday (except where a continuous process or other normal manufacturing operation should not be interrupted), the processing area or tanks, vessels, bins or bulk containers containing such substances shall be securely locked, with adequate security for the area or building. If such security requires an alarm, such alarm, upon unauthorized entry, shall transmit a signal directly to a central station protection company, or local or state police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant.

(b) Manufacturing activities with controlled substances shall be conducted in an area or areas of clearly defined limited access which is under surveillance by an employee or employees designated in writing as responsible for the area. "Limited access" may be provided, in the absence of physical dividers such as walls or partitions, by traffic control lines or restricted space designation. The employee designated as responsible for the area may be engaged in the particular manufacturing operation being conducted: *Provided*, That he is able to provide continuous surveillance of the area in order that unauthorized persons may not enter or leave the area without his knowledge.

(c) During the production of controlled substances, the manufacturing areas shall be accessible to only those employees required for efficient operation. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass through manufacturing areas during production of controlled substances, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

36 FR 18731, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973 [sic] and amended at 39 FR 37984, Oct. 25, 1974]

§ 1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

(a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

(c) The registrant shall notify the Field Division Office of the Administration in his area of any theft or significant loss of any controlled substances upon discovery of such theft or loss. The supplier shall be responsible for reporting in-transit losses of controlled substances by the common or contract carrier selected pursuant to § 1301.74(e), upon discovery of such theft or loss. The registrant shall also complete DEA Form 106 regarding such theft or loss. Thefts must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them.

(d) The registrant shall not distribute any controlled substance listed in Schedules II through V as a complimentary sample to any potential or current customer (1) without the prior written request of the customer, (2) to be used only for satisfying the legitimate medical needs of patients of the customer, and (3) only in reasonable quantities. Such request must contain the name, address, and registration number of the customer and the name and quantity of the specific controlled substance desired. The request shall be preserved by the registrant with other records of distribution of controlled substances. In addition, the requirements of part 1305 of the chapter shall be complied with for any distribution of a controlled substance listed in Schedule II. For purposes of this paragraph, the term "customer" includes a person to whom a complimentary sample of a substance is given in order to encourage the prescribing or recommending of the substance by the person.

(e) When shipping controlled substances, a registrant is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses. When storing controlled substances in a public warehouse, a registrant is responsible for selecting a warehouseman which will provide adequate security to guard against storage losses; wherever possible, the registrant shall store controlled substances in a public warehouse which complies with the requirements set forth in § 1301.72. In addition, the registrant shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or in-transit losses.

(f) When distributing controlled substances through agents (e.g., detailmen), a registrant is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

(g) Before the initial distribution of carfentanil etorphine hydrochloride and/or diprenorphine to any person, the registrant must verify that the person is authorized to handle the substances(s) [sic] by contacting the Drug Enforcement Administration.

(h) The acceptance of delivery of narcotic substances by a narcotic treatment program shall be made only by a licensed practitioner employed at the facility or other authorized individuals designated in writing. At the time of delivery, the licensed practitioner or other authorized individual designated in writing (excluding persons currently or previously dependent on narcotic drugs), shall sign for the narcotics and place his specific title (if any) on any invoice. Copies of these signed invoices shall be kept by the distributor.

(i) Narcotics dispensed or administered at a narcotic treatment program will be dispensed or administered directly to the patient by either (1) the licensed practitioner, (2) a registered nurse under the direction of the licensed practitioner, (3) a licensed practical nurse under the direction of the licensed practitioner, or (4) a pharmacist under the direction of the licensed practitioner.

(j) Persons enrolled in a narcotic treatment program will be required to wait in an area physically separated from the narcotic storage and dispensing area. This requirement will be enforced by the program physician and employees.

(k) All narcotic treatment programs must comply with standards established by the Secretary of Health and Human Services (after consultation with the Administration) respecting the quantities of narcotic drugs which may be provided to persons enrolled in a narcotic treatment program for unsupervised use.

(l) DEA may exercise discretion regarding the degree of security required in narcotic treatment programs based on such factors as the location of a program, the number of patients enrolled in a program and the number of physicians, staff members and security guards. Similarly, such factors will be taken into consideration when evaluating existing security or requiring new security at a narcotic treatment program.

[36 FR 7778, Apr. 24, 1971; 36 FR 13386, July 21, 1971, as amended at 36 FR 18731, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973 [sic]]

EDITORIAL NOTE: For Federal Register citations affecting § 1301.74, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 1301.90 Employee screening procedures.

It is the position of DEA that the obtaining of certain information by non-practitioners is vital to fairly asses the likelihood of an employee committing a drug security breach. The need to know this information is a matter of business necessity, essential to overall controlled substances security. In this regard it is believed that conviction of crimes and unauthorized use to controlled substances are activities that are proper subjects for inquiry. It is, therefore, assumed that the following questions will become a part of an employer's comprehensive employee screening program:

Question. Within the past five years, have you been convicted of a felony, or within the past two years, of any misdemeanor or are you presently formally charged with committing a criminal offense? (Do not include any traffic violations, juvenile offenses or military convictions, except by general court-martial.) If the answer is yea, furnish details of convictions, offense, location, and date and sentence.

Question. In the past three years, have you ever knowingly used any narcotics, amphetamines or barbiturates, other than those prescribed to you by a physician? If the answer is yes, furnish details.

Advice. An authorization, in writing, that allows inquiries to be made of courts and law enforcement agencies for possible pending charges or convictions must be executed by a person who is allowed to work in an area where access to controlled substances clearly exists. A person must be advised that any false information or omission of information will jeopardize his or her position with respect to employment. the application for employment should inform a person that information furnished or recovered as a result of any inquiry will not necessarily preclude employment, but will be considered as part of an overall evaluation of the person's qualifications. The maintaining of fair employment practices, the protection of the person's right of privacy, and the assurance that the result of such inquiries will be treated by the employer in confidence will be explained to the employee.

[40 FR 17143, Apr. 17, 1975]

§ 1301.91 Employee responsibility to report drug diversion.

Reports of drug diversion by fellow employees is not only necessary part of an overall employee security program but also serves the public interest at large. It is, therefore, the position of DEA that an employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information. A failure to report information of drug diversion will be considered in determining the feasibility of continuing to allow an employee to work in a drug security area. The employer shall inform all employees concerning this policy.

[40 FR 17143, Apr. 17, 1975]

§ 1301.92 Illicit activities by employees.

It is the position of DEA that employees who possess, sell, use or divert controlled substances will subject themselves not only to State and Federal prosecution for any illicit activity, but shall also immediately become the subject of independent action regarding their continued employment. The employer will assess the seriousness of the employee's violation, the position of responsibility held by the employee, past record of employment, etc., in determining whether to suspend, transfer, terminate or take other action against the employee.

[40 FR 17143, Apr. 17, 1975]

§ 1301.93 Sources of information for employee checks.

DEA recommends that inquires concerning employees' criminal records be made as follows:

Local inquiries. Inquiries should be made by name, date and place of birth, and other identifying information, to local courts and law enforcement agencies for records of pending charges and convictions. Local practice may require such inquiries to be made in person, rather than by mail, and a copy of an authorization from the employee may be required by certain law enforcement agencies.

DEA inquiries. Inquiries supplying identifying information should also be furnished to DEA field Division Offices along with written consent from the concerned individual for a check of DEA files for records of convictions. The Regional check will result in a national check being made by the Field Division Office.

[40 FR 17143, Apr. 17, 1975, as amended at 47 FR 41735, Sept. 22, 1982]

PART 1304—RECORDS AND REPORTS OF REGISTRANTS

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1304.38 Reports from manufacturers importing poppy straw or concentrate of poppy straw.

AUTHORITY: 21 U.S.C. 821, 827, 871(b), 958(d), 965, unless otherwise noted.

Note to reader: Only those paragraphs in this Part that apply specifically to methadone maintenance treatment programs are provided.

§ 1304.03 Persons required to keep records and file reports.

(a) Each registrant shall maintain the records and inventories and shall file the reports required by this part, except as exempted by this section. Any registrant who is authorized to conduct other activities without being registered to conduct those activities, either pursuant to § 1301.22(b) of this chapter or pursuant to § 1307.11-1307.15 of this chapter, shall maintain the records and inventories and shall file the reports required by

this part for persons registered to conduct such activities. This latter requirement should not be construed as requiring stocks of controlled substances being used in various activities under one registration to be stored separately nor that separate records are required for each activity. The intent of the Administration is to permit the registrant to keep one set of records which are adapted by the registrant to account for controlled substances used in any activity. Also, the Administration does not wish to acquire separate stocks of the same substance to be purchased and stored for separate activities. Otherwise, there is no advantage gained by permitting several activities under one registration. Thus, when a researcher manufactures a controlled item, he must keep a record of the quantity manufactured; when he distributes a quantity of the item, he must use and keep invoices or order forms to document the transfer; when he imports a substance, he keeps as part of his records the documentation required of an importer; and when substances are used in chemical analysis, he need not keep a record of this because such a record would not be required of him under a registration to do chemical analysis. All of these records may be maintained in one consolidated record system. Similarly, the researcher may store all of his controlled items in one place, and every two years take inventory of all items on hand, regardless of whether the substances were manufactured by him, imported by him, or purchased domestically by him, of whether the substances will be administered to subjects, distributed to other researchers, or destroyed during chemical analysis.

(b) A registered individual practitioner is required to keep records, as described in § 1304.04, of controlled substances in Schedules II, III, IV, and V which are dispensed, other than by prescribing or administering in the lawful course of professional practice.

(c) A registered individual practitioner is not required to keep records of controlled substances in Schedules II, III, IV, and V which are prescribed in the lawful course of professional practice, unless such substances are prescribed in the course of maintenance or detoxification treatment of an individual.

(d) A registered individual practitioner is not required to keep records of controlled substances listed in Schedules II, III, IV and V which are administered in the lawful course of professional practice unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges patients, either separately or together with charges for other professional services, for substances so dispensed or administered. Records are required to be kept for controlled substances administered in the course of maintenance or detoxification treatment of an individual.

(e) A registered person using any controlled substance in research conducted in conformity with an exemption granted under section 505(i) or 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i) or 360b(j)) at a registered establishment which maintains records in accordance with either of those sections is not required to keep records if he notifies the Administration of the name, address, and registration number of the establishment maintaining such records.

(f) A registered person using any controlled substance in preclinical research or in teaching at a registered establishment which maintains records with respect to such substances is not required to keep records if he notifies the Administration of the name, address, and registration number of the establishment maintaining such records.

(g) Notice required by paragraphs (e) and (f) of this section shall be given at the time the person applies for registration or reregistration and shall be made in the form of an attachment to the application, which shall be filed with the application.

[36 FR 7790, Apr. 24, 1971, as amended at 36 FR 18731, Sept. 21, 1971; 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 50 FR 40523, Oct. 4, 1985; 51 FR 5320, Feb. 13, 1986; 51 FR 26154, July 21, 1986]

§ 1304.04 Maintenance of records and inventories.

(a) Every inventory and other records required to be kept under this part shall be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration, except that financial and shipping records (such as invoices and packing slips but not excuted [sic] order forms subject to § 1305.13 of this chapter) may be kept at a central location, rather than at the registered location, if the registrant has notified the Administration of his intention to keep central records. Written notification must be submitted by registered or certified mail, return receipt requested, in triplicate, to the Special Agent in Charge of the Administration in the area in which the registrant is located. Unless the registrant is informed by the Special Agent in Charge that permission to keep central records is denied, the registrant may maintain central records commencing 14 days after receipt of his notification by the Special Agent in Charge.

All notifications must include:

(1) The nature of the records to be kept centrally.

(2) The exact location where the records will be kept.

(3) The name, address, DEA registration number and type of DEA registration of the registrant whose records are being maintained centrally.

(4) Whether central records will be maintained in a manual, or computed readable form.

(b) All registrants that are authorized to maintain a central recordkeeping system shall be subject to the following conditions:

(1) The records to be maintained at the central record location shall not include executed order forms, prescriptions and/or inventories which shall be maintained at each registered location.

(2) If the records are kept on microfilm, computer media or in any form requiring special equipment to render the records easily readable, the registrant shall provide access to such equipment with the records. If any code system is used (other than pricing information), a key to the code shall be provided to make the records understandable.

(3) The registrant agrees to deliver all or any part of such records to the registered location within two business days upon receipt of a written request from the Administration for such records, and if the Administration chooses to do so in lieu of requiring delivery of such records to the registered location, to allow authorized employees of the Administration to inspect such records at the central location upon request by such employees without a warrant of any kind.

(4) In the event that a registrant fails to comply with these conditions, the Special Agent in Charge may cancel such central recordkeeping authorization, and all other central recordkeeping authorizations held by the registrant without a hearing or other procedures. In the event of a cancellation of central recordkeeping authorizations under this paragraph the registrant shall, within the time specified by the Special Agent in Charge, comply with the requirements of this section that all records be kept at the registered location.

(c) Registrants need not notify the Special Agent in Charge or obtain central recordkeeping approval in order to maintain records on an in-house computer system.

(d) ARCOS participants who desire authorization to report from other than their registered locations must obtain a separate central reporting identifier. Request for central reporting identifiers will be submitted to: ARCOS Unit, P.O. Box 28293, Central Station, Washington, DC 20005.

(e) All central recordkeeping permits previously issued by the Administration will expire on September 30, 1980. Registrants who desire to continue maintaining central records will make notification to the local Special Agent in Charge as provided in paragraph (a) of this section.

(f) Each registered manufacturer, distributor, importer, exporter, narcotic treatment program and compounder for narcotic treatment program shall maintain inventories and records of controlled substances as follows:

(1) Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and

(2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.

(g) Each registered individual practitioner required to keep records and institutional practitioner shall maintain inventories and records of controlled substances in the manner prescribed in paragraph (f) of this section.

(h) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file; and

(2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy, and prescriptions for such substances shall be maintained either in separate prescription file for controlled substances listed in Schedules III, IV, and V only or in such form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than 1-inch high and filed

either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for non-controlled substances.

(21 U.S.C. 821 and 871(b); 28 CFR 0.100)

[36 FR 7790, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973 [sic], and amended at 39 PR 37985, Oct. 25, 1974; 45 FR 44266, July 1, 1980; 47 FR 41735, Sept. 22, 1982; 51 FR 5320, Feb. 13, 1986]

INVENTORY REQUIREMENTS

§ 1304.11 General requirements for inventories.

(a) Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, substances ordered by a customer but not yet invoiced, substances stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples.

(b) A separate inventory shall be made by a registrant for each registered location. In the event controlled substances in [sic] the possession or under the control of the registrant at a location for which he is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. Each inventory for a registered location shall be kept at the registered location.

(c) A separate inventory shall be made by a registrant for each independent activity for which he is registered, except as provided in § 1304.18.

(d) A registrant may take an inventory on a date that is within 4 days of his biennial inventory date pursuant to § 1304.13 if he notifies in advance the Special Agent in Charge of the Administration in his area of the date on which he will take the inventory. A registrant may take an inventory either as of the opening of business or as of the close of business on the inventory date. The registrant shall indicate on the inventory records whether the inventory is taken as of the opening or as of the close of business and the date the inventory is taken.

(e) An inventory must be maintained in a written, typewritten or printed form. An inventory taken by use of an oral recording device must be promptly transcribed.

[36 FR 7790, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973 [sic], and amended at 47 FR 41735, Sept. 22, 1982]

§ 1304.12 Initial inventory date.

(a) Every person required to keep records who is provisionally registered on May 1, 1971, shall take an inventory of all stocks of controlled substances on hand on that date in accordance with §§ 1304.15-1304.19, as applicable.

(b) Every person required to keep records who is registered after May 1, 1971, and who was not provisionally registered on that date, shall take an inventory of all stocks of controlled substances on hand on the date he first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with §§ 1304.15-1304.19, as applicable. In the event a person commences business with no controlled substances on hand, he shall record this fact as his initial inventory.

[36 FR 7791, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971; 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1304.13 Biennial inventory date.

Every 2 years following the date on which the initial inventory is taken by a registrant pursuant to § 1304.12, the registrant shall take a new inventory of all stocks of controlled substances on hand. The biennial inventory may be taken (a) on the day of the year on which the initial inventory was taken or (b) on the registrant's regular general physical inventory date, if any, which is nearest to and does not vary by more than

6 months from the biennial date that would otherwise apply or (c) on any other fixed date which does not vary by more than 6 months from the biennial date that would otherwise apply. If the registrant elects to take the biennial inventory on his regular general physical inventory date or another fixed date, he shall notify the Administration of this election and of the date on which the biennial inventory will be taken.

[36 FR 7791, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1304.17 Inventories of dispensers and researchers.

Each person registered or authorized (by § 1301.22(b) of this chapter) to dispense or conduct research with controlled substances and required to keep records pursuant to § 1304.03 shall include in his inventory the same information required of manufacturers pursuant to § 1304.15 (c) and (d). In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser shall do as follows:

(a) If the substance is listed in Schedule I or II, he shall make an exact count or measure of the contents; and

(b) If the substance is listed in Schedule III, IV, or V, he shall make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he must make an exact count of the contents.

[36 FR 7791, Apr. 24, 1971, as amended at 36 FR 18732, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

CONTINUING RECORDS

§ 1304.21 General requirements for continuing records.

(a) On and after May 1, 1971, every registrant required to keep records pursuant to § 1304.03 shall maintain on a current basis a complete and accurate record of each such substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him, except that no registrant shall be required to maintain a perpetual inventory.

(b) Separate records shall be maintained by a registrant for each registered location except as provided in § 1304.04 (a). In the event controlled substances are in the possession or under the control of a registrant at a location for which he is not registered, the substances shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible.

(c) Separate records shall be maintained by a registrant for each independent activity for which he is registered, except as provided in §§ 1304.25 and 1304.26.

(d) In recording dates of receipt, importation, distribution, exportation, or other transfers, the date on which the controlled substances are actually received, imported, distributed, exported, or otherwise transferred shall be used as the date of receipt or distribution of any documents of transfer (e.g., invoices or packing slips).

[36 FR 7792, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1304.28 Records for maintenance treatment programs and detoxification treatment programs.

(a) Each person registered or authorized (by § 1301.22 of this chapter) to maintain and/or detoxify controlled substance users in a narcotic treatment program shall maintain records with the following information for each narcotic controlled substance:

(1) Name of substance;
(2) Strength of substance;
(3) Dosage form;
(4) Date dispensed;
(5) Adequate identification of patient (consumer);
(6) Amount consumed;
(7) Amount and dosage form taken home by patient; and
(8) Dispenser's initials.

(b) The records required by paragraph (a) of this section will be maintained in a dispensing log at the narcotic treatment program site and will be maintained in compliance with § 1304.24 without reference to § 1304.03.

(c) All sites which compound a bulk narcotic solution from bulk narcotic powder to liquid for on-site use must keep a separate batch record of the compounding.

(d) Records of identity, diagnosis, prognosis, or treatment of any patients which are maintained in connection with the performance of a narcotic treatment program shall be confidential, except that such records may be disclosed for purposes and under the circumstances authorized by part 310 and part 1401 of this title.

[39 FR 37985, Oct. 25, 1974]

§ 1304.29 Records for treatment programs which compound narcotics for treatment programs and other locations.

Each person registered or authorized by § 1301.22 of this chapter to compound narcotic drugs for off-site use in a narcotic treatment program shall maintain records which include the following information for each narcotic drug:

(a) For each narcotic controlled substance in bulk form to be used in or capable of use in, or being used in, the compounding of the same or other noncontrolled substance in finished form:

(1) The name of the substance;

(2) The quantity compounded in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch compounded;

(3) The quantity received from other persons, including the date and quantity of each receipt and the name, address and registration number of the other person from whom the substance was received;

(4) The quantity imported directly by the registrant (under a registration as an importer) for use in compounding by him, including the date, quantity and import permit or declaration number of each importation;

(5) The quantity used to compound the same substances in finished form, including:

(i) The date and batch or other identifying number of each compounding;

(ii) The quantity used in the compound;

(iii) The finished form (e.g., 10-milligram tablets or 10-milligram concentration per fluid ounce or milliliter;

(iv) The number of unites of finished form compounded;

(v) The quantity used in quality control;

(vi) The quantity lost during compounding and the causes therefore, if known;

(vii) The total quantity of the substance contained in the finished form;

(viii) The theoretical and actual yields; and

(ix) Such other information as is necessary to account for all controlled substance used int he compounding process;

(6) The quantity used to manufacture other controlled and non-controlled substances; including the name of each substance manufactured and the information required in paragraph (a)(5) of this section;

(7) The quantity distributed in bulk form to other programs, including the date and quantity of each distribution and the name, address and registration number of each program to whom a distribution was made;

(8) The quantity disposed of by destruction, including the reason, date and manner of destruction. All other destruction of narcotic controlled substances will comply with § 1307.22.

(9) The quantity disposed of the destruction, including the reason, date and manner of destruction, including the reason, date and manner of destruction. All other destruction of narcotic controlled substances with comply with § 1307.22.

(b) For each narcotic controlled substance in finished form:

(1) The name of the substance;

(2) Each finished form (e.g., 10-milligram tablet or 10 milligram concentration per fluid ounce or milliliter) and the number of units or volume or finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

(3) The number of containers of each such commercial finished form compounded from bulk form by the registrant, inclining the information required pursuant to paragraph (a)(5) of this section;

(4) The number of units of finished forms and/or commercial containers received from other person, including the date of and number of units and.or commercial containers in each receipt and the name, address and registration number of the person from whom the units were received;

(5) The number of units of finished forms and/or commercial containers imported directly by the person (under a registration or authorization to import), including the date of, the number of units and/or commercial containers in, and the import permit or declaration number for, each importation;

(6) The number of units and/or commercial containers compounded by the registrant from units in finished form received from other or imported, including:

(i) The date and batch or other identifying number of each compounding;

(ii) The operation performed (e.g., repackaging or relabeling);

(iii) The number of units of finished form used in the compound, the number compounded and the number lost during compounding, with the causes for such losses, if known; and

(iv) Such other information as is necessary to account for all controlled substances used in the compounding process;

(7) The number of containers distributed to other programs, including the date, the number of containers in each distribution, and the name, address and registration number of the program to whom the containers were distributed;

(8) The number of commercial containers exported directly by the registrant (under a registration as an exporter), including the date, number of containers and export permit or declaration number for each exportation; and

(9) The number of units of finished forms and /or commercial containers destroyed in any manner by the registrant, including the reason, the date and manner of destruction. All other destruction of narcotic controlled substances will comply with § 1307.22.

[39 FR 37985, Oct. 25, 1974]

PART 1305—ORDER FORMS

Sec.

1305.01 Scope of Part 1305.
1305.02 Definitions.
1305.03 Distributions requiring order forms.
1305.04 Persons entitled to obtain and execute order forms.
1305.05 Procedure for obtaining order forms.
1305.06 Procedure for executing order forms.
1305.07 Power of attorney.
1305.08 Persons entitled to fill order forms.
1305.09 Procedure for filling order forms.
1305.10 Procedure for endorsing order forms.
1305.11 Unaccepted and defective order forms.
1305.12 Lost and stolen order forms.
1305.13 Preservation of order forms.
1305.14 Return of unused order forms.
1305.15 Cancellation and voiding of order forms.
1305.16 Special procedure for filling certain order forms.

AUTHORITY: 21 U.S.C. 821, 828, 871(b), unless otherwise noted.

SOURCE: 36 FR 7796, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

Note to reader: Only those paragraphs in this Part that apply specifically to methadone maintenance treatment programs are provided.

§ 1305.08 Persons entitled to fill order forms.

An order form may be filled only by a person registered as a manufacturer or distributor of controlled substances listed in Schedule I or II under section 303 of the Act (21 U.S.C. 823) or as an importer of such substances under section 1008 of the Act (21 U.S.C. 958), except for the following:

(a) A person registered to dispense such substances under section 303 of the Act, or to export such substances under section 1008 of the Act, if he is discontinuing business or if his registration is expiring without reregistration, may dispose of any controlled substances listed in Schedule I or II in his possession pursuant to order forms in accordance with § 1307.14 of this chapter;

(b) A person who has obtained any controlled substance in Schedule I or II by order form may return such substance, or portion thereof, to the person from whom he obtained the substance or the manufacturer of the substance pursuant to the order form of the latter person;

(c) A person registered to dispense such substances may distribute such substances to another dispenser pursuant to, and only in the circumstances described in, § 1307.11 of this chapter; and

(d) A person registered or authorized to conduct chemical analysis or research with controlled substances may distribute a controlled substance listed in Schedule I or II to another person registered or authorized to conduct chemical analysis, instructional activities, or research with such substances pursuant to the order form of the latter person, if such distribution is for the purpose of furthering such chemical analysis, instructional activities, or research.

(e) A person registered as a compounder of narcotic substances for use at off-site locations in conjunction with a narcotic treatment program at the compounding location, who is authorized to handle Schedule II narcotics, is authorized to fill order forms for distribution of narcotic drugs to offsite narcotic treatment programs only.

[36 FR 7796, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971; 36 FR 18732, Sept. 21, 1971; 37 FR 15921, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

EDITORIAL NOTE: For FR citations affecting § 1305.08, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 1305.09 Procedure for filling order forms.

(a) The purchaser shall submit Copy 1 and Copy 2 of the order form to the supplier, and retain Copy 3 in his own files.

(b) The supplier shall fill the order, if possible and if he desires to do so, and record on Copies 1 and 2 the number of commercial or bulk containers furnished on each item and the date on which such containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the order form. No order form shall be valid more than 60 days after its execution by the purchaser, except as specified in paragraph (f) of this section.

(c) The controlled substances shall only be shipped to the purchaser and at the location printed by the Administration on the order form, except as specified in paragraph (f) of this section.

(d) The supplier shall retain Copy 1 of the order form for his own files and forward Copy 2 to the Special Agent in Charge of the Drug Enforcement Administration in the area in which the supplier is located. Copy 2 shall be forwarded at the close of the month during which the order is filled; if an order is filled by partial shipments, Copy 2 shall be forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.

(e) The purchaser shall record on Copy 3 of the order form the number of commercial or bulk containers furnished on each item and the dates on which such containers are received by the purchaser.

(f) Order forms submitted by registered procurement officers of the Defense Personnel Support Center of Defense Supply Agency for delivery to armed services establishments within the United States may be shipped to locations other than the location printed on the order form, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

[36 FR 7796, Apr. 24, 1971, as amended at 36 FR 18732, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 47 FR 41735, Sept. 22, 1982]

§ 1305.11 Unaccepted and defective order forms.

(a) No order form shall be filled if it:

(1) Is not complete, legible, or properly prepared, executed, or endorsed; or

(2) Shows any alteration, erasure, or change of any description.

(b) If an order form cannot be filled for any reason under this section, the supplier shall return Copies 1 and 2 to purchaser with a statement as to the reason (e.g., illegible or altered). A supplier may for any reason refuse to accept any order and if a supplier refuses to accept the order, a statement that the order is not accepted shall be sufficient for purposes of this paragraph.

(c) When received by the purchaser, Copies 1 and 2 of the order form and the statement shall be attached to Copy 3 and retained in the files of the purchaser in accordance with § 1305.13. A defective order form may not be corrected; it must be replaced by a new order form in order for the order to be filled.

§ 1305.12 Lost and stolen order forms.

(a) If a purchaser ascertains that an unfilled order form has been lost, he shall execute another in triplicate and a statement containing the serial number and date of the lost form, and stating that the goods covered by the first order form were not received through loss of that order form. Copy 3 of the second form and a copy of the statement shall be retained with Copy 3 of the order form first executed. A copy of the statement shall be attached to Copies 1 and 2 of the second order form sent to the supplier. If the first order form is subsequently received by the supplier to whom it was directed, the supplier shall mark upon the face thereof "Not accepted" and return Copies 1 and 2 to the purchaser, who shall attach it to Copy 3 and the statement.

(b) Whenever any used or unused order forms are stolen form or lost (otherwise than in the course of transmission) by any purchaser or supplier, he shall immediately upon discovery of such theft or loss, report the same to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station Washington, DC 20005, stating the serial number of each form stolen or lost. If the theft or loss includes any original order forms received from purchasers and the supplier is unable to state the serial numbers of such order forms, he shall report the date or approximate date of receipt thereof and the names and addresses of the purchaser is unable to state the serial numbers of the order forms contained therein, he shall report, in lieu of the numbers of the forms contained in such book, the date or approximate date of issuance thereof. If any unused order form reported stolen or lost is subsequently recovered or found, the Registration Branch of the Administration shall immediately be notified.

[36 FR 7796, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 51 FR 5319, Feb. 13, 1986]

§ 1305.13 Preservation of order forms.

(a) The purchaser shall retain Copy 3 of each order form which has been filled. He shall also retain in his files all copies of each unaccepted or defective order form and each statement attached thereto.

(b) The supplier shall retain Copy 1 of each order form which he has filled.

(c) Order forms must be maintained separately from all other records of the registrant. Order forms are required to be kept available for inspection for a period of 2 year. If a purchaser has several registered locations, he must retain Copy 3 of the executed order forms and any attached statements or other related documents (not including unexecuted order forms which may be kept elsewhere pursuant to §1305.06(e)) at the registered location printed on the order form.

(d) The supplier of carfentanil etorphine hydrochloride and diprenorphine shall maintain order forms for these substances separately from all other order forms and records required to be maintained by the registrant.

[36 FR 7796, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 39 FR 17839, May 21, 1974; 54 FR 33674, Aug. 16, 1989]

PART 1307--MISCELLANEOUS

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1307.31 Native American Church.

AUTHORITY: 21 U.S.C. 821, 822(d), 871(b), unless otherwise noted.

SOURCE: 36 FR 7801, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

Note to reader: Only those paragraphs in this Part that apply specifically to methadone maintenance treatment programs are provided.

DISPOSAL OF CONTROLLED SUBSTANCES

§ 1307.14 Distribution upon discontinuance or transfer of business.

(a) Any registrant desiring to discontinue business activities altogether or with respect to controlled substances (without transferring such business activities to another person) shall return for cancellation his certificate of registration, and any unexecuted order forms in his possession, to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005. Any controlled substances in his possession may be disposed of in accordance with § 1307.21.

§ 1307.21 Procedure for disposing of controlled substances.

(a) Any person in possession of any controlled substance and desiring or required to dispose of such substance may request the Special Agent in Charge of the Administration in the area in which the person is located for authority and instructions to dispose of such substance. The request should be made as follows:

(1) If the person is a registrant required to make reports pursuant to part 1304 of this chapter, he shall list the controlled substance or substances which he desires to dispose of on the "b" subpart of the report normally filed by him, and submit three copies of that subpart to the Special Agent in Charge of the Administration in his area.

(2) If the person is a registrant not required to make reports pursuant to part 1304 of this chapter, he shall list the controlled substance or substances which he desires to dispose of on DEA Form 41, and submit three copies of that form to the Special Agent in Charge in his area; and

(3) If the person is not a registrant, he shall submit to the Special Agent in Charge a letter stating:

(i) The name and address of the person;

(ii) The name and quantity of each controlled substance to be disposed of;

(iii) How the applicant obtained the substance, if known; and

(iv) The name, address, and registration number, if known, of the person who possessed the controlled substances prior to the applicant, if known.

(b) The Special Agent in Charge shall authorize and instruct the applicant to dispose of the controlled substance in one of the following manners:

(1) By transfer to person registered under the Act and authorized to possess the substance;

(2) By delivery to an agent of the Administration or to the nearest office of the Administration;

(3) By destruction in the presence of an agent of the Administration or other authorized person; or

(4) By such other means as the Special Agent in Charge may determine to assure that the substance does not become available to unauthorized persons.

(c) In the event that a registrant is required regularly to dispose of controlled substances, the Special Agent in Charge may authorize the registrant to dispose of such substances, in accordance with paragraph (b) of this section, without prior approval of the Administration in each instance, on the condition that the registrant keep records of such disposals and file periodic reports with the Special Agent in Charge summarizing the disposals made by the registrant. In granting such authority, the Special Agent in Charge may place such conditions as he deems proper on the disposal of controlled substances, including the method of disposal and the frequency and detail of reports.

(d) This section shall not be construed as affecting or altering in any way the disposal of controlled substances through procedures provided in laws and regulations adopted by the State.

[36 FR 7801, Apr. 24, 1971, as amended at 37 FR 15922, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 47 FR 41735, Sept. 22, 1982]

PART 1316—ADMINISTRATIVE FUNCTIONS, PRACTICES, AND PROCEDURES

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SOURCE: 36 FR 7820 Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

SUBPART A—ADMINISTRATIVE INSPECTIONS

§1316.03 Authority to make inspections.

In carrying out his functions under the Act, the Administrator, through his inspectors, is authorized in accordance with sections 510 and 1015 of the Act (21 U.S.C. 880 and 965) to enter controlled premises and conduct administrative inspections thereof, for the purpose of:

(a) Inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept or made under the Act and regulations promulgated under the Act, including, but not limited to, inventory and other records required to be kept pursuant to part 1304 of this chapter, order form records required to be kept pursuant to part 1305 of this chapter, prescription and distribution records required to be kept pursuant to part 1306 of this chapter, records of listed chemicals, tableting machines, and encapsulating machines required to be kept pursuant to part 1310 of this chapter, import/export records of listed chemicals required to be kept pursuant to part 1313 of this chapter, shipping records identifying the name of each carrier used and the date and quantity of each shipment, and storage records identifying the name of each warehouse used and the date and quantity of each storage.

(b) Inspecting within reasonable limits and to a reasonable manner all pertinent equipment, finished and unfinished controlled substances and other substances or materials, containers, and labeling found at the controlled premises relating to this Act;

(c) Making a physical inventory of all controlled substances on-hand [sic] at the premises;

(d) Collecting samples of controlled substances or precursors (in the event any samples are collected during an inspection, the inspector shall issue a receipt for such samples on DEA Form 84 to the owner, operator, or agent in charge of the premises);

(e) Checking of records and information on distribution of controlled substances by the registrant as they relate to total distribution of the registrant (i.e., has the distribution in controlled substances increased markedly within the past year, and if so why); and

(f) Except as provided in §1316.04, all other things therein (including records, files, papers, processes, controls, and facilities) appropriate for verification of the records, reports, documents referred to above or otherwise bearing on the provisions of the Act and the regulations thereunder.

[36 FR 7820, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 51 FR 5319, Feb. 13, 1986; 55 FR 50827, Dec. 11, 1990]

§1316.06 Notice of inspection.

The notice of inspection (DEA (or DNB) Form 82) shall contain:

(a) The name and title of the owner, operator, or agent in charge of the controlled premises;

(b) The controlled premises name;

(c) The address of the controlled premises to be inspected;

(d) The date and time of the inspection;

(e) A statement that a notice of inspection is given pursuant to section 510 of the Act (21 U.S.C. 880);

(f) A reproduction of the pertinent parts of section 510 of the Act; and

(g) The signature of the inspector.

SUBPART C—ENFORCEMENT PROCEEDINGS

AUTHORITY: 21 U.S.C. 871(B), 883.

§1316.31 Authority for enforcement proceeding.

A hearing may be ordered or granted by any Special Agent in Charge of the Drug Enforcement Administration, at his discretion, to permit any person against whom criminal and/or civil action is contemplated under the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951) an opportunity to present his views and his proposals for bringing his alleged violations into compliance with the law. Such hearing will also permit him to show cause why prosecution should not be instituted, or to present his views on the contemplated proceeding.

[36 FR 7820, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 47 FR 41735, Sept. 22, 1982]

§1316.32 Notice of proceeding; time and place.

Appropriate notice designating the time and place for the hearing shall be given to the person. Upon request, timely and properly made, by the person to whom notice has been given, the time or place of the hearing, or both, may be changed if the request states reasonable grounds for such change. Such request shall be addressed to the Special Agent in Charge who issued the notice.

[36 FR 7820, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 47 FR 41735, Sept. 22, 1982]

§1316.33 Conduct of proceeding.

Presentation of views at a hearing under this subpart shall be private and informal. The views presented shall be confined to matters relevant to bringing violations into compliance with the Act or to other contemplated proceedings under the Act. These views may be presented orally or in writing by the person to whom the notice was given, or by his authorized representative.

§1316.34 Records of proceeding.

A formal record, either verbatim or summarized, of the hearing may be made at the discretion of the Special Agent in Charge. If a verbatim record is to be made, the person attending the hearing will be so advised prior to the start of the hearing.

[37 FR 15924, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 47 FR 41735, Sept. 22, 1982]

U.S. DEPARTMENT
OF HEALTH AND
HUMAN SERVICES
Public Health Service
Substance Abuse and
Mental Health Services
Administration

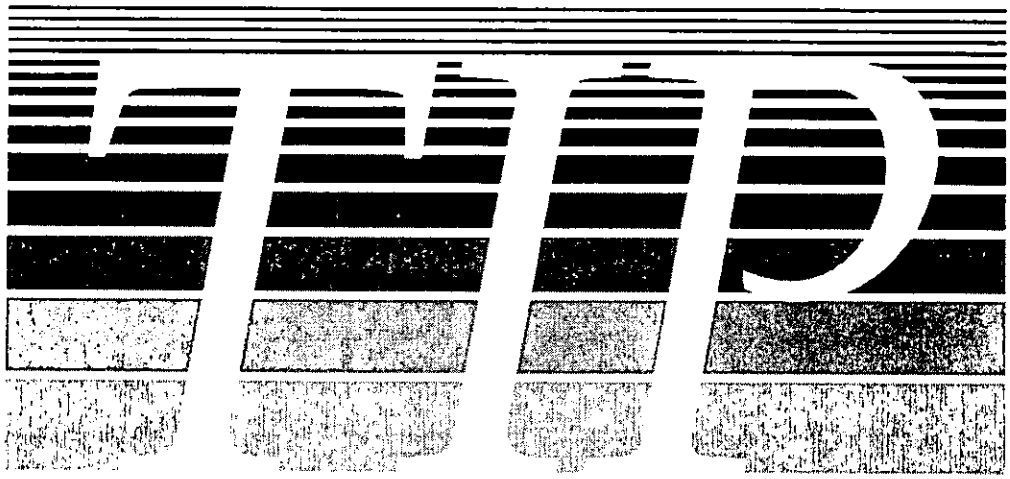
Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Treatment

Matching Treatment to Patient Needs in Opioid Substitution Therapy

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Chapter 1—Patient Matching: Historical Perspective and Overview

The purpose of this Treatment Improvement Protocol (TIP) is to develop guidelines to assess the needs of patients in opioid substitution therapy and to match patients, based on their needs, to a variety of services, including medical, psychiatric, social, and other support services. Several studies show that patients who receive the services they need are more likely than others to stay in treatment and to have positive outcomes. The concept of matching patients to services according to their needs is widely accepted in other medical treatment settings but until recently was not used in the field of opioid substitution therapy. This TIP details the current knowledge about patient matching in opioid substitution therapy; its goal is to help programs more fully develop the important aspects of treatment that derive from matching strategies.

Another TIP in this series, *State Methadone Treatment Guidelines*, presents a structure for States to follow to comply with Federal regulations when providing methadone treatment (the most common form of opioid substitution therapy). The methadone document describes the best treatment practices in separate chapters on admissions procedures, dose determination, use of urinalysis as a clinical tool, take-home medication, and patient retention. The methadone guidelines discuss the provision of methadone treatment to pregnant women, multiple substance abusers, and persons with human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS) and other infectious diseases. The TIP on methadone also discusses matching strategies.

The current TIP focuses on ways to develop matching strategies on a comprehensive, programmatic level. This TIP and the previous one provide useful information about the best practices for providing opioid substitution therapy and about how to improve patients' chances for recovery by matching services to patient needs.

This document on patient matching continues the efforts of the Center for Substance Abuse Treatment (CSAT) to ensure that opioid substitution therapy programs throughout the United States provide high-quality, cost-effective services. Two other TIPs *LAAM in the Treatment of Opiate Addiction* and *Assessment and Treatment of Cocaine-Abusing Methadone-Maintained Patients* provide information on delivering the highest quality and most cost-effective treatments to the broadest range of persons with opiate dependence.

In addition, this TIP on patient matching describes a further evolution of opioid substitution therapy as an effective treatment. The epidemics of AIDS and tuberculosis (TB) and the advent of managed care have a strong influence on opioid substitution therapy programs. These epidemics make it more important than ever that programs find ways to address the wide range of patient needs, retain patients in treatment, and use resources efficiently. Patient matching is a critical strategy in attaining these goals.

In recent years, phased treatment models have been developed to help planners and providers better conceptualize opioid substitution therapy to improve service delivery and resource allocation. This document presents a six-phase treatment model, which includes an initial evaluation and an ongoing assessment of progress; it describes patient treatment needs during each phase and the types of services that can best meet these needs. Since effective patient matching depends on careful ongoing assessment, this TIP outlines the assessment process and describes clinical indicators for transition to other treatment phases. It also reviews treatment elements, including a core group of treatment and support services and a variety of counseling and therapeutic services that will enable opioid substitution therapy programs to meet patient needs via matching strategies.

Also addressed are the issues of program self-evaluation and cost-benefit analysis to help programs stay responsive to the realities of managed

care and to provide input into managed-care policies and decisions.

Managed Care and Opioid Substitution Therapy

Managed care is an evolving process that was first developed in the private sector, mainly for individuals who are regularly employed. It was only recently applied to the public sector and to opioid substitution therapy programs. Many States are moving toward the use of a managed care model to provide healthcare services to Medicaid patients. The public sector, especially substitution programs, has large numbers of chronically ill and disadvantaged persons with multiple problems. Persons with multiple and chronic problems present a special dilemma for managed care programs, which traditionally focus on achieving cost savings by reducing or denying services. This strategy may be cost effective when applied to relatively healthy persons with illnesses that are usually time limited; it may be counterproductive if applied unwisely to opioid substitution therapy, which is a long-term process.

On the other hand, the managed care approach has considerable potential to facilitate treatment matching within opioid substitution therapy programs, provided that the managed care entity is held responsible for treating the medical, psychiatric, family, social, and other problems of patients in the program's care. When managed care organizations attempt to help the patient to obtain the most cost-effective medical, psychiatric, and other services for opioid substitution therapy, they do so within the opioid substitution programs. Emergency psychiatric and medical hospitalizations can be reduced when appropriate outpatient treatment and preventive services are provided to persons who are high users of inpatient treatment.

Thus, managed care, rather than being regarded as a nemesis for opioid substitution therapy, can be seen as having the potential to support this treatment, especially in regard to developing effective matching strategies. The reasons are financial. Very high costs result when patients are hospitalized. Most opioid-dependent patients are potential frequent users of hospital beds—for detoxification or for psychiatric, medical, surgical, or other conditions that may or may not be related to their substance use disorder. It is most cost effective to prevent hospitalization (including emergency room use) by ensuring that opioid substitution therapy programs have the professional resources necessary to develop effective psychiatric, medical, and other matching strategies.

Many of the services described in this TIP have not been routinely available to most substitution therapy programs. However, they may become more available when managed care organizations fully realize the cost savings that can be achieved by using matching strategies and outpatient professional services to prevent hospitalization and other more expensive treatments. If this view is held, managed care could help opioid substitution therapy programs to become the backbone of an effective outpatient, medical, and psychiatric treatment delivery system, which functions to reduce overall health costs for a group of patients who are high users of expensive inpatient services.

> Although the managed care approach may be cost effective when applied to relatively healthy persons with time-limited illnesses, it has a great potential to be extremely counterproductive if applied to long-term therapy.

Many States currently lack a model to assess the appropriateness of treatment levels and patient matching in opioid substitution therapy programs. Models could be based on those being considered for treatment of other chronic diseases, such as HIV infection, that recognize the chronic nature of the condition and the need for extended therapy. It is very important that opioid substitution therapy programs work with managed care companies to establish assessment and treatment guidelines that are both cost effective and that match the needs of the patients.

Patient Matching

Patient matching is the process of individualizing treatment resources to patient needs and preferences. It requires an assessment of the extent, nature, and duration of the individual's alcohol and other drug (AOD) use and treatment history, as well as an assessment of medical, psychiatric, and psychosocial needs and functional status. The patient's gender, culture, ethnicity, sexual orientation, and language are of key importance. Matching is a participatory activity that involves both the clinician and the patient. Also important is the patient's motivation as well as the level of support available to the patient to achieve and maintain a life-style free of AOD abuse.

Most patients who require opioid substitution therapy have long-term, chronic addiction ailments that cause serious problems in many life areas. Patient matching should be undertaken with the

understanding that many persons who are addicted to opioids have multiple needs. Because of the complexity of patients' needs and the scope of services required, matching is best accomplished through a three-step process that involves 1) assessing, 2) selecting the most suitable treatment modality and site, and 3) identifying the most appropriate ancillary services.

An individualized treatment plan with well-defined short- and long-term goals is the product of the patient-matching process. This plan is reevaluated at regular intervals to determine if it should be modified in respect to new issues that may arise as earlier identified problems are resolved.

Advantages of Patient Matching

Data from matching studies have become available only within the last 10 to 15 years, and thus the subject of this TIP is relatively new. In addition, the available data address relatively few of the many areas that could be investigated in this complex subject. However, the available data indicate that matching increases the likelihood of positive treatment outcomes. Provision of individualized, comprehensive services were shown to increase rates of retention in treatment (Condelli, 1993; Joe et al., 1991); the longer a patient is in treatment, the better the chances for recovery.

Matching also improves resource allocation by ensuring that patients receive the appropriate level and type of services. It ensures appropriate use of the specific training and experience of all members of the multidisciplinary clinical team, thereby increasing the quality of care as well as team members' job satisfaction. The short-term cost of providing individualized, professionalized services may be higher than that of providing more limited care. However, the ultimate cost to the healthcare system and to society, as measured in terms of increased productivity and reduction in criminal activity, is likely to be greatly reduced.

The Need for Patient Matching Guidelines

The idea of patient matching, while not new, has become more attractive in the wake of pressures to contain the overall cost of healthcare, particularly if matching in an outpatient setting can reduce the need for hospitalization. Nonetheless, the concept of matching is as methodologically elusive to researchers as it is attractive to clinicians (McLellan and Alterman, 1991), and many of the basic concepts of patient matching have not yet been clearly defined or fully accepted. As additional data becomes available, these problems may be resolved.

> The services that are described in this TIP may become more available when managed care organizations fully realize the cost savings that can be achieved by using matching strategies and outpatient professional services.

One example of the early development of the concept of patient matching within the substance abuse treatment field is that, despite the existence of detailed Federal and State regulations, methadone treatment services and outcomes vary dramatically from program to program (Ball, 1991; General Accounting Office, 1990). Some programs are still basing patient management decisions on outdated clinical paradigms that are not consistent with current research findings. For example, many programs administer low dosages of methadone (i.e., 25-40 mg as the average) in the belief that lower is better, despite the abundant research supporting the efficacy of higher dosages (60 mg or more), with dosage levels individualized for each patient. Further, some programs encourage time-limited treatment rather than long-term substitution therapy. In these cases, clinical practice does not reflect research findings that demonstrate the efficacy of higher doses and long-term, very extended, or even indefinite treatment.

In other cases, State regulations prohibit the use of methadone in settings and modalities that are an important part of treatment matching and the continuum of care. For example, consider the case of a homeless patient who might do well on substitution therapy if he or she had a stable living arrangement; however, the housing or shelter that could provide such an arrangement does not admit persons on methadone. Another example is the case of a methadone-maintained patient who needs brief hospitalization for medically supervised withdrawal (detoxification) from another substance, but the detoxification program does not allow the patient to be maintained on methadone during the process.

This TIP describes the problems and points out rules that need attention and revision. As a result, it is hoped that some regulations will be modified to become more consistent with an integrated, comprehensive system of treatment that includes patient matching within a continuum of care.

The lack of resources and staff to provide an appropriate range of services is an impediment to

developing matching strategies within the current AOD, health, psychiatric, and social service systems. There is a tendency in some programs to wall off substance abuse treatment from other services, as if to say, "We are responsible only for the substance use disorder and nothing else." This type of organizational structure is a significant obstacle to the use of effective matching strategies and often inconveniences the patient to the point that he or she does not comply with important treatment recommendations. In addition, it runs counter to AOD provider's growing awareness of the need to develop increasingly effective systems of primary care that treat the whole person.

> Regulations in some States prohibit the use of methadone in settings and modalities that are an important part of treatment matching and the continuum of care.

It is not necessary for each program to offer the full spectrum of needed resources and services to successfully apply patient-matching techniques. Through staff training and the use of carefully developed referral networks supported by appropriate guidelines, staff can identify the need for additional services and work with patients to offer them access to services that a single program is unable to provide. Psychiatric, medical, and social work services are the most commonly needed and used. Programs should place the highest priority on obtaining resources or developing relationships with providers that can provide these services in a convenient and cost-effective manner.

The remainder of this chapter provides a historical review of the development of opioid substitution therapy and ongoing treatment issues. HIV/AIDS and the concept of harm reduction are discussed, and additional comments about the impact of managed care on the delivery of substitution therapy are reviewed.

Historical Perspective

When new treatments are developed, matching patients to these treatments can be done relatively quickly. Clinicians in most medical settings readily accept the concept of matching. There are numerous examples of this phenomenon. For instance, clinicians began using a combination of drugs to treat HIV infection when it was found that the HIV virus was able to quickly develop resistance to AZT when it was used alone (Cheesman et al., 1994).

However, in the case of opioid substitution therapy, the progression from the development of a treatment for a very serious disorder to further treatment refinements, including the use of matching strategies, has been delayed. For example, many single State agencies have been slow to approve use of the opioid substitute levo-alpha-acetyl-methadol (LAAM), even though its use reduces the risk of diversion. In addition, although methadone has now been used for almost 30 years, patient-treatment matching strategies have only just begun to be formally addressed in opioid substitution therapy programs.

Reasons for this halting progression may be found in the historical development of substitution therapy and in the ambivalence that has always surrounded its use. Treatment of opioid dependence with substitution therapy has been tried in isolated cases by individual practitioners and applied on a larger scale as part of organized treatment programs for at least 100 years. Until the advent of methadone maintenance in the 1960s, there was little or no scientific evidence that opioid substitution therapy was generally helpful. Perhaps because of this lack of evidence, reports of improper use, and diversion of legally prescribed opioids, substitution therapy fell into public disrepute during the 1920s.

An administrative structure to control prescription and consumption of addictive substances was put into place by the Harrison Act of 1914, which required dispensers of opioids and cocaine to register annually, to pay a fee, and to use special forms provided by the Internal Revenue Service. This move toward more controls on addictive substances was consistent with the temperance movement and the enactment of Prohibition in 1919. These structures to introduce controls over prescribing, though seemingly modest in scope, were interpreted by law enforcement agencies in increasingly restrictive ways beginning in the 1920s. As a result, the few physicians who continued to prescribe opioids to addicted persons were forced to discontinue this practice; to do so, even in the absence of diversion or overt criminal behavior, became defined as an illegal act that could result in suspension of a physician's medical license or even a prison sentence.

This movement toward strict limits on prescribing was greatly strengthened under the leadership of Harry Anslinger, who was commissioner of the Federal Bureau of Narcotics (FBN) from 1930 to 1964. (The FBN became the Drug Enforcement Administration [DEA] in 1973.) Treatment became totally abstinence oriented, and two Federal hospitals with long-term residential settings were established

during the 1930s to treat opiate-addicted individuals. One hospital was at Lexington, Kentucky, and the other at Fort Worth, Texas. Each hospital accepted voluntary patients as well as prisoners who had been convicted of Federal crimes that were often related to opiate dependence. Much of the early research on opioid dependence was conducted in these settings, especially the Lexington facility. These treatment facilities were very small and required patients to remain for long periods in residential therapy. In addition, they were expensive, and although patients improved, relapse rates were high after discharge from the residential setting.

Treatment of opiate dependence with substitution therapy has been tried in isolated cases by individual practitioners and applied on a larger scale as part of organized treatment programs for at least 100 years. With the advent of methadone maintenance studies in the 1960s, scientific evidence established that opioid substitution therapy is often effective.

In the early 1960s, Drs. Marie Nyswander and Vincent Dole became interested in opioid addiction and relapse. They were aware of the problems that had been associated with previous attempts at substitution therapy but did not give up on the idea. They began to examine methadone as a possible solution. This drug had been developed during World War II by Germany when its opiate supplies were interrupted by the war. Methadone has all the pharmacological effects of other opioids; however, it also has two properties which make it potentially useful for substitution therapy: 1) It is well absorbed when given orally, and 2) it suppresses opioid withdrawal symptoms for 24 to 36 hours.

Thus, a single oral dose of methadone can prevent opiate withdrawal symptoms for a day, while also avoiding the complications associated with parenteral use. Using high doses of methadone for substitution therapy was found to produce significant cross-tolerance to illicit opiate, thus diminishing the high produced by heroin, which further contributed to methadone's efficacy. In addition, methadone provides much more control over diversion or improper use, since a single daily dose can be administered under direct observation.

Dole and Nyswander began a series of experiments in which they selected persons with a long history of opioid dependence who were free of serious medical or psychiatric problems and who were willing to participate in a study of methadone substitution therapy (Dole and Nyswander, 1966; 1967). Careful followup showed a significant change in the behavior that had been typical of these patients. Illicit heroin use and criminal behavior were markedly reduced, patients' sense of well-being and self-respect were significantly improved, employment increased, and family problems were improved. In addition, medical evaluations demonstrated no significant adverse effects as a consequence of long-term maintenance (Kreek, 1973; 1978; 1983). On the basis of these early and very positive results, methadone was approved in the early 1970s by the Food and Drug Administration (FDA) as a substitution therapy for chronic opioid users who had demonstrated an inability to achieve sustained abstinence.

Change in Public Policy

Thus, after more than 50 years of public and legal opposition to substitution therapy, a new drug, methadone, had been studied, applied, and found effective. Within a period of several years, almost 100,000 opioid-addicted persons were being treated with methadone in the United States. Methadone maintenance became and remains the single treatment that is most acceptable to opiate-addicted individuals.

This marked change in policy occurred rapidly and was not without its opponents, especially among law enforcement agencies that had played a significant role in implementing the earlier restrictive policies. Some medical professionals, particularly those committed to long-term drug-free treatment, also opposed its use as did some lay persons and politicians who felt that it represented "giving in" to the problem or that it was another form of "slavery." These factors contributed to a lack of public and professional acceptance of opioid substitution therapy. In fact, attempts were made to arrest Dr. Dole, even after he reported the very positive results that could be achieved by methadone maintenance treatment.

Perhaps as a result of the legal and political ambivalence surrounding methadone maintenance, a large number of studies were done to confirm its efficacy (Ball and Ross, 1991; Dole and Joseph, 1978; Dole and Nyswander, 1967; Dole et al., 1966; Gearing and Schweitzer, 1974; Gerstein and Hartwood, 1990; Hartel et al., 1988; Kreek, 1983). Though few found results as dramatic as those of the early studies of Dole and Nyswander, almost all studies confirmed the original findings: marked reductions in opioid use and crime and improvement in employment and overall social adjustment.

Federal Regulations and Public Policy

The Need for Regulations

Since methadone can be abused like any other opioid, regulations were developed by States, FDA, and DEA to limit and control its use. These regulations govern who can administer methadone maintenance, eligibility for treatment, evaluation procedures, dosages, take-home medications, frequency of patient visits, medical and psychiatric services, counseling, support services, and related details. The various regulations are complex, and State regulations are not always identical to FDA regulations. For example, Federal regulations do not specify a limit on time in treatment; however, some States and some programs set such limits. Similarly, some States limit dosages of methadone to 80 mg a day or less, a lower limit than is permitted by Federal regulations.

The FDA regulations were enacted in 1973 and revised in 1980 and 1989; they have been described in detail in a previous TIP *State Methadone Treatment Guidelines*. Copies of the most current FDA regulations are included in appendices to that document.

The FDA has responsibility for approving programs and ensuring compliance with FDA regulations; the DEA monitors the security of program facilities and compliance with regulations concerning the handling of controlled substances. Programs must also receive approval from the State methadone authority, which monitors the same areas as the FDA and the DEA, and also serves as a source of technical assistance. In addition, methadone treatment programs must meet other requirements to be accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the Commission on Accreditation of Rehabilitation Facilities (CARF), if they choose to be certified by these agencies.

Influence of Regulations on Developing Matching Strategies

The emphasis on regulatory compliance that has dominated opioid substitution therapy programs since their inception has probably inhibited the development of patient-treatment matching strategies. Although it is probably necessary to have a clinically informed set of regulations that are reasonably enforced by qualified and well-trained persons (characteristics that have not always been the case [Institute of Medicine, 1995]), the regulatory emphasis has consumed so much of treatment providers' energy that it has in all likelihood diverted attention from more clinically focused activities and impaired the development of clinically focused approaches, such as matching strategies and treatment guidelines.

An emphasis on regulatory controls may have been necessary when opioid substitution therapy was first developed. However, the relevance of a regulatory emphasis at the present time is not so clear. For example, a recent report on methadone by the Institute of Medicine concluded that the emphasis on regulations has focused too much on protecting society from methadone and not enough on developing methadone programs to best help persons with opioid dependence and to protect society from the social disruption caused by heroin addiction (Institute of Medicine, 1995).

The potentially adverse effects of an overemphasis on regulatory control may be strongest in the area of patient-treatment matching. The original patients selected by Dole and Nyswander for substitution therapy were generally not polydrug abusers; they were free of serious medical or psychiatric problems. After methadone was approved for general use, a much more heterogeneous group of patients, in particular those with serious psychiatric and medical problems, was admitted to treatment. These patients did not progress as well as the original treatment group (McLellan et al., 1983b).

The number of multiplicatively impaired patients has been growing, especially since the AIDS epidemic. Patients with medical and psychiatric impairments are those who can best be served by treatment matching strategies; they usually do not progress unless these approaches are instituted. An emphasis on regulatory compliance or overly restrictive interpretation of existing regulations can impair the development of matching strategies and reduce the chances of good treatment outcomes for patients with multiple problems.

LAAM

LAAM is a long-acting opioid that can be used in place of methadone for opioid substitution therapy. It was approved by the FDA in July 1994, after two decades of study. Its effects are similar to those of methadone; that is, it creates a pharmacologic cross-tolerance to heroin and other opioids and therefore blocks the euphoric effects of those drugs while also controlling craving. LAAM can suppress the signs and symptoms of opiate withdrawal for 48 to 72 hours, whereas methadone is effective for 24 to 36 hours.

A 1995 report on methadone by the Institute of Medicine concluded that the emphasis on regulations has focused too much on protecting society from methadone and not enough on developing methadone programs to best help persons with opioid dependence and to protect society from the social disruption caused by heroin addiction.

Use of LAAM allows patients to visit the clinic less frequently; instead of daily visits for methadone, LAAM can be administered every other day from the beginning of treatment. In addition, some patients report that they feel better on LAAM than on methadone, perhaps because of LAAM's longer duration of action. Some patients have reported a "smoother" effect, with fewer ups and downs.

LAAM is an alternative to methadone for opioid substitution therapy; it allows the patient and clinician another choice. Although LAAM has been approved by the FDA, it must also be approved by the individual State in which it is to be used. As of this writing, approximately 20 States have approved the use of LAAM, and it is being used in Portugal and several other European countries.

LAAM is discussed in detail in another TIP in this series, *LAAM in the Treatment of Opiate Addiction.*

Treatment Issues

Since opioid substitution therapy became widespread, some important treatment issues have come into focus. Several of these issues have a direct bearing on the ability of programs to effectively carry out patient-treatment matching. Two of the most important issues involve questions about the most effective methadone dose and the optimal level of psychosocial services to provide in substitution therapy programs. Other issues relate to the problems of polydrug abuse and to choosing the best approaches for treating dually diagnosed patients, dispensing take-home medications, and managing behavioral problems in the immediate vicinity of the methadone clinic facility.

Several studies have been done to explore the issues of dose, psychosocial services, and management of dually diagnosed patients. Studies of dose have shown conclusively that, although some patients do well on 30 to 50 mg per day, those on higher doses (60 mg per day or more) generally do better (Ball and Ross, 1991). One of the best designed of these studies was done by Ling and associates in the Veterans Administration (Ling et al., 1976). It showed that patients randomly assigned to receive 100 mg of methadone a day did significantly better than those receiving 50 mg a day. The more positive effects of higher doses are probably mainly a result of the significant levels of cross-tolerance that are obtained.

Other studies have addressed questions regarding the most appropriate levels of psychosocial services and the treatment of dually diagnosed patients. One of the most consistent findings of these studies is that there is no single predictor of success for patients in treatment. Some have problems only with substance abuse, while others have many problems, including psychiatric, legal, medical, family-social, and employment problems. Studies have usually found that the provision of more services is associated with better treatment outcomes. Studies that have more closely examined interactions between services and outcomes have found that patients are usually helped when services are targeted to specifically identified problems (McLellan et al., 1993). For example, studies have shown that professional psychotherapy given in addition to drug-focused paraprofessional counseling can improve outcomes of patients with recurrent and coexisting psychiatric symptoms (Woody et al., 1991).

Ambivalence about opioid substitution therapy continues in spite of the overwhelming scientific evidence of its effectiveness. Many people are uncomfortable maintaining patients on methadone for long periods, especially when maintenance may be indefinite. Some of the controversial issues focus on very real problems such as how best to treat methadone-maintained patients who abuse or are dependent on other drugs. Some programs want to withdraw from methadone those patients who have other AOD problems or serious medical or psychiatric problems. Use of cocaine, benzodiazepines, and alcohol has presented special difficulties, since administration of methadone does not directly address the use of these substances. Evidence is accumulating, however, that the psychosocial and behavioral aspects of methadone treatment programs are often helpful in suppressing nonopioid drug abuse (Arndt, 1992; McLellan et al. 1993) however, psychosocial treatments alone leave much room for improvement.

Other issues sometimes focus on the goals of methadone treatment. Should methadone maintenance be a stepping stone to eventual abstinence, or is it an acceptable lifelong treatment? From the data, one could argue that it is an acceptable lifelong treatment for many patients but that some can

achieve long-term and stable drug-free adjustment. Who are these patients, and how are they best identified? These questions need further research.

A current and important issue, and one on which little research data are available, is how to decide that methadone treatment either is appropriate for a patient or is not working. Studies indicate that overall drug use by most methadone patients is markedly reduced, even though total abstinence may not be achieved. Although the goal of most treatment providers is to maintain patients on methadone in the absence of illicit drug use, this goal is often not achieved. At what level of drug use does one conclude that methadone maintenance is not helping and another treatment should be tried, even to the point of terminating methadone treatment against the patient's wishes?

> Ambivalence about opioid substitution therapy continues in spite of the overwhelming scientific evidence of its effectiveness. Many people are uncomfortable maintaining patients on methadone for long periods, especially when maintenance may be indefinite.

Decisions in this area have always been difficult, but they have become even more complex with the advent of HIV infection. As discussed later in this chapter, data are accumulating showing that opioid-addicted persons who are maintained on methadone have a substantially reduced chance of becoming infected with HIV, even though they might not completely stop illicit drug use (Metzger, et al., 1993). At what point can it be said that enough harm reduction has occurred to justify continued methadone maintenance despite the fact that the patient's progress is not at the expected level? More data are needed to guide decisions in this area. Available data indicate that substantial risk reduction can occur without the achievement of total abstinence. However, patients who continue to use drugs may erode clinic morale as other patients come to the conclusion that compliance and abstinence are not expected.

In summary, although many important issues remain, the data strongly indicate that opioid substitution therapy can provide substantial benefits to persons with opioid dependence. This important point should not be obscured in our attempts to identify problems and improve upon methadone treatment, to find newer substitution therapies that may be more efficacious for some patients than methadone, such as LAAM, and to develop guidelines and strategies for treating addicted patients with opioid substitution therapy.

HIV/AIDS and Harm Reduction

As discussed earlier, there is growing evidence that involvement in opioid substitution therapy reduces the risk of HIV infection, even if illicit drug use is not completely eliminated. In addition, HIV-positive patients who are receiving substitution therapy are engaged in a treatment program in which they are seen frequently. Their engagement in treatment generally allows them better access to important medical services than they might otherwise have (provided the services are available). Engaging this patient population in continued care has significant public health implications. Not only can these patients receive treatment for HIV disease and its complications, but they also can receive counseling about the disease and about behavioral changes that will reduce the risk of HIV transmission.

A prime example of a public health benefit that can be achieved by effectively run opioid substitution therapy programs is screening for tuberculosis (TB), which has increased significantly in recent years, especially in association with HIV disease. The medical evaluations that occur at intake to substitution therapy programs provide an opportunity to identify patients who carry TB or have active TB. One of the difficulties of treating TB is that many persons fail to comply with medication regimens and must be carefully monitored. The frequent clinic visits that are part of opioid substitution therapy provide an opportunity for direct observation of antituberculosis pharmacotherapy.

A more recent harm reduction intervention is interim substitution therapy. This treatment involves daily administration of methadone without provision of regular counseling services. It is applicable only on a time-limited basis and only when there are waiting lists for methadone programs. The aim of interim therapy is to provide some reduction in opiate use while a patient is waiting for a place to open in a more fully staffed treatment program. Interim treatment has been found to decrease the use of heroin and other opioids; however, patients who participate in programs in which more comprehensive services are available achieve greater reductions in use (Yancovitz et al., 1991; McLellan, 1993).

Concerns about interim therapy have been raised, especially if it is seen by providers and managed care companies as a less expensive and equally effective model for the treatment of opiate dependence. Interim

therapy should never be viewed as an alternative to comprehensive opioid substitution therapy programs.

> Engaging this patient population in continued care has significant public health implications. Not only can these patients receive treatment for HIV disease and its complications, but they also can receive counseling about the disease and about behavioral changes that will reduce the risk of HIV transmission.

The Need for Resources

Meeting patients' needs in opioid substitution therapy cannot be addressed without looking at the cost benefits of providing comprehensive services to opioid-dependent patients. These are often persons with no readily available entry point into the healthcare system, and methadone treatment programs often provide an entry. Therefore, appropriate decisions about what services are needed, for how long, and in what setting are crucial. As described above, untreated addicted patients meet their healthcare needs in a crisis-oriented episodic fashion—by utilizing emergency services as their primary care provider. Implementation of comprehensive outpatient models providing long-term care decreases the high utilization of more expensive acute care services.

Many programs are not able to afford comprehensive services for patients entering opioid substitution therapy. Therefore, programs must develop other models for effective services. One option is to develop linkages or networks between services and to refer patients to offsite services, thus attempting to contain costs while providing necessary services. Unfortunately, because of the fragmented system of publicly funded healthcare, public ambivalence about treating persons with opioid dependence, and extremely restricted resources in the public outpatient treatment area, many programs have great difficulty or even find it impossible to establish these liaisons. In these cases, programs must do the best they can and hope for improvements in service delivery that will make meaningful, comprehensive treatment possible.

As discussed earlier in this chapter, the potential financial advantages to managed care companies from combining psychiatric and medical services with substance abuse treatment may change this situation. Treatment providers and taxpayers could benefit from serious efforts to combine these important services and realize the cost savings that may result.

Recent Federal block grant requirements have created a mandatory link between the provision of substance abuse treatment and other healthcare services for pregnant and parenting women, persons from minority groups, individuals with dual diagnoses, injection drug users, disabled persons, HIV-infected persons, and persons with TB. While not designed specifically for opioid substitution therapy, these requirements must be met by all programs receiving Federal funding under the State block grant mechanisms. Now being implemented, the regulations are particularly important for State AOD directors who must determine how to establish the mandated links. These requirements may encourage States, HMOs, managed care companies, and other healthcare providers to increase their efforts to develop the treatment resources that will make matching strategies more of a reality than they are at present. Many of these aims can be achieved through networking.

Examples of Networking

Effective networking should cut across several disciplines. Some examples of networking are described below:

- Contact with State and city public health, mental health, and vocational rehabilitation departments.
- Creation of ad hoc alliances. For example, under the Yale/New Haven Model, a methadone treatment program became allied with the mayor's task force to create a women's health consortium. The consortium established a referral network through which each client had two counselors, one for methadone treatment and one for other health, mental health, and ancillary needs.
- Access to services supported by the Federal Government, including clearinghouses, electronic databases, and training and technical assistance programs.
- Access to programs for special populations, including abused children, victims of domestic violence, the homeless, and persons with disabilities.
- Use of *pro bono* legal services.
- Establishment of relationships with health, mental health, and civil rights advocacy groups.
- Use of educational, training, and technical assistance resources available through professional organizations.

Equally important is the development of a proactive attitude toward community outreach. For example, program staff might seek opportunities to sit on the boards of directors of other agencies and

organizations, and members of these organizations might be invited to join the opioid substitution program board. Such relationships broaden understanding of individual and shared program goals and increase the likelihood of appropriate referrals. Given the multiplicity of patient needs and limited resources, "turfism" and insularity are ill advised.

In addition to providing concrete services, networking can create a feeling of shared responsibility for patient welfare. It also increases program visibility and broadens public understanding of the purpose of opioid substitution therapy and its role in substance abuse treatment and rehabilitation.

Optimizing Methadone Treatment Outcome: The Challenges

Persons who are addicted to opioids share many of the problems and needs of those with other substance use disorders. At the same time, opioid-addicted persons present unique treatment challenges. The CSAT consensus panel believes that the following five challenges are especially important.

Challenge 1: Understanding That Opiate Addiction Is a Chronic, Relapsing Disorder

Among the most important factors to be understood when assessing the progress of an opioid-addicted patient is the probability of relapse, or recurrence of opioid use. Posttreatment followup studies have shown that roughly 80 percent of all patients resume daily use of opioids within the first year of leaving treatment (Ball, 1992; Hubbard and Marsden, 1986; Simpson and Marsh, 1986). However, it has also been shown that relapses may lead to a series of readmissions that are eventually associated with successive reductions in drug use and even extended periods of remission (Simpson and Savage, 1980). A 12-year followup study of 490 opioid-addicted patients treated in the Drug Abuse Reporting Program showed that each patient averaged more than six AOD treatment admissions. However, improvement occurred over time, and only one patient in four was still using opiates in the year preceding the last followup interview (Marsh et al., 1990).

Even patients who are highly motivated to achieve total abstinence and who terminate treatment under the best of circumstances have a less than 50 percent chance of remaining in full remission for as long as 3 years (Hargreaves, 1983). Such surveys substantiate the General Accounting Office conclusion that heroin addiction is a chronic, relapsing condition that many persons "will battle the rest of their lives" (General Accounting Office, 1990).

Relapses are, in other words, a predictable part of opioid addiction. The number of relapses does not predict failure in treatment; in fact, past relapses correlate positively with ultimate treatment success, and resistance to relapse increases as long-term abstinence increases (Simpson and Marsh, 1986).

Studies that explore additional predictors of treatment outcome have shown that patients who are older, have a stable family and an intact marriage, and are employed are more likely to have positive results than younger, unemployed patients with less stable family support.

Polydrug and alcohol abuse, psychopathology, and a history of criminal activity that is independent of the substance use disorder are associated with poorer treatment outcomes (Anglin and Hser, 1990; McLellan, 1986).

Challenge 2: Providing Comprehensive Services to Ensure Successful Opioid Substitution Therapy

Substitution therapy often has been mistakenly perceived as a simple and inexpensive pharmacologic treatment for opioid addiction. On the contrary, most patients who enter opioid substitution therapy have multiple needs and the most effective programs provide comprehensive services to meet these needs (Anglin and Hser, 1990; Ball and Ross, 1991; Joe et al., 1991). One recent study has shown that 85 percent of patients entering methadone treatment had problems in more than one of the following areas: physical or mental health; family and peer relationships; and legal, educational, vocational, and financial matters.

Unfortunately, because of 1) the fragmented system of publicly-funded healthcare, 2) public ambivalence about treating persons with opioid dependence, and 3) extremely restricted resources in the public outpatient treatment area, many programs have great difficulty or even find it impossible to establish liaisons with other agencies to provide needed services.

Although most patients' needs were in more than one of these areas, only 25 percent reported receiving any medical, psychiatric, or social services during the critical first month of treatment (Condelli, 1993).The role of ancillary services in improving treatment outcome is illustrated in studies such as that of McLellan et al. (1993), who documented an improvement in AOD treatment outcomes associated with provision of appropriate psychosocial services to methadone patients. As discussed in later chapters of this TIP, some patients require assistance in gaining access to and utilizing needed services. An addictions counselor or case manager often performs this function.

Challenge 3: Engaging and Retaining the Patient in Treatment

Length of time in treatment is one of the most consistent indicators of positive treatment outcomes. It has repeatedly been shown to be associated with reduced use of opioids and other drugs, greater productivity, and reduced criminal activity (Ball and Ross, 1991; D'Aunno and Vaughn, 1992; General Accounting Office, 1990; Simpson and Sells, 1982). A minimum of 3 months in treatment is usually necessary before progress toward recovery begins (Simpson and Sells, 1982).

Retention is thus a primary objective of treatment, and the challenge to the clinical team is to take every reasonable action to keep the patient actively engaged. Several investigators have sought to determine the factors most likely to be associated with retention. Among these are comprehensive and individualized services, caring staff, "user friendly" program protocols, and an adequate methadone dosage (Condelli, 1993; Joe et al., 1991).

To promote retention, patients should be engaged in treatment and participate actively in the therapeutic process. More frequent attendance, compliance with psychiatric services, and use of other ancillary services are associated with improved treatment outcomes (McLellan et al., 1993; Simpson et al., 1995). Thus, augmenting program resources and encouraging their use should be prime concerns of program staff. One recent study found that elimination of treatment fees increased retention during the first year of treatment (Maddux et al., 1994). Consideration also should be given to developing techniques for monitoring service delivery and levels of patient engagement over time (see Chapter 5 on program evaluation). As is discussed later in this TIP, case managers can play an important role in retaining patients in treatment by ensuring that they gain access to and use needed services.

> Factors most likely to be associated with retention in treatment are comprehensive and individualized services, caring staff, "user friendly" program protocols, and an adequate methadone dosage.

Challenge 4: Managing Patient Noncompliance in a Positive Manner

Recent research has deepened understanding of the contribution of patient motivation and readiness for change to positive outcome in persons with AOD disorders (Miller and Rollnick, 1991; Prochaska and DiClemente, 1986). For this reason, it is important to explore patient motivation at the time of assessment and throughout treatment. Most patients are initially ambivalent about treatment, and clinicians must help them resolve this ambivalence. Many patients may have attitudes or experiences that create obstacles to engaging in treatment. For example, some patients have the fixed notion that only methadone will work for them and that methadone is all they need. Others may not want to participate in 12-step programs because of negative past experiences with persons in those programs who rejected opioid substitution therapy. Some patients may resist medical care because healthcare providers in the past have reacted negatively to their addiction and its associated behavior.

Clinicians must be prepared to identify and overcome these obstacles. They also must be prepared to clarify and negotiate mutually acceptable treatment goals. The more committed patients are to their treatment goals, the more likely they are to remain in the program and have a positive outcome (Simpson and Joe, 1993).

Patient noncompliance—whether it manifests as a deviation from an individual treatment plan or as a violation of program rules—should be seen not only as a sign of potentially poor outcome, but also as an indication of possible problems in the treatment plan. Providers should continually review and examine their delivery of services before "blaming" the patient for not complying with treatment. Program staff must be alert to subtle attitudinal changes of patients and be prepared to address those attitudes even before problems stemming from noncompliance arise and interfere with treatment. The reasons underlying a loss of motivation or ambivalence about treatment goals should be promptly explored and resolved, if possible, with the objective of making the treatment plan more realistic. For example, a patient's response

to a brief relapse to opioid use could lead to discouragement and premature termination if the staff did not encourage and educate the patient about the realistic course of addiction treatment.

Challenge 5: Expanding Community Awareness of the Purpose and Outcome of Opioid Substitution Therapy

Clinicians who provide opioid substitution therapy must create opportunities to educate the community, including the public, legislators, and third-party payers, about the nature of opiate addiction, its anticipated outcomes, and the benefits of treatment. Methadone is commonly seen as a "chemical crutch," and opioid substitution therapy is viewed as replacing one drug with another. Added to such philosophical and ideological reservations may be fears of public and personal safety stemming from drug sales or clients' loitering in neighborhoods where opioid substitution therapy programs are located.

Treatment program staff must make efforts to overcome misconceptions concerning opioid addiction and inform the public about the entire range of treatment options and the overall positive benefits of opioid substitution therapy. They can do this through networking, public education (giving examples of patients who were helped by substitution therapy), and outreach.

Treatment program staff must make efforts to overcome misconceptions concerning opioid addiction and inform the public about the entire range of treatment options and the overall positive benefits of opioid substitution therapy.

Organization of This TIP

This TIP provides guidelines for meeting patient needs in opioid substitution therapy. It takes into consideration the needs of patients, limited resources, the current knowledge base, and outcome evaluation.

Chapter 2 *Assessing Patient Needs* provides a brief overview of opioid substitution therapy and definitions of terms used in the TIP. Guidelines are offered for conducting both a preliminary assessment to determine a person's appropriateness for substitution therapy and a comprehensive biopsychosocial assessment upon entry into the program. Areas to assess are recommended, including the patient's expectations and motivation. Effective matching depends on careful ongoing assessment, which is also discussed.

Chapter 3 *Phases of Treatment* proposes a six-phase model of opioid substitution therapy that includes the acute and rehabilitation phases, the supportive care phase, medical maintenance, tapering and readjustment, and aftercare. Patient needs characteristic of each phase are described, and strategies for meeting these needs are outlined. Clinical indicators for transition into other treatment phases are described.

Chapter 4 *Treatment Elements* looks at core services essential for opioid substitution therapy programs and the responsibilities of staff from various disciplines who facilitate the use of treatment matching strategies in these programs. Common comorbid medical and psychiatric disorders are discussed and the roles of counseling and psychotherapy are summarized. Special considerations, such as childcare and access for disabled persons, are addressed.

Chapter 5 *Self-Monitoring and Evaluation* addresses the importance of program self-monitoring and evaluation of treatment outcomes. Goals of these processes are outlined, and a step-by-step guide for conducting self-monitoring and evaluation is presented. A detailed hypothetical example is included in an easy-to-follow chart format that lays out the evaluation steps described in the text.

Chapter 6 *Cost-Effectiveness of Opioid Substitution Therapy* addresses the costs of opioid substitution therapy services and describes approaches to calculating treatment costs.

Appendix A lists references cited in the text, as well as other useful articles. Appendix B contains the Massachusetts Methadone Treatment Criteria, which were modeled on the American Society of Addiction Medicine patient placement criteria (American Society of Addiction Medicine, 1991). They provide admission, continuing care, and discharge criteria for AOD abuse treatment including methadone substitution therapy. For readers who are interested in designing and conducting research on the costs of AOD treatment, Appendix C presents several methodological approaches to consider. Appendix D is a list of the Federal resource panel members who contributed suggestions during the initial phases of the development of this TIP. Appendix E is a list of experts who participated in the field review of the TIP.

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April 5, 2000

Representative David A. Welch
Chairman
Criminal Justice and Public Safety Committee
State of New Hampshire
House of Representatives
33 North State Street
Concord, NH 03301

Dear Representative Welch:

I am writing in support of legislation that will enable methadone treatment programs to open within the state of New Hampshire. I understand that a hearing date has been set for April 11, 2000 to consider this matter.

I am aware of the legislation, which passed in New Hampshire during 1994, precluding the development or operation of any methadone maintenance program throughout the state.

I am also aware of the amendment, which was passed during the 1996 session allowing pregnant and post partum heroin users to be able to access methadone through an extended detoxification. Our Association viewed the amended legislation as the necessary evolution to the legislation that is under present consideration.

Our Association was founded in 1984 and represents methadone treatment providers throughout the United States. Our Association was involved in developing the State Methadone Treatment Guidelines in the conjunction with the American Society of Addiction Medicine during 1993 for the Center for Substance Abuse Treatment. These guidelines establish recommended standards of medical practice for opiate dependence in methadone treatment settings.

I am enclosing a copy of the methadone fact sheet with graphic illustrations, representing the long standing efficacy of methadone maintenance treatment. It is safe to conclude that methadone maintenance treatment is the most thoroughly researched medication for any disease in the world.

The National Institutes of Health in cooperation with the National Institute on Drug Abuse developed a Consensus Conference on Effective Medical Treatment of Opiate Addiction in November 17-19, 1997 and concluded that methadone maintenance treatment is clearly the most effective pharmacotherapy available in treating chronic opiate dependence in the United States. The accompanying fact sheets with graphs underscore these facts.

It is our collective hope that the New Hampshire Legislature will enact legislation to allow methadone treatment programs to operate in your state so that opiate dependant individuals will receive access to critically needed medical and counseling care. The presence of methadone treatment programs does not increase crime in communities, it reduces crime, as evidenced through the attached findings. The cost savings to society is enormous as patients enter and remain in treatment as evidenced by the research.

Please let me know if our organization can provide any additional information to you during these critical deliberations. Ultimately, lives are at stake. At present, New Hampshire residents must travel long distances into neighboring states to access methadone treatment services in order to avoid relapsing to heroin use and being vulnerable to life threatening infections, such as HIV and Hepatitis C.

We applaud your initiative in this regard and will do all that we can to assist you in reversing the previous prohibitive legislation.

Sincerely yours,

Mark W. Parrino, MPA
President

MWP/sq
040500b

WHY METHADONE TREATMENT WORKS

- The National Institutes of Health Consensus Development Conference on "Effective Medical Treatment of Heroin Addiction" (November, 1997) concluded that it is necessary to increase access to methadone treatment services throughout the United States and to increase funding for methadone treatment, including providing benefits for methadone treatment as part of public and private health insurance programs.

- General Barry McCaffrey, Director of the United States Office of National Drug Control Policy, has called for an increase in the availability of methadone treatment services. "Clearly many more persons could be freed from the slavery of heroin addiction only if this proven effective therapy were more widely available . . . Methadone therapy is one of the longest established, most thoroughly evaluated forms of drug treatment. The science is overwhelming in its findings about methadone treatment's effectiveness."

- The General Accounting Office reports that "The National Institute on Drug Abuse and the National Institute on Alcohol Abuse and Alcoholism, the federal government's two primary agencies for researching drug and alcohol abuse issues, respectively, have concluded that methadone is the most effective method available for treating heroin addiction." [Source: General Accounting Office, Report to the Chairman, Select Committee on Narcotics Abuse and Control, House of Representatives – Methadone Maintenance, March, 1990]

- According to the Office of National Drug Control Policy, there are over 800,000 untreated heroin dependent individuals in the United States. Drug Enforcement Administration data indicate that heroin is increasingly available at purer levels throughout the nation and the National Institute on Drug Abuse has cited an alarming increase in the number of young people using heroin in suburban and urban areas.

- Approximately 179,000 patients in this country are treated with methadone on any given day. [Source: American Methadone Treatment Association, Methadone Maintenance Provider Survey, 1998]

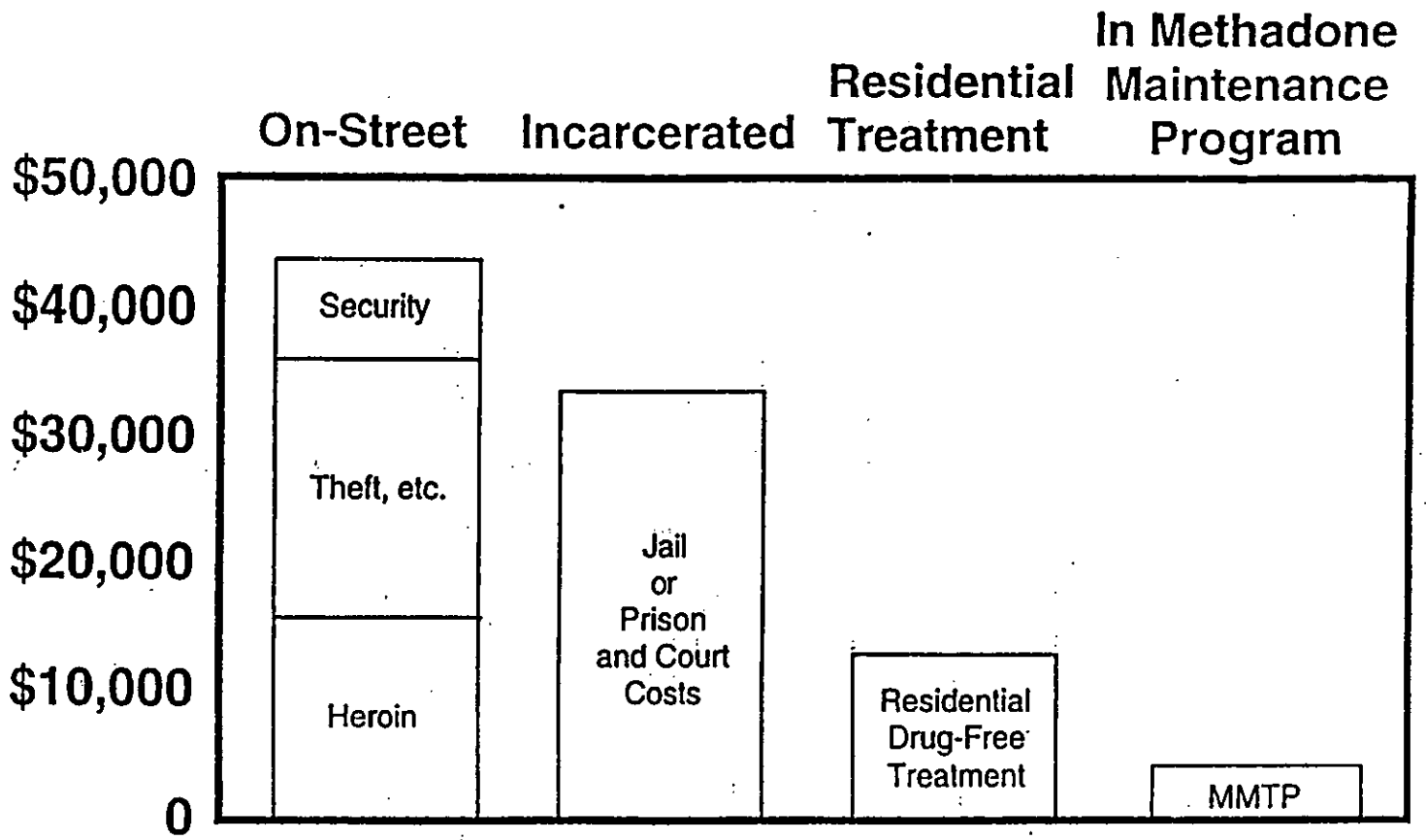
- A comprehensive examination of the economic benefits and cost of methadone treatment reveals the benefits to cost ratio of 4:1; $4.00 in economic benefits accrue for every $1.00 spent on methadone treatment. [Source: Harwood, et. al., *The Costs of Crime and the Benefits of Drug Abuse Treatment*. NIDA Monograph Series 86, DHHS, 1988]

- Research indicates that methadone treatment has significantly decreased the rate of HIV infection for patients in continuous methadone treatment. [Source: Ball, John. *The Effectiveness of Methadone Maintenance Treatment*, Springer-Verlag, 1991]

- Studies have continually demonstrated that more than 70% of the people enrolled in methadone maintenance reduce or eliminate criminal activity during their first year in treatment.

AVERAGE COSTS PER YEAR FOR ONE HEROIN ADDICT

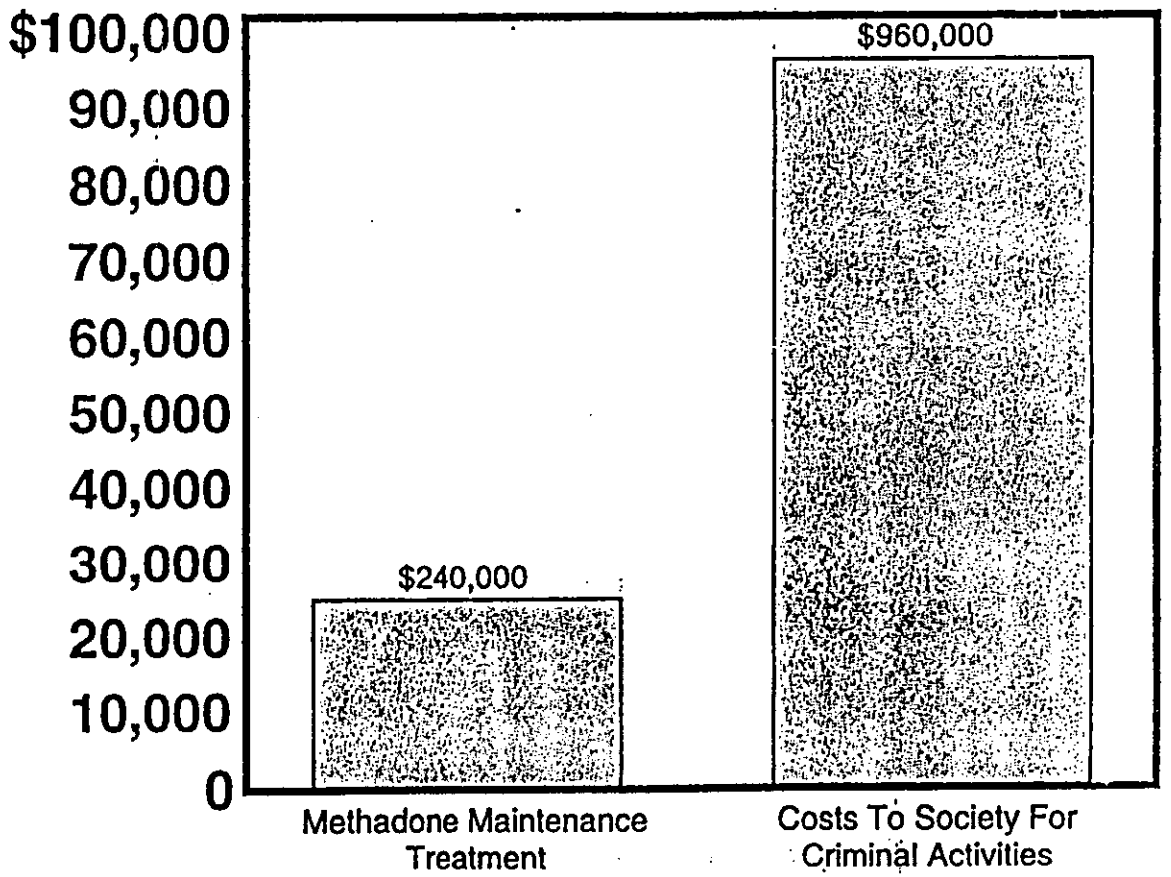
(Adapted from New York State Division of Substance Abuse Services, 1991 by Dole and DesJarlais)



V10-A

APPROXIMATE U.S. ANNUAL COSTS FOR 100 MM TX PATIENTS AND APPROXIMATE U.S. COSTS TO SOCIETY FOR CRIMINAL ACTIVITIES OF 100 ACTIVE HEROIN ADDICTS

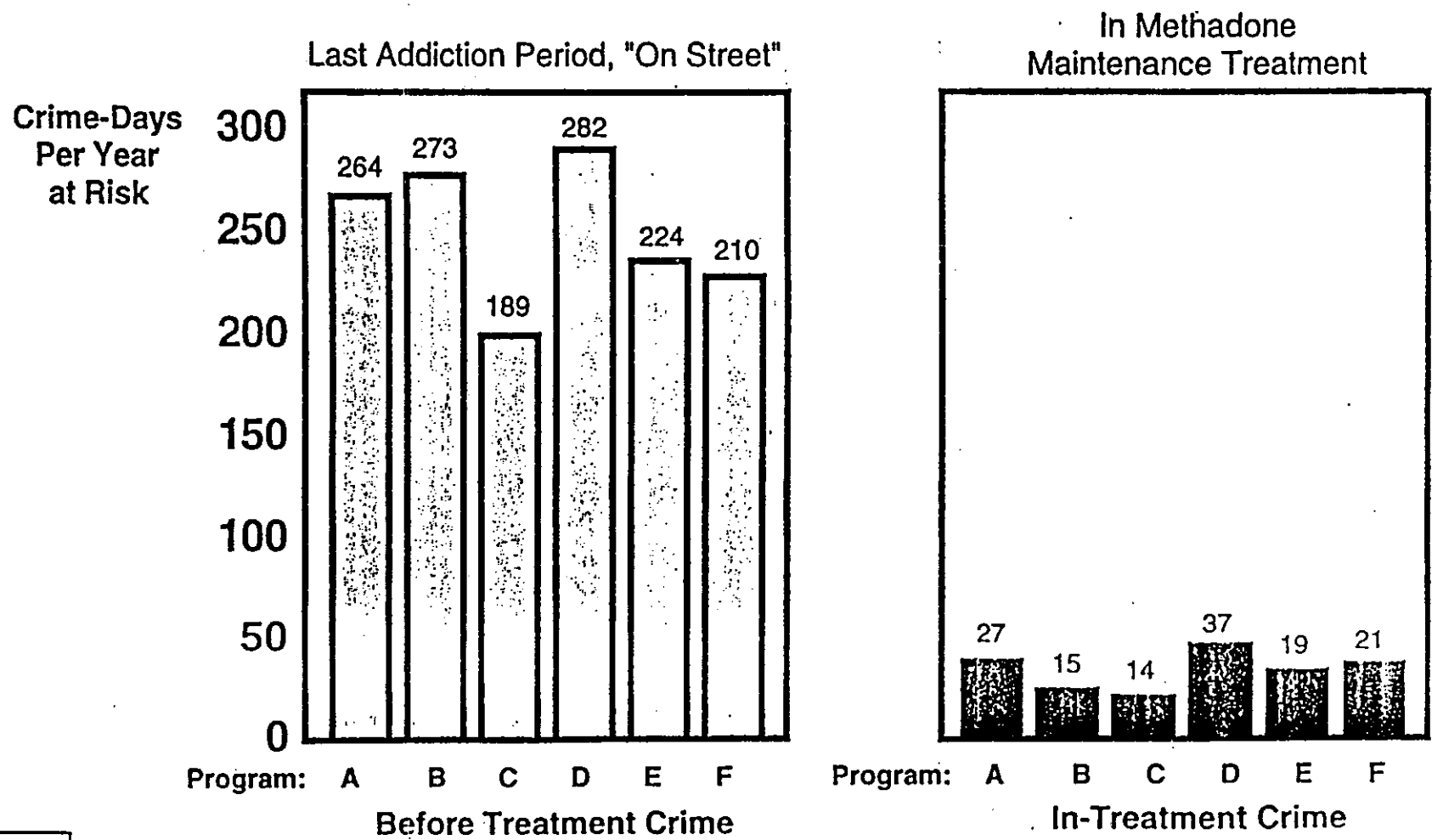
(Created from Harwood, et al., data, 1988)



V10

CRIME BEFORE AND DURING MM TREATMENT AT 6 PROGRAMS

(Ball and Ross, 1991)

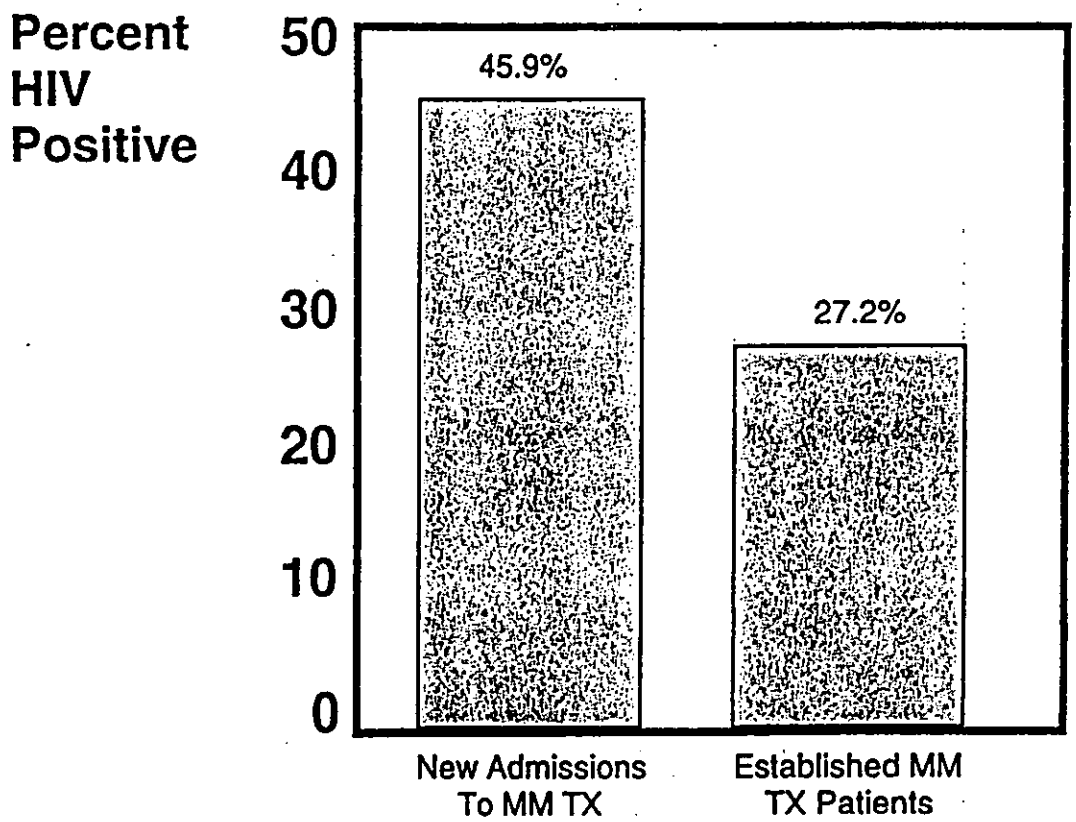


V4-A

Grey bars = crime-days per year when addicted. Solid bars = crime-days per year after 6 months or more in treatment. (N = 491)

HIV SEROPOSITIVITY AMONG NEW AND ESTABLISHED MM TX PATIENTS

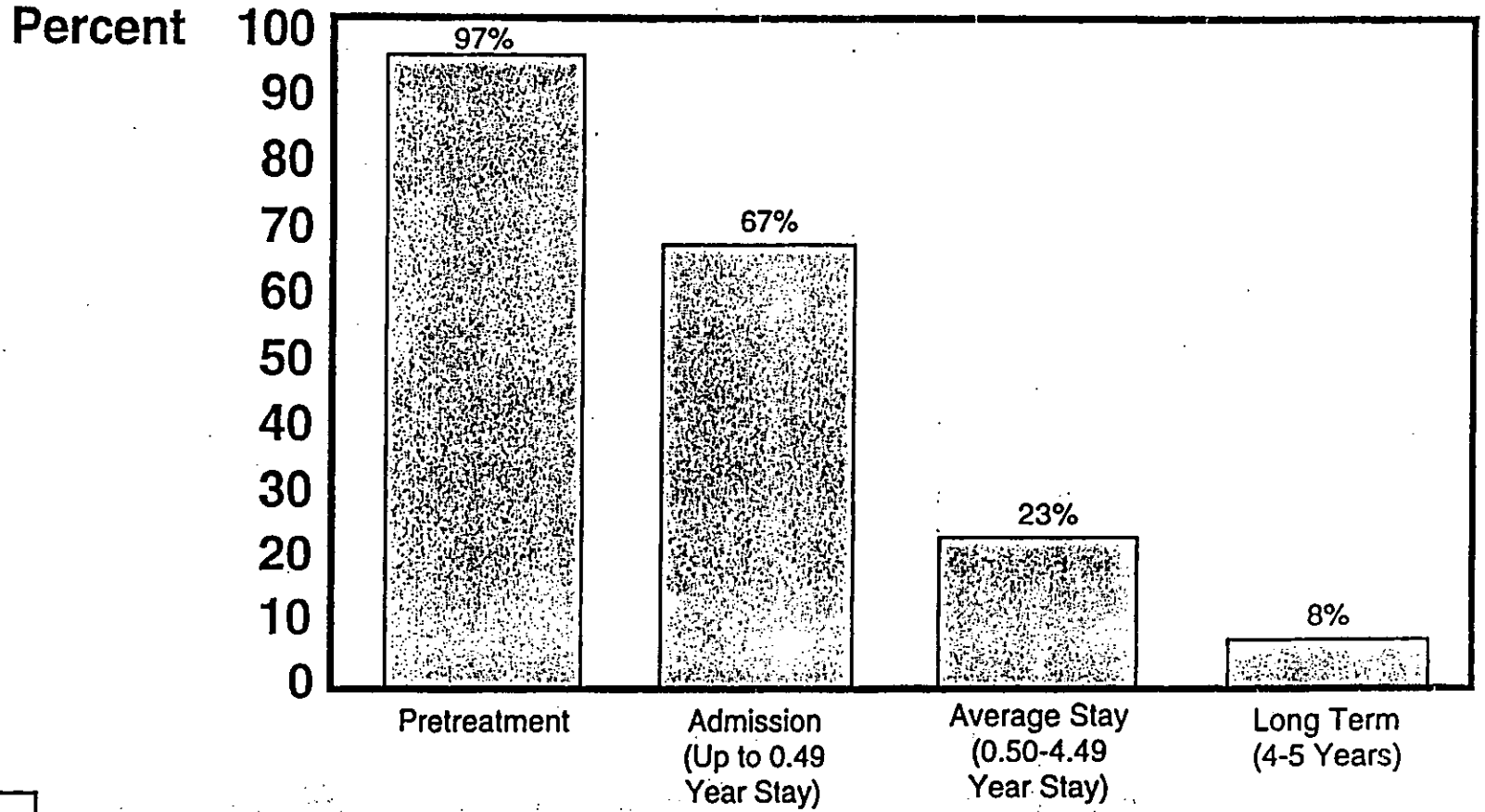
(Truman and Brown, 1989)



V6

REDUCTION OF HEROIN USE BY LENGTH OF STAY IN MM TX

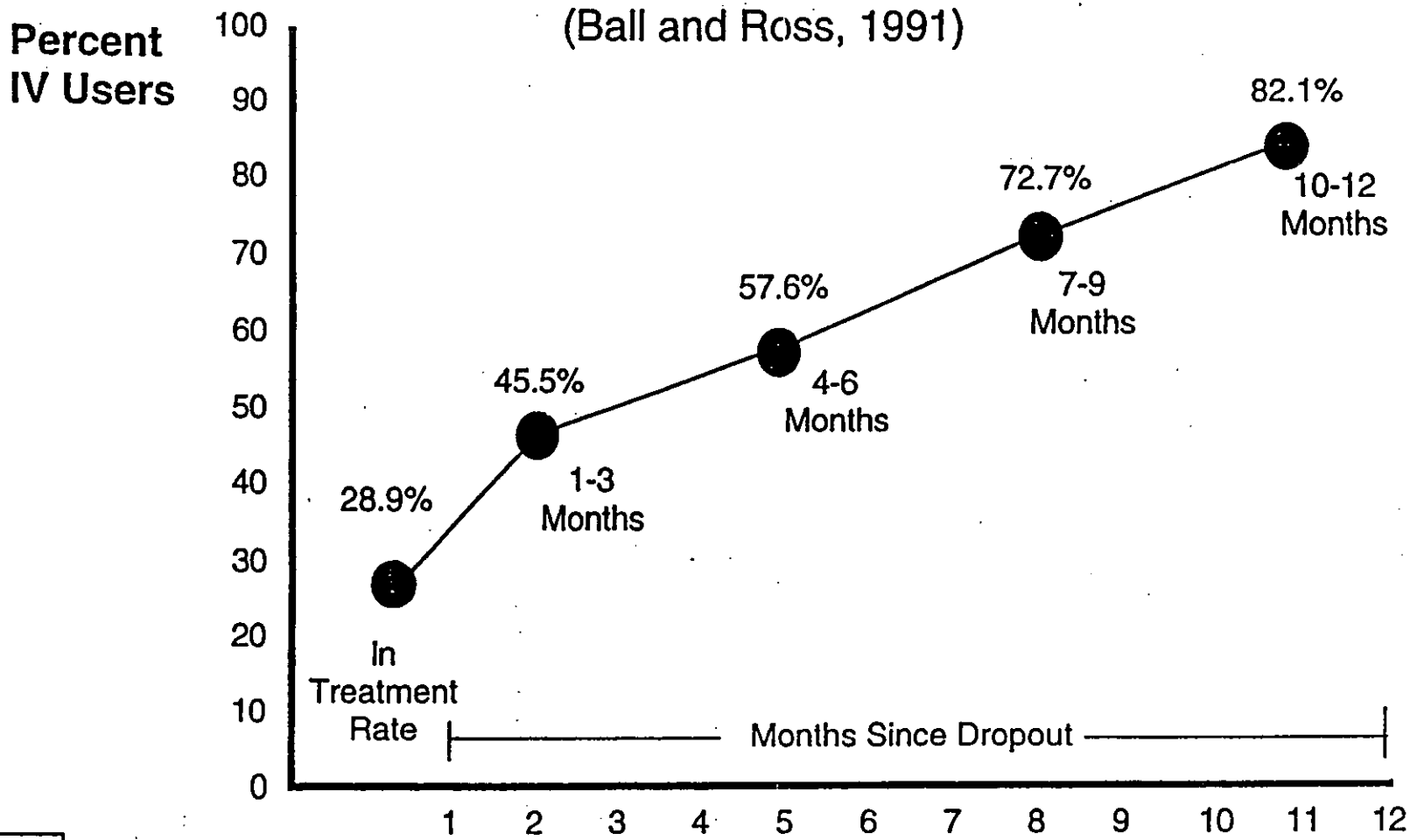
(Ball and Ross, 1991)



V2-B

RAPID RETURN TO INJECTION DRUG USE FOLLOWING PREMATURE TERMINATION OF MM TX

(Ball and Ross, 1991)



V6-A

(N = 105 male patients)

Comparison Chart of Illicit Heroin Addiction and Stabilized Methadone Maintenance

Topic	Illicit Heroin Addiction	Stabilized Methadone Maintenance
Onset of action	Immediate	Thirty minutes
Duration of action	Four to 6 hours	Twenty-four to 36 hours or half life
Route of administration	Injection, snorting, smoking, several times a day	Orally administered once per day
Effective dose	Not applicable	For many patients 60 mg/day is lowest effective dose; doses between 80 and 120 mgs/day are most effective for preventing HIV transmission, retention in treatment, reducing the use of other drugs and increasing social productivity
Overall safety	Potentially lethal	Medically safe, no toxic effects found in patients maintained on methadone for up to 18 years
Overdose	Can die from overdose of narcotics; potentially lethal, even for tolerant individuals death can occur quite fast without proper medical treatment with narcan	A degree of protection from death by overdose is achieved when receiving 100 mg/day or more; methadone is potentially lethal for non tolerant individuals, death can occur but more slowly than heroin overdose however, overdose reaction can be reversed and person's life saved if narcotic antagonist such as narcan is prescribed for 24-36 hours
Narcotic effects of other opiates (if tried)	Feels narcotic effects of opiates	At 80 mgs/day or more narcotic effects of opiates are blocked
Withdrawal syndrome	Can be severe, but can be controlled with methadone	Less severe than heroin but more extended, can be controlled by slow reduction in methadone dose
Mood alteration	Constant swings	None, if patient is not emotionally disturbed or using other drugs
Euphoric effects	Approximately 2 hours duration after administration	None after administration
Tolerance level	Increasing dosage needed	Stable level at same dose
Narcotic craving	Recurring	Relieved and blocked
HIV transmission	Effective transmission	Transmission of HIV by injection reduced or eliminated for patients who remain in treatment
Immune and endocrine functioning in HIV- persons	Impaired	Normalizes during treatment
Immune system in HIV+ persons	Rapid progression to AIDS	Preliminary studies indicate that progression to AIDS is slower
Hypothalamus Pituitary Adrenal Axis	Suppressed	Normalizes during treatment

Methadone clinics backed in Bay State, illegal in Vt. and NH

By DAVID GRAM
The Associated Press

GREENFIELD, Mass. — The 77 people who make regular — often daily — trips to the Community Substance Abuse Centers clinic on the west end of town are using methadone to try to kick a heroin habit.

Instead of getting heroin's quick high and then crashing and craving more as little as four hours later, an addict on methadone gets no high but a 24-to-36-hour absence of what clinic director Vincent Tobin calls "the sick."

"When it starts to wear off you get the sick," Tobin says of heroin. "You start to feel a little edgy, nervous. You get leg aches, cramps. You might get nausea. You get sweaty. You're sick. You have to cop (acquire heroin). You have to get something to take away the sick."

A typical course of methadone treatment takes up to two years, though some patients remain on methadone indefinitely.

Typically, a patient will start with a small daily dose, build it to a maintenance level and then taper off, with the aim of being drug-free at the end of treatment, Tobin said.

There's an initial medical screening, the daily methadone doses — often involving a long, round-trip drive to the clinic, and frequent counseling sessions. "You have to completely change your lifestyle ... the criminal activity, the negative, self-defeating type thinking," Tobin said.

He acknowledged there's a high rate of addicts returning to heroin after treatment. Many people first tried heroin to kill some sort of emotional pain. "You have to face all kinds of challenges in your life that have to be met and overcome," he said.

The treatment costs $105 a week. Massachusetts Medicaid, for which most of the addicts are eligible, pays for it. But not all the addicts are from the Bay State. About 20 come from Vermont, one from New Hampshire. Vermont and New Hampshire are two of the eight states where methadone centers are illegal.

Long-term methadone treatment is not the only way heroin addiction gets addressed. Other synthetic opiates are being tried. Vermont Gov. Howard Dean has been talking up buprenorphine, which is undergoing clinical trial at the University of Vermont, as an alternative to methadone.

But buprenorphine has yet to win approval from the federal Food and Drug Administration.

And the nation's drug policy chief, Gen. Barry McCaffrey, said last week that "buprenorphine would not be a replacement for methadone ... but an auxiliary treatment option."

McCaffrey said that nationwide, 170,000 patients were in methadone treatment at the end of 1998. But he said 980,000 people were addicted to heroin, indicating a big need for expanded methadone treatment.

file

A BATTLE OVER BATTLING HEROIN

The Union Leader, Manchester, N.H.

Tuesday, April 18, 2000

In one town, methadone clinic doubts recede

GREENFIELD, Mass. (AP) — Tom Bridges gazed through the screen door of his small ranch house toward the cream-colored stucco house that stands at the end of his block.

"They're no problem with us," the Franklin Medical Center maintenance man said as he prepared to leave for a swing shift at the hospital one afternoon last week.

His mother, who occupies the other wing of the two-unit house "wasn't too happy when they were going in," Bridges recalled. "This is kind of a quiet street. There are kids on the street. But they haven't been any problem."

Bridges was speaking about the neighbor that set up shop 16 months ago in a mixed neighborhood abutting Interstate 91, one of houses, a restaurant, a car dealership, a discount store and other businesses.

The new neighbor is one of seven methadone clinics set up to treat heroin addicts in Massachusetts and Connecticut by Community Substance Abuse Centers Inc.

It's the sort of clinic that Gov. Howard Dean has said he doesn't want to see in Vermont — and he's threatened to veto legislation that would allow them.

Addicts congregate around clinics, Dean said recently. "I don't want to besmirch a whole class of people, but addicts tend to have a higher rate of committing crimes. They're not people that you'd like to have in your neighborhood."

The little house where the Greenfield clinic is situated right next to an embankment leading up to the interstate, which effectively separates it from the main part of town.

The clinic serves 77 people from around northwestern Massachusetts and beyond. Most come to the Greenfield clinic each morning, enter through a front door bearing no sign and line up at a small window where registered nurse Mary Ann Gendreau dispenses little tablets that the patients dissolve in water and then drink.

One Vermonter, a self-employed carpenter from Colchester, told a legislative committee recently that he had been making a 374-mile round trip to Greenfield each day to get methadone — until the clinic decided he was trustworthy enough to be given a week's supply at a time.

Many local residents were skeptical about the idea of having a methadone clinic in Greenfield at all. Among them was David McCarthy, police chief since 1982.

Meetings with clinic staff got his own comfort level up, the chief said. "As a result of the information I got, it kind of opened up my mind."

Since it opened, the clinic hasn't added a bit to the burdens of the police department, McCarthy said. Until recent inquiries about the clinic from Vermont, "I had forgotten they were in town."

— *David Gram*

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New Hampshire House of Representatives
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Concord, New Hampshire 03301
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603-271-3600

TO: Representative Merton S Dyer
Executive Departments and Administration

FROM: Marie-Hélène Bailinson, Committee Researcher MHB
House Committee Research Office

DATE: April 20, 2000

RE: Methadone

Pursuant to your request, attached please find the federal rules and regulations relating to methadone treatment.

Also, you asked a few specific questions regarding whether methadone is appropriate for detoxification and maintenance of drugs other than heroin. I spoke to Rosemary Shannon, Department of Health and Human Services, who stated that methadone is appropriate for detoxification and maintenance when other prescribed drugs have been misused. For example drugs such as opiate derivatives, percocet, darvocet, morphine.

Cocaine is a stimulant and methadone is not an appropriate treatment for cocaine addiction.

Methadone Detoxification is also an appropriate treatment for the addiction to Tylenol with codeine.

I hope this proves helpful. Please do not hesitate to contact me if you have questions or comments.

COMMENTS FOR SUB-COMMITTEE CST 12 PART II

MUST HAVE APPROVAL OF STATE HEALTH OFFICER HAS HEALTH OFFICER APPEARED BEFORE COMMITTEE PG16

LIMITATIONS OF DOSAGE SHOULD BE IN RULES PG 19

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patients may also become more sensitive to pain after the opiate has worn off. Allergic reactions to opiates, as itching (urticaria) and other skin rashes, may occur. Patients with low amounts of blood are more likely to have their blood pressure lowered because of morphine and other drugs like it. Opiates should be used very carefully in overweight patients and in those with head injuries, or any problems linked to breathing. In patients with a large prostate, morphine may cause a serious buildup of urine, making it necessary to use a tube in the urinary tract (catheter). Also called **opioid.**

opisthorchiasis /ō'pisthôrkī'əsis/, infection with a kind of *Opisthorchis* liver worms commonly found in Asia, the Pacific Islands, and parts of Europe. Cancer of the bile ducts may be a late result. The disease is best prevented by avoiding eating raw fish or freshwater fish that have not been cooked long enough.

opisthotonos /ō'pisthot'ənəs/, a continuous severe spasm of the muscles causing the back to arch back, the head to bend back on the neck, the heels to bend back on the legs, and the arms and hands to flex rigidly at the joints.

opium, a dried or partly dried milky sap from the unripe capsules of the opium poppy (*Papaver somniferum* and *Papaver album*) producing nearly 10% or more of morphine. It is a narcotic painkiller, a drug that brings on sleep or hypnosis, and a drug that reduces the flow of body liquids (astringent). Opium contains several alkaloids, including codeine, morphine, and papaverine. See also **codeine, morphine sulfate, opium tincture, papaverine hydrochloride, paregoric.**

opium alkaloid, any of several substances taken from the unripe seed pods of the opium poppy (*Papaver somniferum*), a kind of plant that grows only in the Near East. Three of the alkaloids, codeine, papaverine, and morphine, are used in medicine for pain relief, but their use risks physical or psychologic addiction. Morphine is the basic, most common drug of its kind against which the painkiller effect of newer drugs for pain relief are tested. The opium alkaloids and the semiartificial drugs that are made from them, including heroin, act on the central nervous system, causing loss of pain, a change in mood, drowsiness, and mental slowness. The effects in a patient who has pain are usually pleasant; a higher sense of well-being and pain-free sleep are common, but nausea and vomiting sometimes occur. In usual doses, the relief from pain is achieved without loss of consciousness. Morphine and other opiates cause the level of actual pain to go down, and what is left is less uncomfortable to the patient. The opium alkaloids have several other effects on the different systems of the body: Coughing is halted; the brain waves look like those of sleep; the pupils get smaller; breathing is slowed down; the workings of the stomach and intestines are slowed down: and biliary and pancreatic fluids are reduced. Morphine was used to treat diarrhea for hundreds of years before it was used as a painkiller. It is still the best constipating drug available.

opium tincture, a painkiller and antidiarrheal drug given to treat too much intestinal activity, cramping, and diarrhea.
★CAUTION: Drug addiction, the presence of poison in the bowel, or known allergy to this drug prohibits its use.
★ADVERSE EFFECTS: Among the more serious side effects are drug addiction, an enlarged colon, and central nervous system effects.

Oppenheim reflex /op'ənhīm/, a different type of Babinski's reflex. It is caused by firmly stroking downward on the front and inner surfaces of the lower leg, causing the great toe to straighten out and causing the fanning of other toes. It is a sign of central nervous system disease. Compare **Chaddock reflex, Gordon reflex.** See also **Babinski's reflex.**

Oppenheim's disease, an inborn disorder of infants, marked by flabby muscles, especially in the legs, and the lack of or very slow deep muscle reflexes. The infant seems unable to move during its first few months of life and almost a third of the patients do not survive for 1 year. Also called **amyotonia congenita.** See also **myotonia congenita.**

opportunistic infection, an infection caused by a virus or by germs that are usually not harmful to normal persons. The patient becomes infected because his or her ability to fight off diseases has been reduced by diseases, as diabetes mellitus or cancer; by surgery, as a cerebrospinal fluid shunt; or a tube in the heart or urinary tract. The result is an unusual infection with a common germ or virus.

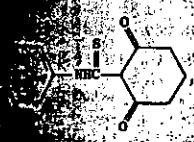
opsonin /op'sənin/, a substance that clings to foreign material, a germ or virus, or other germ or virus fighter (antigen). It speeds the destruction of that material faster by white blood cells (leukocytes) and other cells able to digest germs and viruses. —**opsonize,** *v.*

optic, referring to the eyes or to sight. Also **optical.**

optic atrophy, wasting away of the optic disc in the innermost part of the eye (retina), caused by a breakdown of optic nerve fibers. In primary optic atrophy the disc is white with sharp outer edges and the central depression is large. In secondary atrophy the disc is gray, its outer edges are blurred, and the depression is filled in. Optic atrophy may be caused by a birth defect, swelling blockage of the central retinal artery or internal carotid artery, or by alcohol, arsenic, lead, nicotine, or other poisons. Breakdown of the disc may be seen with

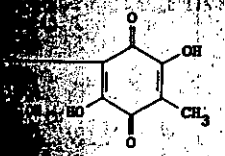
propyl bisulfide, *S*-(1-propenyl)cys-propenylsulfenic acid which is thought ...nions: Virtanen, Sprare, *Suom.* ...(1962); *Chem. Ztg.* 86, 816 (1962). ...ng odor of onions. d_4^{25} 0.9289. Solid ... $[\alpha]_D^{20}$ −1.5°. Sol in ether, chloro-

...(*o*-Chlorophenyl)-2,6-dioxocyclohex-...chloro-2,6-dioxothiocyclohexanecar-... $C_{13}H_{12}ClNO_2S$; mol wt 281.76; C 55.42%, H ... O 11.36%, S 11.38%. Prepn: H. ... 2,039,466 corresp to U.S. pat. ... (Hoechst); of sodium, potassium, ... pat. 2,317,579 (1974 to Hoechst).



...1-115°C. LD_{50} in rats (mg/kg): ...chig *et al.*, U.S. pat. 3,746,765. ...$ClKNO_2S$. *Terondit.*

...3,3'-Tetrahydroxy-4,4'-dimethyl-...3,3',6,6'-tetrone; 3,3',6,6'-tet-...2,2'-bi-*p*-benzoquinone; chaeto-... $H_{18}O_8$; mol wt 306.22; C 54.91%, ... pigment isolated from *Oospora* ... van Wessem, *Rec. Trav. Chim.* ...*aureum* Chivers and identity ... *al.*, *J. Chem. Soc.* 1955, 2163; ...Divekar *et al.*, *Can. J. Chem.* 37, ...*bassiana* (Bals.) Vuill., Vining ... 231 (1962). Identity with iso-... *Tetrahedron* 10, 148, (1960). ... *Helv. Chim. Acta* 57, 2368 ...ner *et al.*, *ibid.* 2377.



...ethanol, mp 290-295°. uv max ... (log ε 3.51, 4.67).

...yellow needles from methanol, ... 262 nm (log ε 4.41).

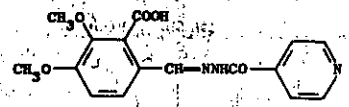
$C_{18}H_{18}O_8$; orange needles from aq ... max (ethanol): 285.5, 394 nm (log ε ...

...6-Formyl-2,3-dimethoxybenzoic ...aldehydic acid.* $C_{10}H_{10}O_5$; mol wt ... O 38.06%. Obtained (together ...arcotine with dil HNO_3. Prepn: ...16, 792 (1951); Blair, *J. Chem.* ...dies; Buu-Hoi *et al.*, *Bull. Soc.*



...50°. Sol in 400 parts cold, 60 ...alcohol, ether. uv max: 215, 284 ...

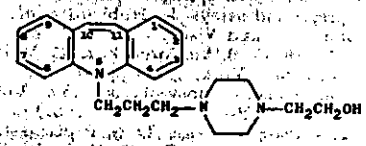
...ridinecarboxylic acid [(2-carb-oxy-3,4-dimethoxyphenyl)methylene]hydrazide; 5,6-dimethoxyphthalaldehydic acid isonicotinoylhydrazone;* 1-(2-carboxy-3,4-dimethoxybenzylidene)-2-isonicotinoylhydrazine; 2-carboxy-3,4-dimethoxybenzal isonicotinylhydrazone; saluside; saluzide; saliuzid; saluzid. $C_{16}H_{15}N_3O_6$; mol wt 329.32. C 58.36%, H 4.59%, N 12.76%, O 24.29%. Description: G. N. Pershin, S.A. Vichkanova, *C.A.* 51, 10747e (1957); *C.A.* 52, 1485-1486 (1958); V. A. Buskina, *C.A.* 54, 744f (1960). Bioavailability: A. F. Zacko, V. G. Perkova, *Farmatsiya (Moscow)* 28, 28 (1979), *C.A.* 92, 185805g (1980).



LD_{50} i.v. in guinea pigs: 1.634 g/kg, R. A. Akhundov, *C.A.* 86, 50678y (1977).

THERAP CAT: Antibacterial (tuberculostatic).

6808. Opipramol. *4-[3-(5H-Dibenz[b,f]azepin-5-yl)propyl]-1-piperazineethanol;* 5-[γ-[4-(β-hydroxyethyl)piperazino]propyl]dibenzo[*b,f*]azepine; *N*-[3-[4-(2-hydroxyethyl)-piperazino]propyl]iminostilbene; 4'-[3-(5*H*-dibenzo[*b,f*]azepin-5-yl)propyl]-1-(2-hydroxyethyl)piperazine. $C_{23}H_{29}N_3O$; mol wt 363.49. C 75.99%, H 8.04%, N 11.56%, O 4.40%. Prepn: Fr. pat. M209 (1961 to Rhône-Poulenc), *C.A.* 58, 3442f (1963), Schindler, Ger. pat. 1,133,729 and Swiss pats. 359,143 and 360,061 (all 1962 to Geigy), *C.A.* 58, 10219a, 10218f, 10218h (1963).



Crystals, mp 100-101°.

Dihydrochloride, $C_{23}H_{31}Cl_2N_3O$; *Dinsidon, Ensidon, Insidon, Nisidana.* Crystals from ethanol, mp 210° (Fr. pat., *loc. cit.*), mp 228-230° (Schindler, *loc. cit.*). Sol in water, alcohol; sparingly sol in acetone.

THERAP CAT: Antidepressant; antipsychotic.

6809. Opium. Gum opium; crude opium. Air-dried, milky exudation from incised, unripe capsules of *Papaver somniferum* L., or *P. album* Mill., *Papaveraceae. Habit.* of the plant: Asia Minor, Persia, China, Africa, India; cultivated in the Balkan States, Hungary, Southern Russia. In Japan the strain cultivated from the production of opium is called "Ikkanshu." Appearance and sources: *Chem. & Eng. News* 32, 2701 (1954). *Constit.* About 20 alkaloids, constituting about 25% of the opium; meconic acid, some lactic and sulfuric acids, sugar, resinous and waxy-like substances; 12-25% water. Morphine is the most important alkaloid and occurs to the extent of 10-16%, noscapine 4-8%, codeine 0.8-2.5%, papaverine 0.5-2.5%, thebaine 0.5-2%.

Deodorized opium, *"denarcotized" opium,* powdered opium freed from its odor and nauseating substances by treatment with petr ether. Contains 10-10.5% anhydr morphine.

Granulated opium, opium dried at not above 70°, reduced to a 16-50 mesh powder and adjusted with lactose or other inert diluent to contain 10-10.5% anhydr morphine.

Powdered opium, opium dried at a temp not above 70°, finely powdered amd adjusted with lactose or other inert diluent to contain 10-10.5% anhydr morphine.

Caution: May be habit forming. This is a controlled substance (opiate) listed in the U.S. Code of Federal Regulations, Title 21 Parts 329.1 and 1308.12 (1987).

USE: Largely for the manuf of morphine, codeine and other opium alkaloids.

THERAP CAT: Narcotic analgesic. Hypnotic.

THERAP CAT (VET): Narcotic analgesic; antidiarrheal; antitussive.

6810. Opromazine. *2-Chloro-N,N-dimethyl-10H-phenothiazine-10-propanamine 5-oxide; 2-chloro-10-[3-(di-*

Auxiliary labeling:
- May cause drowsiness.
- Avoid alcoholic beverages.
- May be habit-forming.

Note: Controlled substance in both the U.S. and Canada.

Parenteral Dosage Forms

MEPERIDINE HYDROCHLORIDE INJECTION USP

Usual adult dose:

Analgesic—

Intramuscular (preferred) or subcutaneous, 50 to 150 mg (usually 100 mg) every three to four hours as needed.

Intravenous infusion, 15 to 35 mg per hour as required, administered using an infusion pump.

Note: Dosage must be adjusted according to the severity of pain and patient response.

Obstetrical analgesia: Intramuscular (preferred) or subcutaneous, 50 to 100 mg administered when pains become regular. May be repeated at one- to three-hour intervals as needed.

Anesthesia adjunct—

Preoperative: Intramuscular (preferred) or subcutaneous, 50 to 100 mg thirty to ninety minutes prior to anesthesia.

Intravenous, by repeated slow injection of fractional doses of a solution diluted to 10 mg per mL.

Intravenous infusion, as a solution diluted to 1 mg per mL.

Note: Dosage must be titrated to the needs of the patient, depending on the premedication given, the type of anesthesia, and the nature and duration of the surgical procedure.

Usual pediatric dose:

Analgesic—Intramuscular (preferred) or subcutaneous, 1.1 to 1.76 mg per kg of body weight, not to exceed 100 mg, every three to four hours as needed.

Preoperative—Intramuscular (preferred) or subcutaneous, 1 to 2.2 mg per kg of body weight, not to exceed 100 mg, thirty to ninety minutes prior to anesthesia.

Strength(s) usually available:

U.S.—

With preservative:

25 mg per mL (Rx) [GENERIC].

50 mg per mL (Rx) [*Demerol* (metacresol); GENERIC].

75 mg per mL (Rx) [GENERIC].

100 mg per mL (Rx) [*Demerol* (metacresol); GENERIC].

Without preservative:

25 mg per mL (Rx) [*Demerol*].

50 mg per mL (Rx) [*Demerol*].

75 mg per mL (Rx) [*Demerol*].

100 mg per mL (Rx) [*Demerol*].

Canada—

With preservative:

100 mg per mL (Rx) [*Demerol* (metacresol)].

Without preservative:

10 mg per mL (Rx) [GENERIC].

25 mg per mL (Rx) [GENERIC].

50 mg per mL (Rx) [*Demerol;* GENERIC].

75 mg per mL (Rx) [*Demerol;* GENERIC].

100 mg per mL (Rx) [*Demerol;* GENERIC].

Packaging and storage: Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), unless otherwise specified by manufacturer. Protect from light. Protect from freezing.

Incompatibilities: Solutions of meperidine are chemically incompatible with aminophylline, barbiturates, heparin, iodides, methicillin, phenytoin, sodium bicarbonate, sulfadiazine, and sulfisoxazole.

Auxiliary labeling:
- May cause drowsiness.
- Avoid alcoholic beverages.
- May be habit-forming.

Note: Controlled substance in both the U.S. and Canada.

METHADONE

Note: In the U.S., hospital and community pharmacies must have approval from FDA and appropriate state authorities to engage in methadone detoxification or maintenance programs. Approved maintenance programs are authorized to dispense methadone in the oral form only and must comply with treatment requirements as set forth in the Federal Methadone Regulations. Consult the manufacturer's labeling for federal laws that apply when dispensing methadone as a narcotic abstinence syndrome suppressant.

In Canada, methadone is a controlled substance (Classification N). It is available only through physicians who have received special authorization to prescribe the medication.

Summary of Differences

Indications:

Also, indicated as narcotic abstinence syndrome suppressant.

Also, used as antitussive.

Not recommended for obstetrical analgesia.

Pharmacology:

Mechanism of action/effect—An opioid agonist analgesic; exerts agonist activity primarily at the mu receptor.

Equivalence—10 mg via intramuscular injection or 20 mg via oral administration therapeutically equivalent to 10 mg of intramuscular morphine.

Protein binding—High.

Half-life—15–25 hours; increases with repeated administration.

Onset of action—

Intramuscular: 10–20 minutes.

Oral: 30–60 minutes.

Time to peak effect—

Intramuscular: 1–2 hours.

Intravenous: 15–30 minutes.

Oral: 1.5–2 hours.

Duration of action (in nontolerant patients, may increase considerably with chronic use because of accumulation of methadone or active metabolites; may then decrease as tolerance develops during chronic therapy)—

Intramuscular: 4–5 hours.

Intravenous: 3–4 hours.

Oral: 4–6 hours.

Elimination—Primarily renal (rate increased in acidic urine); also some biliary elimination.

Drug interactions and/or related problems:

Urinary acidifiers may increase methadone elimination, thereby reducing the plasma concentration; withdrawal symptoms may occur in some physically dependent patients.

Phenytoin or rifampin may increase methadone metabolism and precipitate withdrawal symptoms in physically dependent patients.

Side/adverse effects: May be more likely than most other opioids to cause constipation.

Additional Dosing Information

See also *General Dosing Information.*

In the U.S., use of methadone in a detoxification regimen (to suppress withdrawal symptoms following discontinuation of an opioid drug in dependent patients) consists of administering gradually decreasing doses of methadone for up to 3 weeks. After 3 weeks, treatment is considered to be maintenance therapy (to discourage the patient from returning to illicit opioid drug use) and must be undertaken only in approved methadone maintenance programs. Dosage in maintenance programs may be gradually increased to meet the needs of the individual patient. Oral administration is preferred for detoxification and mandatory for maintenance.

For parenteral dosage forms only

Intramuscular administration is recommended when repeated doses are required. Repeated subcutaneous administration causes local tissue irritation and induration.

Oral Dosage Forms

METHADONE HYDROCHLORIDE ORAL CONCENTRATE USP

Usual adult dose:
Analgesic—Oral, 5 to 20 mg every four to eight hours. Dosage may be increased or the interval between doses decreased if pain is very severe or if the patient becomes tolerant to the medication.
Suppressant (narcotic abstinence syndrome)—
Detoxification: Oral, 15 to 40 mg once a day or as needed to control observed withdrawal symptoms; dosage to be reduced at one- or two-day intervals according to patient response.
Maintenance: Dosage must be individualized.

Usual adult prescribing limits: Up to 120 mg per day.

Usual pediatric dose: Analgesic—Dosage must be individualized by physician on the basis of patient's age and size. Use of a calibrated measure is recommended to prevent possible overdosage in children up to 6 years of age.

Strength(s) usually available:
U.S.—
10 mg per mL (Rx) [*Methadose;* GENERIC].

Packaging and storage: Store between 15 and 30 °C (59 and 86 °F). Store in a tight container. Protect from light. Protect from freezing.

Preparation of dosage form: Each dose must be diluted with water or another liquid before administration. For use in the treatment of chronic pain, each dose should be diluted to at least 30 mL. For use in methadone maintenance programs, it is recommended that the medication be diluted to a larger volume (90 mL or more), and that it be given to the patient only after dilution, as a deterrent to misuse by injection.

Auxiliary labeling:
- May cause drowsiness.
- Avoid alcoholic beverages.
- May be habit-forming.

Note:
Controlled substance in the U.S.
When preparing the label, indicate that the medication must be diluted with water or another liquid to 30 mL or more prior to administration.
If the concentrate is being taken home, make sure the patient understands the dilution requirements.

METHADONE HYDROCHLORIDE ORAL SOLUTION USP

Usual adult dose: Analgesic—Oral, 5 to 20 mg every four to eight hours. Dosage may be increased or the interval between doses decreased if pain is very severe or if the patient becomes tolerant to the medication.

Usual pediatric dose: Analgesic—Dosage must be individualized by physician on the basis of patient's age and size. Use of a calibrated measure is recommended to prevent possible overdosage in children up to 6 years of age.

Strength(s) usually available:
U.S.—
5 mg per 5 mL (Rx) [GENERIC].
10 mg per 5 mL (Rx) [GENERIC].

Packaging and storage: Store between 15 and 30 °C (59 and 86 °F). Store in a tight container. Protect from light. Protect from freezing.

Auxiliary labeling:
- May cause drowsiness.
- Avoid alcoholic beverages.
- May be habit-forming.

Note: Controlled substance in the U.S.

METHADONE HYDROCHLORIDE TABLETS USP

Usual adult dose: Analgesic—Oral, 2.5 to 10 mg every three to four hours as needed initially. For chronic use, dose and dosing interval to be adjusted according to patient response.

Usual pediatric dose: Analgesic—Dosage must be individualized by physician on the basis of patient's age and size.

Strength(s) usually available:
U.S.—
5 mg (Rx) [*Dolophine* (lactose, sucrose); GENERIC].
10 mg (Rx) [*Dolophine* (lactose, sucrose); GENERIC].

Packaging and storage: Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F). Store in a well-closed container.

Auxiliary labeling:
- May cause drowsiness.
- Avoid alcoholic beverages.
- May be habit-forming.

Note: Controlled substance in the U.S.

METHADONE HYDROCHLORIDE TABLETS USP (DISPERSIBLE)

Usual adult dose: Suppressant (narcotic abstinence syndrome)—
Detoxification: Oral, 15 to 40 mg once a day or as needed to control observed withdrawal symptoms; dosage to be reduced at one- or two-day intervals according to patient response.
Maintenance: Dosage must be individualized.

Usual adult prescribing limits: Up to 120 mg per day.

Usual pediatric dose: Children up to 16 years of age cannot legally be enrolled in methadone maintenance programs in the U.S.

Strength(s) usually available:
U.S.—
40 mg (Rx) [GENERIC].

Packaging and storage: Store between 15 and 30 °C (59 and 86 °F). Store in a well-closed container.

Preparation of dosage form: Disperse the contents of the tablet in water or fruit juice before administration. The dispersible tablets have been formulated with insoluble excipients as a deterrent to misuse of the medication by injection.

Auxiliary labeling:
- May cause drowsiness.
- Avoid alcoholic beverages.
- May be habit-forming.

Note: Controlled substance in the U.S.

Parenteral Dosage Forms

METHADONE HYDROCHLORIDE INJECTION USP

Usual adult dose:
Analgesic—Intramuscular or subcutaneous, 2.5 to 10 mg every three to four hours as needed.
Suppressant (narcotic abstinence syndrome)—For detoxification only: Intramuscular or subcutaneous, 15 to 40 mg once a day or as needed to control observed withdrawal symptoms; dosage to be reduced at one- or two-day intervals according to patient response.
Note: Parenteral administration in a detoxification regimen is recommended only for patients unable to take medication orally.

Usual pediatric dose: Analgesic—Dosage must be individualized by physician on the basis of patient's age and size.

Strength(s) usually available:
U.S.—
With preservative:
10 mg per mL (Rx) [*Dolophine* (chlorobutanol)].
Without preservative:
10 mg per mL (Rx) [*Dolophine*].

Packaging and storage: Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), in a light-resistant container. Protect from freezing.

Auxiliary labeling:
- May cause drowsiness.
- Avoid alcoholic beverages.
- May be habit-forming.

Note: Controlled substance in the U.S.

Gastric hypersecretory conditions (e.g., Zollinger-Ellison syndrome, systemic mastocytosis, multiple endocrine adenomas)—Oral, 60 mg once a day, the dosage being adjusted as needed, and therapy continued for as long as clinically indicated.

[Duodenal ulcer]—Oral, 20 mg once a day.

Note: The dosage can be increased to 40 mg once a day for duodenal ulcer refractory to other treatment regimens.

[Gastric ulcer, active]—Oral, 20 mg once a day.

Note: The dosage can be increased to 40 mg once a day for gastric ulcer refractory to other treatment regimens.

If healing of gastric ulcer has not occurred within 4 weeks, an additional 4 weeks of treatment is recommended.

ote: In geriatric patients, the daily dose usually should not exceed 20 mg.

sual pediatric dose: Dosage has not been established.

trength(s) usually available:

U.S.—

20 mg (Rx) [*Prilosec*].

Canada—

20 mg (Rx) [*Losec*].

ackaging and storage: Store between 15 and 30 °C (59 and 86 °F), in a tight container, unless otherwise specified by manufacturer. Protect from light.

uxiliary labeling:

- Take before meals.
- Swallow capsules whole.

OPIOID (NARCOTIC) ANALGESICS (Systemic)

INN: Included in brackets after individual generic listings, if different from U.S. generic names.

VA CLASSIFICATION (Primary/Secondary):

Butorphanol—CN101/CN205

Codeine—

Oral: CN101/RE301; GA400

Parenteral: CN101/GA400

Hydrocodone—CN101/RE301

Hydromorphone—

Oral: CN101/RE301

Parenteral: CN101/CN205; RE301

Rectal: CN101

Levorphanol

Oral: CN101

Parenteral: CN101/CN205

Meperidine

Oral: CN101

Parenteral: CN101/CN205

Methadone—CN101/AD900; RE301

Morphine

Oral: CN101/RE301; GA400

Parenteral: CN101/CN205; RE301; GA400

Rectal: CN101/RE301

Nalbuphine—CN101/CN205

Opium

Oral: GA400/CN101

Parenteral: CN101

Oxycodone—CN101

Oxymorphone

Parenteral: CN101/CN205

Rectal: CN101

Pentazocine

Oral: CN101

Parenteral: CN101/CN205

Propoxyphene—CN101

Note: Controlled substances in the U.S. and Canada as follows:

Drug	U.S.	Canada
Butorphanol	**	C
Codeine	II	N
Hydrocodone	††	N
Hydromorphone	II	N
Levorphanol	II	N
Meperidine	II	N
Methadone	II	N‡‡
Morphine	II	N
Nalbuphine	**	C
Opium	II	N
Oxycodone	II	N
Oxymorphone	II	N
Pentazocine	IV	N
Propoxyphene	IV	N

**Not a controlled substance in the U.S.

††Not available in the U.S.

‡‡Available in Canada only through authorized practitioners.

Opioid analgesics are banned and tested for in athletes by the U.S. Olympic Committee (USOC).

Some commonly used *brand names* are:

In the U.S.—

Astramorph [Morphine]
Astramorph PF [Morphine]
Darvon [Propoxyphene]
Darvon-N [Propoxyphene]
Demerol [Meperidine]
Dilaudid [Hydromorphone]
Dilaudid-HP [Hydromorphone]
Dolene [Propoxyphene]
Dolophine [Methadone]
Doraphen [Propoxyphene]
Doxaphene [Propoxyphene]
Duramorph [Morphine]
Levo-Dromoran [Levorphanol]
Methadose [Methadone]
M S Contin [Morphine]
MSIR [Morphine]
Nubain [Nalbuphine]
Numorphan [Oxymorphone]
Pantopon [Opium]
Profene [Propoxyphene]
Pro Pox [Propoxyphene]
Propoxycon [Propoxyphene]
RMS Uniserts [Morphine]
Roxanol [Morphine]
Roxanol 100 [Morphine]
Roxanol SR [Morphine]
Roxicodone [Oxycodone]
Stadol [Butorphanol]
Talwin [Pentazocine]
Talwin-Nx [Pentazocine and Naloxone]

In Canada—

Darvon-N [Propoxyphene]
Demerol [Meperidine]
Dilaudid [Hydromorphone]
Dilaudid-HP [Hydromorphone]
Dolophine [Methadone]
Epimorph [Morphine]
Hycodan [Hydrocodone]
Levo-Dromoran [Levorphanol]
Morphine H.P. [Morphine]
Morphitec [Morphine]
M.O.S. [Morphine]
M.O.S.-S.R. [Morphine]
M S Contin [Morphine]
Novopropoxyn [Propoxyphene]
Nubain [Nalbuphine]
Numorphan [Oxymorphone]
Pantopon [Opium]
Paveral [Codeine]
Robidone [Hydrocodone]
Roxanol [Morphine]
642 [Propoxyphene]
Stadol [Butorphanol]
Statex [Morphine]
Supeudol [Oxycodone]
Talwin [Pentazocine]

Other commonly used names are:

Dextropropoxyphene [Propoxyphene]
Dihydromorphinone [Hydromorphone]
Laudanum [Opium Tincture]
Levorphan [Levorphanol]
Pethidine [Meperidine]
Papaveretum [Opium (Parenteral)]

ALFENTANIL—See Fentanyl Derivatives (Systemic).

BUPRENORPHINE—See Buprenorphine (Systemic).

BUTORPHANOL

Parenteral

Butorphanol Tartrate Injection USP

In the U.S. and Canada—*Stadol*

CODEINE

Oral

Codeine Phosphate Oral Solution

In the U.S.—GENERIC

In Canada—*Paveral*

bral complications of viral hepatitis and tetanus. Some neurologic complications are thought to be due to allergic responses to the heroin-adulterant mixture.

Other complications include superficial cutaneous abscesses, cellulitis, lymphangitis, lymphadenitis, and phlebitis from contaminated needles. Many heroin addicts begin with subcutaneous injections ("skin popping"). They may return to this mode when extensive scarring makes their veins no longer accessible. As addicts become more desperate, cutaneous ulcers in unlikely sites may be found. Contaminated needles and inoculum may also lead to bacterial endocarditis.

Pregnancy and opiate addiction: Problems of the heroin-addicted mother are transferred to the fetus; because heroin and methadone freely cross the placental barrier, the fetus readily becomes drug-dependent. Pregnant addicts seen early enough should be encouraged to enter a methadone maintenance program. Obviously, such plans should include the obstetrician and pediatrician who will treat the dependent infant. Pregnant women withdrawn from heroin or methadone late in the 3rd trimester of pregnancy risk the precipitation of labor. Pregnant women seen at or near term may be stabilized on methadone. The infants of dependent mothers may present with tremors, a high-pitched cry, jitters, convulsions, and tachypnea. For a discussion of problems of the neonate, including the **fetal alcohol syndrome**, see METABOLIC CONDITIONS in Ch. 189.

Treatment

The clinical management of narcotics addicts is extremely difficult. Physicians treating narcotic drug addicts should be fully aware of the federal, state, and local regulations concerning the treatment of addicts. Few physicians have had formal training or experience in the difficulties encountered in dealing with narcotic addicts and their companions and families, as well as the attitudes of society (including law enforcement officers, other physicians, and allied health personnel) toward the treatment of such individuals. The physician should be aware of locally available resources and usually should refer narcotics addicts to specialized treatment centers and not attempt to care for them in an office. If there are no specialized centers, close supervision of the patient with frequent contacts and close work with the patient's family and friends are necessary.

In order to legally use a narcotic drug in treating an addict, the existence of physiologic heroin dependence must be established. This is a difficult diagnosis since many individuals seeking treatment have minimal physical opiate dependence; this high incidence of psychologic heroin dependence has occurred because recently only low-grade heroin has been available and most addicts have not maintained a high enough level of heroin use to produce physiologic dependence. The following are helpful in assessing physiologic dependence: (1) a history of 1 or more narcotic injections/day, (2) the presence of fresh needle marks, (3) the presence of narcotic in a properly obtained urine specimen, and (4) observation of withdrawal symptoms and signs.

Management of acute intoxication (overdose): Naloxone (0.4 to 0.8 mg) given IV is the drug of choice, since it possesses no respiratory depressant properties. If the patient's unconsciousness is due to a narcotic, dramatic recovery occurs immediately following the administration of this antagonist. Since some patients become agitated, delirious, and combative as they recover from their comatose state, secure physical restraints may be required and should be applied before the narcotic antagonist is given. All patients treated for narcotic overdose should be hospitalized and observed for at least 24 h, since the action of the opiate antagonist is relatively short and respiratory depression may recur within several hours (especially with methadone). Pulmonary edema that may be severe enough to cause

ath from hypoxia is usually not responsive to naloxone and has an unclear lationship to overdosage.

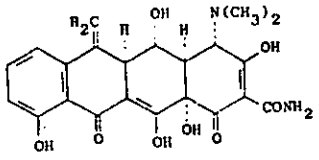
The opiate withdrawal syndrome is self-limited, and although severely discom- rug is not life-threatening. A patient admitted for withdrawal should be told at he will probably experience some unpleasant symptoms and should be reas- ed that they will not be allowed to progress to a dangerous level but that the edication he receives will be based on some objective physical signs of with- awal. The patient's drug-seeking behavior usually begins with the first symp- ms of withdrawal, and hospital personnel must always be alert to the possibility at he will try to obtain illicit supplies of drugs. Visitors may have to be re- icted. Many patients with withdrawal symptoms have other medical problems at must be diagnosed and treated. Opiate users may have mixed addictions, and hough providing appropriate withdrawal measures for each drug is theoreti- lly feasible, for practical purposes this is not required.

Currently, methadone substitution is the preferred method of opiate withdrawal. ethadone is given orally in the smallest amount that will prevent severe signs of ithdrawal but not necessarily all signs. Close observation of the patient is impor- nt, since his subjective symptoms are unreliable. Many of the symptoms of ithdrawal can be mimicked by anxiety states. Generally, 20 mg/day of metha- one will block the symptoms of severe withdrawal in almost all addicts. Higher oses should be given only on direct observations of the physical signs of with- awal, since addicts are notoriously unreliable in reporting the size of their hab- Doses of 25 to 45 mg can produce unconsciousness if the person has not veloped tolerance for heroin or methadone. Once a suppressing dose has been tablished, it should be reduced progressively *by not more than 20% each day*. idicts commonly become emotionally upset and frequently request additional edication. Chloral hydrate 500 to 1000 mg may be given orally for several nights improve sleep. The acute manifestations of withdrawal usually subside within 7 10 days, but patients often complain of weakness, insomnia, and a severe rvasive anxiety for several months. Minor metabolic and physiologic effects of ithdrawal may persist for up to 6 mo. It is appropriate to treat heroin with- awal with oral methadone, but the usual low-grade level of dependence can be ated with propoxyphene napsylate or even benzodiazepines, which are not ss tolerant to opiates.

It is now well documented that the central α-adrenergic drug clonidine can halt ntially all signs of opiate withdrawal. This probably relates to diminution of ntral adrenergic outflow secondary to stimulation of central α receptors (the e mechanism by which clonidine lowers BP). This theory supports the impor- nt of central adrenergic discharge in the evolution of the opiate withdrawal drome. Clonidine is not a benign drug. In addition to causing hypotension and owsiness, its withdrawal may precipitate restlessness, insomnia, irritability, ycardia, and headache. Its general utility in treating opiate withdrawal awaits ther study.

Recently a narcotic antagonist, buprenorphine, has provoked some interest. Un- other antagonists used in treating opiate dependence, it has some agonist ts and users may find a tempering of withdrawal. Early studies indicate that drug provokes little physical dependence itself. If this proves true the drug ld be valuable both in detoxification and long-term treatment of opiate depen-

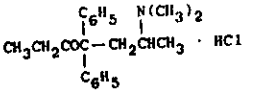
Withdrawal from methadone: The abstinence syndrome induced by methadone milar to that of heroin, but its onset is more gradual and delayed, beginning to 72 h after discontinuing the drug. Deep muscle aches and "bone pains" are ent complaints. Because the abstinence syndrome begins gradually, metha-



Hydrochloride.–$C_{22}H_{23}ClN_2O_8$. *Adriamicina, Ciclobiotic, Germiciclin, Globociclina, Megamycine, Metadomus, Metilenbiotic, Londomycin, Optimycin, Physiomycine, Rindex, Rondomycin.* Obtained as crystals containing 0.5 mol water and 0.5 mol methanol from methanol + acetone + concd HCl + ether. Yellow, crystalline powder, dec ~205°. Bitter taste. Soluble in water, sparingly sol in alcohol. Practically insol in ether, chloroform. uv max (methanol + 0.01*N* HCl): 253, 345 nm (log ε 4.37, 4.19). LD_{50} in rats, mice (mg/kg): 252, 288 i.p. (Goldenthal).

THERAP CAT: Antibacterial.

5852. Methadone Hydrochloride. *6-Dimethylamino-4,4-diphenyl-3-heptanone hydrochloride;* 1,1-diphenyl-1-(2-dimethylaminopropyl)-2-butanone hydrochloride; 4,4-diphenyl-6-dimethylamino-3-heptanone hydrochloride. $C_{21}H_{28}ClNO$; mol wt 345.90. C 72.91%, H 8.16%, Cl 10.25%, N 4.05%, O 4.63%. Prepn: Eisleb, *Office of Publication Board, Department of Commerce,* Report no. PB-981, 96A; Schultz *et al., J. Am. Chem. Soc.* 69, 2454 (1947); Easton *et al., ibid.* 2941 (1947). Resolution: Larsen *et al., ibid.* 70, 4194 (1948); Howe, Sletzinger, *ibid.* 71, 2935 (1949); Brode, Hill, *J. Org. Chem.* 13, 191 (1948); Howe, Tishler, U.S. pat. 2,644,010 (1953 to Merck & Co.); Zaugg, U.S. pat. 2,983,757 (1961 to Abbott). Pharmacokinetics in patients with chronic pain: C. E. Inturrisi *et al., Clin. Pharmacol. Ther.* 41, 392 (1987). Toxicity data: Finnegan *et al., J. Pharmacol. Exp. Ther.* 92, 269 (1948); Winter, Flataker, *ibid.* 98, 305 (1950). *Review:* Eddy, *J. Am. Pharm. Assoc., Pract. Pharm. Ed.* 8, 536 (1947). Comprehensive description: R. H. Bishara in *Analytical Profiles of Drug Substances* vol. 3, K. Florey, Ed. (Academic Press, New York, 1974) pp 365-439. Review of use in opioid dependence: E. C. Senay, *Int. J. Addict.* 20, 803-821 (1985).



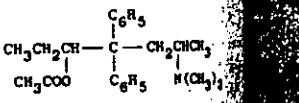
dl-Form, *Adanon hydrochloride, Algidon, Algolysin, Amidon hydrochloride, AN-148, Butalgin, Depridol, Diaminon hydrochloride, Dolophine hydrochloride, Fenadone, Heptadon hydrochloride, Heptanon, Hoechst 10820, Ketalgin hydrochloride, Mecodin, Mephenon, Miadone, Moheptan, Phenadone hydrochloride, Physeptone, Tussal.* Platelets from alcohol + ether, mp 235°. Bitter taste. uv max: 292 nm. Soly (g/100 ml): water 12; alcohol 8; isopropanol 2.4. Practically insol in ether, glycerol. The pH of a 1% aq soln: 4.5-5.6. The free base (mp 78°) is pptd from solns of pH > 6. Aq solns can be autoclaved at 120° for one hour without loss of potency. LD_{50} orally in rats: 95 mg/kg (Finnegan).

l-Form, *Levadone, Levothyl,* L-*Polamidon.* Crystals, mp 241°. $[\alpha]_D^{20}$ −145° (c = 2.5); $[\alpha]_D^{20}$ −169° (c = 2.1 in alc). LD_{50} s.c. in rats: 44 mg/kg (Winter, Flataker).

Caution: May be habit forming. This is a controlled substance (opiate) listed in the U.S. Code of Federal Regulations, Title 21 Part 1308.12 (1985).

THERAP CAT: Narcotic analgesic.

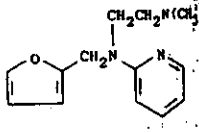
5853. Methadyl Acetate. *β-[2-(Dimethylamino)propyl]-α-ethyl-β-phenylbenzeneethanol acetate (ester); 6-(dimethylamino)-4,4-diphenyl-3-heptanol acetate (ester); O*-acetyl-6-dimethylamino-4,4-diphenyl-3-heptanol; 3-acetoxy-6-dimethylamino-4,4-diphenylheptane; 5-acetoxy-2-dimethylamino-4,4-diphenylheptane; acetylmethadol; acemethadone; amidolacetate; race-acetylmethadol. $C_{23}H_{31}NO_2$; mol wt 353.49. C 78.14%, H 8.84%, N 3.96%, O 9.05%. Congener of methadone, *q.v.* Prepn of *β-dl*-form: M. Bockmühl, G. Ehrhart, *Ann.* 561, 52 (1948); of *α-dl*-form: M. E. Speeter *et al., J. Am. Chem. Soc.* 71, 57 (1949); R. L. Clark, U.S. pats. 2,565,592; 2,668,814 (1951, 1954 to Merck & Co.); M. E. Speeter, U.S. pat. 2,649,445 (1953 to Brist
α-l-forms: A. Pohland *et al., J. Am. Che*
(1949). The *α-dl*-form is more active and le
β-dl-form. The *α-l*-form (levomethadyl a
active than the *α-d*-form but is longer acti
of the *α-dl*-form: R. E. McMahon *et al., J.*
Ther. 149, 436 (1965). Analgesic, depre
α-dl-form in mice, rats: N. B. Eddy *et al.*
(1950); of enantiomers: N. B. Eddy *et al., J.*
321 (1952). Comparison of methadone wi
the treatment of heroin addiction: J. H. Jaf
Med. Assoc. 211, 1834 (1970).



α-dl-Form hydrochloride, $C_{23}H_{32}ClNO_2$
ethyl acetate, mp 213-214°. Sol in water.
mice (mg/kg): 61.0 s.c., 118.3 orally (Eddy
α-dl-Form hydrobromide, $C_{23}H_{32}BrNO_2$
193-194.5°. Sol in water.
α-d-Form, *alphacetylmethadol.*
α-d-Form hydrochloride, crystals from e
215°, $[\alpha]_D^{25}$ +61.2° (c = 0.2). Sol in wate
(mg/kg): 72.2 s.c., 130.4 orally (Eddy, 19
α-l-Form, *See* levomethadyl acetate.
β-l-Form, *betacetylmethadol.*
β-dl-Form hydrochloride, crystals, mp 21
water. LD_{50} in mice (mg/kg): 42.0 s.c.,
1952).

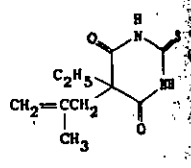
Caution: May be habit forming. This is a
stance (opiate) listed in the U.S. Code of
tions, Title 21 Part 1308.11 (1985).

5854. Methafurylene. *N-(2-Furanyl*
methyl-N-2-pyridinyl-1,2-ethanediamine; N-(2-dimethylaminoethyl)furfurylamino]pyridine; N,N-dimethyl-N'-(2-pyridyl)-N'-furfurylethylenediamine; N'-(2-furylmethyl)-N'-(2-pyridyl)-N,N-dimethylethylenediamine. $C_{14}H_{19}N_3O$; mol wt 245.32. C 68.54%, H 7.80%, N 17.
Prepn: Vaughan, Anderson, *J. Am. Chem.*
(1948); Kyrides, Zienty, *ibid.* 71, 1122 [1
U.S. pat 2,502,151 (1950 to Rhône-Po



Light yellow oil, $bp_{0.2}$ 117.5-118°.
Hydrochloride, $C_{14}H_{20}ClN_3O$, needles fr
mp 117-119°.
Dihydrogen citrate, $C_{20}H_{27}N_3O_7$, crystals
ether or from methyl ethyl ketone, mp 95-
Fumarate, $C_{18}H_{23}N_3O_5$, *F-151, Foralam*
THERAP CAT: Antihistaminic.

5855. Methallatal. *5-Ethyldihydro-5-(2-methylallyl)-2-thioxo-4,6(1H,5H)-pyrimidinedione; 5-ethyl-5-methylallyl)-2-thiobarbituric acid;* ethyl-(2-methylallyl)-2-thiobarbituric acid; V-12; Mosidal. $C_{10}H_{14}N_2O_2S$; mol wt 226.29. C 53.07%, H 6.24%, N 12.38%, O 14.
Prepn: Volwiler, Tabern, U.S. pat. 2,1
Abbott).



Voting Sheets

HOUSE COMMITTEE ON CRIMINAL JUSTICE AND PUBLIC SAFETY

EXECUTIVE SESSION on SB 445-FN

BILL TITLE: **(New Title) relative to methadone maintenance treatment.**

DATE: May 3, 2000

LOB ROOM: 204

Amendments:

Sponsor: Rep. CJ & PS Committee — OLS Document #: 2000 4358h

Sponsor: Rep. — OLS Document #:

Sponsor: Rep. — OLS Document #:

Motions: OTP, OTP/A, ITL, Re-Refer, Interim Study (Please circle one.)

Moved by Rep. Flora

Seconded by Rep. Rodd

Vote: 13-2 (Please attach record of roll call vote.)

Motions: OTP, OTP/A, ITL, Re-Refer, Interim Study (Please circle one.)

Moved by Rep.

Seconded by Rep.

Vote: (Please attach record of roll call vote.)

CONSENT CALENDAR VOTE: No

(Vote to place on Consent Calendar must be unanimous.)

Statement of Intent: Refer to Committee Report

Respectfully submitted,

Rep. Maxwell D. Sargent, Clerk

CRIMINAL JUSTICE AND PUBLIC SAFETY

Bill #: SB345-FN **Title:** relative to methadone maintenance treatment

PH Date: 4/11/00 **Exec Session Date:** 5/3/00

Motion: Ought to pass with amendment **Amendment #:** 2000-4358h

MEMBER	YEAS	NAYS
Welch, David A, Chairman	✓	
Christie, Andrew, V Chairman	absent	
Hansen, Herbert R	absent	
Dunham, Vivian L	absent	
Sargent, Maxwell D, Clerk	✓	
Pepino, Leo P	✓	
Flora, Kathleen M	✓	
Mikowlski, Walter J		✓
Fesh, Robert M	absent	
Weare, Everett A		✓
Andrews, Frederick B	✓	
Johnson, James M	✓	
Tholl, John E	✓	
Knowles, William V	✓	
Doucette, Richard F	absent	
Berube, Roger R	absent	
Schanda, Frank M	✓	
O'Keefe, Patricia M	✓	
McCarthy, William J	absent	
Robertson, Timothy N	✓	
Callaghan, Frank D	✓	
Rodd, Beth	✓	
TOTAL VOTE:	13	2

Printed: 12/30/1999

Committee Report

COMMITTEE REPORT

COMMITTEE: **Criminal Justice and Public Safety**

BILL NUMBER: **SB 445-FN**

TITLE: (New Title) relative to methadone maintenance treatment.

DATE: May 3, 2000 CONSENT CALENDAR YES ☐ NO ☒

☐ OUGHT TO PASS

☒ OUGHT TO PASS WITH AMENDMENT

☐ INEXPEDIENT TO LEGISLATE

☐ RE-REFER

☐ REFER TO COMMITTEE FOR INTERIM STUDY
(Available only in second year of biennium.)

STATEMENT OF INTENT
(Include Committee Vote)

SB 445-FN, as amended, closes a loophole in current law by repealing RSA 318B:10VII under which methadone detoxification treatment programs for heroin addiction have been allowed to operate under federal statute but without the oversight of state rules. The amendment requires the Commissioner of Health and Human Services to adopt rules relative to methadone detoxification and methadone maintenance treatment for heroin addiction by June 30, 2001. In addition, SB 445, as amended, allows methadone maintenance treatment programs to operate in New Hampshire once rules are adopted. These rules will require that methadone maintenance be provided within a rehabilitative framework. This brings New Hampshire law for the treatment of heroin addiction in line with the most current recommendations of the National Institute of Health, the National Institute on Drug Abuse, the New Hampshire State Medical Society and our own division of Alcohol, Drug Abuse Prevention and Recovery as an effective treatment modality for this addition. Testimony from the medical community strongly supports this action to enable the addicted persons to return as quickly as possible to contributing members of society. Patients on methadone are able to become functional members of their families and communities. They are able to maintain employment and get the necessary counseling, needed to achieve long term success in defeating their addiction. Law enforcement officials including the New Hampshire Attorney General supported enforcement, education and treatment as a three pronged approach to eradicate illegal drug use in the State of New Hampshire. Studies have demonstrated a decrease in criminal activity corresponding to the initiation of methadone treatment. We have a growing, statewide heroin problem in New Hampshire. SB 445, as amended, allows for the provision of well-regulated comprehensive treatment and rehabilitation for heroin addition.

Vote 13-2.

Rep. Kathleen M. Flora
FOR THE COMMITTEE

Criminal Justice and Public Safety

SB 445-FN, (New Title) relative to methadone maintenance treatment. OUGHT TO PASS WITH AMENDMENT

Rep. Kathleen M. Flora for Criminal Justice and Public Safety: SB 445-FN, as amended, closes a loophole in current law by repealing RSA 318B:10VII under which methadone detoxification treatment programs for heroin addiction have been allowed to operate under federal statute but without the oversight of state rules. The amendment requires the Commissioner of Health and Human Services to adopt rules relative to methadone detoxification and methadone maintenance treatment for heroin addiction by June 30, 2001. In addition, SB 445, as amended, allows methadone maintenance treatment programs to operate in New Hampshire once rules are adopted. These rules will require that methadone maintenance be provided within a rehabilitative framework. This brings New Hampshire law for the treatment of heroin addiction in line with the most current recommendations of the National Institute of Health, the National Institute on Drug Abuse, the New Hampshire State Medical Society and our own division of Alcohol, Drug Abuse Prevention and Recovery as an effective treatment modality for this addition. Testimony from the medical community strongly supports this action to enable the addicted persons to return as quickly as possible to contributing members of society. Patients on methadone are able to become functional members of their families and communities. They are able to maintain employment and get the necessary counseling, needed to achieve long term success in defeating their addiction. Law enforcement officials including the New Hampshire Attorney General supported enforcement, education and treatment as a three pronged approach to eradicate illegal drug use in the State of New Hampshire. Studies have demonstrated a decrease in criminal activity corresponding to the initiation of methadone treatment. We have a growing, statewide heroin problem in New Hampshire. SB 445, as amended, allows for the provision of well-regulated comprehensive treatment and rehabilitation for heroin addition Vote 13-2.

COMMITTEE REPORT

COMMITTEE: Criminal Justice & Public Safety

BILL NUMBER: SB 445 FN

TITLE: relative to methadone maintenance treatment

DATE: 5/3/00 CONSENT CALENDAR YES ___ NO X

___ OUGHT TO PASS

X OUGHT TO PASS WITH AMENDMENT

___ INEXPEDIENT TO LEGISLATE

___ RE-REFER

___ REFER TO COMMITTEE FOR INTERIM STUDY
(Available only in second year of biennium.)

STATEMENT OF INTENT
(Include Committee Vote)

SB 445 as amended closes a loophole in current law by repealing RSA 318B:10 VII under which methadone detoxification treatment programs for heroin addiction have been allowed to operate under federal statute but without the oversight of state rules. The amendment requires the Commissioner of Health & Human Services to adopt rules relative to →

Vote. 13-2

Rep. FLORA
FOR THE COMMITTEE

Original: House Clerk
cc: Committee Bill file

USE ANOTHER REPORT FOR MINORITY REPORT

methadone detoxification & methadone maintenance treatment for heroin addiction by June 30, 2001.

In addition, SB445 as amended, allows methadone maintenance treatment programs to operate in NH once rules are adopted. These rules will require that methadone maintenance be provided within a rehabilitative framework. This brings NH law for the treatment of heroin addiction in line with the most current recommendations of the National Institutes of Health, the Nat'l Institute on Drug Abuse, the NH State Medical Society & our own division of Alcohol, Drug Abuse Prevention & Recovery as an effective treatment modality for this addiction.

Testimony from the medecal community strongly supports this action to enable so addicted persons to return as quickly as possible to contributing members of society. Patients on methadone are able to become functional members of their families & communities. They are able to maintain employment & get the necessary counseling needed to achieve long term success in defeating their addiction

Law enforcement officials including the NH Attorney General supported enforcement, education & treatment as a three pronged approach to eradicate illegal drug use in the State of NH.

Studies have demonstrated a decrease in criminal activity corresponding to the initiation of methadone treatment.

We have a growing, state-wide heroin problem in NH. SB 445 as amended allows for the provision of well regulated, comprehensive treatment & rehabilitation for heroin addiction.