National Alliance of Methadone Advocates

435 Second Avenue
New York, NY 10010
Voice/Message/Fax
(212) 595-NAMA

Education Series Number 10
June 2003

The New Federal Regulations
What Do They Mean for Patients?

Methadone treatment in the U.S. is changing before our eyes. Some of this change has been rapid; some of it will take years or decades. Some patients have heard about new federal regulations, including an end to automatic dose caps and clinic-wide observed urines, and the possibility of 30-day take-homes. Some patients have already seen these changes at their clinics. Others ask staff members about them, and staff doesn't know.

What's going on? While patients are especially concerned about the changes that make an immediate difference to them, these changes are really just the tip of the iceberg. It is important to understand the new system as a whole, and the change it can make.

For 30 years the Food and Drug Administration, the federal agency that monitors the production of food and drugs primarily for purity regulated methadone treatment. The regulations focused on safety of the medication and preventing diversion. There was little attention to the nature of methadone as a drug treatment, the needs of the patients, or even the needs of the staff providing the treatment. Methadone was dispensed only in special clinics, under a thick load of regulations. States often added their own regulations, which were stricter than the basic federal rules, and the clinics sometime set their own policies even more inflexible than the states required. Some clinic staff became afraid of doing anything that might violate state rules; states worried about the federal rules; and the patients had regulations dictated to them. It was not unusual for clinic staff to not know or understand regulations, or which were regulations and which were clinic policy; everything was a regulation. Decisions on clinic policies and even individual patient treatment were often made more by regulators, rather than being made by treatment professionals according to known scientific standards.

After 8 years of committees, advisory groups, meetings and consultations, the new federal regulations took effect in May 2001. NAMA is proud of the part it has played representing patients in many of these settings. Many of the changes that patients have would not have happened if NAMA had not been there.

The Key Changes

- The federal agency responsible for oversight of methadone treatment is now the Center for Substance Abuse Treatment (CSAT), an agency of the Substance Abuse and Mental Health Services Administration (SAMHSA) which is part of the U.S. Department of Health and Human Services. CSAT is also in charge of the national standards for drug treatment and a good complement.

- Clinics will no longer simply need a license to operate. To get CSAT approval to stay in operation, they will need to be accredited, like most other clinics and health-care facilities (i.e. hospitals). An accrediting agency will visit the clinic, see its procedures, talk to its staff and patients, give it "grades," and determine if it will be accredited.

- There are several accreditation agencies, but all will work within general accreditation guidelines put together by CSAT, based on research into the most effective treatment. This will require clinics to have systems for records, training, and making treatment decisions, rather than simply quoting "the regulations."

- The new regulations allow the development of treatment programs outside the clinic system, for example in doctors' offices. These would serve the long-term, stable patients. This is not simple, but it is now within the regulations and can be done. More important it will help move methadone treatment into mainstream medical services.

Patients will not see changes at the same speed, it depends on their state and clinic. States are changing their regulations to reflect the new system. Some are adopting the new federal regulations as their own state regulations. Other states are developing their own. States and clinics can still create regulations stricter than the basic federal ones, but if they are too strict they may violate standards for clinic accreditation. At the best clinics, the new regulations lift some unneeded restrictions. At the worst clinics, the changes may be as small as the clinics can keep them. It is in the great majority of "average" clinics that we will see the most change, as both staff and patients educate themselves about the new system and learn to do things differently to reach the full potential of methadone treatment. We do not expect things to change overnight. Many clinics are still trying to understand the new system. The accrediting agencies are learning about methadone treatment. The new regulations have gray areas, and we don't know how strictly the new regulations will be enforced. But we do know that things will never be quite the same again.

At NAMA, we like to say that "Together, we can make a difference." Now it's time for all of us involved in methadone treatment, whether as patients, staff, or regulators, to make that slogan a reality.

Some Q & A's About the New Regs

What changes have happened to the Federal Regulations?

On May 18, 2001 methadone treatment changed from being regulated by the Food and Drug Administration (FDA) to the Center for Substance Abuse Treatment (CSAT), which is a Federal agency under the Substance Abuse and Mental Health Services Administration (SAMHSA). Methadone treatment has been put on an accreditation system, which is how all other medical procedures are certified. One of the reasons for doing this was to destigmatize and to start to establish methadone treatment as a legitimate medical treatment. This is an historic step towards methadone treatment taking its rightful place in medicine as the most effective, and the "gold standard" for treating opiate addiction.

Will the new guidelines change take-home medication?

Yes, one of the major changes that patients will notice immediately will be the new change in take-home schedules. In order to qualify a patient must be in compliance, or "good standing with their Program" by meeting the eight conditions that are listed in the new guidelines. These conditions are: (1) no recent drug use, (2) attends clinics regularly, (3) no serious behavioral problems, (4) no criminal activity, (5) stable home environment and good social relationships, (6) length of time in treatment (see chart), (7) assurance that take-home medication will be safely stored, and (8) judgment that the rehabilitative benefit to the patient will outweigh the risk of diversion (CRF42.8.12.i (2) (i-viii)). These eight conditions are very similar to the previous criteria that were used to grant take-home medication.

Time in Treatment

Period		Schedule
First Quarter	1-90 Days	1 Take Home a Week *
Second Quarter	91-180 Days	2 Take Homes a Week *
Third Quarter	181-270 Days	3 Take Homes a Week *
Fourth Quarter	271-365 Days	6 Take Homes/1X Week *
1 Year		13 Take Homes/2X Month
2 Years		28 Days/1X Month

* If the program is closed for business, including Sundays and State/Federal Holidays.

Patients that meet the eight conditions are eligible for the take home medication based on their length of time in treatment.

However it should be emphasized that just because a patient is eligible does not mean that they will automatically get take-home medication. As with the previous regulations this is decision that is made by the medical director (physician) of the Program. While Programs are being encouraged to be more progressive, this does not mean that they will.

The criteria for Medical Maintenance or Office Based Opioid Treatment (OBOT) may be stricter and some states or programs may require 4 years or more time in treatment.

Do the new guidelines allow Programs to dispense pills or diskettes?

No, Programs will still have to dispense liquid methadone (CRF 42.8.12.h (3) (I)). However for patients with 31 day take-home schedules a Program may request a special exemption (66 FR 4085, January 17, 2001). [1]

What if my Program does not want to implement these new take-home schedules or other provisions?

Unfortunately, although these are Federal Guidelines other authorities such as States, cities/counties, and Programs themselves can still have their own, more strict, policies. And realize that as long as one patient gets take-home medication the Program is considered compliant. But, the new Federal Guidelines clearly state that Programs that do not substantially conform with the Federal Opioid Treatment Guidelines will risk losing their SAMHSA certification (CRF 42.8.11.c (2) (ii)) and if a Program is not SAMHSA certified, it cannot become accredited and cannot operate. [(2)]

Does CSAT have to be notified if patients on doses higher than 100mgs get take-homes?

No, this reporting requirement has been eliminated and any patient with a dose over 100mgs can have take-homes. The medical director of the Program now makes this decision. In fact it was eliminated by the FDA in the early 1990's because of HIV and other medications that affect methadone.

Are there any changes in the urine analysis requirements?

No, the same federal requirement of eight random urine analyses per year remains (CRF 42.8.12.f (6)). But, if your Program uses "observed urine analysis for all patients," this will no longer be allowed under the new guidelines. The guidelines are very clear that Programs that utilize observed urine analysis for every patient on the Program until they leave treatment is not necessary. Neither do the Federal Guidelines require urine testing for marijuana. However, the guidelines do not rule out any type of drug testing and a Program can decide which drugs to screen for, since different drug trends exist in different areas of the country.

Do the Guidelines make any provisions for patient grievances?

The Federal Guidelines, as well as the Accreditation Standards developed from them, include provisions for accepting and acting upon patient grievances (CRF 42.8.4.e; 66 FR 4082, January 17, 2001). For the first time, patients will have access to a formal grievance procedure through the accreditation bodies. However, the process is more of a reporting system for the accrediting body to act on for the next time the program is accredited. Patients should access the offices of their State Methadone Authority as well as the CSAT 800 number. There are a number of states that have a grievance process already set up such as Wisconsin, Michigan, New York, and Florida.

Do the new Federal Guidelines address fees that Programs charge?

No, there is no mention of fees in the new guidelines. In some cases a fee increase could be considered reasonable if the Program has kept low fees in order to make treatment more available and to be fair to their patients.

Do the new guidelines allow any doctor to prescribe methadone to treat opiate addiction?

No. Current Federal Guidelines enforced by the Drug Enforcement Administration (DEA) do not permit doctors to prescribe narcotic drugs for the treatment of opiate addiction. However, a physician may prescribe methadone if they operate as a satellite to a Program (66 FR 4079, January 17, 2001; Clark, H. Westley, M.D., Lepay, David, M.D. "Dear Colleague Letter on Medical Maintenance" March 30, 2000). There are provisions for physicians in non-metropolitan areas to seek an exemption from staffing and record keeping requirements exemption to treat a patient or a small number of patients. Also some states are setting up various kinds of methadone treatment that include Office Based Opioid Treatment (OBOT) and pharmacy based opioid treatment (Barthwell, M.D., A.G., Physicians' Guide: Opioid Agonist Medical Maintenance Treatment (Draft Guidelines, 2000. Available from CSAT).

Do privately owned clinics have to comply with the new Federal Guidelines?

Yes. All clinics in the U.S. not only have to comply with the Federal Guidelines but they must also become accredited. However, there may be instances in which small clinics in rural areas are exempt from the accreditation process, but they still must follow the intent of the guidelines to the best of their ability (CRF 42.8.11.h).

What are the Accreditation Guidelines?

The CSAT Accreditation Guidelines (often referred to as Treatment Standards or Best Practices) is a set of objectives created by addiction treatment professionals, Federal, and State officials and patient advocates. The "Guidelines" are an up-to-date "best practice" guidelines based on Part 8.12 of the Code of Federal Regulations as well as the Treatment Improvement Protocols (TIPs) and Treatment Assessment Protocols (TAPs) that address opiate addiction treatment. [(3)]

The accreditation agencies use these guidelines to judge the quality of treatment when they review a Program. Programs must comply with these guidelines or they will risk not being accredited. These guidelines can be changed without the formal process that must be adhered to in changing the Federal Regulation Code.

Do all Programs have to comply with the Accreditation Guidelines in addition to the Federal Regulations?

While it's true that States can make their regulations stricter than the Federal Guidelines, all clinics and States still have to comply with these treatment standards; guidelines set forth by CSAT as being 'Best Practices'.

The Federal Register states, "As noted in the July 22, 1999, proposal, the Secretary believes that the standards are "enforceable regulatory requirements that treatment. Programs must follow as a condition of certification (64 FR 39810, July 22, 1999)." While the new Guidelines increase the flexibility and clinical judgment in the way OTPs meet the regulatory requirements, they are set forth under section 8.12 as the services, assessments, procedures, etc., that OTPs "must" and "shall" provide. As such, the new standards are as enforceable as the previous regulations under 21 CFR 291.505. OTPs that do not substantially conform with the Federal Opioid Treatment standards set forth under section 8.12 will risk losing SAMHSA certification" (66 FR 4082, January 17, 2001).

Are Programs that have a policy of dose caps violating treatment standards?

Yes. Programs that have policies that require 100% of the patient population to participate in such "dose caps" or "observed urinalysis," will be cited by accreditation agencies. *Across the Board* clinical policies will not be tolerated under the accreditation system. CSAT is clear that treatment is to be individualized depending on a patient's needs.

Can Programs help patients by seeking exemptions to the new Federal Guidelines?

Yes. The new Federal Guidelines allow a Program the opportunity to request from SAMHSA an exemption from any of the regulatory requirements set forth in Part 8.12 of the Federal Code.

Abbreviations

CARF Commission for the Accreditation of Rehabilitation Facilities (pronounced Carf)
CRF Code of Federal Regulations (or Federal Code)
CSAT Center for Substance Abuse Treatment (pronounced Cee-Sat)
FDA Food and Drug Administration
FR or Federal Register (a weekly government publication containing new Federal Code, grant announcements, etc.)
JCAHO Joint Commission for the Accreditation of Healthcare Organizations (pronounced Jay-Ho or called Joint Commission)
OBOT Office Based Opioid Treatment (pronounced O-Bot)
SAMHSA Substance Abuse and Mental Health Services Administration (pronounced Sam-Sa)

Notes

1. In line with the idea of individualized treatment, Programs are being encouraged by Federal authorities to request a special exemption for deserving patients. For example, if a patient had only been in treatment for 6 months and coming to the Program 4 times a week was interfering with work and the patient was concerned about losing their job then the Program would be encouraged to apply for a special exemption. There are also other reasons such as living a long distance from the clinic and the weather made travel difficult then the Program might request a special exemption for this patient to come less if the patient met all other requirements.
2. If a Program loses their accreditation or certification and cannot operate it will be the responsibility of Federal and State authorities to make sure that all the patients enrolled on that Program would continue to receive treatment.
3. TIPS and TAPS are a series of published treatment guidelines that can be obtained from the National Clearinghouse on Drug and Alcohol Information (website) or by calling 1-800-SAY-NO TO (DRUGS). The new Federal Guidelines are primarily based on the State Methadone Treatment Guidelines (TIP1).

Resources

National Alliance of Methadone Advocates — www.methadone.org
Center for Substance Abuse Treatment — www.treatment.org or csat.samhsa.gov

TIP 43 Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs
http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid-hstat5.chapter.86276

Education Series
Cost per each $2

Number 1. Methadone Maintenance and Patient Self Advocacy by Arlene Ford. (March, 1991).

Number 2. Drug Policy in the Age of AIDS: The Philosophy of Harm Reduction by Rod Sorge (April, 1991).

Number 3. Myths About Methadone by Emmett Velten (March, 1992).

Number 4. Methadone, HIV Infection and Immune Function by Herman Joseph (August, 1994).

Number 5.1. The Basics of Pharmacology, Basic Pharmacology: How Methadone Works? by J.T. Payte, Jeffrey Smith and Joycelyn Woods (February, 2001 Revised).

Number 5.2. The Pharmacology of Opioids, Basic Pharmacology: How Methadone Works? by J.T. Payte, Jeffrey Smith and Joycelyn Woods (February, 2001 Revised).

Number 5.3. Drugs and Conditions That Impact On the Action of Methadone, Basic Pharmacology: How Methadone Works? by J.T. Payte, Jeffrey Smith and Joycelyn Woods (February, 2001 Revised).

Number 6. (Not available).

Number 7. Managed Care (August, 2003 Revised).

Number 8. Methadone Does Not Work Bibliography (October, 1995).

Number 9. The Methadone Maintained Patient and the Treatment of Pain by J. Thomas Payte, Elizabeth Khuri, Herman Joseph and Joycelyn Woods (January, 1999).

Number 10. The New Federal Regulations. What Do They Mean for Patients? (June 2003).

Membership

Membership in NAMA is $25 a year for Individual and $40 for International Membership. Additional family members may join at the cost of $10 each a year. Institutional Membership is $110 a year for U.S. and International. If you cannot afford membership dues, or can only afford a part of it, NAMA will still accept your membership request.

National Alliance of Methadone Advocates
435 Second Avenue, New York, NY 10010

NAMA Manuals
Cost per each $10

Number 1. Starting a Methadone Advocacy Group (NAMA Chapter or Affiliate). The basics of starting a methadone advocacy group including history of methadone advocacy, forming a Board of Directors, meeting planning, first projects, politics of methadone, listing of state agencies and other resources.

Number 2. Setting Up a 12 Step Group. A manual to help patients and professionals start a 12 step group. Includes organizing the group, meeting planning, the basics of starting a 12 step group, a generic version of 12 steps and other resources.

The price of the Education Series and Manuals are to cover the cost of duplicating and mailing.

NAMA is a not-for-profit organization.

For membership please complete & mail the coupon below with your dues.

Coupon

Name: _____

Organization: _____

_____

Address: _____

_____

City: _____ **State**: _____

Country: _____ **Postalcode**:_____

Work Phone: _____

Home Phone: _____

Fax: _____

Amount Enclosed: _____