

# Methadone Today

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## OBOT and Medical Maintenance-- Three Years and Counting

by R. Belser

May 15, 2001--almost 3½ years ago--was the day on which the new federal regulations and guidelines went into effect. As most **Methadone Today** readers realize, these new regulations marked a change in the regulatory structure of methadone maintenance treatment (MMT) in the United States. The regulations included a set of guidelines which, if followed, would remedy many of the most common and egregious policies followed by methadone maintenance treatment programs (MMTPs), either as a result of a particular clinic's own policy or observed in compliance with one of the non-methadone-friendly state's draconian regulations\*. Such degrading practices as blanket "supervised" or "monitored" urines, program requirements making take-home methadone non-existent or narrowly limited, etc., were some of the issues addressed by the new federal regulations\*. These regulations also made Office-Based Opioid Treatment (OBOT) and Medical-Maintenance legally available and promoted their wide availability. OBOT is defined as the certifying of private physicians and their practices as providers of MM. Medical Maintenance is a program outside the clinic structure which streamlines and liberalizes MMT in a manner similar to OBOT

Although the new federal protocols could not directly mandate changes in existing state or clinic regulations, the requirement that all clinics accredited by JCAHO or CARF comply with the new guidelines within a reasonable time meant that clinics not implementing these changes would eventually lose accreditation. Since virtually all clinics accepting any public funding must be accredited by one of these organizations, a loss of accreditation would mean a loss of funding.\*\*

From all reports, more than three years after the new federal regulations went into effect--compliance by clinics has been mixed; some clinics have willingly made changes, but others have had to be dragged kicking and screaming to make even modest changes, while still others stubbornly persist in **(Cont p. 4)**

## Federal Regulations Hinder Growth of OBOT and Medical Maintenance

We believe that the real reasons for the lack of Medical-Maintenance and OBOT programs have little to do with lack of patient motivation because there are already traditional methadone clinics providing 14- and 31-day take-homes. By and large, the federal regulations themselves are responsible for the lack of Medical-Maintenance and OBOT. The regulations make it very difficult for a physician or treatment provider that is independent of any opiate treatment provider/methadone clinic to start up a Medical-Maintenance/OBOT program.

As for Medical-Maintenance/OBOT programs run by or somehow tied to a methadone clinic, we wonder whether the author of *OBOT and MM--Three Years and Counting* has overestimated the extent to which the existence of Medical Maintenance/OBOT programs are beneficial to traditional methadone clinics. Granted, there are methadone clinics that are owned and operated by caring professionals who support OBOT and Medical-Maintenance programs because it will benefit both long-term, stable methadone patients who would qualify for such programs and untreated opiate addicts by opening up more treatment slots and reducing waiting lists at traditional methadone clinics, thereby making treatment more accessible to such individuals.

But the fact is that many methadone clinics are more concerned about their financial profits than the best interests of their patients, and they see OBOT and Medical-Maintenance programs as a threat to them rather than an opportunity. Individual methadone clinics have a virtual monopoly in many areas, so they are not excited about having to compete with OBOT and Medical-Maintenance programs even if the programs are somehow tied to them. Even in the case of OBOT/Medical-Maintenance programs that are actually owned/run by a methadone clinic, many methadone clinics are wary of OBOT/Medical-Maintenance. It is safe to say that such programs are less profitable on a per patient basis than a traditional methadone clinic. Even where there are waiting lists for private/cash-pay treatment slots, it is not necessarily in a methadone clinic's best financial interest to open a Medical-Maintenance/OBOT program; after all, they **(p. 3)**

## Doctor offers voting advice:

We received a report of a doctor at a methadone clinic trying to tell patients how they should vote in the November 2nd election.

In a sense, this doctor had a captive audience, as these patients were seeing the doctor for a specific purpose (i.e., a 60-day evaluation). Obviously, the doctor in question did not violate the law; the individual was simply offering an opinion. But some might argue that the doctor's behavior was unprofessional. It may have made some patients uncomfortable, and there were no doubt patients who did not appreciate being held up for several minutes or so.

We gather that this was not merely a friendly chat. We would certainly not fault a counselor or doctor for discussing politics or some other topic with a patient, but this sounded more like a 'lecture' than a discussion with a willing patient.

This is hardly the worst thing a methadone clinic doctor could do, but it makes us wonder how much regard and respect this doctor has for methadone patients--as if the patients are not mature or intelligent enough to decide how to vote on their own.

***Do you have a question for us or an article or story you would like to share with our readers? Please write or e-mail us. See the bottom of page 4 for contact information.***

***We welcome and encourage material from all interested individuals--patients and their family members and friends, methadone clinic staff, or anyone else interested in this subject matter.***

***Readers frequently comment that they like the patient stories, but we cannot print them if we do not get submissions!***

## Does Methadone Spoil?

*\*Reprinted from the Addiction Treatment Forum, Vol. XIII, No. 3 (Summer 2004), Feedback Q&A. (Website: www.atforum.com)*

**Q:** *With greater flexibility in prescribing doses of take-home methadone now permitted by Federal Regulations, will liquid methadone "go bad" if stored for too long? What is the best way to dispense and store it?*

**A:** Since up to 30 days of methadone hydrochloride may be prescribed at one time for take-home, there has been concern about the extended shelf life of liquid methadone. Also, once the original methadone container is opened for dispensing, FDA regulations prohibit manufacturers from attesting to long-term product stability.

However, independent research and commentary confirms that methadone itself is a stable medication. In one published report, pharmacists noted that potential problems relate more to what is used to dilute the methadone at the time of dispensing, due to possible contamination with mold or fungal growth.[1]

Bacterial growth also might be a concern. One investigation found that storage of methadone mixtures at room temperature fostered visibly unacceptable bacterial growth within 2 weeks, unless appropriate preservatives were included (such as sodium benzoate). Some manufacturers do include such preservatives. As for potency, methadone mixed with Kool-Aid, Tang, apple juice, or Crystal Light and refrigerated (41°F) maintained its strength for 30 days or much longer.[2]

Based on a review of existing literature and a consensus of opinion among consulted pharmacists, the American Association for the Treatment of Opioid Dependence (AATOD) issued several recommendations in June 2004:[3]

1. Dilution of methadone hydrochloride products should be with distilled water only.
2. New, clean, air tight, light resistant containers should be used for dispensing.
3. Take-home containers should be securely refrigerated as soon as possible and remain refrigerated until used.

AATOD specified that if these procedures are followed, liquid methadone should remain stable for up to 30 days from the date of MMT clinic dispensing.

The World Health Organization recently recognized that, "The stigma associated with substance use and dependence can prevent individuals from seeking treatment and can prevent adequate policies regarding prevention and treatment from being implemented."

However, there may be a question as to whether dilution at the time of clinic dispensing is required or necessary. Federal Regulations do not specifically require dilution.[4] Typically, product labeling specifies, "to be diluted with water or other liquid to 30 mL (1 fl. oz.) or more before oral administration." [5] This could mean dilution "just before the dose is taken," in which case the patient might be the one to add liquid for dilution. Tap water or other fluid could be used, since storage is not a concern. Dilution simply makes it easier to consume the full amount of otherwise thick, undiluted methadone that is in the take-home container.

### Citations:

1. Allen LV, Stiles ML. Methadone lemonade. U.S. Pharmacist. 1988 (September):82.
2. Lauriault G, LeBelle MJ, Lodge BA, Savard C. Stability of methadone in four vehicles for oral administration. AJHP. 1991;48:1252-1256.
3. Parinno MW. Shelf life for methadone hydrochloride products following OTP compounding [memo]. June 11, 2004. AATOD.

4. Federal Register. Opioid drugs in maintenance and detoxification treatment of opiate addiction; final rule. 2001 (Jan 17);66(11):4085. 42 CFR Part 8. Available at: <http://www.atforum.com>.

5. Package Insert. Methadose® Oral Concentrate. 2001.

**Editor's Comments:** As we discussed in a previous issue of *Methadone Today*, the ideal solution would be to dispense extended take-home supplies of methadone (13-31 days) in solid form. Not only would this be more convenient, it would avoid potential problems with germ growth or loss in potency. The usual solid formulation dispensed to methadone patients takes the form of diskettes or wafers. One plus of using diskettes or wafers for take-home purposes is that patients can choose whether to swallow the medication or mix with water or juice right before ingestion and drink the solution. Methadone wafers and diskettes are designed to be dissolved in juice, as opposed to a normal pill or tablet. Unlike the previous federal regulations, the current federal regulations do not specify that the medication be dispensed in liquid form; it only indicates that it be dispensed in oral form, as opposed to it being injectable. For this reason, some methadone clinics have begun dispensing the medication in a solid form, at least to those patients receiving an extended supply of take-homes.

Unfortunately, many states still require that when being used for the treatment of opiate addiction methadone be dispensed in liquid form. In these states, methadone treatment providers should follow the above AATOD recommendations.

While we welcome AATOD's recommendations for the dispensing and storage of liquid methadone, it appears that they were not completely thought through. Methadone clinics typically urge patients NOT to store their take-home medication in the refrigerator out of fear that a child will mistake the medication [especially if colored and flavored] for juice and accidentally overdose. We assume that by "securely refrigerated", they mean that the medication should be in a lock box and the lock box put inside the refrigerator. In the case of extended take-home supplies, there may not be enough extra space in the patient's refrigerator for a lock box big enough to hold all the doses--in fact, in the case of a 31-day take-home supply, all the doses may not fit in the refrigerator even if they are not enclosed in a lock box. Furthermore, the patient and his/her family may not want to explain to guests [who are bound to notice a lock box or even loose take-home bottles] what a lock box or bottles of medication are doing in their refrigerator--never mind the possibility that an untrustworthy guest attempts to steal it.

Perhaps some of the most serious problems could be avoided if the treatment providers would refrain from adding water or juice to liquid formulations of methadone before dispensing take-home doses. Why the manufacturers do not change the product labeling to indicate that dilution is not necessary or desirable when dispensing take-home doses is beyond us. There is no good reason for dilution--patients can prevent medication from sticking to the side of a dosing cup or take-home bottle by adding water to the solution at the time of ingestion or by filling the cup or bottle with water a couple of times after having drank the undiluted solution.

Still, there are good reasons to allow dispensing of methadone in solid form. First, It would make it easier for patients to guard against dosage mistakes. It is far easier for a patient to count wafers than to eyeball a bottle of liquid to determine the dose. Second, the risk of accidental ingestion by a child is somewhat less with solid medication. Solid medication is easier to conceal from children and much less attractive than a colored liquid that resembles juice. Finally, solid medication is more convenient, especially when traveling.

**Medical Maintenance (from p. 4).**

So why haven't more Medical Maintenance programs been created? One factor may paradoxically be a result of the liberalized federal regulations themselves: by providing for monthly take-homes within the clinic setting, the impetus for patients themselves to advocate and lobby for these programs may be lacking. In the case of my clinic, on the other hand, once the decision was made to open a Medical-Maintenance program at the parent agency, the clinic dropped any plan to offer monthly take-homes, since it was felt that this would be an unnecessary duplication of services offered at the Medical Maintenance program. Instead, clinic patients being "groomed" for eventual transfer to that program are first moved up to 13-day take-homes for a period of time.

It's not hard to understand why patients whose clinics provide monthly take-homes might feel so (relatively) liberated that seeking out or trying to advocate for more Medical Maintenance programs may seem like looking a gift horse in the mouth. But such patients should remember that even the best clinics can change policies literally overnight, and even if this doesn't happen, the patient is still left to deal with his status as a second-class citizen, a status inherent in being a clinic patient.

The clinic system creates a notion of methadone as being something uniquely dangerous, even evil and those whose medicine it is as moral lepers. It does so by surrounding the dispensing of methadone with the kinds of procedures which remind one of how radioactive substances have to be handled and by mandating all sorts of "mental health" type "treatment" for patients. Naturally, such a modality is by its very nature expensive, and this is an expense which private clinics are happy to amplify at will but which finds publicly-funded clinics increasingly under fire from taxpayers and politicians. The warning signs are already being sounded for Social Security and other government programs which a contracting economy will inevitably pare down to bare essentials.

The bottom line: to have a decent future, the delivery of MM services is clearly going to have to be streamlined, and a significant role in that process can and should be played by Medical Maintenance. Eventually, clinics are going to have to be part of that process too or be done in by

their own short-sightedness.

\*In this respect, a major shortcoming in the federal regulations is that the states are free to place additional, stricter regulations on methadone treatment. For example, a state may require that all urine tests be monitored. Hopefully, most states will come to accept and generally follow the federal guidelines.

\*\*Although not discussed in this article, the federal regulations require ALL methadone clinics to be accredited by a



CSAT (Center for Substance Abuse Treatment—a government agency) certified accreditator--JCAHO and CARF are the two largest accreditation organizations. Thus, private methadone clinics will also have to generally follow these federal guidelines if they want to remain in business. However, as discussed\*, this does not stop individual states from adopting additional regulations that run counter to federal guidelines.

\*\*\*Also note that some of the current Medical Maintenance and OBOT programs have a policy of random callbacks on an across-the-board basis, making them inferior to programs such as the Medical-Maintenance program the author is on. Random callbacks mean that patients are selected on a random basis to return to the facility prior to their scheduled appointment with the remainder of their take-home medication in order for the staff to make sure that the correct amount of medication is left over--that way, they know whether the patients are abusing or diverting the medication.

The editors of *Methadone Today* believe that such policies are insulting and

unnecessary. The only patients who are even eligible for Medical-Maintenance or OBOT are those who have been in treatment and stable for a long time and have repeatedly proven themselves to be responsible and trustworthy when it comes to handling take-home medication. A policy of random callbacks defeats the whole purpose of Medical-Maintenance, especially when it comes to freeing the patient from weekly clinic attendance. Random callbacks effectively tie the patient to the treatment facility, as the patient must **always be prepared** to return to the facility within 24-48 hours of callback notification).

**Medical-Maintenance (from p. 1)**

could probably make more money by simply opening another methadone clinic site or even expanding one of their existing sites to accommodate more patients.

For these reasons, AATOD, an organization that represents methadone treatment, resisted Medical-Maintenance and OBOT for years. When it finally became apparent that the proposed regulations would permit Medical-Maintenance/OBOT, AATOD pressured the policymakers to make eligibility requirements so strict that only a handful of patients would be eligible and to require that Medical Maintenance/OBOT programs be tied to accredited OTPs. In other words, they would have to be tied to or owned by a methadone clinic. Otherwise, a prospective Medical Maintenance/OBOT provider would have to BECOME an accredited OTP. It would be way too costly for such a provider to obtain accreditation, so this meant that methadone clinics would run the show.

While policymakers did not follow the patient eligibility requirements proposed by AATOD, they did basically tie Medical Maintenance/OBOT to OTPs. This is one of the most disappointing parts of the current federal regulations.

If policymakers are truly interested in expanding Medical Maintenance/OBOT, they need to amend the federal regulations to make it easier to open and operate such programs without being tied to a methadone clinic/OTP. One option is to regulate such programs in the same manner as buprenorphine treatment providers are regulated now. The only difference would be the patient eligibility requirements; only long-term, stable methadone patients are eligible for Medical Maintenance.

Finally, Medical Maintenance/OBOT doesn't exist in many states because state regulations don't permit it. Advocates must pressure states to amend their laws to allow Medical Maintenance and OBOT.

**Medical Maintenance (from p. 1).**

business as usual. Some states have updated their own regulations to dovetail with the federal regulations and, to their credit, have championed the availability of OBOT and Medical-Maintenance. This article looks at the status of OBOT and Medical Maintenance today and examines what factors encourage or discourage these modalities.

One federal official wrote in answer to my questions about OBOT and Medical-Maintenance that nationally there are about 1,109 opioid treatment programs with an average of three new ones applying for approval each month. By contrast, he told me that there are "about ten or fewer" (*ten!*) Medical-Maintenance programs.\*\*\* Seven of these are located in New York State; five are in New York City, one is in Rochester and the other is my own program in Albany. To my knowledge, one of the three (or fewer!) other Medical-Maintenance programs is in Baltimore, and one is in the process of opening in San Francisco after the initial attempt at starting such a program ended in a fiasco of the designed-to-fail variety, having nothing to do with the patients. I was also informed that these ten (or fewer!) programs had a patient population of roughly 850.

As for OBOT, growth of such programs was, he said, "very moderate"; from what I've been hearing from my contacts around the country, that's a very bureaucratic way of saying: virtually nil--at least as far as OBOT *for methadone* is concerned! There is no shortage of doctors lining up to get in on the big Buprenorphine promotion, however. But the lack of OBOT availability for MM patients and the role of Buprenorphine in this is a topic for another day. . . .

There are about 200,000 patients in this country's MMTPs, with waiting lists at many clinics and nothing but increased demand for "treatment slots" for the foreseeable future. In light of the large number of people waiting--sometimes for a year or more--to get into a clinic, it is totally absurd that today there are such a tiny number of Medical-Maintenance programs and that such a minuscule percentage of the total clinic population has "graduated" to Medical-Maintenance's far less restrictive and far less costly regimen. For example, while Medicaid pays clinics in New York State \$130 per week per patient regardless of whether a patient goes to his clinic daily, weekly or every two weeks, it pays that same amount *monthly* for a patient in the Medical-Maintenance program; that is 75% cheaper. Our program, which currently has about 12 patients, is certified for a maximum of 30 patients and will soon be filled to capacity--after which the program is likely to request [and get] a waiver allowing it to accept more patients.

It's clear enough that New York State has one of the

largest populations of opiate-dependent persons in the country and that this has created such a great demand for "treatment slots" at clinics that there have often been long waiting lists. This results in motivation for clinics to explore every way possible to make slots available--and moving long-stabilized, compliant and trustworthy patients out of the clinics and into Medical Maintenance is such a common sense solution to the problem that clinics will actually work to create Medical Maintenance programs either as "sister" facilities allied with their clinics or as part of the same parent agency. This is what happened at my clinic, which at one point had more than 200 people waiting to get on the clinic, with up to a year or more before intake. It was glaringly obvious that there were a considerable number of clinic patients who would meet and exceed all federal requirements for Medical Maintenance, that these patients did not need or want the state-mandated monthly counseling and had long outgrown the need for the restrictive clinic requirements. Had the Medical Maintenance program not been started, there would have been increasing pressure for another provider to open another clinic in our city.

In fact, my Medical Maintenance program is reportedly the first of its kind: that is, it is a program operated as part of a general health clinic (Whitney M. Young Jr Health Center) which also operates a MMTP. Had the MMTP not been an integral part of the health center, it is very unlikely that WMY would ever have been interested in the idea of opening a Medical Maintenance program. Other Medical Maintenance programs are, according to my information, stand-alone programs. It is hoped by many of those who helped make my Medical Maintenance program a reality that it will serve as a model for other Medical Maintenance programs. Certainly such a model has a lot to recommend it:

1. It helps to mainstream MMT by placing Medical Maintenance in a setting with other health services. If this integration into a regular medical setting could continue to develop, eventually it could mean an end of the clinic system as we know it--an outcome most of us would love to see!

2. It is a "low-maintenance" service, costing relatively little to operate and consuming far fewer resources than regular MMTPs. For example, each of the patients in my program comes in once a month on a Thursday. The patient load is distributed over the month, with each one-fourth of the Medical Maintenance patients coming in on each Thursday of the month. The actual patient visit takes perhaps ten minutes or less of the doctor's time, less than five minutes of the nurse's time (collecting an unmonitored urine specimen) and no more time at the on-site pharmacy than does the filling of a "regular" prescription. **(Cont. p. 3)**

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