

Comments Re: Docket No. CSAT 001 PROPOSED RULE-MAKING, 42 CFR Part 8

“Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction;
Buprenorphine and Buprenorphine Combination; Approved Opioid Treatment
Medications Use”

Current regulations demand of all patients receiving buprenorphine in OTPs daily attendance for several months followed by rigidly defined criteria for less frequent visits thereafter. In marked contrast, patients receiving buprenorphine outside an OTP setting can receive at the first physician visit a prescription to be filled at any pharmacy for a month’s supply of the medication. **The proposed rule-making change eliminates this arbitrary and unwarranted disparity by providing that precisely the same flexibility will apply to OTPs as has governed “waivered” physicians for several years; it is to be welcomed!**

The proposed regulatory change, however, is exceedingly narrow in scope, focusing exclusively on the administration, dispensing and prescribing of buprenorphine. In stressing that buprenorphine providers and patients in OTPs shall be obliged to “adhere to all other Federal treatment standards established for methadone” the proposed rule-making notice calls attention to these “other standards,” and they demand comment. To say they are extraordinary would be an understatement; they would appear to be unique in American medicine. For example:

- It is demanded that treatment be denied to all those seeking maintenance with methadone, and those seeking buprenorphine maintenance from OTPs – **but not from individual practitioners** – if they did not “become addicted at least one year before admission . . .” or, if under 18 years of age, they can not prove “. . . two documented unsuccessful attempts at short-term detoxification or drug-free treatment within a 12-month period . . .”;
- applicants seeking detoxification with methadone, or with buprenorphine from OTPs – **but not from individual practitioners** – must be denied such treatment if they have had two detoxification episodes during the past year;
- for all methadone patients and for those receiving buprenorphine from OTPs - **but not from individual practitioners** – availability on-site or through a “formal documented agreement” is required for all of the following: “adequate medical, counseling, vocational, education and other assessment and treatment services”;
- for all methadone patients and for those receiving buprenorphine from OTPs - **but not from individual practitioners** – a “full medical examination, including the results of serology and other tests . . .” must be completed within 14 days after admission;
- for all methadone patients and for those receiving buprenorphine from OTPs - **but not from individual practitioners** – providers must document that assessment has been made “. . . initially and periodically by qualified personnel to determine the most appropriate combination of services and treatment . . .”;
- for all methadone patients and for those receiving buprenorphine from OTPs - **but not from individual practitioners** – providers must document “. . . the

patient's requirements for education, vocational rehabilitation, and employment; and the medical, psychosocial, economic, legal or other supportive services that a patient needs . . . [and] identify the frequency with which these services are to be provided . . . “;

- for all methadone patients and for those receiving buprenorphine from OTPs - **but not from individual practitioners** – providers are required to give “adequate substance abuse counseling to each patient as clinically necessary . . . by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients . . . “;
- for all methadone patients and for those receiving buprenorphine from OTPs - **but not from individual practitioners** – there is an obligation for “adequate testing or analysis for drugs of abuse, including at least 8 random drug abuse tests per year . . . “;
- for all methadone patients and for those receiving buprenorphine from OTPs - **but not from individual practitioners** – providers “must maintain current procedures adequate to identify the theft or diversion of take-home medications . . . [and] must ensure that take-home supplies are packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers . . . “.

The disparities in what is demanded of patients with the identical medical condition and, in the case of buprenorphine, receiving the identical medication, based solely on the treatment setting, are inexplicable on any clinical basis. It should be anticipated,

however, that some observers might conclude that the answer to the riddle lies in the ethnic and socioeconomic characteristics of the patients. Thus, in an evaluation report by SAMHSA/CSAT in mid-2005 it was stated that of buprenorphine patients treated by waived physicians 92% (!) were white, compared to 53% of a sample of methadone patients, who by law can only be treated in OTPs.(1) In fact, the contrast is far greater in most parts of the country; for example, in New York State in mid-2009 only 29% of patients in OTPs were white.(2) In addition to the striking ethnic imbalance, the 2005 SAMHSA/CSAT evaluation reported 50% of buprenorphine patients cared for by unaffiliated physicians were employed full-time and 56% had “some post-secondary education”; among methadone patients 29% were full-time employed and only 18% had post-secondary education. (1) (A followup evaluation by SAMHSA/CSAT one year later provided no data regarding ethnicity, employment or education.(3))

The vastly more stringent demands on patients who are disproportionately non-white, unemployed and with considerably less formal schooling might be characterized by some as discrimination based on racial and socioeconomic profiling. Indeed, one would be hard-put to dismiss out of hand the possibility that Government regulators, consciously or unconsciously, deem these patients as a group to be untrustworthy and dishonest (and thus, for example, requiring at least 8 toxicology tests annually); and so in need of “counseling” and a host of “supportive services” that without their availability they are to be refused the help that opiate agonists might offer! The mere possibility that such a rationale might explain the gross regulatory disparities would reinforce the

enormous stigma that already is associated with OTPs and their patients, even among treatment providers themselves.

Whatever might underlie the current regulatory demands on addiction treatment in OTPs, the consequences are staggering. Many who desperately want and need help must be turned away because of “eligibility” criteria and the costs associated with mandated provision of services that may or may not be needed or wanted. Those who do get admitted are made painfully aware of the highly pejorative, stereotyped, manner in which they are perceived by regulators – and thus, inevitably, by clinical staff and the community as a whole.

Of course, there is more than one way to eliminate disparities, and a disturbing possibility is that the regulatory burdens currently imposed on OTPs would be placed on those giving and receiving care in the offices of unaffiliated clinicians as well. A hopeful indication that this approach will **not** be considered is the current proposed change, which would make buprenorphine in OTPs available on the same terms as apply to addiction treatment in individual practice settings, and not the other way around. In any event, it is imperative that SAMHSA/CSAT take the logical next step, which is to eliminate all discrimination on the basis of the setting in which treatment is delivered - and, by extension, the racial and socioeconomic characteristics of the patients.

Rules and regulations that are unique in the field of medicine, add significantly to cost, stigmatize patients, and create barriers to giving and receiving potentially life-saving

care should be eliminated, not extended! Only this option is consistent with the needs and the rights of those needing treatment, as well as the interests of the general society which ultimately suffers the consequences of bureaucratic hurdles that discourage both providers and recipients of desperately needed medical care.

Thank you for your consideration.

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2. New York State Office of Alcoholism and Substance Abuse Services. *Data Warehouse*, July, 2009

3. Stanton A, McLeod C, Luckey B, Kissin WB, Sonnefeld LJ. SAMHSA/CSAT Evaluation of the Buprenorphine Waiver Program. Expanding Treatment of Opioid Dependence: Initial Physician and Patient Experiences with the Adoption of Buprenorphine. Presented at American Society of Addiction Medicine, May 5, 2006. Accessed at http://buprenorphine.samhsa.gov/ASAM_06_Final_Results.pdf August 10, 2009