THE NATIONAL ALLIANCE OF ADVOCATES FOR BUPRENORPHINE TREATMENT
— naabt.org —

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Docket No. CSAT 001 NAABT

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"

Since 2003 Buprenorphine has been shown to be an effective and exceptionally safe treatment for opioid addiction with remarkably little abuse liability. Increasing availability of this lifesaving treatment is a positive step forward. The proposed rule will help ease the financial and staffing burden incurred with the unnecessary daily supervised administration of buprenorphine at OTPs. This may allow OTPs to increase their patient capacity to match the community's needs.

The highly regulated environment of the OTP has been effective at protecting the public from diverted schedule II opioid medications (methadone) By far the vast majority of methadone related death or injury occur from methadone prescribed for pain, not from OTPs. Although necessary, the intense regulation adds to the cost of providing the treatment. Buprenorphine a schedule III opioid drug (schedule V prior to Oct. 2002) may not need such intense and expensive regulation as potential diversion is significantly less risk to public health. So in addition to normalizing the dispensing schedule, reform of other regulations intended for methadone should also be adjusted to reflect buprenorphine's safer profile.

Effective treatment for opioid addiction has been out of reach for many because of unprecedented restrictive regulation not seen anywhere else in medicine. Besides the highly regulated environment of the OTP, physicians must be specially certified and limited to how many patients they can treat. Although virtually all 700,000 of US physicians can prescribe the opioid drugs people become addicted to, once addicted less than 3 % can prescribe the safer treatment for addiction, and those few who can are further restricted with patient caps forcing an unnecessary rationing of healthcare.

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We welcome any additional access to effective and safe addiction treatment from OTPs. However, in areas where there are no OTPs physicians are restricted by an arbitrary patient cap on how many patients they can save regardless of how many are actually in need in their community. Since it makes perfect sense for OTPs to match their care capacity to the needs of the community, physicians should be able help those in need in areas without OTPs. Currently the policy is- if the addicted population in a given community exceeds 100 per certified physician, the remainder are to be left untreated, or are forced to seek inferior, possibly dangerous, treatment options.

Logic would dictate that anyone who can prescribe the opioids drugs people become addicted to should not be prohibited by law to treat any resulting addiction disorders with the safer treatment medication. However, that is the policy, if a non-certified physician (97%) discovers that their patient has developed an addiction to the opioid medication he/she is prescribing, the physician cannot, by law, continue the opioid medication nor begin treating the addiction with any of the opioid medications currently approved for the treatment of opioid addiction.

Based in stigma, an irrational fear of “pill mills” was the impetus for the patient caps. Apparently lawmakers interpreted excessive need for care as a negative consequence. In practice it has become a barrier to treatment in areas disproportionately affected by opioid addiction. We’ve been contacted by parents who have bought diverted buprenorphine illegally for their child until legitimate treatment could be procured. There is no reason to continue this arbitrary rationing of lifesaving addiction treatment and the 100 patient cap should be removed. Lawmakers may have anticipated current circumstances as they included provisions in DATA-2000 for the Secretary to change the limit by regulation.

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