

Testimony Before House Committee on Human Services

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There are three conditions under which Prior Authorization must be obtained for buprenorphine prescription.

1. **Doses in excess of 16mg:** This restriction applies solely to prescribers who are practicing in an office or clinic other than a federally designated opioid treatment center, or 'hub', where the limit is 24mg. All prescribers are required to take the same course to obtain a waiver for prescribing buprenorphine, and all prescribers are subject to the same supervision by the DEA. The FDA regulations state that "*doses above 24 milligrams have not been shown to be clinically effective*" but there are no federal restrictions on doses between 16 and 24mg. It is not appropriate to regulate the dose prescription of buprenorphine **solely on the basis of where the prescriber is working**. The Prior Authorization limit should be raised to 24mg for all practitioners.
2. **Prescriptions of buprenorphine only formulations:** Misuse of all controlled substances, as well as of several non-controlled substances occurs throughout our community. This includes both buprenorphine and buprenorphine/naloxone preparations. It is the obligation of any practitioners who prescribes substances of potential misuse to be vigilant in minimizing this risk, and it is an obligation that all practitioners take very seriously. Many of these substances do not require prior authorizations, for example, full opioid agonists and stimulants. As our experiment with prohibition demonstrated many years ago, it is not possible by regulatory efforts substantially to impact the misuse of potentially addictive substances. Misuse occurs with both buprenorphine and buprenorphine/naloxone products. The most common misuse is for people to share or sell their medication. Sharing of medication of all varieties is a universal phenomenon, not restricted to potentially addictive substances. People share antibiotics, acid reducing medications, antidepressants, and virtually any medication for which prescription is required. The other misuse is to inject buprenorphine. There are several reasons for doing this, including avoidance of the bitter taste of the medication, as well as a way of reducing costs. The equivalent dose of buprenorphine by injection is approximately one half that by the sublingual route. In my experience, it is exceedingly uncommon, however, for people to use buprenorphine products for their euphorogenic potential. There are two reasons for this. The first is that injection of buprenorphine by a person who has been using a full agonist such as heroin or fentanyl, will precipitate acute withdrawal, which is exceedingly unpleasant. The second is that when it comes to euphoria there are, unfortunately, much better and cheaper products available, and neither heroin nor fentanyl are subject to Prior Authorization. I hardly need remind the committee that it is these products, not buprenorphine, that are responsible for our epidemic of opioid overdose. I know of no evidence that requiring Prior Authorization for buprenorphine only products has any effect on reducing misuse. Recognizing that there naloxone can produce undesirable side effects in some people, the Sta approves the vast majority of buprenorphine only applications. The last Legislative Report states that of the applications for buprenorphine only pills, over four-fifths were approved. Prior Authorization should no longer be required for buprenorphine only preparations.
3. **Annual Renewal of Prior Authorization:** This is both the least useful and the most burdensome restriction to those being treated with buprenorphine. Opioid use disorder is a chronic illness, and its treatment with buprenorphine is intended to be long-term. In this respect it is no different than treatment of other chronic illnesses like hypertension or diabetes. To require annual approval of the treatment dose makes no clinical sense, but more importantly, it can be a major source of discomfort and stress for those in treatment, when they go to their pharmacy in the evening or on a holiday and discover that their prescription refill, which had been filled just two weeks ago, cannot be filled, because the prior authorization has expired. They must then notify their prescriber, who then has to reapply, and that reapplication must be approved, and the pharmacy must then resubmit the prescription. These multiple steps often mean delaying the refill until the next day, risking the

precipitation of withdrawal. I have never had a Prior Authorization for renewal denied. This restriction creates unnecessary hardship for all involved and should be removed.

Beach Conger M.D. Curriculum Vitae

Medical School: Harvard Medical School, 1967

Residency: Internal Medicine Harvard Service Boston City Hospital and University of California San Francisco Medical Center, 1967-1969, 1971-1972

Uniformed Services: Epidemic Intelligence Service Center for Disease Control 1969-1971

Employment:

Medical Consult Methadone Maintenance Program San Francisco 1971-1972

Director and Founder Community Health Center San Francisco 1972-1977

Internist Mount Ascutney Hospital: 1977-2002, 2006-2015

Chief Hospital Medicine Temple University Hospital 2002-2006

Internist Community Health Centers of Burlington 2010-present

Buprenorphine waiver- 2015