October 31, 2013

Roger L. Williams, MD
Chief Executive Officer
U.S. Pharmacopeial Convention
12601 Twinbrook Parkway
Rockville, MD 20852

Dear Dr. Williams,

Thank you for the opportunity to comment on the US Pharmacopeial Convention's (USP) Medicare Model Guidelines (v6.0). Specifically, the American Academy of Addiction Psychiatrists (AAAP), the American Osteopathic Academy of Addiction Medicine (AOAAM), and the American Society of Addiction Medicine (ASAM) would like to comment on the drugs that are included in the "Anti-Addiction/Substance Abuse Treatment Agents" category.

Currently, this category includes 4 classes: alcohol deterrent/anti-craving therapies, opioid dependence treatments, opioid reversal agents and tobacco cessation agents. We are grateful that all of the FDA drugs approved for the treatment of nicotine, alcohol and opioid addiction are included under this category.[i] However, we believe that some of the classes are overly broad and should be subdivided to reflect the different pharmacologic properties inherent in the included drugs. Specifically, we recommend that the USP Guidelines include eight classes of "Anti-Addiction/Substance Abuse Treatment Agents" as illustrated below:

USP Category	USP Class	Example Drugs
Anti-Addiction/Substance Abuse Treatment Agents	alcohol deterrent/anti-craving, long-acting	Extended-Release Injectable Naltrexone
	alcohol deterrent/anti-craving, short-acting	Acamprosate Disulfuram Oral Naltrexone
	opioid dependence partial agonists	Buprenorphine Buprenorphine/Naloxone
	opioid dependence antagonists, long-acting	Extended-Release Injectable Naltrexone
	opioid dependence antagonists, short-acting	Oral Naltrexone
	opioid reversal agents	Naloxone
	tobacco cessation agents, long-acting	Bupropion SR
	tobacco cessation agents, short-acting	Bupropion IR Nicotine Varenicline

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As you can see in the table above, we recommend further dividing the classes currently called "alcohol deterrent/anti-craving," "opioid dependence treatments," and tobacco cessation agents" into separate classes, one each for short-acting therapies and one each for long-acting therapies. Furthermore, we recommend that the "opioid dependence treatment" classes be subdivided into "opioid dependence partial agonists" and "opioid dependence antagonists." The rationale for these recommended changes are tri-fold:

1. Short-acting and long-acting anti-addiction medications have different therapeutic uses in the treatment of alcohol, opioid and/or tobacco dependence and, therefore, require distinct classification from one another. We ask that the revised formulary reflect the distinct classes in a manner consistent with the separation of short and long-acting opioid analgesics.
2. Similarly, opioid dependence medications, while all acting directly upon the opioid receptors, do so via different mechanisms. For example, buprenorphine is a partial mu-receptor agonist and naltrexone is a full antagonist. Because of the very different actions of these medications at the receptor level, they can have very different clinical effects during treatment and, consequently, are often prescribed for different clinical indications and per individual patient needs. For example, pregnant women managing opioid addiction can only be prescribed the single formulation buprenorphine. Conversely, some licensed professionals undergoing treatment may only be allowed to use a non-agonist like naltrexone, if they wish to continue working while undergoing treatment.
3. It has been proposed that the USP Guidelines be used as a "benchmark" formulary for prescription drug coverage offered by qualified health plans regulated by the Affordable Care Act. Per the regulations governing the implementation of these prescription drug benefits, qualified health plans need only provide coverage for one drug in each class included in the formulary. Grouping short-acting and long-acting addiction deterrent/anti-craving drugs into the same respective classes could result in a de facto exclusion of one class over another.

Finally, there are many "anti-addiction" drugs that are commonly used as detoxification adjuncts in the treatment of alcohol and/or opioid dependence (examples include, clonidine, gabapentin, trazodone, zolpidem, odansetron and topiramate), even though they are not clinically indicated for that reason. We encourage the USP to consider the extent to which these drugs are used by addiction physician specialists as detoxification therapies and the evidence that exists to point to their clinical effectiveness as such.

Our work is guided by our collective mission to increase access to high quality addiction treatment, including life-saving alcohol, tobacco and opioid addiction pharmacotherapies. Addiction medications are but a few of the treatment modalities used by addiction treatment providers but, for many patients, they are essential to relapse and overdose prevention. As with all chronic diseases, addiction patients require long-term treatment that often changes over time, as their treatment needs change. It is essential that these patients have access to the full continuum of addiction treatment therapies, including all of the medications approved by the FDA for the treatment of alcohol, tobacco and opioid dependence.

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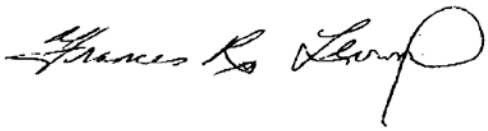
In closing, we again thank the USP for this opportunity to comment on the Medicare Model Guidelines. We look forward to working with you as you finalize this important guideline and develop updated versions in the future.

Sincerely,



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[i] In response to a September 2013 ASAM communication to USP regarding the omission of methadone to treat opioid dependence from the USP draft formulary, USP informed ASAM that it cannot include methadone to treat opioid dependence on the model formulary since it is not considered a Medicare Part D drug.