American Society of Addiction Medicine

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Treat Addiction ● Save Lives

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April 2, 2012

Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244

RE: CMS–2345–P

Dear Ms. Tavenner:

The American Society of Addiction Medicine (ASAM) is pleased to have the opportunity to comment on provisions in the Covered Outpatient Drugs in the Medicaid Program Proposed Rule (CMS-2345-P).

Established in 1954, ASAM has nearly 3,000 members and chapters that cover 42 states. Our members specialize in the treatment of addiction and practice in a wide range of primary care and specialty care settings. As such, we feel uniquely qualified to comment on the provisions of the proposed rule that affect drugs with the potential for abuse.

We respectfully recommend CMS exclude existing or future reformulated products incorporating an abuse deterrent technology from the additional rebate formulate under the Affordable Care Act. Furthermore, we ask CMS to ensure medications intended for the treatment of addiction (such as Buprenorphine) are not subject to the additional rebate.

The last two decades have seen dramatic increases in the use of and addiction to potentially addictive pharmaceuticals. The diversion of prescription drugs from the person to whom they were originally prescribed, and the non-medical, sometimes lethal use of these drugs, are components of our nation's overall drug problem, and they are of special concern to physicians. Although the non-medical use of prescription drugs is not a new phenomenon, increases in cases of diversion, misuse, and overdose deaths have been striking and have drawn the attention of public health officials, regulatory agencies, and public policy makers on the state and national level. Notable among the proposed responses to

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these problems is the published strategy of the White House Office of National Drug Control Policy, addressing educational, rehabilitative and disciplinary approaches to the problem it discusses under the term "prescription drug abuse."

Two of the most commonly misused classes of prescription medications are opioid analgesics and sedative hypnotics, both of which are considered "controlled substances" in that they appear in schedules for pharmaceuticals under the federal Controlled Substance Act. According to the Centers for Disease Control and Prevention, the number of opioid analgesic prescriptions filled at pharmacies has increased from 175 million in 2000 to 254 million in 2009.

The time-released characteristics of opioids are compromised when crushed or dissolved resulting in the full potency of the drug being released all at once, and studies have shown that drug abusers tend to crush or otherwise break down time-released products into a form that can be snorted or injected for a more intense high. As such, manufacturers should be encouraged to re-formulate their products to make them harder to abuse. Imposing an additional rebate on manufacturers for products re-formulated to decrease the likelihood of abuse could discourage manufacturers from incorporating anti-abuse technologies into their products, thereby resulting in a missed opportunity for addressing an aspect of the prescription drug abuse epidemic.

We also ask CMS to ensure pharmacotherapies approved by the Food and Drug Administration (FDA) to treat addiction are not inadvertently subject to a higher rebate, which could further discourage manufacturers from investing in the development of medications to treat addiction. Unfortunately, because of a combination of factors including insurance discrimination, stigma and lack of a stable market for addiction pharmacotherapies, there are fewer available medications to treat addiction today than there are for other chronic illnesses we see in primary care. For example, today, 235 new medications are currently in development to treat diabetes and related conditions. For HIV infected patients, compared to 1990 when there was one medication, there are now more than 20. In 1990 there were 3 medications to treat addictive disorders, today there are five. That is an improvement but the rate of improvement is nowhere comparable to the need and an additional rebate could further depress this market.

Again, ASAM thanks CMS for the opportunity to submit comments regarding this important issue. We look forward to a continued collaboration with the Centers for Medicare and Medicaid Services on advances in and increased access to alcohol and drug addiction treatment.

Sincerely,

Stuart Gitlow, MD, MBA, MPH, FAPA

Acting President, American Society of Addiction Medicine