May 19, 2016

The Honorable Cliff Rosenberger
Speaker of the House
Ohio House of Representatives
77 S. High Street, 14th Floor
Columbus, OH 43215

RE: Sub. H. B. No. 248

Dear Speaker Rosenberger:

The Academy of Managed Care Pharmacy (AMCP) believes that abuse-deterrent opioid analgesic drug products should be used in a clinically appropriate manner; however, we are opposed to Sub. H. B. No. 248 as it requires special consideration for this class of drugs.

AMCP is a national professional association of pharmacists and other health care practitioners including 265 members in Ohio who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's nearly 8,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

Opioid analgesic drug products have proven to be very effective in controlling short and long-term pain due to a variety of medical conditions. These drugs are also the most commonly abused medications in the United States, and have reached epidemic levels of abuse. AMCP is deeply concerned with both the proper management of patients suffering from uncontrolled pain, as well as limiting abuse and diversion of opioids because the improper use of opioids carries enormous costs to society that go beyond traditional healthcare costs.

Managed care pharmacists work with patients and other health care professionals to ensure the appropriate use of opioids and that these drugs are dispensed and utilized for legitimate medical reasons. Therefore, AMCP supports the ability of health plans, managed care organizations (MCOs), and pharmacy benefit managers (PBMs) to use managed care tools to effectively manage the use of opioids in a clinically appropriate manner.

Promising advancements in technology have resulted in the further development of "tamper resistant" or "abuse-deterrent" formulations of certain opioids. This has served as another strategy in combating abuse and diversion. These formulations are designed to make it more difficult for abusers to crush, chew, snort, or inject the products, a common practice by individuals who abuse these products. It is important to note that while there is no such thing as a *tamper-proof* product, there is a limited, and increasing, field of research suggesting that these products have the potential to reduce the overall rates of abuse and diversion.

There is also empirical data indicating these products have a "reduced street value" due to the difficulty of converting them into an abusable product. However, there is insufficient evidence about the efficacy in deterrence and the prevention of abuse. AMCP supports expanding the ability of health plans to manage these products, since these products may vary in their clinical effectiveness and ability to limit abuse potential.

Sub. H. B. No. 248 would require access to abuse deterrent opioid analgesic drugs products coupled with the requirements that prior authorization and utilization review requirements have to be the same for an opioid analgesic drug product. Although the bill states that it does not prevent the use of prior authorization or utilization management it defines and restricts those processes. Those requirements limit the health plan's and PBM's ability to use these proven and effective managed care tools with insufficient data concerning actual benefit in reducing abuse and misuse. Unfortunately, mandating coverage will deter the effective use of these drugs, which would be detrimental to patients and health benefit programs for the following reasons:

- current data on the public health impact of abuse-deterrent formulations is limited because of their newness in the marketplace;
- these new formulations are priced up to ten times the cost of generic drugs;
- early studies have shown that the there is a subset of the population that is more likely at risk for abuse[1] who may benefit from these formulations; however not every patient prescribed an opioid needs an abuse-deterrent formulation; For example, a patient's environment and overall situation can be a factor. Often times, it isn't just a patient abusing these products; it is their spouses, children, or other relatives. Teen access to opioids is a particularly challenging problem and a common gateway to addiction. Patients need to be educated on the proper disposal of these drugs when they are no longer in use; and
- this legislation does not address the need to educate patients and prescribers on issues surrounding opioid abuse.

Post-marketing studies have not yet determined whether opioids with abuse-deterrent properties effectively curb the misuse or abuse of opioids. Mandating coverage requirements may not result in lowering the incidence of misuse or abuse of opioids and could potentially result in higher overall medication costs for public and private payers with no benefit for at-risk patients. Thus, the better course of action at this time is to allow health plans to continue to work with patients and providers to determine the appropriate opioid or other agent for the patient's condition.

We respectfully urge you to vote against passage of this legislation. We appreciate the opportunity to share our views on Sub. H. B. No. 248. If you have any additional questions, you may contact AMCP's local advocacy leader, Mark Hopman, RPh, MBA at (513)659-8158 or hopman_mark@hotmail.com, or you may contact AMCP's Director of Legislative Affairs, Reginia Benjamin, at (703)683-8416 or rbenjamin@amcp.org.

Sincerely,

Susan A. Cantrell, RPh, CAE
Chief Executive Officer

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[1] Addressing the Evolution of the Epidemic. National Prescription Drug Abuse Prevention Strategy. March 26, 2015
http://aspe.hhs.gov/sp/reports/2015/OpioidInitiative/ib_OpioidInitiative.pdf