May 4, 2016

The Honorable Anne Gonzales
Chair of the Ohio House Health Committee
Ohio House of Representatives
77 S. High Street
Columbus, OH 43215

Dear Chairwomen Gonzales,

On behalf of the Ohio Association of Health Plans (OAHP), I would like to thank you for the opportunity to provide written comments on House Bill 248 (HB 248), legislation mandating access to abuse deterrent formulations (ADF) for opioids and restricting utilization management tools used by health plans today that ensure appropriate, safe and cost effective opioid prescribing.

OAHP is the leading state trade association representing the health insurance industry. OAHP members provide health benefits to more than 9 million Ohioans through employer-sponsored coverage, the individual insurance market, and public programs such as Medicare, Medicaid and the Health Insurance Exchange marketplace. Our members offer a broad range of health insurance products in the commercial marketplace and are committed partners in public programs.

The nation's opiate epidemic is a crisis of unparalleled proportions. Today I write to publicly express our appreciation to Representatives Sprague and Antonio for their continued commitment, leadership and vigorous work to create public policy tools to help make inroads in the fight against the prescription drug and heroin crisis in Ohio. The health insurance industry is committed to continuing to innovate and utilize nationally recognized tools and guidelines that will continue to combat the opioid epidemic crisis that has directly and indirectly impacted so many Ohioans.

Abuse deterrent formulations (ADF) for opioids have recently surfaced in a number of state policy discussions as being the solution to the opiate problem. Health plans recognize the important role ADFs play today -- when utilization is based on an individual basis -- in combating the opioid abuse crisis. Generally, ADFs are prescribed to individuals that:

- Might abuse or be predisposed to abuse or
- Are in contact with someone, such as a child or babysitter, who is an abuser or is predisposed to abuse.

Thus it is important that an individual's specific situation be assessed when determining whether and how an ADF should play a role for that particular individual to treat pain.

On October 14, 2015, OAHP testified before this Committee in opposition to HB 248. The basis for that testimony was:

1. ADFs do not prevent abuse or overdose.
2. ADFs can lead to unintended harmful consequences.
3. HB 248 restricts the use of pharmacy benefit tools that are in place to help combat opioid misuse.
4. HB 248 will increase costs for Ohio's purchasers of health care coverage.
5. HB 248's restrictions on formulary management tools will raise costs to patients.

Since this testimony, Representatives Sprague and Antonio have worked extensively with the stakeholders, including OAHP, to address a number of the concerns identified. A number of changes that were made to the substitute version of the bill were made specifically to address a key concern raised by OAHP in that October 2015 testimony. Those include:

- Revising the original bill's mandate of coverage of all ADFs to mandating access to ADFs.
- Eliminating the cost parity requirements between ADFs and non-ADFs.

Both of these changes recognize that: (1) ADFs are much more expensive than non-ADFs and (2) the bill's original language mandating coverage and cost parity would have created an unintended consequence of guaranteed market share and profits for the pharmaceutical companies that have a FDA approved ADF.

OAHP appreciates the work that has been done to date, and I cannot overstate the amount of time and effort that has gone into the changes reflected in the substitute bill that is pending before this Committee. However, despite these significant improvements, *OAHP remains concerned with the provisions in the bill that would restrict a health plans ability to use utilization review measures, including prior authorization and step therapy, to combat the opioid epidemic.* Specifically, OAHP is concerned that the bill's restrictions fail to recognize the evidence-based clinical guidelines related to prescribing an abuse deterrent formula opioid and the information that prescribing needs to provide when submitting a prior authorization request. To address this concern, OAHP requested an amendment that would clarify the bill's language restricting how a plan may utilize prior authorization (see attached amendment). The proposed

language would make clear that asking additional/different information (patient's history of abuse and/or an individual in close contact with a patient that has a history of abuse) about why treatment with an ADF was prescribed is not in violation of the "no more restrictive" language included in Sections**.** 1751.691 Division (C)(7), 3923.851 Division (C)(7), 5164.091 Division (C)(7)).

OAHP remains committed to working with the bill sponsors, this Committee's members and the Senate to address these concerns. In addition, OAHP remains committed to working with state leaders to further combat this terrible problem and would like to offer the following information to the Committee as this bill and future bills are considered.

Experts have repeatedly suggested that solutions to this crisis needs to be focused on reducing the abuse of opioids and other controlled prescription drugs while ensuring patients with both temporary and chronic pain are safely and effectively treated. This expert advice also aligns with many, of the witnesses that have testified before this Committee on this bill and have indicated that – **DOCTORS ARE STILL PRESCRIBING TOO MANY OPIOIDS**. ***HB 248 will not solve that problem; HB 248 just supports the prescribing of a different type of addictive drug. To that end, OAHP believes meaningful policy solutions can be found in recently issued national guidance.***

As part of the urgent response to the epidemic of overdose deaths, the Centers for Disease Control and Prevention (CDC) recently issued new guidelines for prescribing opioid mediation for chronic pain (excluding cancer, palliative and end-of-life care) that provide national consensus for a non-pharmacologic therapy and non-opioid pharmacologic therapy approach to prescribing for chronic conditions. See http://www.cdc.gov/media/dpk/2016/dpk-opioid-prescription-guidelines.html

The guidelines are intended to improve the way opioids are prescribed through clinical practice guidelines and to ensure patients have access to safer, more effective chronic pain treatment while reducing the number of people who misuse, abuse, or overdose from these drugs. Broadly, there are 12 recommendations in the guidelines with the three following principles key to improving patient care:

(1) Non-opioid therapy is preferred for chronic pain outside of active cancer, palliative, and end-of-life care.
(2) When opioids are used, the lowest possible effective dosage should be prescribed to reduce risks of opioid use disorder and overdose.
(3) Providers should always exercise caution when prescribing opioids and monitor all patients closely.

Many in the health care industry have suggested that these new CDC guidelines are a "game-changer" and, while at this point they are only recommendations, many believe that these will have a significant impact on prescribing patterns/practices of providers. In light of these new

national standards, OAHP recommends aligning opioid-related legislation, including HB 248, to these principals.

It is also important to note that the jury is still out about whether these ADFs are a tool that should be used to combat the current opioid problem. The Food and Drug Administration (FDA) has not made any determination that an ADF opioid is any safer to a patient than an equivalent non-abuse resistant drug. In April of this year, the FDA developed its standards for evaluation of ADFs. The document in its entirety is attached for your review. However, we wanted to highlight a few statements from this FDA guidance:

"The science of abuse deterrence is relatively new, and both the formulation technologies and the analytical, clinical, and statistical methods for evaluating those technologies are rapidly evolving. Based on the evolving nature of the field, FDA intends to take a flexible, adaptive approach to the evaluation and labeling of potentially abuse-deterrent products. Methods for evaluating the abuse-deterrent properties of new molecular entities may have to be adapted based on the characteristics of those products and the anticipated routes of abuse. The development of an abuse-deterrent opioid product should be guided by the need to reduce the abuse known or expected to occur with similar products."

Even the FDA recognizes that these are opioids with *abuse-deterrent properties (*meaningfully ***deter*** abuse); they do not prevent abuse.

Additionally:

> "There are several important concepts about the state of the science of pre- and post-market studies of abuse deterrence that should be considered as these are reflected in labeling. First, as stated earlier in the guidance, abuse-deterrent does not mean abuse-proof. Therefore, labeling should reflect a product's abuse-deterrent properties, as supported by the data, but should include a caveat that abuse is still possible. Next, premarket studies are intended to demonstrate properties that are predictive of a meaningful abuse-deterrent effect for a particular route of administration. FDA has limited data correlating the abuse-deterrent properties of certain opioid drug products, as demonstrated by premarket studies, with the impact of those properties on abuse or adverse events associated with abuse in the post-approval setting. Even though post-market studies have the potential to demonstrate such effects, the findings of post-market studies are not available at the time of initial product approval. Labeling should reflect the predictive quality of premarket studies and include results of relevant completed post-market studies."

Abuse deterrent formulations like OxyContin have been available for some time. While the studies of this drug appear to indicate a reduction in opioid overdoses, early studies also identified 3 phenomena that developed:

(1) A transition from non-oral routes of administration to oral use;

(2) Successful efforts to defeat the ADF mechanism leading to a continuation of inhaled or injected use; and

(3) Exclusive use of the oral route independent of formulation type.

At the same time, one study showed an increase in heroin use in the same community. The studies concluded that while abuse-deterrent formulas may decrease the diversion of opioids, other methods of reducing drug abuse must also be considered. See rates of opioid dispensing and overdose after introduction of abuse-deterrent extended-release oxycodone and withdrawal of propoxyphene. JAMA Intern Med. 2015 Jun;175(6):978-87. Larochelle MR, Zhang F, Ross-Degnan D, Wharam JF. Abuse-Deterrent Formulations and the Prescription Opioid Abuse Epidemic in the United States: Lessons Learned From OxyContin. JAMA Psychiatry. 2015 May;72(5):424-30. Cicero TJ, Ellis MS.

We urge you to thoughtfully consider the revision OAHP has submitted to this bill, this data and the impact this bill will have on Ohio's opioid epidemic. We recognize that we must continue to find sound policy solutions to our state's problem and we stand ready to assist in that regard.

Again, thank you for the opportunity to comment on behalf of OAHP and its member plans.

Sincerely,

Miranda C. Motter

Miranda C. Motter
President and CEO
Ohio Association of Health Plans