JOINT STATEMENT FOR THE HOUSE PROFESSIONAL LICENSURE COMMITTEE

Public Hearing on HB 1635

Amending the Pharmacy Act to Prevent the Substitution of Certain Opioid Drugs

September 18, 2012

The Pennsylvania Department of Health and Pennsylvania Department of State would like to thank Chairwoman Harhart, Chairman Readshaw and the House Professional Licensure Committee, for the opportunity to provide you with a joint statement regarding our agencies' perspective on House Bill 1635, which, if enacted, would amend the Pharmacy Act to prevent the substitution of certain opioid drugs.

In our agencies' review of the bill, we have identified some areas of concern. While the intent of this bill is to prevent the abuse of prescription drugs by limiting a substitution of a tamper-resistant formulation of an opioid for a non-tamper resistant or weaker tamper-resistant technology, the way the current language is written could prevent well-meaning pharmacists from substituting some opioid drugs for a generic drug. Because pharmacists often make substitutions in an effort to ensure that the drugs are more affordable to consumers, the bill. in turn, could be extremely costly to consumers.

The majority of opioids manufactured do not have tamper-resistant technology, and bioequivalent, less

expensive generic drugs have been available for these drugs for many years. Our experience is that the generic formulations are no more abused than brand name formulations.

Long-acting opioids are sometimes abused by crushing the tablet prior to ingesting, which causes an immediate full-release of the medication that was intended to be delivered slowly over time (ie., OxyContin, Opana). As a result, drug manufacturers began incorporating technology in the tablet that, when crushed, or tampered with, causes the drug to be inactivated by a counter drug or it renders the strength no differently than a dose of a standard immediate release tablet. To prevent abuse, the tamper-resistant formulation is generally added to a long-acting opioid or combination drug rather than to single immediate release tablets. There would be little advantage to the strength or deliverable amount of the drug into crushing a single immediate release tablet.

We would suggest changes in the definition of opioid analgesic drug (section 2) and in what is not substitutable (section 9.5 d) to limit the applicability of this bill to tamper-resistant opioid drugs. We will be happy to work with the committee to find agreeable language.

We hope these comments are helpful, as the committee deliberates on this bill. We thank you for the opportunity to provide you with comments on HB 1635.