



June 13, 2016

The Honorable Dana Bumgardner, Chairman  
House Insurance Committee  
North Carolina House of Representatives  
16 W. Jones Street, Room 2119  
Raleigh, NC 27601-1096

RE: House Bill 1048

Dear Representative Bumgardner:

The Academy of Managed Care Pharmacy (AMCP) acknowledges that abuse deterrent opioid analgesic drug products are appropriately prescribed for certain patients, but should not be required by state mandates. For this reason, AMCP opposes House Bill 1048 because it implements a state mandate requiring the use of the abuse deterrent products that may not be necessary for every patient. The legislation limits the ability of health plans to implement prior authorization to determine if an abuse deterrent product is necessary and also mandates requirements for a medical exceptions process that usurps the ability of the plan to manage medication benefits for the patient population served.

AMCP is a national professional association of pharmacists and other health care practitioners including over 120 members in North Carolina 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.

**§ 58-3-295. Coverage for Abuse-Deterrent Opioid Analgesics**

Opioid analgesics have proven to be very effective in controlling short and long-term pain for cancer and other chronic and acute causes of pain associated with surgery, accidents, or other illnesses. However, these medications are also the most commonly abused medications in the United States, reaching epidemic levels.<sup>1</sup> AMCP is deeply concerned both about the proper management of patients suffering from uncontrolled pain, as well as limiting abuse, misuse, and diversion of opioids because of the implications to society and health care costs associated with misuse and abuse. Managed care pharmacists use clinical and scientific evidence to work with patients and other health care professionals to ensure that opioid prescriptions are dispensed for legitimate medical purposes and used appropriately. Post-marketing studies have not yet determined whether opioids with abuse-deterrent properties effectively curb the misuse or abuse of opioids and no product is *tamper proof*. Given the lack of specific evidence available, increasing access and coverage for these products 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. Current data on the public health impact of abuse deterrent formulations is limited because of their newness in the marketplace; these new formulations are also significantly more expensive than generic non-abuse deterrent counterparts.<sup>2</sup>

House Bill 1048 would replace a health benefit plan's ability to determine the appropriate placement of these drugs on a formulary with a government mandate. Notwithstanding the fact that there is little data regarding the actual benefit of abuse deterrent opioids in reducing abuse and misuse, House Bill 1048 would also mandate their coverage and limit the ability of a health benefit plan to use managed care tools such as prior authorization and cost sharing. Given the lack of evidence to establish the ability to limit abuse and the potential to increase health system costs unnecessarily, AMCP supports expanding, not restricting, the ability of health benefit plans to manage these products.

### **§ 58-50-310. Exceptions Process Transparency**

AMCP supports the patients' ability to request a step therapy override determination and to seek reconsideration of a health benefit plan's decision. Therefore, AMCP supports the language in § 58-50-310(a) which permits health benefit plans to continue using their existing medical exceptions processes.

AMCP cannot support the provisions in §§ 58-50-305 (Clinical Review) and 58-50-310(b) (Override Determinations) which would replace a health benefit plan's processes and independent judgement with a government defined and mandated process. AMCP urges you to strike both sections in their entirety.

Section (b) defines five specific exceptions when a health plan must grant an exception. While these serve as examples of circumstances that a health plan may consider in determining whether to grant a request, these circumstances may not be the only considerations for a health plan and may not reflect current clinical and scientific evidence. Health benefit plans have experience evaluating peer-reviewed medical literature to design drug regimens consistent with current scientific, medical, and pharmaceutical treatment evidence and guidelines. To ensure that individuals have continued access to appropriate medication therapy, health benefit plans must retain the flexibility to make judgments regarding the reliability of medical literature when designing the pharmacy benefit. Therefore, AMCP requests that the Committee strike this mandate in its entirety and allow health plans flexibility in managing medications for a patient population.

Recent examples of vetoes of abuse deterrent legislation in other states suggest support for AMCP's rationale about the uncertain evidence of effectiveness of abuse deterrent formulations and potential for unnecessary cost. Similar legislation has been vetoed by New Jersey Governor Chris Christie and New York Governor Andrew Cuomo. In their veto messages, both Governors cited the uncertain benefits of abuse deterrent formulations and high cost of these drugs.

---

<sup>1</sup> McHugh, R. Kathryn, Ph.D et al. "Prescription Drug Abuse: From Epidemiology to Public Policy." *Journal of Substance Abuse Treatment* 48.1 (2015): 1-7. *Journalofsubstanceabusetreatment.com*. Jan. 2015. Web. 1 June 2016.

<[http://www.journalofsubstanceabusetreatment.com/article/S0740-5472\(14\)00187-1/abstract](http://www.journalofsubstanceabusetreatment.com/article/S0740-5472(14)00187-1/abstract)>.

<sup>2</sup> Simon, K., Worthy, S. L., Barnes, M. C., & Tarbell, B. (2015). Abuse-deterrent formulations: transitioning the pharmaceutical market to improve public health and safety. *Therapeutic Advances in Drug Safety*, 6(2), 67–79.

<http://doi.org/10.1177/2042098615569726>

For the reasons presented, we respectfully urge you to vote against House Bill 1048. We appreciate the opportunity to share our views on House Bill 1048. If you have any additional questions you may contact AMCP's Director of Legislative Affairs, Regina Benjamin, at (703) 683-8416 or rbenjamin@amcp.org.

Sincerely,

A handwritten signature in black ink, appearing to read "S. Cantrell", with a long horizontal flourish extending to the right.

Susan A. Cantrell, RPh, CAE  
Chief Executive Officer