



July 27, 2020

The Honorable Vincent Gray, Councilmember
Chairperson, Committee on Health
Council of The District of Columbia
1350 Pennsylvania Avenue, NW
Washington, DC 20004

Via email: vgray@dccouncil.us

RE: Comments in Opposition to B23-0535 the “Opioid Labeling Amendment Act of 2019”

Dear Councilman Gray:

On behalf of our members operating pharmacies throughout the District of Columbia, the National Association of Chain Drug Stores (NACDS) is writing to express concerns with and opposition to the Committee on Health (“Committee”) regarding proposed legislation, DC B23-0535, the “Opioid Labeling Amendment Act of 2019.” Though we strongly agree with the intent of the legislation, NACDS and its member companies are concerned that unique opioid labeling may infringe upon patient privacy during prescription medication pick up at the pharmacy counter and unintentionally disclose confidential information as to what type of medication the patient is taking. Also, any specific, government-mandated, standardized labeling requirements may actually facilitate bad actors’ efforts to divert opioids by drawing attention to the fact that a prescription bottle contains an opioid, and lead to greater opioid diversion. In short, the unique color-coded label could essentially put a “bullseye” on opioids, drugs that are often the target of diversion and abuse.

Additionally, in light of the considerable information that pharmacies are already mandated to provide to patients, both pursuant to federal and District requirements, we are concerned that adding more duplicative patient information requirements to the patient prescription label may lead to other information being omitted from the prescription label given the limited space available on the prescription bottle.^{1, 2}

The federal Drug Enforcement Administration regulates the contents of opioid, and all controlled substance, prescription labels at 21 CFR §1306.14 and 21 CFR § 1306.24. In addition, warnings about addiction, dependence and overdose are already provided to patients as required by the federal Food and Drug Information (FDA). FDA’s drug labeling provisions regulate the written materials that pharmacies provide to patients.

In September 2018, the FDA updated the FDA-mandated Risk Evaluation and Mitigation Strategy (REMS) for opioids that includes a Patient Counseling guide and a Medication Guide (MedGuide) that must be provided to patient who receive opioid prescriptions. The patient counseling guide is available [here](https://www.accessdata.fda.gov/drugsatfda_docs/remss/Opioid_Analgesic_2018_09_18_Patient_Counseling_Guide.pdf) or at this link: https://www.accessdata.fda.gov/drugsatfda_docs/remss/Opioid_Analgesic_2018_09_18_Patient_Counseling_Guide.pdf

¹ <https://code.dccouncil.us/dc/council/code/sections/47-2885.14.html#> (Accessed on June 16, 2020.)

² <http://dcrules.elaws.us/dcmr/22-b1912> (Accessed on June 16, 2020)

Notably, the Opioid Patient Counseling Guide includes the following information:

What are the serious risks of using opioids?

- Opioids have serious risks of addiction and overdose.
- Too much opioid medicine in your body can cause your breathing to stop – which could lead to death. This risk is greater for people taking other medicines that make you feel sleepy or people with sleep apnea.
- Addiction is when you crave drugs (like opioid pain medicines) because they make you feel good in some way. You keep taking the drug even though you know it is not a good idea and bad things are happening to you. Addiction is a brain disease that may require ongoing treatment.

Each opioid medication has its own unique MedGuide; a complete list of all opioids and their MedGuides is available at this link: <https://opioidanalgesicrems.com/RpcUI/products.u>. While each MedGuide may be different, the information provided does advise patients at a high level and in detail about the risks of overdose, dependence, addiction, and death.

NACDS' member pharmacies have a long-standing and ongoing commitment to serving as part of the opioid abuse solution, while caring for those in pain. Examples of their work includes programs to help assure they and their employees comply with regulations; education for patients, communities, parents, and teens; helping to make naloxone – the overdose antidote – available; and many more. As such, chain pharmacies are active partners in helping to address the opioid epidemic. We urge the Council to consider all the educational materials and labeling pharmacies currently use to address this issue, as well as the programs already in place to educate patients about the dangers of opioid use. Though extremely well-intentioned, this legislation may have unintentional adverse effects without a net benefit to the patient.

If you have any questions, please do not hesitate to contact Jill McCormack at jmccormack@nacds.org or 717-525-8962.

Sincerely,

A handwritten signature in black ink, appearing to read "Steven C. Anderson". The signature is fluid and cursive, with a long horizontal stroke at the end.

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer

cc: The Honorable Phil Mendelson, Chairman, DC Council