

## Department of Planning and Budget 2019 Fiscal Impact Statement

1. **Bill Number:** HB2248

**House of Origin**     Introduced     Substitute     Engrossed  
**Second House**     In Committee     Substitute     Enrolled

2. **Patron:** Bell, John J.

3. **Committee:** Health, Welfare and Institutions

4. **Title:** Practice of pharmacy; regulation by Board of Pharmacy.

5. **Summary:** Provides that compounding of drugs provided to the Department of Corrections for the purpose of carrying out an execution by lethal injection shall constitute the practice of pharmacy and be subject to the requirements of the Drug Control Act and the jurisdiction of the Board of Pharmacy. The bill provides that only outsourcing facilities may compound such drugs; currently, both pharmacies and outsourcing facilities may compound such drugs. The bill also clarifies that the Board of Pharmacy may inspect any pharmacy or other place where drugs, cosmetics, or devices are manufactured, stored, or dispensed in response to complaints received by the Board, in any case in which the Board has reason to believe that the pharmacy or other place where drugs, cosmetics, or devices are manufactured, stored, or dispensed has violated any state or federal law, or as otherwise deemed necessary by the Board to protect the health and safety of the public. The bill amends the membership of the Board of Health to include a pharmacist with experiencing in compounding, requires the Board of Health to educate the public about safe use of compounded drugs, and requires the Board of Health and the Board of Pharmacy to report annually to the Governor and the General Assembly on actions taken to (i) ensure the safety and quality of compounded drugs produced by compounding pharmacies and outsourcing facilities located in the Commonwealth and compounding pharmacies and outsourcing facilities located outside the Commonwealth that provide compounded drugs to patients in the Commonwealth; (ii) reduce illegal use of opioids and opioid abuse in the Commonwealth; and (iii) implement provisions of and ensure compliance with the requirements of Title II of the federal Drug Supply Chain Security Act of 2013 related to prescription drug identification, tracing, and verification.

6. **Budget Amendment Necessary:** See item #8.

7. **Fiscal Impact Estimates:** Indeterminate, see item #8.

8. **Fiscal Implications:** This bill would have a fiscal impact on the Commonwealth, however the total impact cannot be determined. The provisions of the bill require the Board of Health to educate the public about the safe use of compounded drugs, and requires the Board of Health and the Board of Pharmacy to report annually to the Governor and the General Assembly. The report shall include actions taken to ensure the safety and quality of

compounded drugs produced, reduce illegal use of opioids and opioid abuse in the Commonwealth, and implement provisions of and ensure compliance with the requirements of Title II of the federal Drug Supply Chain Security Act of 2013 related to prescription drug identification, tracing, and verification.

The Board of Pharmacy cannot determine the amount of time it would take to collect the required data and prepare a report. Depending on the increase in workload, the Board of Pharmacy may need half a position (\$50,000) for data collection and research for the annual report. According to the agency, current revenues are not sufficient to support this position and it is unknown whether the Board of Pharmacy will need additional funding to support a position. Currently, the Board of Pharmacy has identified the need for a fee increase and has proposed regulation that is under review. If approved, these revenues should be sufficient to support this position.

The Board of Health estimates that in order to add a programmatic component to focus on the safe use of compounded drugs to the patient and community health education services offered by the Board of Health, they would need at a minimum half a position (\$50,000) to research, coordinate, produce, and disseminate such information. This position would also be responsible for the reporting requirement for the Board of Health to coordinate information and produce an annual report from multiple stakeholders. The minimal costs associated with producing a report should be able to be absorbed using existing resources. It is unknown the extent of the education requirement on the Board of Health and a fiscal impact cannot be determined.

**9. Specific Agency or Political Subdivisions Affected:** The Department of Health Professions and the Virginia Department of Health.

**10. Technical Amendment Necessary:** No.

**11. Other Comments:** None.