

Department of Planning and Budget

2015 Fiscal Impact Statement

1. Bill Number: HB 1737

House of Origin ☐ Introduced ☐ Substitute ☐ Engrossed
Second House ☐ In Committee ☐ Substitute ☒ Enrolled

2. Patron: Hodges**3. Committee:** Passed Both Houses.**4. Title:** Regulatory framework for facilities that compound drugs for office-based administration.

5. Summary: Outsourcing facilities and nonresident outsourcing facilities and compounding for office-based administration. Creates a new regulatory framework for permitting of outsourcing facilities that compound drugs and are located within the Commonwealth and registering nonresident outsourcing facilities in the Commonwealth.

6. Budget Amendment Necessary: Yes.**7. Fiscal Impact Estimates:** FINAL.**7a. Expenditure Impact:**

<i>Fiscal Year</i>	<i>Dollars</i>	<i>Positions</i>	<i>Fund</i>
2015	-	-	-
2016	120,150	1	Nongeneral
2017	98,900	1	Nongeneral
2018	108,715	1	Nongeneral
2019	93,745	1	Nongeneral
2020	99,240	1	Nongeneral

7b. Revenue Impact:

<i>Fiscal Year</i>	<i>Dollars</i>	<i>Fund</i>
2015	-	-
2016	62,000	Nongeneral
2017	37,300	Nongeneral
2018	38,500	Nongeneral
2019	40,500	Nongeneral
2020	42,500	Nongeneral

- 8. Fiscal Implications:** This bill would have a fiscal impact on the Commonwealth. The increase in expenditures was calculated based on applications from approximately 75 outsourcing facilities. The agency states that the provisions of the bill would require a very specialized inspection, so training of a pharmacy inspector in standards of Good Manufacturing Practices is essential. The Board would rely on an inspection by the FDA for facilities located in other states, but a consultant familiar with the complexities of such an inspection would be employed to review those inspections and applications for a permit in Virginia. The bulk of the cost is for the first year of permitting outsourcing facilities, which would need to be inspected every two years.

All direct and allocated costs relating to licensure of outsourcing facilities by the Board of Pharmacy would be attributed to the budget of that board. Analyzing the data through FY 2020 indicates a fee increase will not be necessary. It is anticipated that fees charged to applicants and renewal fees for outsourcing facilities will cover approximately one third to one half of the projected cost. However, the Administrative Office Specialist position will also cover other work for the Board of Pharmacy, so some of the cost for that position can be attributable to other aspects of licensure and discipline.

It is not anticipated that the Board will require a fee increase through 2020 to absorb additional expenditures relating to licensure of outsourcing facilities.

- 9. Specific Agency or Political Subdivisions Affected:** Department of Health Professions.

- 10. Technical Amendment Necessary:** No.

- 11. Other Comments:** None.