Department of Planning and Budget 2023 Fiscal Impact Statement

1.	Bill Number:	HB1597					
	House of Origin	\boxtimes	Introduced		Substitute		Engrossed

Second House □ In Committee □ Substitute □ Enrolled

2. Patron: Robinson

3. Committee: House Committee on Health, Welfare and Institutions

4. Title: Transition medical cannabis program from Board of Pharmacy to Virginia

Cannabis Control Authority

5. Summary: The proposed bill amends § 4.1-606 (Regulations of the Board) to establish that in determining the number of licenses issued, the Cannabis Control Authority ("CCA") must not consider any license granted pursuant to subsection C of § 4.1-805 to (i) a pharmaceutical processor that has been issued a permit by the CCA pursuant to § 4.1-1602 as established by this legislation or (ii) an industrial hemp processor registered with the Commissioner of Agriculture and Consumer Services pursuant to Chapter 41.1 (§ 3.2-4112 et seq.) of Title 3.2.

In regards to governing licenses, the bill requires the CCA to make reasonable efforts to (i) align its regulations with the applicable regulations formerly promulgated by the Board of Pharmacy that establish health, safety, and security requirements for pharmaceutical processors and cannabis dispensing facilities ad (ii) to deem in compliance with applicable regulations promulgated pursuant to this legislation such pharmaceutical processors and cannabis dispensing facilities that have been found to be in compliance with regulations formerly promulgated by the Board of Pharmacy that mirror or are more extensive in scope than similar regulations.

The bill adds Chapter 16 (Medical Cannabis Program) by transferring oversight and administration of the Commonwealth's medical cannabis program from the Board of Pharmacy to the Virginia Cannabis Control Authority (4.1-1600 through 4.1-1605)

The bill amends § 63.2-1803.01 (Possession or administration of cannabis oil) to establish that assisted living facility staff members who are authorized to possess, distribute, or administer medications to residents in accordance with the facility's written plan for medication management can be permitted to store, dispense, or administer cannabis oil to a resident who has been issued a valid written certification for the use of cannabis oil.

Enactment clause 2 repeals §§ 54.1-3442.5 through 54.1-3442.8) of Chapter 34 of Title 54.1 of the Code of Virginia.

Enactment clause 3 repeals the twenty-first enactment of Chapter 550 and the twenty-first enactment of Chapter 551 of the Acts of Assembly of 2021, Special Session I.

Enactment clause 4 establishes that the Regulations Governing Pharmaceutical Processors (18VAC110-60) as promulgated or amended by the Board of Pharmacy prior to July 1, 2023, shall remain in full force and effect and shall be administered by the CCA) until the CCA Board promulgates regulations to implement the provisions of this legislation, which must model, to the greatest extent practicable, the Regulations Governing Pharmaceutical Processors (18VAC110-60) promulgated by the Board of Pharmacy. With the exception of § 2.2-4031 of the Code of Virginia, neither the provisions of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia) nor public participation guidelines adopted pursuant thereto shall apply to the CCA Board's initial adoption of regulations to implement the provisions of this legislation. The CCA must be vested with all powers and duties held by the Board of Pharmacy prior to July 1, 2023, in its administration of the provisions set forth in § 54.1-3408.3 of the Code of Virginia, as amended by this legislation, Article 4.2 (§§ 54.1-3442.5 through 54.1-3442.8) of Chapter 34 of Title 54.1 of the Code of Virginia, as repealed by this legislation, and any regulations promulgated pursuant thereto.

Enactment 5 establishes that any valid, active permits, certifications, and registrations issued by the Board of Pharmacy pursuant to § 54.1-3408.3 of the Code of Virginia, as amended by this legislation, Article 4.2 (§§ 54.1-3442.5 through 54.1-3442.8) of Chapter 34 of Title 54.1 of the Code of Virginia, as repealed by this legislation, or regulations promulgated pursuant thereto prior to July 1, 2023, must remain valid until their expiration date and be considered to have been issued by the CCA Board.

- **6. Budget Amendment Necessary**: Yes, Item 397 (Nongeneal Fund Appropriation)
- 7. Fiscal Impact Estimates: Preliminary (see Item 8 below)
- **8.** Fiscal Implications: During the 2020 General Assembly Session, the Department of Health Professions ("DHP") received \$204,828 in nongeneral fund appropriation and 2 FTE for the Board of Pharmacy to administer the operations of the five cannabis processors pursuant to SB976 (Chapter 1278). The bill included language providing DHP with emergency regulatory authority for the Board of Pharmacy to increase fees to fund the additional positions. The medical cannabis program ("MCP") is 100 percent nongeneral fund supported through license fees. The license fees, as established under 18VAC110-60-20, are listed in 4 categories: 1) Registration of practitioner, 2) Registration by a qualifying patient, parent, legal guardian, or registered agent, 3) Pharmaceutical processor permit, and 4) Cannabis dispensing facility permit. During the 2022 General Assembly Session, patient registration fees were eliminated (SB671). According to DHP, the agency has the equivalent of 6.75 FTE working on the MCP (3 FTE, 2 wage employees and 2 part-time employees). In addition, DHP used other agency resources from IT, HR, Finance and Procurement departments to support the MCP. If this legislation were to pass, DHP anticipates transferring 4.75 FTE to other Board of Pharmacy duties leaving 2 FTE and associated nongeneral appropriation to transfers over to the Cannabis Control Authority ("CCA").

According to the CCA, the agency anticipates requiring a total of 8 FTE (5 Programmatic FTE's and 3 Enforcement FTE's) to operate the MCP.

Program Personnel	Enforcement Personnel		
3 Program Associates	2 Enforcement Specialist		
1 Program Manager	1 Enforcement Manager		

1 Administrative Assistant	

In addition to personnel costs, the CCA indicates that a seed-to-sale system will be needed to guard against illegal diversion into and out of the MCP and to ensure that tainted/adulterated product can be identified and promptly removed to protect patients. The estimated cost for a seed-to-sale system is \$2,500,000.

The total estimated fiscal impact of this legislation on the CCA is \$3,708,818. However, after factoring in existing appropriation that the CCA has earmarked for the seed-to-sale system and the transfer of two positions and associated funding from DHP, the net fiscal impact in FY 2024 is expected to be \$1,003,990 and 6 FTE (see table below):

Expenditures	FY24
Seed-to-Sale Tracking Software	\$2,500,000
Medical Cannabis Program Licensing	300,000
Software	
Medical Cannabis Program Enforcement	335,002
Personnel (3 FTE)	
Medical Cannabis Program Administration	573,816
(5 FTE)	
Subtotal	\$3,708,818
Less: Existing appropriation earmarked for	2,500,000
seed-to-sale	
Less: Transfer from DHP (2 FTE)	204,828
Net nongeneral fund fiscal impact for	\$1,003,990
CCA	

According to DHP, the MCP nongeneral fund cash balance at the end of FY 2023 is estimated to be \$2.1 million. License fee revenue is renewable annually and with the estimated year end nongeneral fund cash balance in the program, it is anticipated that this estimated balance could be available to support the MCP program at the CCA for FY 2024 and FY 2025 to support the nongeneral fund appropriation required by this legislation

- **9. Specific Agency or Political Subdivisions Affected:** Virginia Cannabis Control Authority and Department of Health Professions Board of Pharmacy
- 10. Technical Amendment Necessary: No

11. Other Comments: None