

**The Florida Senate**  
**BILL ANALYSIS AND FISCAL IMPACT STATEMENT**

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Budget Committee

BILL: SPB 7086  
 INTRODUCER: Budget Committee  
 SUBJECT: Drugs, Devices, and Cosmetics Regulatory Program  
 DATE: February 13, 2012      REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Howard	Rhodes	BC	<b>Pre-meeting</b>
2.	_____	_____	_____	_____
3.	_____	_____	_____	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

**I. Summary:**

Chapter 2010-161, Laws of Florida, transferred the Drugs, Devices, and Cosmetics Regulatory Program (DDC) and the administration of chapter 499, Florida Statutes, from the Department of Health (DOH) to the Department of Business and Professional Regulation (DBPR), effective October 1, 2011.

This bill transfers the funding of the DDC between trust funds within the DBPR and includes the DDC within the DBPR’s organizational structure.

Specifically, the bill:

- Terminates the Drugs, Devices, and Cosmetics Trust Fund and transfers funding of the DDC to the Professional Regulation Trust Fund.
- Designates Drugs, Devices, and Cosmetics as a division in the department’s organizational structure in section 20.165, F.S.
- Updates references in chapter 499, F.S., to replace DOH with DBPR.
- Requires a report regarding the Drugs, Devices, Cosmetics Regulatory Program to provide detailed options and recommendations regarding: (1) eliminating the program deficit by operational changes or improved efficiencies; (2) how to cost effectively align the licensure renewal with other professions, and (3) bringing the program under the provisions of chapter 455, Florida Statutes.

- This report should be submitted to the Chairs of the Senate Budget Subcommittee on General Government Appropriations, Senate Regulated Industries Committee, House Government Operations Appropriations Subcommittee and the House Business & Consumer Affairs Subcommittee by January 15, 2013.

The bill conforms to the proposed Senate General Appropriations Act for Fiscal Year 2012-2013 as \$2.7 million in trust fund appropriations for the DDC have been transferred from the Drugs, Devices, and Cosmetics Trust Fund to the Professional Regulation Trust Fund.

## II. Present Situation:

Chapter 2010-161, Laws of Florida, transferred the Drugs, Devices, and Cosmetics Regulatory Program and the administration of chapter 499, Florida Statutes, from the Department of Health to the Department of Business and Professional Regulation, effective October 1, 2011.

The 2011 Legislature created the Drugs, Devices, and Cosmetics Trust Fund (Chapter 2011-30, Laws of Florida) within the DBPR and provided nine months of funding for the DDC in the FY 2011-2012 General Appropriations Act. The DBPR has requested that the DDC be placed within the Professional Regulation Trust Fund with similar regulated professions that the department currently regulates.

## III. Effect of Proposed Changes:

The bill transfers funding for the DDC from the Drugs, Devices, and Cosmetics Trust Fund to the Professional Regulation Trust Fund and designates the DDC as a division within DBPR's organizational structure in section 20.165, F.S. The bill terminates the Drugs, Devices, and Cosmetics Trust Fund.

In addition, the definition of the department and numerous references in chapter 499, F.S., are updated to delete the DOH and surgeon general with the secretary and DBPR.

**Section 1** amends paragraph (d) of subsection 20.165(2)(d), F.S., to create the Division of Drugs, Devices, and Cosmetics within DBPR.

**Section 2** amends subsection 455.116(8), F.S., by eliminating the Drugs, Devices, and Cosmetics Trust Fund.

**Section 3** amends subsection 499.003(15), F.S., changing the definition of "Department" from DOH to DBPR. Amends paragraph (a) of subsection 499.003(54), F.S., changing the reference from the "Surgeon General" of DOH, to the "Secretary of Business and Professional Regulation."

**Section 4** amends subsection 499.01211(2), F.S., changing the references from the "Surgeon General" of DOH to the "Secretary of Business and Professional Regulation."

**Section 5** amends section 499.024, F.S., changing the reference from the “Surgeon General” of DOH to the Department (i.e., DBPR).

**Section 6** amends subsection 499.065(2), F.S., changing the reference from the “Surgeon General” of DOH to the “Secretary of Business and Professional Regulation.”

**Section 7** amends subsection 499.601(2), F.S., changing the reference from DOH to the “Department” (i.e., DBPR).

**Section 8** amends subsection 499.61(2), F.S., changing the definition of “Department” from DOH to DBPR.

**Section 9** repeals section 499.0031, F.S., eliminating the Drugs, Device, and Cosmetics Trust Fund.

**Section 10** terminates the Drugs, Devices, and Cosmetics Trust Fund and transfers current balance and remaining revenues of Drugs, Devices, and Cosmetics Trust Fund to the Professional Regulation Trust Fund. Requires that DBPR pay outstanding debts from the Drugs, Devices, and Cosmetics Trust Fund as soon as practicable. This section is effective November 1, 2012.

**Section 11** amends paragraphs (d), (e), and (l) of subsection 499.01(2), F.S., to replace references to the Drugs, Devices, and Cosmetics Trust Fund with references to the Professional Regulation Trust Fund.

**Section 12** amends subsection 499.028(13), F.S., to replace references to the Drugs, Devices, and Cosmetics Trust Fund with references to the Professional Regulation Trust Fund.

**Section 13** amends subsection 499.04, F.S., to replace references to the Drugs, Devices, and Cosmetics Trust Fund with references to the Professional Regulation Trust Fund.

**Section 14** amends subsection 499.057, F.S., to replace references to the Drugs, Devices, and Cosmetics Trust Fund with references to the Professional Regulation Trust Fund. Provides that unless otherwise provided in the General Appropriations Act all salaries and operational expenses of the DDC shall be paid from the Professional Regulation Trust Fund.

**Section 15** amends subsection 499.062, F.S., to replace references to the Drugs, Devices, and Cosmetics Trust Fund with references to the Professional Regulation Trust Fund.

**Section 16** amends subsection 499.066, F.S., to replace references to the Drugs, Devices, and Cosmetics Trust Fund with references to the Professional Regulation Trust Fund.

**Section 17** amends subsection 499.62 (7), F.S., to replace references to the Drugs, Devices, and Cosmetics Trust Fund with references to the Professional Regulation Trust Fund.

**Section 18** amends subsection 499.72, F.S., to replace references to the Drugs, Devices, and Cosmetics Trust Fund with references to the Professional Regulation Trust Fund.

**Section 19** amends subsection 499.79, F.S., to replace references to the Drugs, Devices, and Cosmetics Trust Fund with references to the Professional Regulation Trust Fund. Clarifies that moneys of the DDC shall be used by the DBPR in the administration of chapter 499, F.S.

**Section 20** requires that the Department of Business and Professional Regulation maintain a separate account in the Professional Regulation Trust Fund for the Drugs, Devices, and Cosmetics Program. In addition, the bill requires a report from the DBPR by January 15, 2013, to provide detailed options and recommendations regarding: (1) eliminating the program deficit by operational changes or improved efficiencies; (2) how to cost effectively align the licensure renewal with other professions, and (3) bringing the program under the provisions of chapter 455, Florida Statutes.

This report should be submitted to the Chairs of the Senate Budget Subcommittee on General Government Appropriations, Senate Regulated Industries Committee, House Government Operations Appropriations Subcommittee and the House Business & Consumer Affairs Subcommittee.

**Section 21** provides an effective date July 1, 2012, except as otherwise expressly provided in the bill.

#### **IV. Constitutional Issues:**

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

#### **V. Fiscal Impact Statement:**

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The bill conforms to the proposed Senate General Appropriations Act for Fiscal Year 2012-13 as \$2.7 million in trust fund appropriations for the DDC have been transferred

from the Drugs, Devices, and Cosmetics Trust Fund to the Professional Regulation Trust Fund.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Additional Information:**

A. **Committee Substitute – Statement of Substantial Changes:**  
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. **Amendments:**

None.