Department of Planning and Budget 2015 Fiscal Impact Statement

1.	Bill Number	er: SB 732					
	House of Orig	in 🗌	Introduced		Substitute		Engrossed
	Second House		In Committee		Substitute	\boxtimes	Enrolled
2.	Patron:	Stanley					
3.	Committee:	Passed Both Houses.					
4.	Title:	Expanded access to investigational drugs.					

- **5.** Summary: Provides that a manufacturer of an investigational drug, biological product, or device may make such drug, product, or device available to a person who has a terminal illness when (i) the person has, in consultation with his treating physician, considered all other treatment options currently approved by the U.S. Food and Drug Administration; (ii) the person has been denied opportunity to participate in a clinical trial for the treatment of his terminal illness within one week of completion of the clinical trial application process or has been unable to participate in a clinical trial for the treatment of his terminal illness within 100 miles of his home address; (iii) the person's treating physician has recommended treatment with an investigational drug, biological product, or device; and (iv) the person has provided written informed consent. The bill provides that a manufacturer that provides such drug, product, or device may provide it free of charge or may require the person to pay costs associated with its manufacture. The bill also provides that health insurance providers may, but are not required to, provide coverage for costs associated with use of such drug, product, or device; that a health insurance provider may deny coverage other than coverage for preexisting conditions or benefits that commenced prior to the time treatment with the investigational drug, biological product, or device began to a person receiving treatment with an investigational drug, biological product, or device during the period of treatment; and that no health care provider who recommends such treatment shall be deemed to have engaged in unprofessional conduct solely on the grounds of such recommendation.
- 6. Budget Amendment Necessary: No.
- 7. Fiscal Impact Estimates: FINAL.
- **8. Fiscal Implications:** This bill as amended would have no fiscal impact to the Department of Health Professions. According to the department this bill would not impact operations.
- 9. Specific Agency or Political Subdivisions Affected: Department of Health Professions.
- 10. Technical Amendment Necessary: None.

11. Other Comments: None.