Department of Planning and Budget 2015 Fiscal Impact Statement

1.	Bill Number	: SB 12	222					
	House of Origi		Introduced In Committee		Substitute Substitute		Engrossed Enrolled	
2.	_	Reeves	iii Committee		Substitute		Linoned	
3.	Committee:	ommittee: Education and Health						
4.	Title:	Expanded access to investigational drugs, biological products, and devices.						
5.	•	-		_	•		gical products, and devices.	

- Provides that a manufacturer of an investigational drug, biological product, or device may make such investigational drug, biological product, or device available to a person who has a terminal illness when (i) no comparable or satisfactory alternative treatment options approved by the U.S. Food and Drug Administration are available to treat his terminal illness; (ii) the potential benefits of the use of the investigational drug, biological product, or device outweigh the risks of use of the investigational drug, biological product, or device; (iii) his treating physician has recommended use of the investigational drug, biological product, or device; and (iv) the person has provided informed written consent to use of the investigational drug, biological product, or device. The bill provides that a manufacturer that provides an investigational drug, biological product, or device for treatment of a person's terminal illness may provide the investigational drug, biological product, or device for treatment of the investigational drug, biological product, or device free of charge or may require the person to pay costs associated with manufacture of the investigational drug, biological product, or device. The bill also provides that health insurance providers may, but are not required to, provide coverage for costs associated with use of the investigational drug, biological product, or device.
- 6. Budget Amendment Necessary: No.
- 7. No Fiscal Impact.
- **8. Fiscal Implications:** This bill would not have a fiscal impact on the Commonwealth. The Department of Health Professions has stated that this bill would not impact operations.
- 9. Specific Agency or Political Subdivisions Affected: Department of Health Professions.
- 10. Technical Amendment Necessary: No.
- 11. Other Comments: This bill is similar to HB2050, HB1750, SB732, and SB1149.