F I S C A L I M P A C T R E P O R T

SPONSOR SCORC **ORIGINAL DATE** 2/2/17 **LAST UPDATED** 2/21/17 **HB**

SHORT TITLE Regulation of Biosimilar Products **SB** 180/SCORCS/aSFl#1

ANALYST Chilton

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	FY17	FY18	FY19	3 Year Total Cost	Recurring or Nonrecurring	Fund Affected
Total	NFI	NFI	NFI	NFI		

(Parenthesis ( ) Indicate Expenditure Decreases)

The original bill duplicated House Bill 180; amendments adopted by both houses were identical, and most of the amended language has been incorporated into this committee substitution.

SOURCES OF INFORMATION
LFC Files

Responses Received From
Regulation and Licensing Department (RLD)

Responses Not Received From
Department of Health (DOH)
Human Services Department (HSD)

SUMMARY

Synopsis of the Senate Floor Amendment #1to the Senate Coporation and Transportation Committee Substitute for Senate Bill 180

The Senate Floor Amendment changes some of the wording and syntax in the definition of "biologic product" related to the bill and makes a total of eight small corrections to the text, none of which appears to change the meaning of the bill.

Synopsis of the SCORC Committee Substitute

Senate Bill 180, as substituted, makes several changes to Section 26-1-2 NMSA 1978, which deals with regulation of drugs and cosmetics, to allow pharmacists to substitute biosimilar and interchangeable biosimilar biologic products for another biologic product that has been prescribed by a physician. There exists in the law an extensive list of definitions, including for

"biological product" – the bill adds the term "protein" to the list, which also includes serum, toxin, antitoxin and analogous products. The term "protein" is defined as excluding any chemically synthesized polypeptide. A definition of "biosimilar" is added, stating that a biological product to be biosimilar must have only "minor differences in clinically active components" and that there must be no clinically "meaningful differences" between substituted drugs in "safety, purity and potency." The term "interchangeable biological product" is also defined – the extensive definition includes the following parts:

- The product has been licensed by the federal Food and Drug Administration (FDA)
- FDA has determined that the biologic product is biosimilar to the reference (prescribed) product and should produce the same effects
- (If the product is to be administered to the patient more than once), that the risk to the patient of the product is not greater than the reference product and has been determined by FDA to be therapeutically equivalent according the FDA's compendium of therapeutic equivalents.

In Section 26-3-3 NMSA 1978, the bill adds the words "or biological product" to the list of situations where a pharmacist may substitute one interchangeable biological product for another, using the FDA's list of "interchangeable biologic products" as reference. House Bill 260 would require the Board of Pharmacy to make this information available on its website. The pharmacist would then be able to make the substitution, as long as the cost of the substituted biologic was lower in cost than the prescribed biologic. Prescribers could avoid such a substitution by writing "no substitution" or "no sub" on the prescription.

Pharmacists would be required to inform a patient or his/her representative when a substitution was contemplated, as well as giving the patient or representative to know that he/she could decline the substitution.

Pharmacies would be required to notify prescribers of the substitution through one of several listed methods, usually electronically, unless no interchangeable biological product is available or a refill gives the same drug as was substituted previously.

The Board of Pharmacy would be required to have a link on its website to the FDA's list of interchangeable biologic products.

FISCAL IMPLICATIONS

None indicated.

SIGNIFICANT ISSUES

RLD indicates that "A biosimilar product, and also a generic equivalent product, when substituted by a pharmacist must be lower in cost than the original product. The act states that all savings in costs must be passed on to the patient. Instead, insurance companies substitute in order to pay less. But the pharmacist has little, if any, input into what the patient pays for a medication."

TECHNICAL ISSUES

On page 14, line 4, the bill specifies that providers would be required to write "no substitution" or "no sub" on the face of a prescription if he or she did not want the patient to be given a substituted drug. However, since many prescriptions are now transmitted electronically from the prescriber's computer to a pharmacy's computer, it is uncertain how handwriting could enter into those instances.

The bill specifies that "chemically synthesized polypeptides" would not be subject to substitution, while "proteins" would be. There is not a clear differentiation between the two terms, according to a consulted biochemist: all proteins are polypeptides, but those polypeptides referred to as "proteins" are usually larger.

The following information is provided from the FDA's website:

> The Patient Protection and Affordable Care Act (Affordable Care Act), signed into law by President Obama on March 23, 2010, amends the Public Health Service Act (PHS Act) to create an abbreviated licensure pathway for biological products that are demonstrated to be "biosimilar" to or "interchangeable" with an FDA-licensed biological product. This pathway is provided in the part of the law known as the *Biologics Price Competition and Innovation Act* (BPCI Act). Under the BPCI Act, a biological product may be demonstrated to be "biosimilar" if data show that, among other things, the product is "highly similar" to an already-approved biological product.
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> A biosimilar product is a biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products.
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> An *interchangeable* biological product is biosimilar to an FDA-approved reference product and meets additional standards for interchangeability. An interchangeable biological product may be substituted for the reference product by a pharmacist without the intervention of the health care provider who prescribed the reference product.

It is uncertain what would happen in the case of repeal of all or part of the Affordable Care Act.

WHAT WILL BE THE CONSEQUENCES OF NOT ENACTING THIS BILL

Pharmacies would not be able to substitute one prescribed interchangeable protein for another, which might increase costs for the patient or his/her insurer.

LAC/al/jle