ASSEMBLY BILL NO. 245–ASSEMBLYWOMAN BENITEZ-THOMPSON

FEBRUARY 27, 2017

JOINT SPONSORS: SENATORS KIECKHEFER AND PARKS

Referred to Committee on Commerce and Labor

SUMMARY—Enacts provisions governing the dispensing of biological products and interchangeable biological products. (BDR 54-504)

FISCAL NOTE: Effect on Local Government: Increases or Newly Provides for Term of Imprisonment in County or City Jail or Detention Facility.
Effect on the State: Yes.

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EXPLANATION – Matter in ***bolded italics*** is new; matter between brackets [~~omitted material~~] is material to be omitted.

AN ACT relating to pharmacy; requiring a pharmacist or his or her designee to make certain entries any time a biological product is dispensed under certain circumstances; requiring the dispensing of an interchangeable biological product in substitution for a prescribed biological product under certain circumstances; requiring the State Board of Pharmacy to maintain certain lists of approved interchangeable biological products, published by the United States Food and Drug Administration, on its Internet website; providing a penalty; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law provides that under certain circumstances, a pharmacist is required to dispense a generic drug in substitution for a prescribed brand name drug. (NRS 639.2583) **Sections 3, 5 and 7-12** of this bill enact similar provisions to provide for the dispensing of an interchangeable biological product in substitution for a prescribed biological product. **Section 7** provides that under certain circumstances, a pharmacist is required to dispense an interchangeable biological product in substitution for a prescribed biological product if the interchangeable biological product is less expensive than the prescribed biological product. However, while existing law exempts from the substitution requirement a prescription drug dispensed to a person by mail or common carrier by a certified Internet pharmacy,

section 7 provides that the requirement to dispense an interchangeable biological product applies to a biological product dispensed to a person by mail or common carrier by a certified Internet pharmacy. **Section 3** provides that a biological product is interchangeable if the biological product has been found to be interchangeable in accordance with certain federal standards or has been listed as therapeutically equivalent in certain federal publications. (42 U.S.C. § 262) **Section 5** requires the State Board of Pharmacy to maintain on its Internet website a link to the *Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*, published by the United States Food and Drug Administration to be interchangeable.

Section 4 of this bill provides that within 3 business days after dispensing a biological product, the dispensing pharmacist or his or her designee is required to make an entry of the specific product dispensed to the patient that includes, without limitation, the name and the manufacturer of the product. The record must be electronically accessible by the prescribing practitioner through certain systems. If an electronic record is not made, the dispensing pharmacist or his or her designee must provide the notice to the prescriber by certain other means. Under **section 4**, a record of the dispensing of a biological product is not required to be made if: (1) there is no interchangeable biological product for the biological product that has been prescribed; or (2) the dispensed biological product is a refill and is the same product that was dispensed for the prior filling of the prescription.

THE PEOPLE OF THE STATE OF NEVADA, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. Chapter 639 of NRS is hereby amended by adding thereto the provisions set forth as sections 2 to 5, inclusive, of this act.

Sec. 2. ***"Biological product" has the meaning ascribed to it in 42 U.S.C. § 262.***

Sec. 3. ***"Interchangeable biological product" means a biological product that the Food and Drug Administration has:***

1. Licensed and determined meets the standards for interchangeability pursuant to 42 U.S.C. § 262(k)(4); or

2. Determined is therapeutically equivalent as set forth in the most recent edition or supplement of the Approved Drug Products with Therapeutic Equivalence Evaluations, published by the Food and Drug Administration.

Sec. 4. ***1. Except as otherwise provided in subsections 3 and 4, within 3 business days after dispensing a biological product, the dispensing pharmacist or his or her designee shall make an entry of the specific product provided to the patient that includes, without limitation, the name of the product and its manufacturer. The record must be electronically accessible by the prescribing practitioner through:***

(a) An interoperable electronic health records system;

(b) Electronic prescribing technology;

(c) A pharmacy benefit management system; or

(d) A pharmacy record.

2. An electronic record of the dispensing of a biological product made pursuant to subsection 1 is presumed to provide notice to the prescriber of the dispensing of the product.

3. Except as otherwise provided in subsection 4, if an electronic record of the dispensing of a biological product is not made pursuant to subsection 1, the dispensing pharmacist or his or her designee shall, within 3 business days after dispensing the biological product, give notice of the biological product to the prescriber by facsimile, telephone, electronic transmission or other available means.

4. Notice of the dispensing of a biological product pursuant to subsection 1 or 3 is not required if:

(a) There is no interchangeable biological product for the biological product prescribed; or

(b) A prescription for a refill is not changed from the product dispensed on the prior filling of the prescription.

5. As used in this section, "electronic health record" has the meaning ascribed to it in 42 U.S.C. § 17921(5).

Sec. 5. ***The Board shall maintain a link on its Internet website to the Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations, published by the Food and Drug Administration.***

Sec. 6. NRS 639.001 is hereby amended to read as follows:

639.001 As used in this chapter, unless the context otherwise requires, the words and terms defined in NRS 639.0015 to 639.016, inclusive, ***and sections 2 and 3 of this act*** have the meanings ascribed to them in those sections.

Sec. 7. NRS 639.2583 is hereby amended to read as follows:

639.2583 1. Except as otherwise provided in this section, if a practitioner has prescribed a ~~[drug]~~ ***:***

(a) Drug by brand name and the practitioner has not indicated, by a method set forth in subsection 5, that a substitution is prohibited, the pharmacist who fills or refills the prescription shall dispense, in substitution, another drug which is available to him or her if the other drug:

~~[(a)]~~ ***(1)*** Is less expensive than the drug prescribed by brand name;

~~[(b)]~~ ***(2)*** Is biologically equivalent to the drug prescribed by brand name;

~~[(c)]~~ ***(3)*** Has the same active ingredient or ingredients of the same strength, quantity and form of dosage as the drug prescribed by brand name; and

~~(d)~~ ***(4)*** Is of the same generic type as the drug prescribed by brand name.

(b) Biological product and the practitioner has not indicated, by a method set forth in subsection 5, that a substitution is prohibited, the pharmacist who fills or refills the prescription shall dispense, in substitution, another biological product which is available to him or her if the other biological product:

(1) Is an interchangeable biological product for the biological product prescribed; and

(2) Is less expensive than the biological product prescribed by brand name.

2. If the pharmacist has available to him or her more than one drug ***or interchangeable biological product*** that may be substituted for the drug prescribed by brand name ~~,~~ ***or biological product prescribed,*** the pharmacist shall dispense, in substitution, the least expensive of the drugs ***or interchangeable biological products*** that are available to him or her for substitution.

3. Before a pharmacist dispenses a drug ***or biological product*** in substitution for a drug prescribed by brand name ~~,~~ ***or biological product prescribed,*** the pharmacist shall:

(a) Advise the person who presents the prescription that the pharmacist intends to dispense a drug ***or biological product*** in substitution; and

(b) Advise the person that he or she may refuse to accept the drug ***or biological product*** that the pharmacist intends to dispense in substitution, unless the pharmacist is being paid for the drug by a governmental agency.

4. If a person refuses to accept the drug ***or biological product*** that the pharmacist intends to dispense in substitution, the pharmacist shall dispense the drug prescribed by brand name ~~,~~ ***or biological product prescribed,*** unless the pharmacist is being paid for the drug ***or biological product*** by a governmental agency, in which case the pharmacist shall dispense the drug ***or biological product*** in substitution.

5. A pharmacist shall not dispense a drug ***or biological product*** in substitution for a drug prescribed by brand name ***or biological product prescribed*** if the practitioner has indicated that a substitution is prohibited using one or more of the following methods:

(a) By oral communication to the pharmacist at any time before the drug ***or biological product*** is dispensed.

(b) By handwriting the words "Dispense as Written" on the form used for the prescription, including, without limitation, any form used for transmitting the prescription from a facsimile machine to another facsimile machine. The pharmacist shall disregard the words

"Dispense as Written" if they have been placed on the form used for the prescription by preprinting or other mechanical process or by any method other than handwriting.

(c) By including the words "Dispense as Written" in any prescription that is given to the pharmacist by electronic transmission pursuant to the regulations of the Board or in accordance with NRS 439.581 to 439.595, inclusive, and the regulations adopted pursuant thereto, including, without limitation, an electronic transmission from a computer equipped with a facsimile modem to a facsimile machine or from a computer to another computer pursuant to the regulations of the Board.

6. The provisions of this section also apply to a prescription issued to a person by a practitioner from outside this State if the practitioner has not indicated, by a method set forth in subsection 5, that a substitution is prohibited.

7. The provisions of this section do not apply to:

(a) A prescription drug ***or biological product*** that is dispensed to any inpatient of a hospital by an inpatient pharmacy which is associated with that hospital;

(b) A prescription drug that is dispensed to any person by mail order or other common carrier by an Internet pharmacy which is certified by the Board pursuant to NRS 639.23288 and authorized to provide service by mail order or other common carrier pursuant to the provisions of this chapter; or

(c) A prescription drug ***or biological product*** that is dispensed to any person by a pharmacist if the substitution:

(1) Would violate the terms of a health care plan that maintains a mandatory, exclusive or closed formulary for its coverage for prescription drugs ~~[.]~~ ***and biological products;*** or

(2) Would otherwise make the transaction ineligible for reimbursement by a third party.

Sec. 8. NRS 639.2587 is hereby amended to read as follows:

639.2587 If a generic drug ***or interchangeable biological product*** is substituted for a drug prescribed by brand name ~~[.]~~ ***or biological product prescribed,*** the pharmacist or practitioner shall:

1. Note the name of the manufacturer, packer or distributor of the drug ***or biological product*** actually dispensed on the prescription; and

2. Indicate the substitution by writing or typing on the label the words "substituted for," or substantially similar language, following the generic name and preceding the brand name of the drug ***, or following the name of the interchangeable biological product and preceding the brand name of the prescribed biological product, as applicable,*** unless, at the time the initial substitution of the generic drug ***or interchangeable biological product*** for a drug prescribed by

brand name ***or biological product prescribed*** is made, the person for whom the drug ***or interchangeable biological product*** is dispensed elects not to have such an indication written or typed on the label. An election to indicate or not to indicate a substitution on the label pursuant to this subsection applies to both the fill and each refill of the same prescription.

Sec. 9. NRS 639.2589 is hereby amended to read as follows:

639.2589 1. The form used for any prescription which is issued or intended to be filled in this state must contain a line for the signature of the practitioner.

2. Substitutions may be made in filling prescriptions contained in the orders of a physician, or of an advanced practice registered nurse who is a practitioner, in a facility for skilled nursing or facility for intermediate care.

3. Substitutions may be made in filling prescriptions ***for drugs*** ordered on a patient's chart in a hospital if the hospital's medical staff has approved a formulary for specific generic substitutions.

4. Substitutions may be made in filling prescriptions for biological products ordered on a patient's chart in a hospital if the hospital's medical staff has approved a formulary for specific interchangeable biological products.

Sec. 10. NRS 639.259 is hereby amended to read as follows:

639.259 No employer of a pharmacist may require the pharmacist to dispense any specific generic drug ***or interchangeable biological product*** in substitution for another drug ***or biological product*** if the:

1. Substitution is not permitted by the prescription as signed by a practitioner;

2. Substitution would be against the professional judgment of the pharmacist; or

3. Substitution would violate any provision of NRS 639.2583 to 639.2597, inclusive ~~.~~ ***, and sections 4 and 5 of this act.***

Sec. 11. NRS 639.2595 is hereby amended to read as follows:

639.2595 A pharmacist or practitioner who selects a drug ***or interchangeable biological product*** for substitution assumes no greater civil liability than he or she assumes by filling the prescription with the drug under its brand name ~~.~~ ***or the prescribed biological product.***

Sec. 12. NRS 639.2597 is hereby amended to read as follows:

639.2597 A pharmacist or practitioner who proposes to make any substitution must have made use of a list of biologically equivalent drugs ***or interchangeable biological products*** approved by the United States Food and Drug Administration.

Sec. 13. NRS 689A.04045 is hereby amended to read as follows:

689A.04045 1. Except as otherwise provided in this section, a policy of health insurance which provides coverage for prescription drugs must not limit or exclude coverage for a drug if the drug:

(a) Had previously been approved for coverage by the insurer for a medical condition of an insured and the insured's provider of health care determines, after conducting a reasonable investigation, that none of the drugs which are otherwise currently approved for coverage are medically appropriate for the insured; and

(b) Is appropriately prescribed and considered safe and effective for treating the medical condition of the insured.

2. The provisions of subsection 1 do not:

(a) Apply to coverage for any drug that is prescribed for a use that is different from the use for which that drug has been approved for marketing by the Food and Drug Administration;

(b) Prohibit:

(1) The insurer from charging a deductible, copayment or coinsurance for the provision of benefits for prescription drugs to the insured or from establishing, by contract, limitations on the maximum coverage for prescription drugs;

(2) A provider of health care from prescribing another drug covered by the policy that is medically appropriate for the insured; or

(3) The substitution of another drug pursuant to NRS 639.23286 or 639.2583 to 639.2597, inclusive ~~[.]~~ ***, and sections 4 and 5 of this act;*** or

(c) Require any coverage for a drug after the term of the policy.

3. Any provision of a policy subject to the provisions of this chapter that is delivered, issued for delivery or renewed on or after October 1, 2001, which is in conflict with this section is void.

Sec. 14. NRS 689B.0368 is hereby amended to read as follows:

689B.0368 1. Except as otherwise provided in this section, a policy of group health insurance which provides coverage for prescription drugs must not limit or exclude coverage for a drug if the drug:

(a) Had previously been approved for coverage by the insurer for a medical condition of an insured and the insured's provider of health care determines, after conducting a reasonable investigation, that none of the drugs which are otherwise currently approved for coverage are medically appropriate for the insured; and

(b) Is appropriately prescribed and considered safe and effective for treating the medical condition of the insured.

2. The provisions of subsection 1 do not:

(a) Apply to coverage for any drug that is prescribed for a use that is different from the use for which that drug has been approved for marketing by the Food and Drug Administration;

(b) Prohibit:

(1) The insurer from charging a deductible, copayment or coinsurance for the provision of benefits for prescription drugs to the insured or from establishing, by contract, limitations on the maximum coverage for prescription drugs;

(2) A provider of health care from prescribing another drug covered by the policy that is medically appropriate for the insured; or

(3) The substitution of another drug pursuant to NRS 639.23286 or 639.2583 to 639.2597, inclusive ~~[,]~~ ***, and sections 4 and 5 of this act;*** or

(c) Require any coverage for a drug after the term of the policy.

3. Any provision of a policy subject to the provisions of this chapter that is delivered, issued for delivery or renewed on or after October 1, 2001, which is in conflict with this section is void.

Sec. 15. NRS 689C.168 is hereby amended to read as follows:

689C.168 1. Except as otherwise provided in this section, a health benefit plan which provides coverage for prescription drugs must not limit or exclude coverage for a drug if the drug:

(a) Had previously been approved for coverage by the carrier for a medical condition of an insured and the insured's provider of health care determines, after conducting a reasonable investigation, that none of the drugs which are otherwise currently approved for coverage are medically appropriate for the insured; and

(b) Is appropriately prescribed and considered safe and effective for treating the medical condition of the insured.

2. The provisions of subsection 1 do not:

(a) Apply to coverage for any drug that is prescribed for a use that is different from the use for which that drug has been approved for marketing by the Food and Drug Administration;

(b) Prohibit:

(1) The carrier from charging a deductible, copayment or coinsurance for the provision of benefits for prescription drugs to the insured or from establishing, by contract, limitations on the maximum coverage for prescription drugs;

(2) A provider of health care from prescribing another drug covered by the plan that is medically appropriate for the insured; or

(3) The substitution of another drug pursuant to NRS 639.23286 or 639.2583 to 639.2597, inclusive ~~[,]~~ ***, and sections 4 and 5 of this act;*** or

(c) Require any coverage for a drug after the term of the plan.

3. Any provision of a health benefit plan subject to the provisions of this chapter that is delivered, issued for delivery or renewed on or after October 1, 2001, which is in conflict with this section is void.

Sec. 16. NRS 695A.184 is hereby amended to read as follows:

695A.184 1. Except as otherwise provided in this section, a benefit contract which provides coverage for prescription drugs must not limit or exclude coverage for a drug if the drug:

(a) Had previously been approved for coverage by the society for a medical condition of an insured and the insured's provider of health care determines, after conducting a reasonable investigation, that none of the drugs which are otherwise currently approved for coverage are medically appropriate for the insured; and

(b) Is appropriately prescribed and considered safe and effective for treating the medical condition of the insured.

2. The provisions of subsection 1 do not:

(a) Apply to coverage for any drug that is prescribed for a use that is different from the use for which that drug has been approved for marketing by the Food and Drug Administration;

(b) Prohibit:

(1) The society from charging a deductible, copayment or coinsurance for the provision of benefits for prescription drugs to the insured or from establishing, by contract, limitations on the maximum coverage for prescription drugs;

(2) A provider of health care from prescribing another drug covered by the benefit contract that is medically appropriate for the insured; or

(3) The substitution of another drug pursuant to NRS 639.23286 or 639.2583 to 639.2597, inclusive ~~[.]~~ ***, and sections 4 and 5 of this act;*** or

(c) Require any coverage for a drug after the term of the benefit contract.

3. Any provision of a benefit contract subject to the provisions of this chapter that is delivered, issued for delivery or renewed on or after October 1, 2001, which is in conflict with this section is void.

Sec. 17. NRS 695B.1905 is hereby amended to read as follows:

695B.1905 1. Except as otherwise provided in this section, a contract for hospital or medical services which provides coverage for prescription drugs must not limit or exclude coverage for a drug if the drug:

(a) Had previously been approved for coverage by the insurer for a medical condition of an insured and the insured's provider of health care determines, after conducting a reasonable investigation,

that none of the drugs which are otherwise currently approved for coverage are medically appropriate for the insured; and

(b) Is appropriately prescribed and considered safe and effective for treating the medical condition of the insured.

2. The provisions of subsection 1 do not:

(a) Apply to coverage for any drug that is prescribed for a use that is different from the use for which that drug has been approved for marketing by the Food and Drug Administration;

(b) Prohibit:

(1) The insurer from charging a deductible, copayment or coinsurance for the provision of benefits for prescription drugs to the insured or from establishing, by contract, limitations on the maximum coverage for prescription drugs;

(2) A provider of health care from prescribing another drug covered by the contract that is medically appropriate for the insured; or

(3) The substitution of another drug pursuant to NRS 639.23286 or 639.2583 to 639.2597, inclusive ~~[,]~~ ***, and sections 4 and 5 of this act;*** or

(c) Require any coverage for a drug after the term of the contract.

3. Any provision of a contract for hospital or medical services subject to the provisions of this chapter that is delivered, issued for delivery or renewed on or after October 1, 2001, which is in conflict with this section is void.

Sec. 18. NRS 695C.1734 is hereby amended to read as follows:

695C.1734 1. Except as otherwise provided in this section, evidence of coverage which provides coverage for prescription drugs must not limit or exclude coverage for a drug if the drug:

(a) Had previously been approved for coverage by the health maintenance organization or insurer for a medical condition of an enrollee and the enrollee's provider of health care determines, after conducting a reasonable investigation, that none of the drugs which are otherwise currently approved for coverage are medically appropriate for the enrollee; and

(b) Is appropriately prescribed and considered safe and effective for treating the medical condition of the enrollee.

2. The provisions of subsection 1 do not:

(a) Apply to coverage for any drug that is prescribed for a use that is different from the use for which that drug has been approved for marketing by the Food and Drug Administration;

(b) Prohibit:

(1) The health maintenance organization or insurer from charging a deductible, copayment or coinsurance for the provision

of benefits for prescription drugs to the enrollee or from establishing, by contract, limitations on the maximum coverage for prescription drugs;

(2) A provider of health care from prescribing another drug covered by the evidence of coverage that is medically appropriate for the enrollee; or

(3) The substitution of another drug pursuant to NRS 639.23286 or 639.2583 to 639.2597, inclusive ~~[.]~~ ***, and sections 4 and 5 of this act;*** or

(c) Require any coverage for a drug after the term of the evidence of coverage.

3. Any provision of an evidence of coverage subject to the provisions of this chapter that is delivered, issued for delivery or renewed on or after October 1, 2001, which is in conflict with this section is void.

Sec. 19. NRS 695F.156 is hereby amended to read as follows:

695F.156 1. Except as otherwise provided in this section, evidence of coverage which provides coverage for prescription drugs must not limit or exclude coverage for a drug if the drug:

(a) Had previously been approved for coverage by the prepaid limited health service organization for a medical condition of an enrollee and the enrollee's provider of health care determines, after conducting a reasonable investigation, that none of the drugs which are otherwise currently approved for coverage are medically appropriate for the enrollee; and

(b) Is appropriately prescribed and considered safe and effective for treating the medical condition of the enrollee.

2. The provisions of subsection 1 do not:

(a) Apply to coverage for any drug that is prescribed for a use that is different from the use for which that drug has been approved for marketing by the Food and Drug Administration;

(b) Prohibit:

(1) The organization from charging a deductible, copayment or coinsurance for the provision of benefits for prescription drugs to the enrollee or from establishing, by contract, limitations on the maximum coverage for prescription drugs;

(2) A provider of health care from prescribing another drug covered by the evidence of coverage that is medically appropriate for the enrollee; or

(3) The substitution of another drug pursuant to NRS 639.23286 or 639.2583 to 639.2597, inclusive ~~[.]~~ ***, and sections 4 and 5 of this act;*** or

(c) Require any coverage for a drug after the term of the evidence of coverage.

3. Any provision of an evidence of coverage subject to the provisions of this chapter that is delivered, issued for delivery or renewed on or after October 1, 2001, which is in conflict with this section is void.

Sec. 20. NRS 695G.166 is hereby amended to read as follows:

695G.166 1. Except as otherwise provided in this section, a health care plan which provides coverage for prescription drugs must not limit or exclude coverage for a drug if the drug:

(a) Had previously been approved for coverage by the managed care organization for a medical condition of an insured and the insured's provider of health care determines, after conducting a reasonable investigation, that none of the drugs which are otherwise currently approved for coverage are medically appropriate for the insured; and

(b) Is appropriately prescribed and considered safe and effective for treating the medical condition of the insured.

2. The provisions of subsection 1 do not:

(a) Apply to coverage for any drug that is prescribed for a use that is different from the use for which that drug has been approved for marketing by the Food and Drug Administration;

(b) Prohibit:

(1) The organization from charging a deductible, copayment or coinsurance for the provision of benefits for prescription drugs to the insured or from establishing, by contract, limitations on the maximum coverage for prescription drugs;

(2) A provider of health care from prescribing another drug covered by the plan that is medically appropriate for the insured; or

(3) The substitution of another drug pursuant to NRS 639.23286 or 639.2583 to 639.2597, inclusive ~~[.]~~ ***, and sections 4 and 5 of this act;*** or

(c) Require any coverage for a drug after the term of the plan.

3. Any provision of a health care plan subject to the provisions of this chapter that is delivered, issued for delivery or renewed on or after October 1, 2001, which is in conflict with this section is void.

Sec. 21. This act becomes effective:

1. Upon passage and approval for the purpose of adopting any regulations and performing any preparatory administrative tasks necessary to carry out the provisions of this act; and

2. On January 1, 2018, for all other purposes.