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AMENDMENTS TO LB1052

Introduced by Health and Human Services.

1. Strike the original sections and insert the following new sections:

Section 1. Section 28-414.01, Revised Statutes Cumulative Supplement, 2018, is amended to read:

28-414.01 (1) Except as otherwise provided in this section or when administered directly by a practitioner to an ultimate user, a controlled substance listed in Schedule III, IV, or V of section 28-405 shall not be dispensed without a written, oral, or electronic medical order. Such medical order is valid for six months after the date of issuance. Original prescription information for any controlled substance listed in Schedule III, IV, or V of section 28-405 may be transferred between pharmacies for purposes of refill dispensing pursuant to section 38-2871.

(2) A prescription for controlled substances listed in Schedule III, IV, or V of section 28-405 must contain the following information prior to being filled by a pharmacist or dispensing practitioner: (a) Patient's name and address, (b) name of the drug, device, or biological, (c) strength of the drug or biological, if applicable, (d) dosage form of the drug or biological, (e) quantity of the drug, device, or biological prescribed, (f) directions for use, (g) date of issuance, (h) number of refills, including pro re nata or PRN refills, not to exceed five refills within six months after the date of issuance, (i) prescribing practitioner's name and address, and (j) Drug Enforcement Administration number of the prescribing practitioner. If the prescription is a written paper prescription, the paper prescription must contain the prescribing practitioner's manual signature. If the prescription is an electronic prescription, the electronic prescription must contain all of the elements in subdivisions (a) through (j) of this subsection, must be

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digitally signed, and must be transmitted to and received by the pharmacy electronically to meet all of the requirements of 21 C.F.R. 1311, as the regulation existed on January 1, 2014, pertaining to electronic prescribing of controlled substances.

(3)(a) A pharmacist who is exercising reasonable care and who has obtained patient consent may do the following:

(i) Change the quantity of a drug prescribed if:

(A) The prescribed quantity or package size is not commercially available; or

(B) The change in quantity is related to a change in dosage form;

(ii) Change the dosage form of the prescription if it is in the best interest of the patient and if the directions for use are also modified to equate to an equivalent amount of drug dispensed as prescribed;

(iii) Dispense multiple months' supply of a drug if a prescription is written with sufficient refills; and

(iv) Substitute any chemically equivalent drug product for a prescribed drug to comply with a drug formulary which is covered by the patient's health insurance plan unless the prescribing practitioner specifies "no substitution", "dispense as written", or "D.A.W." to indicate that substitution is not permitted. If a pharmacist substitutes any chemically equivalent drug product as permitted under this subdivision, the pharmacist shall provide notice to the prescribing practitioner or the prescribing practitioner's designee. If drug product selection occurs involving a generic substitution, the drug product selection shall comply with section 38-28,111.

(b) A pharmacist who adapts a prescription in accordance with this subsection shall document the adaptation in the patient's pharmacy record.

(4) ~~(3)~~ A controlled substance listed in Schedule III, IV, or V of section 28-405 may be dispensed pursuant to a facsimile of a written, signed paper prescription. The facsimile of a written, signed paper

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prescription shall serve as the original written prescription for purposes of this subsection and shall be maintained in accordance with subsection (2) of section 28-414.03.

(5) ~~(4)~~ A prescription for a controlled substance listed in Schedule III, IV, or V of section 28-405 may be partially filled if (a) each partial filling is recorded in the same manner as a refilling, (b) the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and (c) each partial filling is dispensed within six months after the prescription was issued.

Sec. 2. Section 38-2826, Reissue Revised Statutes of Nebraska, is amended to read:

38-2826 Labeling means the process of preparing and affixing a label to any drug container or device container, exclusive of the labeling by a manufacturer, packager, or distributor of a nonprescription drug or commercially packaged legend drug or device. Any such label shall include all information required by federal and state law or regulation. Compliance with labeling requirements under federal law for devices described in subsection (2) of section 38-2841, medical gases, and medical gas devices constitutes compliance with state law and regulations for purposes of this section. Labeling does not include affixing an auxiliary sticker or other such notation to a container after a drug has been dispensed when the sticker or notation is affixed by a person credentialed under the Uniform Credentialing Act in a facility licensed under the Health Care Facility Licensure Act.

Sec. 3. Section 38-28,107, Reissue Revised Statutes of Nebraska, is amended to read:

38-28,107 (1) To protect the public safety, dispensed drugs or devices:

(a) May be collected in a pharmacy for disposal;

(b) May be returned to a pharmacy in response to a recall by the manufacturer, packager, or distributor or if a device is defective or

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malfunctioning;

(c) Shall not be returned to saleable inventory nor made available for subsequent relabeling and redispensing, except as provided in subdivision (1)(d) of this section; or

(d) May be accepted ~~returned~~ from a long-term care facility by ~~to~~ the pharmacy from which they were dispensed for credit or for relabeling and redispensing, except that:

(i) No controlled substance may be returned;

(ii) No prescription drug or medical device that has restricted distribution by the federal Food and Drug Administration may be returned;

(iii) The decision to accept the return of the dispensed drug or device shall rest solely with the pharmacist;

(iv) The dispensed drug or device shall have been in the control of the long-term care facility at all times;

(v) The dispensed drug or device shall be in the original and unopened labeled container with a tamper-evident seal intact, as dispensed by the pharmacist. Such container shall bear the expiration date or calculated expiration date and lot number; and

(vi) Tablets or capsules shall have been dispensed in a unit dose container which is impermeable to moisture and approved by the board.

(2) Pharmacies may charge a fee for collecting dispensed drugs or devices for disposal or from a long-term care facility for credit or for relabeling and redispensing.

(3) Any person or entity which exercises reasonable care in collecting dispensed drugs or devices for disposal or from a long-term care facility for credit or for relabeling and redispensing pursuant to this section shall be immune from civil or criminal liability or professional disciplinary action of any kind for any injury, death, or loss to person or property relating to such activities.

(4) A drug manufacturer which exercises reasonable care shall be immune from civil or criminal liability for any injury, death, or loss to

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persons or property relating to the relabeling and redispensing of drugs returned from a long-term care facility.

(5) Notwithstanding subsection (4) of this section, the relabeling and redispensing of drugs returned from a long-term care facility does not absolve a drug manufacturer of any criminal or civil liability that would have existed but for the relabeling and redispensing and such relabeling and redispensing does not increase the liability of such drug manufacturer that would have existed but for the relabeling and redispensing.

(6) The pharmacist may package drugs and devices at the request of a patient or patient's caregiver if the drugs and devices were originally dispensed from a different pharmacy.

Sec. 4. Section 68-955, Reissue Revised Statutes of Nebraska, is amended to read:

68-955 (1) Except as otherwise provided in subsection (3) of this section, a ~~A~~ health care provider may prescribe a prescription drug not on the preferred drug list to a medicaid recipient if (a) the prescription drug is medically necessary, (b)(i) the provider certifies that the preferred drug has not been therapeutically effective, or with reasonable certainty is not expected to be therapeutically effective, in treating the recipient's condition or (ii) the preferred drug causes or is reasonably expected to cause adverse or harmful reactions in the recipient, and (c) the department authorizes coverage for the prescription drug prior to the dispensing of the drug. The department shall respond to a prior authorization request no later than twenty-four hours after receiving such request.

(2) A health care provider may prescribe a prescription drug not on the preferred drug list to a medicaid recipient without prior authorization by the department or a managed care organization if the provider certifies that (a) the recipient is achieving therapeutic success with a course of antidepressant, antipsychotic, or anticonvulsant

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medication or medication for human immunodeficiency virus, multiple sclerosis, epilepsy, cancer, or immunosuppressant therapy or (b) the recipient has experienced a prior therapeutic failure with a medication.

(3) Neither the department nor a managed care organization shall require prior authorization for coverage for an antidepressant, antipsychotic, or anticonvulsant prescription drug that is deemed medically necessary by a patient's health care provider for a new or existing medicaid recipient if the medicaid recipient has prior prescription history for the antidepressant, antipsychotic, or anticonvulsant prescription drug within the immediately preceding ninety-day period. A prospective drug utilization review as described in section 38-2869 and applicable federal law for a prescription for an antidepressant, antipsychotic, or anticonvulsant prescription drug for a medicaid recipient with prior prescription history within the immediately preceding ninety-day period shall occur in order to ensure that the prescription for a medicaid recipient is appropriate and is not likely to result in adverse medical results. Use of a pharmaceutical sample is not considered prior prescription history.

Sec. 5. Section 71-401, Reissue Revised Statutes of Nebraska, is amended to read:

71-401 Sections 71-401 to 71-475 and sections 7 and 8 of this act shall be known and may be cited as the Health Care Facility Licensure Act.

Sec. 6. Section 71-403, Reissue Revised Statutes of Nebraska, is amended to read:

71-403 For purposes of the Health Care Facility Licensure Act, unless the context otherwise requires, the definitions found in sections 71-404 to 71-431 and section 7 of this act shall apply.

Sec. 7. MAR means a medication administration record kept by an assisted-living facility, a nursing facility, or a skilled nursing facility.

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Sec. 8. (1) In an assisted-living facility, a nursing facility, or a skilled nursing facility, all drugs and devices shall be labeled in accordance with currently accepted professional standards of care, including the appropriate accessory and cautionary instructions and the expiration date when applicable.

(2) If the dosage or directions for a specific drug or device to be used in an assisted-living facility, a nursing facility, or a skilled nursing facility are changed by a health care practitioner authorized to prescribe controlled substances and credentialed under the Uniform Credentialing Act, a pharmacist shall apply a new label as soon as practicable with the correct dosage or directions to the drug or device package or reissue the drug or device with the correct label. To protect the safety of the resident of such a facility receiving the drug or device until the drug or device can be correctly labeled, the drug or device package shall be temporarily flagged with a sticker indicating dose change, drug change, or MAR, to alert nursing staff or an unlicensed person responsible for providing the drug or device to a resident that the dosage or directions have changed and the drug or device is to be provided according to the corrected information contained in the resident's MAR, if one exists.

Sec. 9. Section 71-2411, Reissue Revised Statutes of Nebraska, is amended to read:

71-2411 For purposes of the Emergency Box Drug Act:

(1) Authorized personnel means any medical doctor, doctor of osteopathy, registered nurse, licensed practical nurse, nurse practitioner, pharmacist, or physician assistant;

(2) Calculated expiration date has the same meaning as in section 38-2808.01;

(3) ~~(2)~~ Department means the Department of Health and Human Services;

(4) ~~(3)~~ Drug means any prescription drug or device or legend drug or

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device defined under section 38-2841, any nonprescription drug as defined under section 38-2829, any controlled substance as defined under section 28-405, or any device as defined under section 38-2814;

(5) ~~(4)~~ Emergency box drugs means drugs required to meet the immediate therapeutic needs of patients when the drugs are not available from any other authorized source in time to sufficiently prevent risk of harm to such patients by the delay resulting from obtaining such drugs from such other authorized source;

(6) ~~(5)~~ Long-term care facility means an intermediate care facility, an intermediate care facility for persons with developmental disabilities, a long-term care hospital, a mental health substance use treatment center, a nursing facility, or a skilled nursing facility, as such terms are defined in the Health Care Facility Licensure Act;

(7) ~~(6)~~ Multiple dose vial means any bottle in which more than one dose of a liquid drug is stored or contained;

(8) NDC means the National Drug Code published by the United States Food and Drug Administration;

(9) ~~(7)~~ Pharmacist means a pharmacist as defined in section 38-2832 who is employed by a supplying pharmacy or who has contracted with a long-term care facility to provide consulting services; and

(10) ~~(8)~~ Supplying pharmacy means a pharmacy that supplies drugs for an emergency box located in a long-term care facility. Drugs in the emergency box are owned by the supplying pharmacy.

Sec. 10. Section 71-2412, Reissue Revised Statutes of Nebraska, is amended to read:

71-2412 (1) Drugs may be administered to residents of a long-term care facility by authorized personnel of the long-term care facility from the contents of emergency boxes located within such long-term care facility if such drugs and boxes meet ~~all of~~ the ~~following~~ requirements of this section. ~~:~~

(2) When electronic or automated emergency boxes are in use in a

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long-term care facility, the supplying pharmacy shall have policies and procedures to ensure proper utilization of the drugs in the emergency boxes. Policies and procedures shall include who is allowed to retrieve drugs from the emergency boxes, security for the location of the emergency boxes within the long-term care facility, and other necessary provisions as determined by the pharmacist-in-charge of the supplying pharmacy.

(3) For emergency boxes that are not electronic or automated:

(a) ~~(1)~~ All emergency box drugs shall be provided by and all emergency boxes containing such drugs shall be sealed by a supplying pharmacy with the seal on such emergency box to be of such a nature that it can be easily identified if it has been broken;

(b) ~~(2)~~ Emergency boxes shall be stored in a medication room or other secured area within the long-term care facility. Only authorized personnel of the long-term care facility or the supplying pharmacy shall obtain access to such room or secured area, by key or combination, in order to prevent unauthorized access and to ensure a proper environment for preservation of the emergency box drugs;

(c) ~~(3)~~ The exterior of each emergency box shall be labeled so as to clearly indicate that it is an emergency box for use in emergencies only. The label shall contain a listing of the drugs contained in the box, including the name, strength, route of administration, quantity, and expiration date of each drug, and the name, address, and telephone number of the supplying pharmacy; and

(d) Emergency ~~(4) All emergency~~ boxes shall be inspected by a pharmacist designated by the supplying pharmacy at least once a month ~~every thirty days~~ or after a reported usage of any drug to determine the expiration date and quantity of the drugs in the box. Every inspection shall be documented and the record retained by the long-term care facility for a period of five years. ~~; and~~

(4) ~~(5)~~ All drugs in emergency boxes shall be in the original

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manufacturer's or distributor's containers or shall be repackaged by the supplying pharmacy in a tight, light-resistant container and shall include the manufacturer's or distributor's name, lot number, drug name, strength, dosage form, NDC number, route of administration, and expiration date on a typewritten label. Any drug which is repackaged shall contain on the label the calculated expiration date.

~~For purposes of the Emergency Box Drug Act, calculated expiration date has the same meaning as in section 38-2808.01.~~

Sec. 11. Section 71-2413, Reissue Revised Statutes of Nebraska, is amended to read:

71-2413 (1) The supplying pharmacy and the medical director and quality assurance committee of the long-term care facility shall jointly determine the drugs, by identity and quantity, to be included in the emergency boxes. The supplying pharmacy shall maintain a list of emergency box drugs which is identical to the list on the exterior of the emergency box or the electronic inventory record of the emergency box and shall make such list available to the department upon request. The supplying pharmacy shall obtain a receipt upon delivery of the emergency box to the long-term care facility signed by the director of nursing of the long-term care facility or his or her designee which acknowledges that the drugs initially placed in the emergency box are identical to the initial list on the exterior of the emergency box or the electronic inventory record of the emergency box. The receipt shall be retained by the supplying pharmacy for a period of five years.

(2) Except for the removal of expired drugs as provided in subsection (4) of this section, drugs shall be removed from emergency boxes only pursuant to a prescription. Whenever access to the emergency box occurs, the prescription and proof of use shall be provided to the supplying pharmacy and shall be recorded on the resident's medical record by authorized personnel of the long-term care facility. Removal of any drug from an emergency box by authorized personnel of the long-term care

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facility shall be recorded on a form showing the name of the resident who received the drug, his or her room number, the name of the drug, the strength of the drug, the quantity used, the dose administered, the route of administration, the date the drug was used, the time of usage, the disposal of waste, if any, and the signature or signatures of authorized personnel. The form shall be maintained at the long-term care facility for a period of five years from the date of removal with a copy of the form to be provided to the supplying pharmacy.

(3) Whenever an emergency box is opened or otherwise accessed, the supplying pharmacy shall be notified by the charge nurse or the director of nursing of the long-term care facility within twenty-four hours and a pharmacist designated by the supplying pharmacy shall restock and refill the box, reseal the box if it is not an electronic or automated emergency box, and update the drug listing on the exterior of the emergency box or update the electronic inventory record of the emergency box as outlined in the policies and procedures of the supplying pharmacy required by section 71-2412 for an electronic or automated emergency box.

(4) Upon the expiration of any drug in the emergency box, the supplying pharmacy shall replace the expired drug, reseal the box if it is not an electronic or automated emergency box, and update the drug listing on the exterior of the emergency box or update the electronic inventory record of the emergency box as outlined in the policies and procedures of the supplying pharmacy required by section 71-2412 for an electronic or automated emergency box. Emergency box drugs shall be considered inventory of the supplying pharmacy until such time as they are removed for administration.

(5) Authorized personnel of the long-term care facility shall examine the emergency boxes once every twenty-four hours and shall immediately notify the supplying pharmacy upon discovering evidence of tampering with any emergency box. Proof of examination by authorized personnel of the long-term care facility shall be recorded and maintained

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at the long-term care facility for a period of five years from the date of examination.

(6) The supplying pharmacy and the medical director and quality assurance committee of the long-term care facility shall jointly establish written procedures for the safe and efficient distribution of emergency box drugs.

Sec. 12. Section 71-2457, Reissue Revised Statutes of Nebraska, is amended to read:

71-2457 Sections 71-2457 to 71-2483 and section 14 of this act shall be known and may be cited as the Prescription Drug Safety Act.

Sec. 13. Section 71-2458, Reissue Revised Statutes of Nebraska, is amended to read:

71-2458 For purposes of the Prescription Drug Safety Act, the definitions found in sections 71-2459 to 71-2476 and section 14 of this act apply.

Sec. 14. Central fill means the preparation, other than by compounding, of a drug, device, or biological pursuant to a medical order where the preparation occurs in a pharmacy other than the pharmacy dispensing to the patient or caregiver.

Sec. 15. Section 71-2468, Reissue Revised Statutes of Nebraska, is amended to read:

71-2468 Labeling means the process of preparing and affixing a label to any drug container or device container, exclusive of the labeling by a manufacturer, packager, or distributor of a nonprescription drug or commercially packaged legend drug or device. Any such label shall include all information required by section 71-2479 and federal law or regulation. Compliance with labeling requirements under federal law for devices described in subsection (2) of section 38-2841, medical gases, and medical gas devices constitutes compliance with state law and regulations for purposes of this section. Labeling does not include affixing an auxiliary sticker or other such notation to a container after

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a drug has been dispensed when the sticker or notation is affixed by a person credentialed under the Uniform Credentialing Act in a facility licensed under the Health Care Facility Licensure Act.

Sec. 16. Section 71-2478, Reissue Revised Statutes of Nebraska, is amended to read:

71-2478 (1) Except as otherwise provided in this section or the Uniform Controlled Substances Act or except when administered directly by a practitioner to an ultimate user, a legend drug which is not a controlled substance shall not be dispensed without a written, oral, or electronic prescription. Such prescription shall be valid for twelve months after the date of issuance.

(2) A prescription for a legend drug which is not a controlled substance shall contain the following information prior to being filled by a pharmacist or practitioner who holds a pharmacy license under subdivision (1) of section 38-2850: (a) Patient's name, (b) name of the drug, device, or biological, (c) strength of the drug or biological, if applicable, (d) dosage form of the drug or biological, (e) quantity of the drug, device, or biological prescribed, (f) directions for use, (g) date of issuance, (h) number of authorized refills, including pro re nata or PRN refills, (i) prescribing practitioner's name, and (j) if the prescription is written, prescribing practitioner's signature. Prescriptions for controlled substances must meet the requirements of sections 28-414 and 28-414.01.

(3)(a) A pharmacist who is exercising reasonable care and who has obtained patient consent may do the following:

(i) Change the quantity of a drug prescribed if:

(A) The prescribed quantity or package size is not commercially available; or

(B) The change in quantity is related to a change in dosage form;

(ii) Change the dosage form of the prescription if it is in the best interest of the patient and if the directions for use are also modified

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to equate to an equivalent amount of drug dispensed as prescribed;

(iii) Dispense multiple months' supply of a drug if a prescription is written with sufficient refills; and

(iv) Substitute any chemically equivalent drug product for a prescribed drug to comply with a drug formulary which is covered by the patient's health insurance plan unless the prescribing practitioner specifies "no substitution", "dispense as written", or "D.A.W." to indicate that substitution is not permitted. If a pharmacist substitutes any chemically equivalent drug product as permitted under this subdivision, the pharmacist shall provide notice to the prescribing practitioner or the prescribing practitioner's designee. If drug product selection occurs involving a generic substitution, the drug product selection shall comply with section 38-28,111.

(b) A pharmacist who adapts a prescription in accordance with this subsection shall document the adaptation in the patient's pharmacy record.

(4) ~~(3)~~ A written, signed paper prescription may be transmitted to the pharmacy via facsimile which shall serve as the original written prescription. An electronic prescription may be electronically or digitally signed and transmitted to the pharmacy and may serve as the original prescription.

(5) ~~(4)~~ It shall be unlawful for any person knowingly or intentionally to possess or to acquire or obtain or to attempt to acquire or obtain, by means of misrepresentation, fraud, forgery, deception, or subterfuge, possession of any drug substance not classified as a controlled substance under the Uniform Controlled Substances Act which can only be lawfully dispensed, under federal statutes in effect on January 1, 2015, upon the written or oral prescription of a practitioner authorized to prescribe such substances.

Sec. 17. Section 71-2479, Reissue Revised Statutes of Nebraska, is amended to read:

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71-2479 (1) Any prescription for a legend drug which is not a controlled substance shall be kept by the pharmacy or the practitioner who holds a pharmacy license in a readily retrievable format and shall be maintained for a minimum of five years. The pharmacy or practitioner shall make all such files readily available to the department and law enforcement for inspection without a search warrant.

(2) Before dispensing a legend drug which is not a controlled substance pursuant to a written, oral, or electronic prescription, a label shall be affixed to the container in which the drug is dispensed. Such label shall bear (a) the name, address, and telephone number of the pharmacy or practitioner and the central fill pharmacy if central fill is used, (b) the name of the patient, (c) the date of filling, (d) the serial number of the prescription under which it is recorded in the practitioner's prescription records, (e) the name of the prescribing practitioner, (f) the directions for use, (g) the name of the drug, device, or biological unless instructed to omit by the prescribing practitioner, (h) the strength of the drug or biological, if applicable, (i) the quantity of the drug, device, or biological in the container, except unit-dose containers, (j) the dosage form of the drug or biological, and (k) any cautionary statements contained in the prescription.

(3) For multidrug containers, more than one drug, device, or biological may be dispensed in the same container when (a) such container is prepackaged by the manufacturer, packager, or distributor and shipped directly to the pharmacy in this manner or (b) the container does not accommodate greater than a thirty-one-day supply of compatible dosage units and is labeled to identify each drug or biological in the container in addition to all other information required by law.

Sec. 18. Original sections 38-2826, 38-28,107, 68-955, 71-401, 71-403, 71-2411, 71-2412, 71-2413, 71-2457, 71-2458, 71-2468, 71-2478, and 71-2479, Reissue Revised Statutes of Nebraska, and section 28-414.01,

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Revised Statutes Cumulative Supplement, 2018, are repealed.