SJ 33 Background: MCA Terms and Definitions

ECONOMIC AFFAIRS INTERIM COMMITTEE
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INTRODUCTION

The following definitions provide a general understanding of terms that may be referenced during the Economic Affairs Interim Committee's study of the prescription drug supply chain (SJ 33). This list is not exhaustive and only includes definitions found in the Montana Code Annotated (MCA), specifically Title 33: Insurance and Insurance Companies, and Title 37: Professions and Occupations.[1] Please note that in some cases the definitions may only apply to a specific chapter or part.

MCA TERMS AND DEFINITIONS PERTAINING TO THE PRESCRIPTION DRUG SUPPLY CHAIN (SJ 33):

A

B

"Bioavailability" means the extent and rate of absorption from a dosage form as reflected by the time-concentration curve of the administered drug in the systemic circulation.

"Bioequivalent" means a chemical equivalent that, when administered to the same individual in the same dosage regimen, will result in comparable bioavailability.

"Biological product" has the meaning provided in 42 U.S.C. 262. *[42 U.S.C. 262(i)(1): The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.]*

"Brand name" means the proprietary or the registered trademark name given to a drug product by its manufacturer, labeler, or distributor and placed upon the drug, its container, label, or wrapping at the time of packaging.

C

"Chemical" means medicinal or industrial substances, whether simple, compound, or obtained through the process of the science and art of chemistry, whether of organic or inorganic origin.

"Chemical equivalent" means drug products that contain the same amounts of the same therapeutically active ingredients in the same dosage forms and that meet present compendium standards.

[1] MCA sections 33-2-2402, 33-22-140, 33-22-170, 37-7-101, 37-7-502, 37-7-602, and 37-7-702.

"Claims processing services" means the administrative services performed in connection with the processing and adjudicating of claims relating to pharmacist services that include either or both of the following: (a) receiving payments for pharmacist services; and (b) making payments to pharmacists or pharmacies.

"Clinical pharmacist practitioner" means a licensed pharmacist in good standing who meets the requirements specified in 37-7-306.

"Collaborative pharmacy practice" means the practice of pharmacy by a pharmacist who has agreed to work in conjunction with one or more prescribers, on a voluntary basis and under protocol, and who may perform certain patient care functions under certain specified conditions or limitations authorized by the prescriber.

"Collaborative pharmacy practice agreement" means a written and signed agreement between one or more pharmacists and one or more prescribers that provides for collaborative pharmacy practice for the purpose of drug therapy management of patients.

"Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device based on: (a) a practitioner's prescription drug order; (b) a professional practice relationship between a practitioner, pharmacist, and patient; (c) research, instruction, or chemical analysis, but not for sale or dispensing; or (d) the preparation of drugs or devices based on routine, regularly observed prescribing patterns.

"Contract pharmacy" means a pharmacy operating under contract with a federally certified health entity to provide dispensing services to the federally certified health entity.

"Controlled substance" means a substance designated in Schedules II through V of Title 50, chapter 32, part 2.

D

"Dispense" or "dispensing" means the interpretation, evaluation, and implementation of a prescription drug order, including the preparation and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for administration to or use by a patient.

"Dispenser" means (a) a retail pharmacy, a hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of the entities listed in this subsection (a), if they are under common ownership and control and do not act as a wholesale distributor. (b) The term does not include a person who dispenses only products used in animals in accordance with FDA laws and regulations.

"Distribute" or "distribution" means the sale, purchase, trade, delivery, handling, storage, or receipt of a drug or device and does not include administering or dispensing a prescription drug, pursuant to section 353(b)(1), or a new animal drug, pursuant to section 360b(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301, et seq.

"Drug" means a substance: (a) recognized as a drug in any official compendium or supplement; (b) intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals; (c) other than food, intended to affect the structure or function of the body of humans or animals; and (d) intended for use as a component of a substance specified in subsection (a), (b), or (c).

"Drug product" means a dosage form containing one or more active therapeutic ingredients along with other substances included during the manufacturing process.

"Drug utilization review" means an evaluation of a prescription drug order and patient records for duplication of therapy, interactions, proper utilization, and optimum therapeutic outcomes. The term includes but is not limited to the following evaluations: (a) known allergies; (b) rational therapy contraindications; (c) reasonable dose and route administration; (d) reasonable directions for use; (e) drug-drug interactions; (f) drug-food interactions; (g) drug-disease interactions; and (h) adverse drug reactions.

E

"Effective rate contracting" means an agreement or arrangement between a pharmacy or a contracting agent acting on behalf of a pharmacy and a pharmacy benefit manager or third-party payer that establishes a reimbursement rate for pharmaceuticals based on the effective rate of payment rather than on a predetermined fixed price or a fixed discount percentage. An effective rate of payment involves any calculation for which pharmacy reimbursement is based on an aggregation of more than one claim, rather than on a per-claim basis. *[HB 740 addition to 33-22-170]*

"Enrollee" means a member, policyholder, subscriber, covered person, beneficiary, dependent, or other individual participating in a health benefit plan.

"Equivalent drug product" means a drug product that has the same established name, active ingredient or ingredients, strength or concentration, dosage form, and route of administration and meets the same standards as another drug product as determined by any official compendium or supplement. Equivalent drug products may differ in shape, scoring, configuration, packaging, excipients, and expiration time.

F

"FDA" means the United States food and drug administration.

"Federally certified health entity" means a 340B covered entity as described in 42 U.S.C. 256b(a)(4).

G

"Generic name" means the chemical or established name of a drug product or drug ingredient published in the latest edition of an official compendium recognized by the board.

H

"Health benefit plan" means a policy, contract, certificate, or agreement entered into, offered, or issued by a health carrier to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services.

"Health care facility" means (a) all or a portion of an institution, building, or agency, private or public, excluding federal facilities, whether organized for profit or not, that is used, operated, or designed to provide health services, medical treatment, or nursing, rehabilitative, or preventive care to any individual. The term includes abortion clinics as defined in 50-20-901, chemical dependency facilities, critical access hospitals, eating disorder centers, end-stage renal dialysis facilities, home health agencies, home infusion therapy agencies, hospices, hospitals, infirmaries, long-term care facilities, intermediate care facilities for the developmentally disabled, medical assistance facilities, mental health centers, outpatient centers for primary care, outpatient centers for surgical services, rehabilitation facilities, residential care facilities, residential treatment facilities, and rural emergency hospitals. (b) The term does not

include offices of private physicians, dentists, or other physical or mental health care workers regulated under Title 37, including licensed addiction counselors.

"Health carrier" means (a) an entity that is subject to the insurance laws and regulations of this state or to the jurisdiction of the commissioner and that contracts or offers to contract or enters into an agreement to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services. (b) The term includes: (i) self-funded multiple employer welfare arrangements as defined in 33-35-103; and (ii) any other entity providing a plan of health insurance, health benefits, or health care services.

"Health clinic" means (a) a facility in which advice, counseling, diagnosis, treatment, surgery, care, or services relating to preserving or maintaining health are provided on an outpatient basis for a period of less than 24 consecutive hours to a person not residing at or confined to the facility. (b) The term includes an outpatient center for primary care and an outpatient center for surgical services, as those terms are defined in 50-5-101, and a local public health agency as defined in 50-1-101. (c) The term does not include a facility that provides routine health screenings, health education, or immunizations.

"Hospital" means (a) a facility providing, by or under the supervision of licensed physicians, services for medical diagnosis, treatment, rehabilitation, and care of injured, disabled, or sick individuals. Except as otherwise provided by law, services provided must include medical personnel available to provide emergency care onsite 24 hours a day and may include any other service allowed by state licensing authority. A hospital has an organized medical staff that is on call and available within 20 minutes, 24 hours a day, 7 days a week, and provides 24-hour nursing care by licensed registered nurses. The term includes: (i) hospitals specializing in providing health services for psychiatric, developmentally disabled, and tubercular patients; and (ii) specialty hospitals. (b) The term does not include critical access hospitals. (c) The emergency care requirement for a hospital that specializes in providing health services for psychiatric, developmentally disabled, or tubercular patients is satisfied if the emergency care is provided within the scope of the specialized services provided by the hospital and by providing 24-hour nursing care by licensed registered nurses.

I

"Independent pharmacy" means a pharmacy as defined in 37-7-101 that: (a) is licensed with the board of pharmacy as a pharmacy; (b) is located in the state; and (c) is not owned or operated by or a subsidiary or affiliate of: (i) a for-profit entity with more than 10 pharmacy locations nationwide; (ii) a pharmacy benefit manager; or (iii) a publicly traded entity. *[HB 740 addition to 33-22-170]*

"Interchangeable biological product" means a biological product that the federal food and drug administration has: (a) licensed; and (b) (i) determined meets the standards for interchangeability pursuant to 42 U.S.C. 262(k)(4); or (ii) determined is therapeutically equivalent as set forth in the latest edition of or supplement to the federal food and drug administration's approved drug products with therapeutic equivalence evaluations.

J

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M

"Manufacturer" means: (a) a person approved by application to the FDA to manufacture a product as defined in section 360eee of the Drug Supply Chain Security Act, 21 U.S.C. 301, et seq., or a biologic pursuant to 42 U.S.C. 262; (b) a person who manufactures a product as defined in section 360eee of the Drug Supply Chain Security Act, 21 U.S.C. 301, et seq., or a biologic pursuant to 42 U.S.C. 262 that is not the subject of an approved application or license by the FDA; (c) a co-licensed partner of a person described in subsection (a) or (b) that obtains the product directly from a person described in subsection (a), (b), or (d); or (d) an affiliate of a person described in subsection (a), (b), or (c) that receives the product directly from a person described in subsection (a), (b), or (c).

"Manufacturing" means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis.

"Maximum allowable cost list" means the list of drugs used by a pharmacy benefit manager that sets the maximum cost on which reimbursement to a network pharmacy or pharmacist is based.

N

O

"Other prescription drug or device services" means services other than claims processing services that are provided directly or indirectly, whether in connection with or separate from claims processing services, including but not limited to: (a) negotiating rebates, discounts, or other financial incentives and arrangements with manufacturers, wholesale distributors, or other third parties; (b) disbursing or distributing rebates; (c) managing or participating in incentive programs or arrangements for pharmacist services; (d) negotiating or entering into contractual arrangements with pharmacists, pharmacies, or both; (e) developing and maintaining formularies; (f) designing prescription drug benefit programs; (g) advertising or promoting services; or (h) administering prior authorization, step therapy, case management, or other utilization review programs.

"Out-of-state mail service pharmacy" means a pharmacy located outside this state that: (1) ships, mails, or delivers by any lawful means a dispensed legend drug to a resident in this state pursuant to a legally issued prescription; (2) provides to a resident of this state information on drugs or devices that may include but is not limited to advice relating to therapeutic values, potential hazards, and uses; or (3) counsels pharmacy patients residing in this state concerning adverse and therapeutic effects of drugs.

"Outsourcing facility" means a facility at one geographic location or address that: (a) engages in compounding of sterile drugs; (b) has elected to register as an outsourcing facility with FDA; and (c) complies with all the requirements of section 353b of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq.

P

"Person" includes an individual, partnership, corporation, association, or other legal entity.

"Pharmaceutical care" means the provision of drug therapy and other patient care services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process.

"Pharmacist" means a person licensed by the state to engage in the practice of pharmacy and who may affix to the person's name the term "R.Ph.".

"Pharmacist services" means products, goods, and services or any combination of products, goods, and services provided as part of the practice of pharmacy.

"Pharmacy" means an established location, either physical or electronic, registered by the board of pharmacy where drugs or devices are dispensed with pharmaceutical care or where pharmaceutical care is provided.

"Pharmacy benefit manager (PBM)" means a person who contracts with pharmacies on behalf of a health insurance issuer, third-party administrator, or plan sponsor to process claims for prescription drugs, provide retail network management for pharmacies or pharmacists, pay pharmacies or pharmacists for prescription drugs, or provide other prescription drug or device services.

"Pharmacy performance measurement entity" means: (a) the electronic quality improvement platform for plans and pharmacies; or (b) an entity approved by the board of pharmacy provided for in 2-15-1733 as a nationally recognized and unbiased entity that assists pharmacies in improving performance measures.

"Pharmacy services administrative organization (PSAO)" means an entity that acts as a contracting agent or provides contracting and other administrative services to pharmacies to assist them in their interactions with third-party payers and pharmacy benefit managers.

"Plan sponsor" means: (a) the employer in the case of a benefit plan established or maintained by a single employer; (b) the employee organization in the case of a benefit plan established or maintained by an employee organization; or (c) in the case of a benefit plan established or maintained by two or more employers or jointly by one or more employers and one or more employee organizations, the association, committee, joint board of trustees, or other similar group of representatives of the parties who establish or maintain the benefit plan.

"Practice of pharmacy" means: (a) interpreting, evaluating, and implementing prescriber orders; (b) administering drugs and devices pursuant to a collaborative practice agreement, except as provided in 37-7-105, and compounding, labeling, dispensing, and distributing drugs and devices, including patient counseling; (c) properly and safely procuring, storing, distributing, and disposing of drugs and devices and maintaining proper records; (d) prescribing drugs and devices in accordance with 37-7-106; (e) monitoring drug therapy and use; (f) initiating or modifying drug therapy in accordance with collaborative pharmacy practice agreements established and approved by health care facilities or voluntary agreements with prescribers; (g) participating in quality assurance and performance improvement activities; (h) providing information on drugs, dietary supplements, and devices to patients, the public, and other health care providers; and (i) participating in scientific or clinical research as an investigator or in collaboration with other investigators.

"Practice pharmacy by means of telehealth" means to provide pharmaceutical care through the use of information technology to patients at a distance.

"Prescriber" means a medical practitioner, as defined in 37-2-101, licensed under the professional laws of the state to administer and prescribe medicine and drugs.

"Prescription drug" means any drug that is required by federal law or regulation to be dispensed only by a prescription subject to section 353(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq.

"Product selection" means to dispense without the prescriber's express authorization a different drug product in place of the drug product prescribed.

"Provisional community pharmacy" means a pharmacy that has been approved by the board, including but not limited to federally qualified health centers, as defined in 42 CFR 405.2401, where prescription drugs are dispensed to appropriately screened, qualified patients [meaning a person who is uninsured, indigent, or has insufficient funds to obtain needed prescription drugs or cancer drugs].

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"Rebates" means (a) all price concessions, however characterized, paid by a manufacturer to a pharmacy benefit manager, including discounts and other remuneration or price concessions, that are based on the actual or estimated utilization of a prescription drug. (b) The term includes price concessions based on the effectiveness of a prescription drug as in a value-based or performance-based contract.

"Reference pricing" means a calculation for the price of a pharmaceutical that uses the most current nationally recognized reference price or amount to set the reimbursement for prescription drugs and other products, supplies, and services covered by a network contract between a plan sponsor, health insurance issuer, or pharmacy benefit manager and a pharmacy or pharmacist.

"Repackager" means a person who owns or operates an establishment that repacks and relabels a product or a package for: (a) further sale; or (b) distribution without a further transaction.

S

T

"Therapeutically equivalent" means those chemical equivalents that, when administered in the same dosage regimen, will provide essentially the same therapeutic effect as measured by the control of a symptom or a disease and/or toxicity.

"Third-party logistics provider" or "3PL" means an entity that provides or coordinates warehousing or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product but does not take ownership of the product or have responsibility to direct the sale or disposition of the product.

U

V

W

"Wholesale" means a sale for the purpose of resale.

"Wholesale acquisition cost" has the meaning provided in 42 U.S.C. 1395w-3a. *[42 U.S.C. 1395w-3a(C)(6): The term "wholesale acquisition cost" means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or*

reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.]

"Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient. The term does not include the exclusions listed in section 353(e)(4) of the Drug Supply Chain Security Act, 21 U.S.C. 301, et seq.

"Wholesale distributor" means a person or entity, other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or a repackager, who is engaged in wholesale distribution of prescription drugs.

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