SENATE BILL NO. 483

INTRODUCED BY E. BOLDMAN

A BILL FOR AN ACT ENTITLED: “AN ACT GENERALLY REVISING HEALTH CARE LAWS; REQUIRING CERTAIN PROTOCOLS FOR STEP THERAPY; PROVIDING DEFINITIONS; PROVIDING EXCEPTIONS; PROVIDING RULEMAKING AUTHORITY; AND AMENDING SECTION 33-32-102, MCA.”

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

Section 1. Section 33-32-102, MCA, is amended to read:

"**33-32-102. Definitions.** As used in this chapter, the following definitions apply:

(1) “AB-rated generic equivalent drug” means a prescription drug product that is considered by the United States food and drug administration to be therapeutically equivalent to a particular name-brand prescription drug.

~~(1)~~(2) "Adverse determination", except as provided in 33-32-402, means:

(a) a determination by a health insurance issuer or its designated utilization review organization that, based on the provided information and after application of any utilization review technique, a requested benefit under the health insurance issuer's health plan is denied, reduced, or terminated or that payment is not made in whole or in part for the requested benefit because the requested benefit does not meet the health insurance issuer's requirement for medical necessity, appropriateness, health care setting, level of care, or level of effectiveness or is determined to be experimental or investigational;

(b) a denial, reduction, termination, or failure to provide or make payment in whole or in part for a requested benefit based on a determination by a health insurance issuer or its designated utilization review organization of a person's eligibility to participate in the health insurance issuer's health plan;

(c) any prospective review or retrospective review of a benefit determination that denies, reduces, or terminates or fails to provide or make payment in whole or in part for a benefit; or

(d) a rescission of coverage determination.

~~(2)~~(3) "Ambulatory review" means a utilization review of health care services performed or provided in

an outpatient setting.

~~(3)~~(4) "Authorized representative" means:

(a) a person to whom a covered person has given express written consent to represent the covered person;

(b) a person authorized by law to provided substituted consent for a covered person; or

(c) a family member of the covered person, or the covered person's treating health care provider, only if the covered person is unable to provide consent.

~~(4)~~(5) "Case management" means a coordinated set of activities conducted for individual patient management of serious, complicated, protracted, or otherwise complex health conditions.

~~(5)~~(6) "Certification" means a determination by a health insurance issuer or its designated utilization review organization that an admission, availability of care, continued stay, or other health care service has been reviewed and, based on the information provided, satisfies the health insurance issuer's requirements for medical necessity, appropriateness, health care setting, level of care, and level of effectiveness.

~~(6)~~(7) "Clinical peer" means a physician or other health care provider who:

(a) holds a nonrestricted license in a state of the United States; and

(b) is trained or works in the same or a similar specialty to the specialty that typically manages the medical condition, procedure, or treatment under review.

(8) “Clinical practice guidelines” means a systematically developed statement to assist decisionmaking by health care providers and patients about appropriate health care for specific clinical circumstances and conditions.

~~(7)~~(9) "Clinical review criteria" means the written policies, written screening procedures, decision abstracts, determination rules, clinical and medical protocols, practice guidelines, or any other criteria or rationale used by a health insurance issuer or its designated utilization review organization to determine the medical necessity of health care services.

~~(8)~~(10) "Concurrent review" means a utilization review conducted during a patient's stay or course of treatment in a facility, the office of a health care professional, or another inpatient or outpatient health care setting.

~~(9)~~(11) "Cost sharing" means the share of costs that a covered member pays under the health

insurance issuer's health plan, including maximum out-of-pocket, deductibles, coinsurance, copayments, or similar charges, but does not include premiums, balance billing amounts for out-of-network providers, or the cost of noncovered services.

~~(10)~~(12)"Covered benefits" or "benefits" means those health care services to which a covered person is entitled under the terms of a health plan.

~~(11)~~(13)"Covered person" means a policyholder, a certificate holder, a member, a subscriber, an enrollee, or another individual participating in a health plan.

~~(12)~~(14)"Discharge planning" means the formal process for determining, prior to discharge from a facility, the coordination and management of the care that a patient receives after discharge from a facility.

~~(13)~~(15)"Emergency medical condition" has the meaning provided in 33-36-103.

~~(14)~~(16)"Emergency services" has the meaning provided in 33-36-103.

~~(15)~~(17)"External review" describes the set of procedures provided for in Title 33, chapter 32, part 4.

~~(16)~~(18)"Final adverse determination" means an adverse determination involving a covered benefit that has been upheld by a health insurance issuer or its designated utilization review organization at the completion of the health insurance issuer's internal grievance process as provided in Title 33, chapter 32, part 3.

~~(17)~~(19)"Grievance" means a written complaint or an oral complaint if the complaint involves an urgent care request submitted by or on behalf of a covered person regarding:

(a) availability, delivery, or quality of health care services, including a complaint regarding an adverse determination made pursuant to utilization review;

(b) claims payment, handling, or reimbursement for health care services; or

(c) matters pertaining to the contractual relationship between a covered person and a health insurance issuer.

~~(18)~~(20)"Health care provider" or "provider" means a person, corporation, facility, or institution licensed by the state to provide, or otherwise lawfully providing, health care services, including but not limited to:

(a) a physician, physician assistant, advanced practice registered nurse, health care facility as defined in 50-5-101, osteopath, dentist, nurse, optometrist, chiropractor, podiatrist, physical therapist, psychologist, licensed social worker, speech pathologist, audiologist, licensed addiction counselor, or licensed professional counselor; and

(b) an officer, employee, or agent of a person described in subsection ~~(18)(a)~~ (20)(a) acting in the course and scope of employment.

~~(19)~~(21)"Health care services" means services for the diagnosis, prevention, treatment, cure, or relief of a health condition, illness, injury, or disease, including the provision of pharmaceutical products or services or durable medical equipment.

~~(20)~~(22)"Health insurance issuer" has the meaning provided in 33-22-140.

(23) "Interchangeable biological product" means a biological product that the United States food and drug administration has either determined meets the safety standards set forth in 42 U.S.C. 262(k)(4) or deemed therapeutically equivalent.

~~(21)~~(24)"Medical necessity" means health care services that a health care provider exercising prudent clinical judgment would provide to a patient for the purpose of preventing, evaluating, diagnosing, treating, curing, or relieving a health condition, illness, injury, or disease or its symptoms and that are:

(a) in accordance with generally accepted standards of practice;

(b) clinically appropriate in terms of type, frequency, extent, site, and duration and are considered effective for the patient's illness, injury, or disease; and

(c) not primarily for the convenience of the patient or health care provider and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the patient's illness, injury, or disease.

(25) "Medically appropriate" means health services and supplies that, under the applicable standard of care, are appropriate:

(a) to improve or preserve health, life, or function;

(b) to slow the deterioration of health, life, or function; or

(c) for the early screening, prevention, evaluation, diagnosis, or treatment of a disease, condition, illness, or injury.

~~(22)~~(26)"Network" means the group of participating providers providing services to a managed care plan.

~~(23)~~(27)"Participating provider" means a health care provider who, under a contract with a health insurance issuer or with its contractor or subcontractor, has agreed to provide health care services to covered

persons with the expectation of receiving payment, other than coinsurance, copayments, or deductibles, directly or indirectly from the health insurance issuer.

~~(24)~~(28)"Person" means an individual, a corporation, a partnership, an association, a joint venture, a joint stock company, a trust, an unincorporated organization, or any similar entity or combination of entities in this subsection.

~~(25)~~(29)"Preservice claim" means a request for benefits or payment from a health insurance issuer for health care services that, under the terms of the health insurance issuer's contract of coverage, requires authorization from the health insurance issuer or from the health insurance issuer's designated utilization review organization prior to receiving the services.

~~(26)~~(30)"Prospective review" means a utilization review conducted of a preservice claim prior to an admission or a course of treatment.

~~(27)~~(31)(a) "Rescission" means a cancellation or the discontinuance of coverage under a health plan that has a retroactive effect.

(b) The term does not include a cancellation or discontinuance under a health plan if the cancellation or discontinuance of coverage:

(i) has only a prospective effect; or

(ii) is effective retroactively to the extent that the cancellation or discontinuance is attributable to a failure to timely pay required premiums or contributions toward the cost of coverage.

~~(28)~~(32)(a) "Retrospective review" means a review of medical necessity conducted after services have been provided to a covered person.

(b) The term does not include the review of a claim that is limited to an evaluation of reimbursement levels, veracity of documentation, accuracy of coding, or adjudication for payment.

~~(29)~~(33)"Second opinion" means an opportunity or requirement to obtain a clinical evaluation by a health care provider other than the one originally making a recommendation for a proposed health care service to assess the clinical necessity and appropriateness of the initial proposed health care service.

~~(30)~~(34)"Stabilize" means, with respect to an emergency condition, to ensure that no material deterioration of the condition is, within a reasonable medical probability, likely to result from or occur during the transfer of the individual from a facility.

(35) “Step therapy exception determination” means a determination as to whether a step therapy protocol should apply in a particular situation or be overridden in favor of immediate coverage of a health care provider’s selected prescription drug based on a review of the patient’s or prescriber’s request for an exception and the supporting rationale and documentation.

(36) “Step therapy protocol” means a protocol or program that requires the use of specific prescription drugs in a specific sequence as a condition of coverage under a policy.

~~(31)~~(37)(a) "Urgent care request" means a request for a health care service or course of treatment with respect to which the time periods for making a nonurgent care request determination could:

(i) seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function; or

(ii) subject the covered person, in the opinion of a health care provider with knowledge of the covered person's medical condition, to severe pain that cannot be adequately managed without the health care service or treatment that is the subject of the request.

(b) Except as provided in subsection ~~(31)(c)~~ (37)(c), in determining whether a request is to be treated as an urgent care request, an individual acting on behalf of the health insurance issuer shall apply the judgment of a prudent lay person who possesses an average knowledge of health and medicine.

(c) Any request that a health care provider with knowledge of the covered person's medical condition determines is an urgent care request within the meaning of subsection ~~(31)(a)~~ (37)(a) must be treated as an urgent care request.

~~(32)~~(38)"Utilization review" means a set of formal techniques designed to monitor the use of or to evaluate the clinical necessity, appropriateness, efficacy, or efficiency of health care services, procedures, or settings. Techniques may include ambulatory review, prospective review, second opinions, certification, concurrent review, case management, discharge planning, or retrospective review.

~~(33)~~(39)"Utilization review organization" means an entity that conducts utilization review for one or more of the following:

(a) an employer with employees who are covered under a health benefit plan or health insurance policy;

(b) a health insurance issuer providing review for its own health plans or for the health plans of

another health insurance issuer;

(c) a preferred provider organization or health maintenance organization; and

(d) any other individual or entity that provides, offers to provide, or administers hospital, outpatient, medical, or other health benefits to a person treated by a health care provider under a policy, plan, or contract."

NEW SECTION. **Section 2. Step therapy protocol -- requirements -- exceptions.** (1) Clinical review criteria used to establish a step therapy protocol must be based on clinical practice guidelines. The guidelines must:

(a) recommend that prescription drugs be taken in the specific sequence required by the step therapy protocol;

(b) be developed and endorsed by a multidisciplinary panel of experts that manages conflicts of interest among the members of the writing and review groups by:

(i) requiring members to disclose any potential conflict of interests with entities, including insurers, health plans, and pharmaceutical manufacturers and to recuse themselves from voting if they have a conflict of interest;

(ii) using a methodologist to work with writing groups to provide objectivity in data analysis and ranking of evidence through preparing evidence tables and facilitating consensus; and

(iii) offering opportunities for public review and comments;

(c) be based on high-quality studies, research, and medical practices;

(d) be established under an explicit and transparent process that:

(i) minimizes biases and conflicts of interest;

(ii) explains the relationship between treatment options and outcomes;

(iii) rates the quality of the evidence supporting recommendations; and

(iv) considers relevant patient subgroups and preferences;

(e) be continually updated through a review of new evidence, research, and newly developed treatments; and

(f) consider the needs of atypical patient populations and diagnoses.

(2) In the absence of a panel, peer-reviewed publications may suffice for clinical practice

guidelines.

(3) Nothing in this section may be construed to require an insurer, a utilization review organization, or a health care provider to create a new entity to develop clinical review criteria used for step therapy protocols.

(4) (a) When coverage of a prescription drug for the treatment of any medical condition is restricted for use by an insurer or a utilization review organization through the use of a step therapy protocol, the patient and the prescribing practitioner must have access to request a step therapy exception through a clear and convenient process that must be readily accessible through the insurer's or utilization review organization's website. An insurer or a utilization review organization may use its existing medical exceptions or appeal process to satisfy this requirement, provided that the process complies with the requirements of this section.

(b) An insurer or a utilization review organization shall upon written request:

(i) provide all written clinical review criteria relating to a particular condition or disease or a step therapy exception determination;

(ii) display the requested clinical review criteria and other clinical information on its website; and

(iii) distribute the requested clinical review criteria and other clinical information to a health care professional on behalf of a patient.

(5) A step therapy exception must be granted to a patient whose relevant medical condition:

(a) is currently stabilized by a particular prescription drug prescribed by the patient's health care provider, regardless of any current or prior insurance coverage, and the patient's health care provider has prescribed continued treatment with the same prescription drug; or

(b) is not currently stabilized by a particular prescription drug and if any prescription drug required under the applicable step therapy protocol:

(i) is contraindicated or will likely cause an adverse reaction by or physical or mental harm to the patient;

(ii) is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug;

(iii) has been previously prescribed to the patient or is in the same pharmacologic class or has the same mechanism of action as another prescription drug that has been prescribed to the patient and was

discontinued by the patient's health care provider due to lack of efficacy or effectiveness, diminished effect, or an adverse event, regardless of any current or prior insurance coverage of the prescription drug; or

(iv) will not serve the best interest of the patient, based on medical necessity.

(6) (a) An insurer or a utilization review organization shall make a step therapy exception determination within 72 hours following receipt of a request for an exception or the filing of an appeal.

(b) If exigent circumstances exist, a determination must be made within 24 hours.

(c) If no determination has been made within the applicable time specified, the exception is deemed to be granted.

(7) If a request for a step therapy exception is incomplete or if additional or clinically relevant information is required, the insurer or the utilization review organization shall notify the prescribing practitioner within the appropriate timeframe pursuant to subsection (6) as to what additional or clinically relevant information is required to approve or deny the step therapy exception request or appeal pursuant to the criteria disclosed in subsection (1). Once the requested information has been submitted, the applicable timeframe as provided in subsection (6) for an insurer or a utilization review organization to make a step therapy exception determination applies.

(8) Upon the grant of a step therapy exception, the insurer or the utilization review organization shall authorize coverage for the particular prescription drug prescribed by the patient's health care provider. Any adverse determination under this subsection is subject to appeal pursuant to the insurer's or utilization review organization's existing appeal procedures.

(9) Every insurer or utilization review organization that is subject to this section shall certify annually to the state commissioner of securities and insurance that the insurer's or utilization review organization's step therapy protocol meets the requirements of this section. Any proposed change in protocol or clinical review criteria must be submitted to the commissioner for approval before it may be implemented by the insurer or the utilization review organization.

(10) The state commissioner of securities and insurance shall adopt rules necessary for the purposes of this section.

(11) Each insurer or utilization review organization shall annually submit a report to the office of the state auditor that includes the following:

(a) the number of step therapy exception requests received;

(b) the type of health care providers or the medical specialties of the health care providers submitting step therapy exception requests;

(c) the number of step therapy exception requests that were:

(i) denied, including the reasons for the denials;

(ii) approved;

(iii) initially denied and then appealed; or

(iv) initially denied and then subsequently reversed by internal appeals or external reviews; and

(d) the medical conditions under which patients were granted step therapy exceptions because of the likelihood that switching from the prescription drug would cause an adverse reaction by or physical or mental harm to the insured.

(12) This section applies to any state-regulated plan or health insurance coverage offered in connection with a state-regulated plan that provides coverage of a prescription drug pursuant to a policy that meets the definition of a step therapy protocol, regardless of whether the policy is described as a step therapy protocol.

(13) Nothing in this section may be construed to prevent:

(a) an insurer or a utilization review organization from requiring a patient to try an AB-rated generic equivalent drug or interchangeable biological product before providing coverage for a name-brand prescription drug, unless the requirement meets the qualifications for a step therapy exception pursuant to subsection (5);

(b) an insurer or a utilization review organization from requiring a pharmacist to provide substitutions of prescription drugs pursuant to 37-7-505; or

(c) a health care provider from prescribing any prescription drug that the provider finds to be medically appropriate for the patient.

NEW SECTION. **Section 3. Codification instruction.** [Section 2] is intended to be codified as an integral part of Title 33, chapter 32, part 2, and the provisions of Title 33, chapter 32, part 2, apply to [section 2].

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