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Representatives Huffman, Pelanda

Cosponsors: Representatives Becker, Johnson, T., Sprague, Ginter, Barnes, Brown, Butler, Schuring, Amstutz, Anielski, Antonio, Baker, Burkley, Dovilla, Gonzales, Green, Grossman, McClain, O'Brien, S., Rogers, Sears, Smith, R., Sweeney

Senators Gardner, Jones, Cafaro, Brown, Beagle, Tavares, Coley, Hackett, Hite, Hughes, Lehner, Patton, Peterson, Schiavoni, Seitz, Thomas, Uecker, Yuko

A BILL

To amend sections 1751.04, 1751.72, 3715.01, 3715.64, 3923.041, 4729.01, 4729.38, 4729.99, and 5160.34 and to enact section 3715.011 of the Revised Code to regulate biological products and the substitution of interchangeable biological products, to revise certain deadlines related to prior authorization requirements, to establish an exemption from the laws governing health insuring corporations, to delay the expiration of certain supervision agreements between physicians and physician assistants, and to declare an emergency.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:

Section 1. That sections 1751.04, 1751.72, 3715.01, 3715.64, 3923.041, 4729.01, 4729.38, 4729.99, and 5160.34 of the Revised Code be amended and section 3715.011 of the Revised Code

be enacted to read as follows:

Sec. 1751.04. (A) Except as provided by division (D) of this section, upon the receipt by the superintendent of insurance of a complete application for a certificate of authority to establish or operate a health insuring corporation, which application sets forth or is accompanied by the information and documents required by division (A) of section 1751.03 of the Revised Code, the superintendent shall review the application and accompanying documents and make findings as to whether the applicant for a certificate of authority has done all of the following with respect to any basic health care services and supplemental health care services to be furnished:

(1) Demonstrated the willingness and potential ability to ensure that all basic health care services and supplemental health care services described in the evidence of coverage will be provided to all its enrollees as promptly as is appropriate and in a manner that assures continuity;

(2) Made effective arrangements to ensure that its enrollees have reliable access to qualified providers in those specialties that are generally available in the geographic area or areas to be served by the applicant and that are necessary to provide all basic health care services and supplemental health care services described in the evidence of coverage;

(3) Made appropriate arrangements for the availability of short-term health care services in emergencies within the geographic area or areas to be served by the applicant, twenty-four hours per day, seven days per week, and for the provision of adequate coverage whenever an out-of-area emergency arises;

(4) Made appropriate arrangements for an ongoing

evaluation and assurance of the quality of health care services provided to enrollees, including, if applicable, the development of a quality assurance program complying with the requirements of sections 1751.73 to 1751.75 of the Revised Code, and the adequacy of the personnel, facilities, and equipment by or through which the services are rendered;

(5) Developed a procedure to gather and report statistics relating to the cost and effectiveness of its operations, the pattern of utilization of its services, and the quality, availability, and accessibility of its services.

(B) Based upon the information provided in the application for issuance of a certificate of authority, the superintendent shall determine whether or not the applicant meets the requirements of division (A) of this section. If the superintendent determines that the applicant does not meet these requirements, the superintendent shall specify in what respects it is deficient. However, the superintendent shall not deny an application because the requirements of this section are not met unless the applicant has been given an opportunity for a hearing on that issue.

(C) If the applicant requests a hearing, the superintendent shall hold a hearing before denying an application because the applicant does not meet the requirements of this section. The hearing shall be held in accordance with Chapter 119. of the Revised Code.

(D) Nothing in this section requires the superintendent to review or make findings with regard to an application and accompanying documents to establish or operate any of the following:

(1) A health insuring corporation to cover solely medicaid recipients;

(2) A health insuring corporation to cover solely medicare beneficiaries;

(3) A health insuring corporation to cover solely medicaid recipients and medicare beneficiaries;

(4) A health insuring corporation to cover solely federal employees and other individuals eligible for coverage in the federal employees health benefits program pursuant to 5 U.S.C. 8905.

Sec. 1751.72. (A) As used in this section:

(1) "Chronic condition" means a medical condition that has persisted after reasonable efforts have been made to relieve or cure its cause and has continued, either continuously or episodically, for longer than six continuous months.

(2) "Clinical peer" means a health care practitioner in the same, or in a similar, specialty that typically manages the medical condition, procedure, or treatment under review.

(3) "Covered person" means a person receiving coverage for health services under a policy, contract, or agreement issued by a health insuring corporation.

(4) "Emergency services" has the same meaning as in section 1753.28 of the Revised Code.

(5) "Fraudulent or materially incorrect information" means any type of intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to the covered person in question.

(6) "Health care practitioner" has the same meaning as in section 3701.74 of the Revised Code.

(7) "NCPDP SCRIPT standard" means the national council for prescription drug programs SCRIPT standard version 201310 or the most recent standard adopted by the the United States department of health and human services.

(8) "Prior authorization requirement" means any practice implemented by a health insuring corporation in which coverage of a health care service, device, or drug is dependent upon a covered person or a health care practitioner obtaining approval from the health insuring corporation prior to the service, device, or drug being performed, received, or prescribed, as applicable. "Prior authorization" includes prospective or utilization review procedures conducted prior to providing a health care service, device, or drug.

(9) "Urgent care services" means a medical care or other service for a condition where application of the timeframe for making routine or non-life threatening care determinations is either of the following:

(a) Could seriously jeopardize the life, health, or safety of the patient or others due to the patient's psychological state;

(b) In the opinion of a practitioner with knowledge of the patient's medical or behavioral condition, would subject the patient to adverse health consequences without the care or treatment that is the subject of the request.

(10) "Utilization review" and "utilization review organization" have the same meanings as in section 1751.77 of the Revised Code.

(B) If a policy, contract, or agreement issued by a health insuring corporation contains a prior authorization requirement, then all of the following apply:

(1) On or before January 1, 2018, the health insuring corporation shall permit health care practitioners to access the prior authorization form through the applicable electronic software system.

(2)(a) For policies issued on or after January 1, 2018, the health insuring corporation or other payer acting on behalf of the health insuring corporation, shall accept prior authorization requests through a secure electronic transmission.

(b) For policies issued on or after January 1, 2018, the health insuring corporation, a pharmacy benefit manager responsible for handling prior authorization requests, or other payer acting on behalf of the health insuring corporation shall accept and respond to prior prescription benefit authorization requests through a secure electronic transmission using NCPDP SCRIPT standard ePA transactions, and for prior medical benefit authorization requests through a secure electronic transmission using standards established by the council for affordable quality health care on operating rules for information exchange or its successor.

(c) For purposes of division (B)(2) of this section, neither of the following shall be considered a secure electronic transmission:

(i) A facsimile;

(ii) A proprietary payer portal for prescription drug requests that does not use NCPDP SCRIPT standard.

(3) For policies issued on or after January 1, 2018, a

health care practitioner and health insuring corporation may enter into a contractual arrangement under which the health insuring corporation agrees to process prior authorization requests that are not submitted electronically because of the financial hardship that electronic submission of prior authorization requests would create for the health care practitioner or if internet connectivity is limited or unavailable where the health care practitioner is located.

(4)(a) For policies issued on or after January 1, 2018, if the health care practitioner submits the request for prior authorization as described in divisions (B)(1) and (2) of this section, the health insuring corporation shall respond to all prior authorization requests within forty-eight hours for urgent care services, or ten calendar days for any prior ~~approval~~ authorization request that is not for an urgent care service, of the time the request is received by the health insuring corporation~~ with all information necessary to support the prior authorization request~~. Division (B)(4) of this section does not apply to emergency services.

(b)~~(i)~~ The response required under division (B)(4)(a) of this section shall indicate whether the request is approved~~,~~ or denied~~, or incomplete~~. If the prior authorization is denied, the health insuring corporation shall provide the specific reason for the denial.

(c) If the prior authorization request is incomplete, the health insuring corporation shall indicate the specific additional information that is required to process the request.

~~(ii) For a response that is considered incomplete, the health care practitioner shall provide the additional information requested under division (B)(4)(b)(i) of this~~

~~section within seventy-two hours of the time the request is received by the practitioner.~~

(5)(a) For policies issued on or after January 1, 2018, if a health care practitioner submits a prior authorization request as described in divisions (B)(1) and (2) of this section, the health insuring corporation shall provide an electronic receipt to the health care practitioner acknowledging that the prior authorization request was received.

(b) For policies issued on or after January 1, 2018, if a health insuring corporation requests additional information that is required to process a prior authorization request as described in division (B)(4)~~(b)(i)~~ (c) of this section, the health care practitioner shall provide an electronic receipt to the health insuring corporation acknowledging that the request for additional information was received.

(6)(a) For policies issued on or after January 1, 2017, for a prior approval related to a chronic condition, the health insuring corporation shall honor a prior authorization approval for an approved drug for the lesser of the following from the date of the approval:

(i) Twelve months;

(ii) The last day of the covered person's eligibility under the policy, contract, or agreement.

(b) The duration of all other prior authorization approvals shall be dictated by the policy, contract, or agreement issued by the health insuring corporation.

(c) A health insuring corporation may, in relation to a prior approval under division (B)(6)(a) of this section, require a health care practitioner to submit information to the health

insuring corporation indicating that the patient's chronic condition has not changed.

(i) The request for information by the health insuring corporation and the response by the health care practitioner shall be in an electronic format, which may be by electronic mail or other electronic communication.

(ii) The frequency of the submission of requested information shall be consistent with medical or scientific evidence as defined in section 3922.01 of the Revised Code, but shall not be required more frequently than quarterly.

(iii) If the health care practitioner does not respond within five calendar days from the date the request was received, the health insuring corporation may terminate the twelve-month approval.

(d) A ~~year long~~ twelve-month approval provided under division (B)(6)(a) of this section is no longer valid and automatically terminates if there are changes to federal or state laws or federal regulatory guidance or compliance information prescribing that the drug in question is no longer approved or safe for the intended purpose.

(e) A twelve-month approval provided under division (B)(6)(a) of this section does not apply to and is not required for any of the following:

(i) Medications that are prescribed for a non-maintenance condition;

(ii) Medications that have a typical treatment of less than one year;

(iii) Medications that require an initial trial period to

determine effectiveness and tolerability, beyond which a one-year, or greater, prior authorization period will be given;

(iv) Medications where there is medical or scientific evidence as defined in section 3922.01 of the Revised Code that do not support a twelve-month prior approval;

(v) Medications that are a schedule I or II controlled substance or any opioid analgesic or benzodiazepine, as defined in section 3719.01 of the Revised Code;

(vi) Medications that are not prescribed by an in-network provider as part of a care management program.

(7) For policies issued on or after January 1, 2017, a health insuring corporation may, but is not required to, provide the twelve-month approval prescribed in division (B)(6)(a) of this section for a prescription drug that meets either of the following:

(a) The drug is prescribed or administered to treat a rare medical condition and pursuant to medical or scientific evidence as defined in section 3922.01 of the Revised Code.

(b) Medications that are controlled substances not included in division (B)(6)(e)(v) of this section.

For purposes of division (B)(7) of this section, "rare medical condition" means any disease or condition that affects fewer than two hundred thousand individuals in the United States.

(8) Nothing in division (B)(6) or (7) of this section prohibits the substitution<u>, in accordance with section 4729.38 of the Revised Code,</u> of any drug that has received a twelve-month approval under division (B)(6)(a) of this section when

there is a release of ~~a~~ either of the following:

(a) A United States food and drug administration approved comparable brand product or a generic counterpart of a brand product that is listed as therapeutically equivalent in the United States food and drug administration's publication titled approved drug products with therapeutic equivalence evaluations;

(b) An interchangeable biological product, as defined in section 3715.01 of the Revised Code.

(9)(a) For policies issued on or after January 1, 2017, upon written request, a health insuring corporation shall permit a retrospective review for a claim that is submitted for a service where prior authorization was required but not obtained if the service in question meets all of the following:

(i) The service is directly related to another service for which prior approval has already been obtained and that has already been performed.

(ii) The new service was not known to be needed at the time the original prior authorized service was performed.

(iii) The need for the new service was revealed at the time the original authorized service was performed.

(b) Once the written request and all necessary information is received, the health insuring corporation shall review the claim for coverage and medical necessity. The health insuring corporation shall not deny a claim for such a new service based solely on the fact that a prior authorization approval was not received for the new service in question.

(10)(a) For policies issued on or after January 1, 2017, the health insuring corporation shall disclose to all

participating health care practitioners any new prior authorization requirement at least thirty days prior to the effective date of the new requirement.

(b) The notice may be sent via electronic mail or standard mail and shall be conspicuously entitled "Notice of Changes to Prior Authorization Requirements." The notice is not required to contain a complete listing of all changes made to the prior authorization requirements, but shall include specific information on where the health care practitioner may locate the information on the health insuring corporation's web site or, if applicable, the health insuring corporation's portal.

(c) All participating health care practitioners shall promptly notify the health insuring corporation of any changes to the health care practitioner's electronic mail or standard mail address.

(11)(a) For policies issued on or after January 1, 2017, the health insuring corporation shall make available to all participating health care practitioners on its web site or provider portal a listing of its prior authorization requirements, including specific information or documentation that a ~~provider~~ practitioner must submit in order for the prior authorization request to be considered complete.

(b) The health insuring corporation shall make available on its web site information about the policies, contracts, or agreements offered by the health insuring corporation that clearly identifies specific services, drugs, or devices to which a prior authorization requirement exists.

(12) For policies issued on or after January 1, 2018, the health insuring corporation shall establish a streamlined appeal

process relating to adverse prior authorization ~~decision~~ determinations that shall include all of the following:

(a) For urgent care services, the appeal shall be considered within forty-eight hours after the health insuring corporation receives the appeal.

(b) For all other matters, the appeal shall be considered within ten calendar days after the health insuring corporation receives the appeal.

(c) The appeal shall be between the health care practitioner requesting the service in question and a clinical peer.

(d) If the appeal does not resolve the disagreement, either the covered person or an authorized representative as defined in section 3922.01 of the Revised Code may request an external review under Chapter 3922. of the Revised Code to the extent Chapter 3922. of the Revised Code is applicable.

(C) For policies issued on or after January 1, 2017, except in cases of fraudulent or materially incorrect information, a health insuring corporation shall not retroactively deny a prior authorization for a health care service, drug, or device when all of the following are met:

(1) The health care practitioner submits a prior authorization request to the health insuring corporation for a health care service, drug, or device.

(2) The health insuring corporation approves the prior authorization request after determining that all of the following are true:

(a) The patient is eligible under the health benefit plan.

(b) The health care service, drug, or device is covered under the patient's health benefit plan.

(c) The health care service, drug, or device meets the health insuring corporation's standards for medical necessity and prior authorization.

(3) The health care practitioner renders the health care service, drug, or device pursuant to the approved prior authorization request and all of the terms and conditions of the health care practitioner's contract with the health insuring corporation.

(4) On the date the health care practitioner renders the prior approved health care service, drug, or device, all of the following are true:

(a) The patient is eligible under the health benefit plan.

(b) The patient's condition or circumstances related to the patient's care has not changed.

(c) The health care practitioner submits an accurate claim that matches the information submitted by the health care practitioner in the approved prior authorization request.

(5) If the health care practitioner submits a claim that includes an unintentional error and the error results in a claim that does not match the information originally submitted by the health care practitioner in the approved prior authorization request, upon receiving a denial of services from the health insuring corporation, the health care practitioner may resubmit the claim pursuant to division (C) of this section with the information that matches the information included in the approved prior authorization.

(D) Any provision of a contractual arrangement entered into between a health insuring corporation and a health care practitioner or beneficiary that is contrary to divisions (A) to (C) of this section is unenforceable.

(E) For policies issued on or after January 1, 2017, committing a series of violations of this section that, taken together, constitute a practice or pattern shall be considered an unfair and deceptive practice under sections 3901.19 to 3901.26 of the Revised Code.

(F) The superintendent of insurance may adopt rules in accordance with Chapter 119. of the Revised Code as necessary to implement the provisions of this section.

(G) This section does not apply to any of the following types of coverage: a policy, contract, certificate, or agreement that covers only a specified accident, accident only, credit, dental, disability income, long-term care, hospital indemnity, supplemental coverage as described in section 3923.37 of the Revised Code, specified disease, or vision care; coverage issued as a supplement to liability insurance; insurance arising out of workers' compensation or similar law; automobile medical payment insurance; insurance under which benefits are payable with or without regard to fault and which is statutorily required to be contained in any liability insurance policy or equivalent self-insurance; a medicare supplement policy of insurance as defined by the superintendent of insurance by rule; coverage under a plan through medicare or the federal employees benefit program; or any coverage issued under Chapter 55 of Title 10 of the United States Code and any coverage issued as a supplement to that coverage.

Sec. 3715.01. (A) As used in this chapter:

(1) "Person" means an individual, partnership, corporation, or association.

(2) "Food" means:

(a) Articles used for food or drink for humans or animals;

(b) Chewing gum;

(c) Articles used for components of any such articles.

(3) "Drug" means:

(a) Articles recognized in the United States pharmacopoeia and national formulary, or any supplement to them;

(b) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(c) Articles, other than food, intended to affect the structure or any function of the body of humans or other animals;

(d) Articles intended for use as a component of any of the foregoing articles, other than devices or their components, parts, or accessories.

(4) "Device," except when used in division (B)(1) of this section and in division (A)(10) of section 3715.52, division (F) of section 3715.60, division (A)(5) of section 3715.64, and division (C) of section 3715.67 of the Revised Code, means any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is any of the following:

(a) Recognized in the United States pharmacopoeia and national formulary, or any supplement to them;

(b) Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in humans or animals;

(c) Intended to affect the structure or any function of the body of humans or animals, and that does not achieve any of its principal intended purposes through chemical action within or on the body of humans or animals and is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

(5) "Cosmetic" means:

(a) Articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance;

(b) Articles intended for use as a component of any such article, except that "cosmetic" does not include soap.

(6) "Label" means a display of written, printed, or graphic matter upon the immediate container, exclusive of package liners, of any article.

Any word, statement, or other information required by this chapter to appear on the label must appear on the outside container or wrapper, if any, of the retail package of the article, or the label must be easily legible through the outside container or wrapper.

(7) "Labeling" means all labels and other written, printed, or graphic matter:

(a) Upon an article or any of its containers or wrappers;

(b) Accompanying such article.

(8) "Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or that are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics.

(9) "New drug" means:

(a) Any drug the composition of which is such that the drug is not generally recognized among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof;

(b) Any drug the composition of which is such that the drug, as a result of investigation to determine its safety for use under such conditions, has become so recognized, but that has not, other than in an investigation, been used to a material extent or for a material time under such conditions.

(10) "Contaminated with filth" applies to any food, drug, device, or cosmetic that has not been protected as far as may be necessary by all reasonable means from dust, dirt, and all foreign or injurious substances.

(11) "Honey" means the nectar and saccharine exudation of plants that has been gathered, modified, and stored in a honeycomb by honeybees.

(12) "Finished dosage form" means the form of a drug that is, or is intended to be, dispensed or administered to humans or animals and requires no further manufacturing or processing other than packaging, reconstituting, or labeling.

(13)(a) "Manufacture" means the planting, cultivating, harvesting, processing, making, preparing, or otherwise engaging in any part of the production of a drug by propagating,

compounding, converting, or processing, either directly or indirectly by extracting from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes the following:

(i) Any packaging or repackaging of the drug or labeling or relabeling of its container, the promotion and marketing of the drug, and other activities incident to production;

(ii) The preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, licensed health professionals authorized to prescribe drugs, or other persons.

(b) "Manufacture" does not include the preparation, compounding, packaging, or labeling of a drug by a pharmacist as an incident to either of the following:

(i) Dispensing a drug in the usual course of professional practice;

(ii) Providing a licensed health professional authorized to prescribe drugs with a drug for the purpose of administering to patients or for using the drug in treating patients in the professional's office.

(14) "Dangerous drug" has the same meaning as in section 4729.01 of the Revised Code.

(15) "Generically equivalent drug" means a drug that contains identical amounts of the identical active ingredients, but not necessarily containing the same inactive ingredients, that meets the identical compendial or other applicable standard of identity, strength, quality, and purity, including potency, and where applicable, content uniformity, disintegration times,

or dissolution rates, as the prescribed brand name drug and the manufacturer or distributor holds, if applicable, either an approved new drug application or an approved abbreviated new drug application unless other approval by law or from the federal food and drug administration is required.

No drug shall be considered a generically equivalent drug for the purposes of this chapter if it has been listed by the federal food and drug administration as having proven bioequivalence problems.

(16) "Licensed health professional authorized to prescribe drugs" and "prescriber" have the same meanings as in section 4729.01 of the Revised Code.

(17) "Home" means the primary residence occupied by the residence's owner, on the condition that the residence contains only one stove or oven used for cooking, which may be a double oven, designed for common residence usage and not for commercial usage, and that the stove or oven be operated in an ordinary kitchen within the residence.

(18) "Potentially hazardous food" means a food that is natural or synthetic, to which any of the following apply:

(a) It has a pH level greater than 4.6 when measured at seventy-five degrees fahrenheit or twenty-four degrees celsius.

(b) It has a water activity value greater than 0.85.

(c) It requires temperature control because it is in a form capable of supporting the rapid and progressive growth of infectious or toxigenic microorganisms, the growth and toxin production of clostridium botulinium, or in the case of raw shell eggs, the growth of salmonella enteritidis.

(19) "Cottage food production operation" means a person who, in the person's home, produces food items that are not potentially hazardous foods, including bakery products, jams, jellies, candy, fruit butter, and similar products specified in rules adopted pursuant to section 3715.025 of the Revised Code.

(20) "Biological product" means, except as provided in section 3715.011 of the Revised Code, a drug that is a biological product, as defined on the effective date of this amendment in subsection (i) of section 351 of the "Public Health Service Act," 42 U.S.C. 262(i).

(21) "Interchangeable biological product" means, except as provided in section 3715.011 of the Revised Code, both of the following:

(a) A biological product that, on the effective date of this amendment, has been determined by the United States food and drug administration to meet the standards for interchangeability set forth in subsection (k) of section 351 of the "Public Health Service Act," 42 U.S.C. 262(k), as amended, and has been licensed under that subsection;

(b) A biological product that, prior to the effective date of this amendment, was determined by the United States food and drug administration to be therapeutically equivalent as set forth in its publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations."

(B) For the purposes of sections 3715.52 to 3715.72 of the Revised Code:

(1) If an article is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading, then in determining whether the

labeling or advertisement is misleading, there shall be taken into account, among other things, not only representations made or suggested by statement, word, design, device, sound, or in any combination thereof, but also the extent to which the labeling or advertisement fails to reveal facts material in the light of such representations or material with respect to consequence which may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual.

(2) The provisions regarding the selling of food, drugs, devices, or cosmetics include the manufacture, production, processing, packing, exposure, offer, possession, and holding of any such article for sale; and the sale, dispensing, and giving of any such article, and the supplying or applying of any such articles in the conduct of any food, drug, or cosmetic establishment. The provisions do not prohibit a licensed health professional authorized to prescribe drugs from administering or personally furnishing a drug or device to a patient.

(3) The representation of a drug, in its labeling or advertisement, as an antiseptic is a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or other use that involves prolonged contact with the body.

(4) Whenever jurisdiction is vested in the director of agriculture or the state board of pharmacy, the jurisdiction of the board shall be limited to the sale, offering for sale, giving away, delivery, or dispensing in any manner of drugs at the wholesale and retail levels or to the consumer and shall be

exclusive in the case of such sale, offering for sale, giving away, delivery, or dispensing in any manner of drugs at the wholesale and retail levels or to the consumer in any place where prescriptions are dispensed or compounded.

(5) To assist in effectuating the provisions of those sections, the director of agriculture or state board of pharmacy may request assistance or data from any government or private agency or individual.

Sec. 3715.011. (A) When one of the following changes occurs under federal law with respect to a biological product or interchangeable biological product, the change is automatically effected under this chapter and Chapter 4729. of the Revised Code, subject to any rule adopted under division (B) of this section to the contrary:

(1) An article is added to or removed from the definition of biological product in subsection (i) of section 351 of the "Public Health Service Act," 42 U.S.C. 262(i).

(2) The United States food and drug administration determines that a biological product meets the standards for interchangeability set forth in section 351 of the "Public Health Service Act," 42 U.S.C. 262(k), and the product is licensed under that subsection.

(3) The United States food and drug administration determines that a biological product no longer meets the standards for interchangeability set forth in section 351 of the "Public Health Service Act," 42 U.S.C. 262(k), and the product's license under that subsection is suspended or revoked.

(B) The state board of pharmacy may adopt rules that exclude a biological product or interchangeable biological

product that, pursuant to division (A) of this section, would otherwise be included under this chapter and Chapter 4729. of the Revised Code. The board's rules shall establish criteria to be used in determining whether a product is to be excluded.

All rules adopted under this division shall be adopted in accordance with Chapter 119. of the Revised Code.

Sec. 3715.64. (A) A drug or device is misbranded within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, if:

(1) Its labeling is false or misleading in any particular.

(2) It is in package form and does not bear a label containing both of the following:

(a) In clearly legible form, the name and place of business of the manufacturer, packer, or distributor;

(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; but reasonable variations shall be permitted, and exemptions as to small packages shall apply as established by rules adopted by the director of agriculture or state board of pharmacy.

(3) It is a dangerous drug and does not bear a label containing in clearly legible form the name and place of business of the manufacturer of the finished dosage form and, if different, the packer or distributor.

(4) It is a dangerous drug in finished solid oral dosage form and it does not have clearly and prominently marked or imprinted on it an individual symbol, company name, national drug code number or other number, words, letters, or any combination thereof, identifying the drug and its manufacturer

or distributor. This requirement does not apply to drugs that are compounded by a licensed pharmacist. The manufacturer or distributor of each such drug shall make available to the state board of pharmacy descriptive material identifying the mark or imprint used by the manufacturer or distributor. The board shall provide this information to all poison control centers in this state. Upon application by a manufacturer or distributor, the board may exempt a drug from the requirements of this division on the grounds that marking or imprinting the drug is not feasible because of its size, texture, or other unique characteristic.

(5) Any word, statement, or other information that is required by or under authority of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code to appear on the label or labeling is not prominently placed on the label or labeling in a conspicuous manner, as compared with other words, statements, designs, or devices on the label or labeling, and in terms that render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(6) It is a drug and it is not designated solely by a name recognized in the United States pharmacopoeia and national formulary, or any supplement to them, unless its label bears:

(a) The common or usual name of the drug, if any;

(b) In case it is fabricated from two or more ingredients, the common or usual name of each active ingredient the drug contains, including the kind and quantity or proportion of any alcohol, and also including whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanalid, acetophenetidin, aminopyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glycosides, mercury,

ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances; but to the extent that compliance with these requirements is impracticable, exemptions shall apply as established by rules adopted by the director of agriculture or state board of pharmacy.

(7) Its labeling does not bear the following:

(a) Adequate directions for use of the drug or device, except that when compliance with this requirement is not necessary for a particular drug or device to protect the public health, the director shall adopt rules exempting the drug or device from the requirement;

(b) Adequate warnings against use in those pathological conditions or by children when its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, presented in a manner and form as necessary for the protection of users.

(8) It purports to be a drug the name of which is recognized in the United States pharmacopoeia and national formulary, or any supplement to them, and it is not packaged and labeled as prescribed in those compendiums, except that the method of packing may be modified with the consent of the director of agriculture. Whenever a drug is recognized in both the homoeopathic pharmacopoeia of the United States and in the United States pharmacopoeia and national formulary, including their supplements, it shall be subject to the requirements of the United States pharmacopoeia and national formulary with respect to packaging and labeling unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the homoeopathic pharmacopoeia of the United States and not to those of the United States

pharmacopoeia and national formulary.

(9) It has been found by the director of agriculture to be a drug liable to deterioration, unless it is packaged in the form and manner, and its label bears a statement of precautions, as required by rules adopted by the director as necessary for the protection of public health. No rule shall be established for any drug recognized in the United States pharmacopoeia and national formulary, or any supplements to them, until the director has informed the appropriate bodies charged with the revision of those compendiums of the need for packaging or labeling requirements and those bodies have failed within a reasonable time to prescribe such requirements.

(10)(a) It is a drug and its container is so made, formed, or filled as to be misleading.

(b) It is an imitation of another drug.

(c) It is offered for sale under the name of another drug.

(d) The drug sold or dispensed is not the brand or drug specifically prescribed or ordered or, when dispensed by a pharmacist upon prescription, <u>the drug</u> is neither the brand or drug prescribed nor a generically equivalent drug<u> or, in the case of a drug that is a biological product, is neither the brand or biological product prescribed nor an interchangeable biological product</u>.

(11) It is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling.

(12) It is a drug intended for human use to which the following apply:

(a) Because of its toxicity or other potentiality for harmful effect, the method of its use, or the collateral measures necessary to its use, the drug is not safe for use except under the supervision of a licensed health professional authorized to prescribe drugs;

(b) The drug is limited by an effective application under section 505 of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, to use under professional supervision by a licensed health professional authorized to prescribe drugs, unless it is dispensed only:

(i) Upon a written or electronic prescription;

(ii) Upon an oral prescription, which is reduced promptly to writing by the pharmacist;

(iii) By refilling a prescription if refilling is authorized by the prescriber either in the original prescription or by oral order, which is promptly reduced to writing by the pharmacist.

(B)(1) Any drug dispensed pursuant to a written, electronic, or oral prescription of a licensed health professional authorized to prescribe drugs shall be exempt from the requirements of division (A) of this section, except divisions (A)(1) and (10) of this section, if the drug bears a label containing the name and address of the dispenser, the serial number and the date the prescription is dispensed, the name of the prescriber, the name of the patient, and, if stated in the prescription, the directions for use and cautionary statements. ~~Unless~~

(2) Unless the ~~prescription directions prohibit labeling~~prescriber instructs otherwise, the label for the

dispensed drug shall include information that meets the following requirements, using abbreviations as necessary:

(a) Except as provided in divisions (B)(2)(b) and (c) of this section, the label shall include the dispensed drug's brand name ~~of the drug dispensed~~. ~~If~~

(b) If the drug dispensed has no brand name and is a generically equivalent drug, the label shall include the generic name of the drug and the distributor of the finished dosage form ~~shall be included~~.

(c) If the drug dispensed has no brand name and is an interchangeable biological product, the label shall include the name of the interchangeable biological product, the manufacturer, and if the distributor is not the same as the manufacturer, the distributor of the finished dosage form.

Sec. 3923.041. (A) As used in this section:

(1) "Chronic condition" means a medical condition that has persisted after reasonable efforts have been made to relieve or cure its cause and has continued, either continuously or episodically, for longer than six continuous months.

(2) "Clinical peer" means a health care practitioner in the same or in a similar, specialty that typically manages the medical condition, procedure, or treatment under review.

(3) "Covered person" means a person receiving coverage for health services under a policy of sickness and accident insurance or a public employee benefit plan.

(4) "Emergency service" has the same meaning as in section 1753.28 of the Revised Code.

(5) "Fraudulent or materially incorrect information" means

any type of intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to the covered person in question.

(6) "Health care practitioner" has the same meaning as in section 3701.74 of the Revised Code.

(7) "NCPDP SCRIPT standard" means the national council for prescription drug programs SCRIPT standard version 201310 or the most recent standard adopted by the United States department of health and human services.

(8) "Prior authorization requirement" means any practice implemented by either a sickness and accident insurer or a public employee benefit plan in which coverage of a health care service, device, or drug is dependent upon a covered person or a health care practitioner obtaining approval from the insurer or plan prior to the service, device, or drug being performed, received, or prescribed, as applicable. "Prior authorization" includes prospective or utilization review procedures conducted prior to providing a health care service, device, or drug.

(9) "Urgent care services" means a medical care or other service for a condition where application of the timeframe for making routine or non-life threatening care determinations is either of the following:

(a) Could seriously jeopardize the life, health, or safety of the patient or others due to the patient's psychological state;

(b) In the opinion of a practitioner with knowledge of the patient's medical or behavioral condition, would subject the patient to adverse health consequences without the care or treatment that is the subject of the request.

(10) "Utilization review" and "utilization review organization" have the same meanings as in section 1751.77 of the Revised Code.

(B) If a policy issued by a sickness and accident insurer or a public employee benefit plan contains a prior authorization requirement, then all of the following apply:

(1) For policies issued on or after January 1, 2018, the insurer or plan shall permit health care practitioners to access the prior authorization form through the applicable electronic software system.

(2)(a) For policies issued on or after January 1, 2018, the insurer or plan, or other payer acting on behalf of the insurer or plan, to accept prior authorization requests through a secure electronic transmission.

(b) For policies issued on or after January 1, 2018, the insurer or plan, a pharmacy benefit manager responsible for handling prior authorization requests, or other payer acting on behalf of the insurer or plan shall accept and respond to prior prescription benefit authorization requests through a secure electronic transmission using NCPDP SCRIPT standard ePA transactions, and for prior medical benefit authorization requests through a secure electronic transmission using standards established by the council for affordable quality health care on operating rules for information exchange or its successor.

(c) For purposes of division (B)(2) of this section, neither of the following shall be considered a secure electronic transmission:

(i) A facsimile;

(ii) A proprietary payer portal for prescription drug requests that does not use NCPDP SCRIPT standard.

(3) For policies issued on or after January 1, 2018, a health care practitioner and an insurer or plan may enter into a contractual arrangement under which the insurer or plan agrees to process prior authorization requests that are not submitted electronically because of the financial hardship that electronic submission of prior authorization requests would create for the health care practitioner or if internet connectivity is limited or unavailable where the health care practitioner is located.

(4)(a) For policies issued on or after January 1, 2018, if the health care practitioner submits the request for prior authorization electronically as described in divisions (B)(1) and (2) of this section, the insurer or plan shall respond to all prior authorization requests within forty-eight hours for urgent care services, or ten calendar days for any prior ~~approval~~ authorization request that is not for an urgent care service, of the time the request is received by the insurer or plan ~~with all information necessary to support the prior authorization request~~. Division (B)(4) of this section does not apply to emergency services.

(b) ~~(i)~~ The response required under division (B)(4)(a) of this section shall indicate whether the request is approved~~,~~ or denied~~, or incomplete~~. If the prior authorization is denied, the insurer or plan shall provide the specific reason for the denial.

(c) If the prior authorization request is incomplete, the insurer or plan shall indicate the specific additional information that is required to process the request.

~~(ii) For a response that is considered incomplete, the health care practitioner shall provide the additional information requested under division (B)(4)(b)(i) of this section within seventy-two hours of the time the request is received by the practitioner.~~

(5)(a) For policies issued on or after January 1, 2018, if a health care practitioner submits a prior authorization request as described in divisions (B)(1) and (2) of this section, the insurer or plan shall provide an electronic receipt to the health care practitioner acknowledging that the prior authorization request was received.

(b) For policies issued on or after January 1, 2018, if an issuer or plan requests additional information that is required to process a prior authorization request as described in division (B)(4)~~(b)(i)~~ (c) of this section, the health care practitioner shall provide an electronic receipt to the issuer or plan acknowledging that the request for additional information was received.

(6)(a) For policies issued on or after January 1, 2017, for a prior approval related to a chronic condition, the insurer or plan shall honor a prior authorization approval for an approved drug for the lesser of the following from the date of the approval:

(i) Twelve months;

(ii) The last day of the covered person's eligibility under the policy or plan.

(b) The duration of all other prior authorization approvals shall be dictated by the policy or plan.

(c) An insurer or plan, in relation to prior approval

under division (B)(6)(a) of this section, may require a health care practitioner to submit information to the insurer or plan indicating that the patient's chronic condition has not changed.

(i) The request for information by the insurer or plan and the response by the health care practitioner shall be in an electronic format, which may be by ~~traditional~~ electronic mail or other electronic communication.

(ii) The frequency of the submission of requested information shall be consistent with medical or scientific evidence, as defined in section 3922.01 of the Revised Code, but shall not be required more frequently than quarterly.

(iii) If the health care practitioner does not respond within five calendar days from the date the request was received, the insurer or plan may terminate the twelve-month approval.

(d) A ~~year long~~ twelve-month approval provided under division (B)(6)(a) of this section is no longer valid and automatically terminates if there are changes to federal or state laws or federal regulatory guidance or compliance information prescribing that the drug in question is no longer approved or safe for the intended purpose.

(e) A twelve-month approval provided under division (B)(6)(a) of this section does not apply to and is not required for any of the following:

(i) Medications that are prescribed for a non-maintenance condition;

(ii) Medications that have a typical treatment of less than one year;

(iii) Medications that require an initial trial period to determine effectiveness and tolerability, beyond which a one-year, or greater, prior authorization period will be given;

(iv) Medications where there is medical or scientific evidence as defined in section 3922.01 of the Revised Code that do not support a twelve-month prior approval;

(v) Medications that are a schedule I or II controlled substance or any opioid analgesic or benzodiazepine, as defined in section 3719.01 of the Revised Code;

(vi) Medications that are not prescribed by an in-network provider as part of the care management program.

(7) For policies issued on or after January 1, 2017, an insurer or plan may, but is not required to, provide the twelve-month approval prescribed in division (B)(6)(a) of this section for a prescription drug that meets either of the following:

(a) The drug is prescribed or administered to treat a rare medical condition and pursuant to medical or scientific evidence as defined in section 3922.01 of the Revised Code.

(b) Medications that are controlled substances not included in division (B)(6)(e)(v) of this section.

For purposes of division (B)(7) of this section, "rare medical condition" means any disease or condition that affects fewer than two hundred thousand individuals in the United States.

(8) Nothing in division (B)(6) or (7) of this section prohibits the substitution<u>, in accordance with section 4729.38 of the Revised Code,</u> of any drug that has received a twelve-month approval under division (B)(6)(a) of this section when

there is a release of ~~a~~ either of the following:

(a) A United States food and drug administration approved comparable brand product or a generic counterpart of a brand product that is listed as therapeutically equivalent in the United States food and drug administration's publication titled approved drug products with therapeutic equivalence evaluations;

(b) An interchangeable biological product, as defined in section 3715.01 of the Revised Code.

(9)(a) For policies issued on or after January 1, 2017, upon written request, an insurer or plan shall permit a retrospective review for a claim that is submitted for a service where prior authorization was required but not obtained if the service in question meets all of the following:

(i) The service is directly related to another service for which prior approval has already been obtained and that has already been performed.

(ii) The new service was not known to be needed at the time the original prior authorized service was performed.

(iii) The need for the new service was revealed at the time the original authorized service was performed.

(b) Once the written request and all necessary information is received, the insurer or plan shall review the claim for coverage and medical necessity. The insurer or plan shall not deny a claim for such a new service based solely on the fact that a prior authorization approval was not received for the new service in question.

(10)(a) For policies issued on or after January 1, 2017, the insurer or plan shall disclose to all participating health

care practitioners any new prior authorization requirement at least thirty days prior to the effective date of the new requirement.

(b) The notice may be sent via electronic mail or standard mail and shall be conspicuously entitled "Notice of Changes to Prior Authorization Requirements." The notice is not required to contain a complete listing of all changes made to the prior authorization requirements, but shall include specific information on where the health care practitioner may locate the information on the insurer or plan's web site or, if applicable, the insurer's or plan's portal.

(c) All participating health care practitioners shall promptly notify the insurer or plan of any changes to the health care practitioner's electronic mail or standard mail address.

(11)(a) For policies issued on or after January 1, 2017, the insurer or plan shall make available to all participating health care practitioners on its web site or provider portal a listing of its prior authorization requirements, including specific information or documentation that a ~~provider~~ practitioner must submit in order for the prior authorization request to be considered complete.

(b) The insurer or plan shall make available on its web site information about the policies, contracts, or agreements offered by the insurer or plan that clearly identifies specific services, drugs, or devices to which a prior authorization requirement exists.

(12) For policies issued on or after January 1, 2018, the insurer or plan shall establish a streamlined appeal process relating to adverse prior authorization determinations that

shall include all of the following:

(a) For urgent care services, the appeal shall be considered within forty-eight hours after the insurer or plan receives the appeal.

(b) For all other matters, the appeal shall be considered within ten calendar days after the insurer or plan receives the appeal.

(c) The appeal shall be between the health care practitioner requesting the service in question and a clinical peer.

(d) If the appeal does not resolve the disagreement, either the covered person or an authorized representative as defined in section 3922.01 of the Revised Code may request an external review under Chapter 3922. of the Revised Code to the extent Chapter 3922. of the Revised Code is applicable.

(C) For policies issued on or after January 1, 2017, except in cases of fraudulent or materially incorrect information, an insurer or plan shall not retroactively deny a prior authorization for a health care service, drug, or device when all of the following are met:

(1) The health care practitioner submits a prior authorization request to the insurer or plan for a health care service, drug, or device;

(2) The insurer or plan approves the prior authorization request after determining that all of the following are true:

(a) The patient is eligible under the health benefit plan.

(b) The health care service, drug, or device is covered under the patient's health benefit plan.

(c) The health care service, drug, or device meets the insurer's or plan's standards for medical necessity and prior authorization.

(3) The health care practitioner renders the health care service, drug, or device pursuant to the approved prior authorization request and all of the terms and conditions of the health care practitioner's contract with the insurer or plan;

(4) On the date the health care practitioner renders the prior approved health care service, drug, or device, all of the following are true:

(a) The patient is eligible under the health benefit plan.

(b) The patient's condition or circumstances related to the patient's care has not changed.

(c) The health care practitioner submits an accurate claim that matches the information submitted by the health care practitioner in the approved prior authorization request.

(5) If the health care practitioner submits a claim that includes an unintentional error and the error results in a claim that does not match the information originally submitted by the health care practitioner in the approved prior authorization request, upon receiving a denial of services from the insurer or plan, the health care practitioner may resubmit the claim pursuant to division (C) of this section with the information that matches the information included in the approved prior authorization.

(D) Any provision of a contractual arrangement entered into between an insurer or plan and a health care practitioner or beneficiary that is contrary to divisions (A) to (C) of this section is unenforceable.

(E) For policies issued on or after January 1, 2017, committing a series of violations of this section that, taken together, constitute a practice or pattern shall be considered an unfair and deceptive practice under sections 3901.19 to 3901.26 of the Revised Code.

(F) The superintendent of insurance may adopt rules in accordance with Chapter 119. of the Revised Code as necessary to implement the provisions of this section.

(G) This section does not apply to any of the following types of coverage: a policy, contract, certificate, or agreement that covers only a specified accident, accident only, credit, dental, disability income, long-term care, hospital indemnity, supplemental coverage as described in section 3923.37 of the Revised Code, specified disease, or vision care; coverage issued as a supplement to liability insurance; insurance arising out of workers' compensation or similar law; automobile medical payment insurance; insurance under which benefits are payable with or without regard to fault and which is statutorily required to be contained in any liability insurance policy or equivalent self-insurance; a medicare supplement policy of insurance as defined by the superintendent of insurance by rule; coverage under a plan through medicare or the federal employees benefit program; or any coverage issued under Chapter 55 of Title 10 of the United States Code and any coverage issued as a supplement to that coverage.

Sec. 4729.01. As used in this chapter:

(A) "Pharmacy," except when used in a context that refers to the practice of pharmacy, means any area, room, rooms, place of business, department, or portion of any of the foregoing where the practice of pharmacy is conducted.

(B) "Practice of pharmacy" means providing pharmacist care requiring specialized knowledge, judgment, and skill derived from the principles of biological, chemical, behavioral, social, pharmaceutical, and clinical sciences. As used in this division, "pharmacist care" includes the following:

(1) Interpreting prescriptions;

(2) Dispensing drugs and drug therapy related devices;

(3) Compounding drugs;

(4) Counseling individuals with regard to their drug therapy, recommending drug therapy related devices, and assisting in the selection of drugs and appliances for treatment of common diseases and injuries and providing instruction in the proper use of the drugs and appliances;

(5) Performing drug regimen reviews with individuals by discussing all of the drugs that the individual is taking and explaining the interactions of the drugs;

(6) Performing drug utilization reviews with licensed health professionals authorized to prescribe drugs when the pharmacist determines that an individual with a prescription has a drug regimen that warrants additional discussion with the prescriber;

(7) Advising an individual and the health care professionals treating an individual with regard to the individual's drug therapy;

(8) Acting pursuant to a consult agreement with one or more physicians authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery, if an agreement has been established;

(9) Engaging in the administration of immunizations to the extent authorized by section 4729.41 of the Revised Code.

(C) "Compounding" means the preparation, mixing, assembling, packaging, and labeling of one or more drugs in any of the following circumstances:

(1) Pursuant to a prescription issued by a licensed health professional authorized to prescribe drugs;

(2) Pursuant to the modification of a prescription made in accordance with a consult agreement;

(3) As an incident to research, teaching activities, or chemical analysis;

(4) In anticipation of orders for drugs pursuant to prescriptions, based on routine, regularly observed dispensing patterns;

(5) Pursuant to a request made by a licensed health professional authorized to prescribe drugs for a drug that is to be used by the professional for the purpose of direct administration to patients in the course of the professional's practice, if all of the following apply:

(a) At the time the request is made, the drug is not commercially available regardless of the reason that the drug is not available, including the absence of a manufacturer for the drug or the lack of a readily available supply of the drug from a manufacturer.

(b) A limited quantity of the drug is compounded and provided to the professional.

(c) The drug is compounded and provided to the professional as an occasional exception to the normal practice

of dispensing drugs pursuant to patient-specific prescriptions.

(D) "Consult agreement" means an agreement that has been entered into under section 4729.39 of the Revised Code.

(E) "Drug" means:

(1) Any article recognized in the United States pharmacopoeia and national formulary, or any supplement to them, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(2) Any other article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(3) Any article, other than food, intended to affect the structure or any function of the body of humans or animals;

(4) Any article intended for use as a component of any article specified in division (E)(1), (2), or (3) of this section; but does not include devices or their components, parts, or accessories.

(F) "Dangerous drug" means any of the following:

(1) Any drug to which either of the following applies:

(a) Under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, the drug is required to bear a label containing the legend "Caution: Federal law prohibits dispensing without prescription" or "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" or any similar restrictive statement, or the drug may be dispensed only upon a prescription;

(b) Under Chapter 3715. or 3719. of the Revised Code, the

drug may be dispensed only upon a prescription.

(2) Any drug that contains a schedule V controlled substance and that is exempt from Chapter 3719. of the Revised Code or to which that chapter does not apply;

(3) Any drug intended for administration by injection into the human body other than through a natural orifice of the human body;

(4) Any drug that is a biological product, as defined in section 3715.01 of the Revised Code.

(G) "Federal drug abuse control laws" has the same meaning as in section 3719.01 of the Revised Code.

(H) "Prescription" means all of the following:

(1) A written, electronic, or oral order for drugs or combinations or mixtures of drugs to be used by a particular individual or for treating a particular animal, issued by a licensed health professional authorized to prescribe drugs;

(2) For purposes of sections 2925.61, 4723.488, 4729.44, 4730.431, and 4731.94 of the Revised Code, a written, electronic, or oral order for naloxone issued to and in the name of a family member, friend, or other individual in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.

(3) For purposes of sections 4723.4810, 4729.282, 4730.432, and 4731.93 of the Revised Code, a written, electronic, or oral order for a drug to treat chlamydia, gonorrhea, or trichomoniasis issued to and in the name of a patient who is not the intended user of the drug but is the sexual partner of the intended user;

(4) For purposes of sections 3313.7110, 3313.7111, 3314.143, 3326.28, 3328.29, 4723.483, 4729.88, 4730.433, 4731.96, and 5101.76 of the Revised Code, a written, electronic, or oral order for an epinephrine autoinjector issued to and in the name of a school, school district, or camp;

(5) For purposes of Chapter 3728. and sections 4723.483, 4729.88, 4730.433, and 4731.96 of the Revised Code, a written, electronic, or oral order for an epinephrine autoinjector issued to and in the name of a qualified entity, as defined in section 3728.01 of the Revised Code.

(I) "Licensed health professional authorized to prescribe drugs" or "prescriber" means an individual who is authorized by law to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual's professional practice, including only the following:

(1) A dentist licensed under Chapter 4715. of the Revised Code;

(2) A clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner who holds a certificate to prescribe issued under section 4723.48 of the Revised Code;

(3) An optometrist licensed under Chapter 4725. of the Revised Code to practice optometry under a therapeutic pharmaceutical agents certificate;

(4) A physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery;

(5) A physician assistant who holds a license to practice as a physician assistant issued under Chapter 4730. of the Revised Code, holds a valid prescriber number issued by the

state medical board, and has been granted physician-delegated prescriptive authority;

(6) A veterinarian licensed under Chapter 4741. of the Revised Code.

(J) "Sale" and "sell" include delivery, transfer, barter, exchange, or gift, or offer therefor, and each such transaction made by any person, whether as principal proprietor, agent, or employee.

(K) "Wholesale sale" and "sale at wholesale" mean any sale in which the purpose of the purchaser is to resell the article purchased or received by the purchaser.

(L) "Retail sale" and "sale at retail" mean any sale other than a wholesale sale or sale at wholesale.

(M) "Retail seller" means any person that sells any dangerous drug to consumers without assuming control over and responsibility for its administration. Mere advice or instructions regarding administration do not constitute control or establish responsibility.

(N) "Price information" means the price charged for a prescription for a particular drug product and, in an easily understandable manner, all of the following:

(1) The proprietary name of the drug product;

(2) The established (generic) name of the drug product;

(3) The strength of the drug product if the product contains a single active ingredient or if the drug product contains more than one active ingredient and a relevant strength can be associated with the product without indicating each active ingredient. The established name and quantity of each

active ingredient are required if such a relevant strength cannot be so associated with a drug product containing more than one ingredient.

(4) The dosage form;

(5) The price charged for a specific quantity of the drug product. The stated price shall include all charges to the consumer, including, but not limited to, the cost of the drug product, professional fees, handling fees, if any, and a statement identifying professional services routinely furnished by the pharmacy. Any mailing fees and delivery fees may be stated separately without repetition. The information shall not be false or misleading.

(O) "Wholesale distributor of dangerous drugs" means a person engaged in the sale of dangerous drugs at wholesale and includes any agent or employee of such a person authorized by the person to engage in the sale of dangerous drugs at wholesale.

(P) "Manufacturer of dangerous drugs" means a person, other than a pharmacist, who manufactures dangerous drugs and who is engaged in the sale of those dangerous drugs within this state.

(Q) "Terminal distributor of dangerous drugs" means a person who is engaged in the sale of dangerous drugs at retail, or any person, other than a wholesale distributor or a pharmacist, who has possession, custody, or control of dangerous drugs for any purpose other than for that person's own use and consumption, and includes pharmacies, hospitals, nursing homes, and laboratories and all other persons who procure dangerous drugs for sale or other distribution by or under the supervision

of a pharmacist or licensed health professional authorized to prescribe drugs.

(R) "Promote to the public" means disseminating a representation to the public in any manner or by any means, other than by labeling, for the purpose of inducing, or that is likely to induce, directly or indirectly, the purchase of a dangerous drug at retail.

(S) "Person" includes any individual, partnership, association, limited liability company, or corporation, the state, any political subdivision of the state, and any district, department, or agency of the state or its political subdivisions.

(T) ~~"Finished dosage form" has the same meaning as in section 3715.01 of the Revised Code.~~

~~(U) "Generically equivalent drug" has the same meaning as in section 3715.01 of the Revised Code.~~

~~(V)~~ "Animal shelter" means a facility operated by a humane society or any society organized under Chapter 1717. of the Revised Code or a dog pound operated pursuant to Chapter 955. of the Revised Code.

~~(W)~~ (U) "Food" has the same meaning as in section 3715.01 of the Revised Code.

~~(X)~~ (V) "Pain management clinic" has the same meaning as in section 4731.054 of the Revised Code.

Sec. 4729.38. (A) As used in this section, "biological product," "finished dosage form," "generically equivalent drug," and "interchangeable biological product" have the same meanings as in section 3715.01 of the Revised Code.

(B) Unless instructed otherwise by the person receiving the drug pursuant to the prescription, a pharmacist filling a prescription for a drug prescribed by its brand name may, subject to the following conditions, select a generically equivalent drug, ~~as defined in section 3715.01 of the Revised Code, subject to the following conditions~~ or, in the case of a drug that is a biological product, select an interchangeable biological product:

(1) The pharmacist shall not select a generically equivalent drug or interchangeable biological product if ~~the prescriber~~ either of the following applies:

(a) In the case of a written or electronic prescription, including a computer-generated prescription, the prescriber handwrites or actively causes to display on the prescription "dispense as written," ~~or~~ "D.A.W.," ~~on the written prescription, or, when ordering a prescription electronically or orally, the prescriber~~ "do not substitute," "brand medically necessary," or any other statement or numerical code that indicates the prescriber's intent to prevent substitution. Such a designation shall not be preprinted or stamped on the prescription, but a reminder to the prescriber of the designation procedure may be preprinted or displayed on the prescription form or electronic system the prescriber uses to issue the prescription.

(b) In the case of an oral prescription, the prescriber specifies that the ~~prescribed~~ drug as prescribed is medically necessary or otherwise indicates the prescriber's intent to prevent substitution. ~~These designations shall not be preprinted or stamped on the prescription. Division (A)(1) of this section does not preclude a reminder of the procedure required to prohibit the selection of a generically equivalent drug from~~

~~being preprinted on the prescription.~~

(2) The pharmacist shall not select a generically equivalent drug or interchangeable biological product unless its price to the patient is less than or equal to the price of the ~~prescribed~~ drug as prescribed.

(3) The pharmacist~~,~~ or the pharmacist's agent, assistant, or employee shall inform the patient or the patient's agent if a generically equivalent drug or interchangeable biological product is available at a lower or equal cost~~,~~ and of the person's right to refuse the drug selected. Division ~~(A)~~ (B)(3) of this section does not apply to any:

(a) Prescription that is billed to any agency, division, or department of this state which will reimburse the pharmacy;

(b) Prescriptions for patients of a hospital, nursing home, or similar patient care facility.

~~(B)~~ (C)(1) Unless the prescriber instructs otherwise, the label for every drug dispensed shall include information that meets the following requirements, using abbreviations as necessary:

(a) Except as provided in divisions (C)(1)(b) and (c) of this section, the label shall include the dispensed drug's brand name~~, if any, or its generic name and the name of the~~ .

(b) If the drug dispensed has no brand name and is a generically equivalent drug, the label shall include the generic name of the drug and the distributor~~, using abbreviations if necessary~~ of the finished dosage form.

(c) If the drug dispensed has no brand name and is an interchangeable biological product, the label shall include the

name of the interchangeable biological product, the manufacturer, and if the distributor is not the same as the manufacturer, the distributor of the finished dosage form.

(2) When dispensing at retail a drug that is a generically equivalent drug or interchangeable biological product for ~~the brand name~~ a drug prescribed by its brand name, the pharmacist shall indicate on the drug's label or container that a ~~generic~~ substitution was made. ~~The~~

(3) The labeling requirements established by ~~this division~~ divisions (C)(1) and (2) of this section are in addition to all other labeling requirements of Chapter 3715. of the Revised Code.

~~(C)~~ (D) A pharmacist who selects a drug that is a generically equivalent drug or interchangeable biological product pursuant to this section assumes no greater liability for selecting the dispensed drug than would be incurred in filling a prescription for a drug prescribed by its brand name.

~~(D)~~ (E) The failure of a prescriber to restrict a prescription by ~~specifying "dispense as written," or "D.A.W.,"~~ indicating an intent to prevent substitution pursuant to division ~~(A)~~(B)(1) of this section shall not constitute evidence of the prescriber's negligence unless the prescriber had reasonable cause to believe that the health condition of the patient for whom the drug was intended warranted the prescription of a specific brand name drug and no other. No prescriber shall be liable for civil damages or in any criminal prosecution arising from the ~~interchange~~ substitution of a generically equivalent drug or interchangeable biological product for a prescribed brand name drug by a pharmacist, unless the prescribed brand name drug would have reasonably caused the

same loss, damage, injury, or death.

(F)(1)(a) Except as provided in division (F)(1)(b) of this section, not later than five business days after a pharmacist dispenses a drug for which an interchangeable biological product is available, regardless of whether a substitution is made, the pharmacist or an individual designated by the pharmacist shall communicate to the prescriber information identifying the specific biological product that was dispensed, including the name of the biological product and its manufacturer.

(b) Communication of the information is not required when a biological product is dispensed by refilling a prescription and the product that is dispensed is the same product that was dispensed when the same prescription was last filled or refilled.

(2) When possible, communication of the information shall be conveyed by entering the information into a recordkeeping system that can reasonably be presumed to be electronically accessible to the prescriber. Such a system may include any of the following:

(a) An interoperable electronic medical records system;

(b) An electronic prescribing system;

(c) An electronic pharmacy benefit management system;

(d) An electronic pharmacy record system.

(3) Entering the complete information into one of the recordkeeping systems listed in division (F)(2) of this section is presumed to provide notice to the prescriber.

(4) When it is not possible to communicate the information by using one of the recordkeeping systems listed in division (F)

(2) of this section, communication of the information shall be conveyed by telephone, facsimile, another form of electronic communication, or any other prevailing means of communication.

(G) No pharmacist shall knowingly engage in conduct that is prohibited by division (B) or (C) of this section.

Sec. 4729.99. (A) Whoever violates section 4729.16, division ~~(A) or (B)~~ (G) of section 4729.38, or section 4729.57 of the Revised Code is guilty of a minor misdemeanor. Each day's violation constitutes a separate offense.

(B) Whoever violates section 4729.27, 4729.28, or 4729.36 of the Revised Code is guilty of a misdemeanor of the third degree. Each day's violation constitutes a separate offense. If the offender previously has been convicted of or pleaded guilty to a violation of this chapter, that person is guilty of a misdemeanor of the second degree.

(C) Whoever violates section 4729.32, 4729.33, or 4729.34 of the Revised Code is guilty of a misdemeanor.

(D) Whoever violates division (A), (B), (D), or (E) of section 4729.51 of the Revised Code is guilty of a misdemeanor of the first degree.

(E)(1) Whoever violates section 4729.37, division (C)(2) of section 4729.51, division (J) of section 4729.54, or section 4729.61 of the Revised Code is guilty of a felony of the fifth degree. If the offender previously has been convicted of or pleaded guilty to a violation of this chapter or a violation of Chapter 2925. or 3719. of the Revised Code, that person is guilty of a felony of the fourth degree.

(2) If an offender is convicted of or pleads guilty to a violation of section 4729.37, division (C) of section 4729.51,

division (J) of section 4729.54, or section 4729.61 of the Revised Code, if the violation involves the sale, offer to sell, or possession of a schedule I or II controlled substance, with the exception of marihuana, and if the court imposing sentence upon the offender finds that the offender as a result of the violation is a major drug offender, as defined in section 2929.01 of the Revised Code, and is guilty of a specification of the type described in section 2941.1410 of the Revised Code, the court, in lieu of the prison term authorized or required by division (E)(1) of this section and sections 2929.13 and 2929.14 of the Revised Code and in addition to any other sanction imposed for the offense under sections 2929.11 to 2929.18 of the Revised Code, shall impose upon the offender, in accordance with division (B)(3) of section 2929.14 of the Revised Code, the mandatory prison term specified in that division.

(3) Notwithstanding any contrary provision of section 3719.21 of the Revised Code, the clerk of court shall pay any fine imposed for a violation of section 4729.37, division (C) of section 4729.51, division (J) of section 4729.54, or section 4729.61 of the Revised Code pursuant to division (A) of section 2929.18 of the Revised Code in accordance with and subject to the requirements of division (F) of section 2925.03 of the Revised Code. The agency that receives the fine shall use the fine as specified in division (F) of section 2925.03 of the Revised Code.

(F) Whoever violates section 4729.531 of the Revised Code or any rule adopted thereunder or section 4729.532 of the Revised Code is guilty of a misdemeanor of the first degree.

(G) Whoever violates division (C)(1) of section 4729.51 of the Revised Code is guilty of a felony of the fourth degree. If

the offender has previously been convicted of or pleaded guilty to a violation of this chapter, or of a violation of Chapter 2925. or 3719. of the Revised Code, that person is guilty of a felony of the third degree.

(H) Whoever violates division (C)(3) of section 4729.51 of the Revised Code is guilty of a misdemeanor of the first degree. If the offender has previously been convicted of or pleaded guilty to a violation of this chapter, or of a violation of Chapter 2925. or 3719. of the Revised Code, that person is guilty of a felony of the fifth degree.

(I)(1) Whoever violates division (B) of section 4729.42 of the Revised Code is guilty of unauthorized pharmacy-related drug conduct. Except as otherwise provided in this section, unauthorized pharmacy-related drug conduct is a misdemeanor of the second degree. If the offender previously has been convicted of or pleaded guilty to a violation of division (B), (C), (D), or (E) of that section, unauthorized pharmacy-related drug conduct is a misdemeanor of the first degree on a second offense and a felony of the fifth degree on a third or subsequent offense.

(2) Whoever violates division (C) or (D) of section 4729.42 of the Revised Code is guilty of permitting unauthorized pharmacy-related drug conduct. Except as otherwise provided in this section, permitting unauthorized pharmacy-related drug conduct is a misdemeanor of the second degree. If the offender previously has been convicted of or pleaded guilty to a violation of division (B), (C), (D), or (E) of that section, permitting unauthorized pharmacy-related drug conduct is a misdemeanor of the first degree on a second offense and a felony of the fifth degree on a third or subsequent offense.

(3) Whoever violates division (E) of section 4729.42 of the Revised Code is guilty of the offense of falsification under section 2921.13 of the Revised Code. In addition to any other sanction imposed for the violation, the offender is forever disqualified from engaging in any activity specified in division (B)(1), (2), or (3) of section 4729.42 of the Revised Code and from performing any function as a health care professional or health care worker. As used in this division, "health care professional" and "health care worker" have the same meanings as in section 2305.234 of the Revised Code.

(4) Notwithstanding any contrary provision of section 3719.21 of the Revised Code or any other provision of law that governs the distribution of fines, the clerk of the court shall pay any fine imposed pursuant to division (I)(1), (2), or (3) of this section to the state board of pharmacy if the board has adopted a written internal control policy under division (F)(2) of section 2925.03 of the Revised Code that addresses fine moneys that it receives under Chapter 2925. of the Revised Code and if the policy also addresses fine moneys paid under this division. The state board of pharmacy shall use the fines so paid in accordance with the written internal control policy to subsidize the board's law enforcement efforts that pertain to drug offenses.

(J)(1) Whoever violates division (A)(1) of section 4729.86 of the Revised Code is guilty of a misdemeanor of the third degree. If the offender has previously been convicted of or pleaded guilty to a violation of division (A)(1), (2), or (3) of section 4729.86 of the Revised Code, that person is guilty of a misdemeanor of the first degree.

(2) Whoever violates division (A)(2) of section 4729.86 of

the Revised Code is guilty of a misdemeanor of the first degree. If the offender has previously been convicted of or pleaded guilty to a violation of division (A)(1), (2), or (3) of section 4729.86 of the Revised Code, that person is guilty of a felony of the fifth degree.

(3) Whoever violates division (A)(3) of section 4729.86 of the Revised Code is guilty of a felony of the fifth degree. If the offender has previously been convicted of or pleaded guilty to a violation of division (A)(1), (2), or (3) of section 4729.86 of the Revised Code, that person is guilty of a felony of the fourth degree.

(K) A person who violates division (C) of section 4729.552 of the Revised Code is guilty of a misdemeanor of the first degree. If the person previously has been convicted of or pleaded guilty to a violation of division (C) of section 4729.552 of the Revised Code, that person is guilty of a felony of the fifth degree.

Sec. 5160.34. (A) As used in this section:

(1) "Chronic condition" means a medical condition that has persisted after reasonable efforts have been made to relieve or cure its cause and has continued, either continuously or episodically, for longer than six continuous months.

(2) "Clinical peer" means a ~~medical~~ health care provider in the same, or in a similar, specialty that typically manages the medical condition, procedure, or treatment under review.

(3) "Emergency services" has the same meaning as in section 1753.28 of the Revised Code.

(4) "Prior authorization requirement" means any practice implemented by a medical assistance program in which coverage of

a health care service, device, or drug is dependent upon a medical assistance recipient or a health care provider, receiving approval from the department of medicaid or its designee, including a medicaid managed care organization, prior to the service, device, or drug being performed, received, or prescribed, as applicable. "Prior authorization" includes prospective or utilization review procedures conducted prior to providing a health care service, device, or drug.

(5) "Urgent care services" means a medical care or other service for a condition where application of the timeframe for making routine or non-life threatening care determinations is either of the following:

(a) Could seriously jeopardize the life, health, or safety of the recipient or others due to the recipient's psychological state;

(b) In the opinion of a practitioner with knowledge of the recipient's medical or behavioral condition, would subject the recipient to adverse health consequences without the care or treatment that is the subject of the request.

(6) "Utilization review" and "utilization review organization" have the same meanings as in section 1751.77 of the Revised Code.

(B) If a medical assistance program has a prior authorization requirement, the department of medicaid or its designee, including a medicaid managed care organization, shall do all of the following:

(1) On or before January 1, 2018, permit a health care provider to access the prior authorization form through the applicable electronic software system.

(2)(a) On or before January 1, 2018, permit the department or its designee to accept and respond to prior prescription benefit authorization requests through a secure electronic transmission.

(b) On or before January 1, 2018, the department or its designee shall accept and respond to prior prescription benefit authorization requests through a secure electronic transmission using NCPDP SCRIPT standard ePA transactions, and for prior medical benefit authorization requests through a secure electronic transmission using standards established by the council for affordable quality health care on operating rules for information exchange or its successor.

(c) For purposes of division (B)(2) of this section, neither of the following shall be considered a secure electronic transmission:

(i) A facsimile;

(ii) A proprietary payer portal for prescription drug requests that does not use NCPDP SCRIPT standard.

(3) On or before January 1, 2018, a health care provider and the department of medicaid or its designee may enter into a contractual arrangement under which the department or its designee agrees to process prior authorization requests that are not submitted electronically because of the financial hardship that electronic submission of prior authorization requests would create for the provider or if internet connectivity is limited or unavailable where the provider is located.

(4)(a) On or before January 1, 2018, if the health care provider submits the request for prior authorization electronically as described in divisions (B)(1) and (2) of this

section, respond to all prior authorization requests within forty-eight hours for urgent care services, or ten calendar days for any prior ~~approval~~ authorization request that is not for an urgent care service, of the time the request is received by the department or its designee~~ with all information necessary to support the prior authorization request~~. Division (B)~~(5)~~(4) of this section does not apply to emergency services.

(b)~~(i)~~ The response required under division (B)(4)(a) of this section shall indicate whether the request is approved~~,~~ or denied~~, or incomplete~~. If the prior authorization is denied, the department or its designee shall provide the specific reason for the denial.

(c) If the prior authorization request is incomplete, the department or its designee shall indicate the specific additional information that is required to process the request.

~~(ii) For a response that is considered incomplete, the health care provider shall provide the additional information requested under division (B)(4)(b)(i) of this section within seventy-two hours of the time the request is received by the provider.~~

(5)(a) On or before January 1, 2018, if a health care provider submits a prior authorization request as described in divisions (B)(1) and (2) of this section, the department or its designee shall provide an electronic receipt to the health care provider acknowledging that the prior authorization request was received.

(b) On or before January 1, 2018, if the department or its designee requests additional information that is required to process a prior authorization request as described in division

(B)(4) ~~(b)(i)~~ (c) of this section, the health care provider shall provide an electronic receipt to the department or its designee acknowledging that the request for additional information was received.

(6)(a) On or before January 1, 2017, honor a prior authorization approval for an approved drug for the lesser of the following from the date of approval:

(i) Twelve months;

(ii) The last day of the medical assistance recipient's eligibility for the medical assistance program.

(b) The duration of all other prior authorization approvals shall be dictated by the medical assistance program.

(c) The department or its designee, in relation to prior approval under division (B)(6)(a) of this section, may require a health care provider to submit information to the department or its designee indicating that the patient's chronic condition has not changed.

(i) The request for information by the department or its designee and the response by the health care provider shall be in an electronic format, which may be by ~~traditional~~ electronic mail or other electronic communication.

(ii) The frequency of the submission of requested information shall be consistent with medical or scientific evidence as defined in section 3922.01 of the Revised Code, but shall not be required more frequently than quarterly.

(iii) If the health care provider does not respond within five calendar days from the date the request was received, the insurer or plan may terminate the twelve-month approval.

(d) A ~~year long~~ twelve-month approval provided under division (B)(6)(a) of this section is no longer valid and automatically terminates if there are changes to federal or state laws or federal regulatory guidance or compliance information prescribing that the drug in question is no longer approved or safe for the intended purpose.

(e) A twelve-month approval provided under division (B)(6)(a) of this section does not apply to and is not required for any of the following:

(i) Medications that are prescribed for a non-maintenance condition;

(ii) Medications that have a typical treatment of less than one year;

(iii) Medications that require an initial trial period to determine effectiveness and tolerability, beyond which a one-year, or greater, prior authorization period will be given;

(iv) Medications where there is medical or scientific evidence as defined in section 3922.01 of the Revised Code that do not support a twelve-month prior approval;

(v) Medications that are a schedule I or II controlled substance or any opioid analgesic or benzodiazepine, as defined in section 3719.01 of the Revised Code;

(vi) Medications that are not prescribed by an in-network provider as part of a care management program.

(7) On or before January 1, 2017, the department or its designee may, but is not required to, provide the twelve-month approval prescribed in division (B)(6)(a) of this section for a prescription drug that meets either of the following:

(a) The drug is prescribed or administered to treat a rare medical condition and pursuant to medical or scientific evidence as defined in section 3922.01 of the Revised Code.

(b) Medications that are controlled substances not included in division (B)(6)(e)(v) of this section.

For purposes of division (B)(7) of this section, "rare medical condition" means any disease or condition that affects fewer than two-hundred thousand individuals in the United States.

(8) Nothing in division (B)(6) or (7) of this section prohibits the substitution, in accordance with section 4729.38 of the Revised Code, of any drug that has received a twelve-month approval under division (B)(6)(a) of this section when there is a release of ~~a~~ either of the following:

(a) A United States food and drug administration approved comparable brand product or a generic counterpart of a brand product that is listed as therapeutically equivalent in the United States food and drug administration's publication titled approved drug products with therapeutic equivalence evaluations;

(b) An interchangeable biological product, as defined in section 3715.01 of the Revised Code.

(9)(a) On or after January 1, 2017, upon written request, the department or its designee shall permit a retrospective review for a claim that is submitted for a service where prior authorization was required, but not obtained if the service in question meets all of the following:

(i) The service is directly related to another service for which prior approval has already been obtained and that has already been performed.

(ii) The new service was not known to be needed at the time the original prior authorized service was performed.

(iii) The need for the new service was revealed at the time the original authorized service was performed.

(b) Once the written request and all necessary information is received, the department or its designee shall review the claim for coverage and medical necessity. The department or its designee shall not deny a claim for such a new service based solely on the fact that a prior authorization approval was not received for the new service in question.

(10)(a) On or before January 1, 2017, disclose to all participating health care providers any new prior authorization requirement at least thirty days prior to the effective date of the new requirement.

(b) The notice may be sent via electronic mail or standard mail and shall be conspicuously entitled "Notice of Changes to Prior Authorization Requirements." The notice is not required to contain a complete listing of all changes made to the prior authorization requirements, but shall include specific information on where the health care ~~practitioner~~ provider may locate the information on the department's or its designee's web site or, if applicable, the department's or its designee's portal.

(c) All participating health care providers shall promptly notify the department or its designee of any changes to the health care provider's electronic mail or standard mail address.

(11)(a) On or before January 1, 2017, make available to all participating health care providers on its web site or provider portal a listing of its prior authorization

requirements, including specific information or documentation that a provider must submit in order for the prior authorization request to be considered complete.

(b) Make available on its web site information about the medical assistance programs offered in this state that clearly identifies specific services, drugs, or devices to which a prior authorization requirement exists.

(12) On or before January 1, 2018, establish a streamlined appeal process relating to adverse prior authorization determinations that shall include all of the following:

(a) For urgent care services, the appeal shall be considered within forty-eight hours after the department or its designee receives the appeal.

(b) For all other matters, the appeal shall be considered within ten calendar days after the department or its designee receives the appeal.

(c) The appeal shall be between the health care provider requesting the service in question and a clinical peer appointed by or contracted by the department or the department's designee.

(d) If the appeal does not resolve the disagreement, the appeal procedures shall permit the recipient to further appeal in accordance with section 5160.31 of the Revised Code.

(C) Beginning January 1, 2017, except in cases of fraudulent or materially incorrect information, the department or its designee shall not retroactively deny a prior authorization for a health care service, drug, or device when all of the following are met:

(1) The health care provider submits a prior authorization

request to the department or its designee for a health care service, drug, or device.

(2) The department or its designee approves the prior authorization request after determining that all of the following are true:

(a) The recipient is eligible for the health care service, drug, or device under the medical assistance program.

(b) The health care service, drug, or device is covered by the medical assistance program.

(c) The health care service, drug, or device meets the department's standards for medical necessity and prior authorization.

(3) The health care provider renders the health care service, drug, or device pursuant to the approved prior authorization request and all of the terms and conditions of the health care provider's contract with the department or the department's designee.

(4) On the date the health care provider renders the prior approved health care service, drug, or device, all of the following are true:

(a) The recipient is eligible for the medical assistance program.

(b) The recipient's condition or circumstances related to the recipient's care has not changed.

(c) The health care provider submits an accurate claim that matches the information submitted by the health care provider in the approved prior authorization request.

(5) If the health care provider submits a claim that includes an unintentional error and the error results in a claim that does not match the information originally submitted by the health care provider in the approved prior authorization request, upon receiving a denial of services from the department or its designee, the health care ~~practitioner~~ provider may resubmit the claim pursuant to division (C) of this section with the information that matches the information included in the approved prior authorization.

(D) Any provision of a contractual arrangement entered into between the department or its designee and a health care provider or recipient that is contrary to divisions (A) to (C) of this section is unenforceable.

(E) The director of medicaid may adopt rules in accordance with Chapter 119. of the Revised Code as necessary to implement the provisions of this section.

Section 2. That existing sections 1751.04, 1751.72, 3715.01, 3715.64, 3923.041, 4729.01, 4729.38, 4729.99, and 5160.34 of the Revised Code are hereby repealed.

Section 3. (A) This section applies to supervision agreements that, in accordance with section 4730.19 of the Revised Code, would expire on January 31, 2017.

(B) Notwithstanding section 4730.19 of the Revised Code, a supervision agreement described in division (A) of this section is valid until February 1, 2018. Beginning August 1, 2017, such a supervision agreement may be renewed in accordance with section 4730.19 of the Revised Code.

Section 4. Sections 1 and 2 of this act take effect on the ninety-first day after the effective date of this act.

Section 5. This act is hereby declared to be an emergency measure necessary for the immediate preservation of the public peace, health, and safety. The reason for the necessity is that immediate action is needed to address in a timely manner issues related to the oversight of supervision agreements between physicians and physician assistants. Therefore, this act shall go into immediate effect.