OHIO LEGISLATIVE SERVICE COMMISSION

Sub. Bill Comparative Synopsis

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(H. Health)

This table summarizes how the latest substitute version of the bill differs from the As Introduced version. It addresses only the topics on which the two versions differ substantively. It does not list topics on which the two bills are substantively the same. For the sake of brevity, "health plan issuer" as used in this synopsis, refers to health plan issuers, as that term is defined in the bill, utilization review organizations, and the Department of Medicaid, unless otherwise noted.

Topic	Previous Version (As Introduced)	Sub. Version (L_132_0774-2)
Clinical practice guideline requirements	Requires that a step therapy protocol be implemented via clinical review criteria that are based on clinical practice guidelines that meet specified criteria *(R.C. 3901.821(A) and (B), 5164.7512(B)(1), and 5164.7513).*	Removes the specified criteria and requires only that a step therapy protocol be implemented via clinical review criteria that are based on clinical practice guidelines or medical or scientific evidence *(R.C. 3901.821(A) and 5164.7512(B)(1))*.
Approval of clinical review criteria	Requires a health plan issuer or utilization review organization to submit proposed clinical review criteria for approval by the Superintendent of Insurance (does not apply to the Department of Medicaid) *(R.C. 3901.821(F)).*	No provision.

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Access to step therapy exemption and appeals process	Allows, generally, both a patient and a health care provider to make a step therapy exemption request or appeal *(R.C. 3901.822(A)(1)(a), (A)(2), and (A)(3) and 5164.7512(B)(2))*.	Allows only a health care provider to make a step therapy exemption request or an appeal *(R.C. 3901.822(A)(1)(a) and (A)(5) and 5164.7514(A)(3))*.
	No provision.	Specifies that an appeal is to be between a health care provider and a clinical peer *(R.C. 3901.822(A)(5)(c) and 5164.7514(B)(3)).*
	No provision.	Allows a patient or the patient's representative to request an external review *(R.C. 3901.822(A)(6) and 5164.7514(C))*.
	Requires a health plan issuer to make the step therapy exemption request process easily accessible on the health plan issuer's website *(R.C. 3901.822(A)(4) and 5164.7514(A)(2)).*	Limits this provision to the Department of Medicaid *(R.C. 5164.7514(A)(2)).*
Existing medical exceptions process	Allows a health plan issuer or utilization review organization to use its existing adverse benefit determination process to provide meet the step therapy exemption process (does not apply to the Department of Medicaid) *(R.C. 3901.822(A)(3))*.	Allows a health plan issuer or utilization review organization to use its existing medical exceptions process to meet the step therapy exemption requirement (does not apply to the Department of Medicaid) *(R.C. 3901.822(A)(1)(a))*.
Step therapy drug list	No provision.	Requires health plan issuers to make available to all health care providers a list of all drugs covered by the issuer that are subject to a step therapy protocol.
	No provision.	Requires a health plan issuer to issue multiple lists if the issuer uses multiple protocols.
	No provision.	Requires a health plan issuer to indicate the information or documentation that must be provided for a step therapy exemption request to be considered complete for each drug.

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	No provision.	Requires that all this information be made available on a health plan issuer's website or provider portal *(R.C. 3901.822(A)(2) and (3) and 5164.7512(B)(3))*.
Step therapy exemption request and appeal deadlines	Requires a health plan issuer to reply to a step therapy exemption request or an appeal within the following timelines: • Within 24 hours, in cases where exigent circumstances exist, of receipt of the request; • 72 hours for all other requests or appeals *(R.C. 3901.822(D)(1) and 5164.7514(B)(1))*. Specifies that if a health plan issuer or utilization review organization does not reply within these deadlines, then the request or appeal is considered approved *(R.C. 3901.822(D)(2) and 5164.7514(B)(2))*. Specifies that exemption request and appeal timelines begin upon receipt of the exemption request or appeal *(R.C. 3901.822(D)(1) and 5164.7514(B)(1))*.	Increases the deadlines as follows: • 48 hours for a request related to urgent care services; • Ten calendar days for all other requests *(R.C. 3901.822(A)(4) and (5) and 5164.7514(B)(1) and (2))*. No provision. Same, except that the timeline for appeals to the Department of Medicaid begins upon receipt of all necessary information *(R.C. 5164.7514(B)(2))*.
Mandatory exemptions	Requires a health plan issuer to grant a step therapy exemption request in certain situations *(R.C. 3901.822(B) and 5164.7514(A)(4))*.	Same, but explicitly requires a health care provider to document the specific reason for the step therapy exemption in the patient's medical record for the following situations: • The required prescription drug is expected to be ineffective based on the characteristics of the drug and the patient; • The required prescription drug is not in the best interest of the patient, based on medical necessity *(R.C. 3901.822(B)(2)*

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		and (4) and 5164.7514(A)(5)(a)(ii) and (iv)).
	Requires a step therapy exemption request to be granted if a drug recipient is stable on the prescribed drug selected by the recipient's provider *(R.C. 3901.822(B)(5) and 5164.7514(A)(4)(b))*.	Same, but also explicitly states that a health plan issuer may require the recipient to try an AB-rated generic equivalent prior to providing coverage for the branded drug *(R.C. 3901.822(B)(5) and 5164.7514(A)(5)(b))*.
Unfair and deceptive practices	No provision.	Specifies that a series of violations by a health plan issuer or utilization review organization of the bill's requirements are to be considered an unfair and deceptive practice in the business of insurance (does not apply to the Department of Medicaid) *(R.C. 3901.822(E))*.
Clinical review criteria entity	Specifies that the bill is not to be construed as requiring a health plan issuer that is not the Department of Medicaid to set up a new entity to develop clinical review criteria *(R.C. 3901.821(D))*.	Adds the Department of Medicaid to this rule of interpretation *(R.C. 5164.7512(C))*.
Rules	Requires the Superintendent of Insurance to adopt rules as necessary to implement the bill's requirements *(R.C. 3901.823)*.	Authorizes the Superintendent of Insurance to adopt rules as necessary to implement the bill's requirements *(R.C. 3901.823)*.
Definitions	No provision.	Defines "medical or scientific evidence" to mean evidence found in any of the following sources: • Peer-reviewed scientific studies published in, or accepted for publication by, medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff; • Peer-reviewed medical literature, including literature relating to therapies

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		reviewed and approved by a qualified institutional review board, biomedical compendia, and other medical literature that meet the criteria of the National Institutes of Health's library of medicine for indexing in Index Medicus and Elsevier Science Ltd. for indexing in excerpta medicus; • Medical journals recognized by the Secretary of Health and Human Services; • The following standard reference compendia: ○ The American Hospital Formulary Service drug information; ○ Drug Facts and Comparisons; ○ The American Dental Association Accepted Dental Therapeutics; ○ The United States Pharmacopoeia Drug Information. • Findings, studies or research conducted by or under the auspices of a federal government agency or nationally recognized federal research institute, including any of the following: ○ The Federal Agency for Health Care Research and Quality; ○ The National Institutes of Health; ○ The National Cancer Institute; ○ The National Academy of Sciences; ○ The Centers for Medicare and Medicaid services;

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		○ The federal Food and Drug Administration; ○ Any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health care services. • Any other medical or scientific evidence that is comparable. Defines "urgent care services" to mean a medical care or other service for a condition where application of the timeframe for making routine or nonlife threatening care determinations is either of the following: • Could seriously jeopardize the life, health, or safety of the patient or others due to the patient's psychological state; • 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 *(R.C. 3901.82(D) and (H) and 5164.7512(A)(3) and (7), and, by reference R.C. 3922.01 and 3923.041, not in the bill)*.
Effective date	Makes the bill's requirements effective January 1, 2018 *(Section 3).*	Makes the bill's requirements effective 90 days after the bill's effective date *(Section 3)*.