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BILL ANALYSIS

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Senate Bill 247 (as enacted) **PUBLIC ACT 60 of 2022**
Sponsor: Senator Curtis S. VanderWall
Senate Committee: Health Policy and Human Services
House Committee: Health Policy

Date Completed: 1-6-23

CONTENT

The bill amended Chapter 22 (The Insurance Contract) of the Insurance Code to modify or delete provisions pertaining to expedited review of a prior authorization request. The bill also added Section 2212e to the Code to do the following:

- **Require an insurer that delivers, issues for delivery, or renews in the State a health insurance policy that requires a prior authorization with respect to any benefit to make available, by June 1, 2023, a standardized electronic prior authorization request transaction process.**
- **Require prior authorization requirements to be based on peer-reviewed clinical review criteria that meet certain requirements.**
- **Require an insurer to post on its website if it implements a new prior authorization requirement or restriction or amends an existing requirement or restriction, with respect to any benefit under a health benefit plan.**
- **Require an adverse determination regarding a request for a prior authorization for a benefit other than a prescription drug benefit to be made by a licensed physician.**
- **Require an adverse determination regarding a request for a prior authorization for a prescription drug to be made by a licensed pharmacist or physician.**
- **Require an insurer or its designee utilization review organization to notify, on issuing a medical benefit denial, the health professional and insured or enrollee of certain information, including the right to appeal the adverse determination, and require an appeal of the denial to be reviewed by a health professional to which certain requirements apply.**
- **Prohibit an insurer or its designee utilization review organization from affirming the denial of an appeal unless the appeal is reviewed by a licensed physician who meets certain qualifications.**
- **Prescribe procedures for granting a prior authorization request that has or has not been certified as urgent by a health care provider.**
- **Require an insurer to report annually to the Department of Insurance and Financial Services certain aggregated trend data.**
- **Require the Department to annually aggregate and deidentify the data collected into a standard report and to post the report on its website.**
- **Require an insurer to adopt a program that promotes the modification of prior authorization requirements of certain prescription drugs, medical care, or related benefits, based on certain factors.**

The bill took effect on April 7, 2022.

Expedited Review

Section 2212c of the Code created the Prescription Drug Prior Authorization Workgroup and required it to develop a standard prior authorization methodology for use by prescribers to request and receive prior authorization from an insurer when a health benefit plan requires prior authorization for prescription drug benefits. (Previously, the Code referred to a policy, certificate, or contract instead of a health benefit plan.) "Health benefit plan" means that term as defined in Section 2212e (see below).

Section 2212c defines "insurer" as any of the following:

-- A health maintenance organization.
-- A health care corporation operating pursuant to the Nonprofit Health Care Corporation Reform Act.
-- A third-party administrator.

Under the bill, as used in Sections 2212c and Section 2212e, "third party administrator" means that term as defined in the Third Party Administrator Act.

Previously, the term also meant an insurer issuing an expense-incurred hospital, medical, or surgical policy or certificate. Instead, the bill refers to an insurer that delivers, issues for delivery, renews, or administers a health benefit plan.

Previously, "prescription drug benefit" meant the right to have a payment made by an insurer pursuant to prescription drug coverage contained within a policy, certificate, or contract delivered, issued for delivery, or renewed in Michigan. Instead, under the bill, the term means the right to have payment made by an insurer for a prescription drug listed on the applicable formulary in accordance with coverage contained within a health benefit plan delivered, issued for delivery, or renewed in the State.

Section 2212c requires the workgroup to include in the standard prior authorization methodology the ability for the prescriber to designate the prior authorization request for expedited review. Previously, in order to designate a prior authorization request for expedited review, the prescriber had to certify that applying the 15-day standard review period could seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function. The bill refers to the review period under Section instead of a 15-day standard review period.

Under Section 2212c, except as otherwise provided, an insurer must use the standard prior authorization methodology if a health benefit plan requires prior authorization for prescription benefits. (Previously, the Code referred to a policy, certificate, or contract instead of a health benefit plan.)

Previously, Section 2212c specified that a prior authorization request that has not been certified for expedited review by the prescriber was considered to have been granted by the insurer if it failed to grant the request, deny the request, or require additional information of the prescriber within 15 days after the date and time of submission of a standard prior authorization request under this section, and prescribed the conditions under which a request was considered granted if additional information was requested by an insurer. The bill deletes these provisions.

Also, Section 2212c specified that a prior authorization request that had been certified for expedited review by the prescriber was considered to have been granted by the insurer if it failed to grant the request, deny the request, or require additional information of the

prescriber within 72 hours after the date and time of submission of a standard prior authorization request. In addition, the section prescribed the conditions under which a prior authorization request was considered granted if additional information was requested by an insurer. The bill deletes these provisions.

Prior Authorization Requirements; Posting on Website

The bill creates Section 2212e, which specifies that for an insurer that delivers, issues for delivery, renews, or administers a health benefit plan in the State, if the health benefit plan requires a prior authorization with respect to any benefit, the insurer or its designee utilization review must make available, by June 1, 2023, a standardized electronic prior authorization request transaction process using an internet webpage, internet webpage portal, or similar electronic, internet, and web-based system.

"Health benefit plan" means an individual or group health insurance policy, an individual or group health maintenance organization contract, or a self-funded plan established or maintained by the State or a local unit of government for its employees. The term includes prescription drug benefits. "Prescription drug benefit" means that term as defined in Section 2212c.

"Prior authorization" means a determination by an insurer or utilization review organization that a requested health care benefit has been reviewed, and based on the information provided, satisfies the insurer or utilization review entity's organization's requirements for medical necessity and appropriateness.

"Utilization review organization" means that term as defined in Section 3 of the Patient's Right to Independent Review Act: a person that conducts utilization review, other than a health carrier performing a review for its own health plans. "Standardized electronic prior authorization transaction process" means a standardized transmission process, identified by the Director and aligned with standards that are nationally accepted to enable prior authorization requests to be accessible, submitted by health care providers, and accepted by insurers or their designee utilization review organization electronically through secure electronic transmissions with the goal of maximizing administrative simplification, efficiency, and timeliness. The term does not include a facsimile.

Beginning June 1, 2023, an insurer or its designee utilization review organization and the health professional must perform a prior authorization using only a standard electronic prior authorization transaction process, which allows the transmission of clinical information, unless the health professional is unable to use the standard process because of a temporary technological or electrical failure. The current prior authorization requirements must be described in detail and written in easily understandable language. An insurer described in the bill or its designee utilization review organization must make any current prior authorization requirements and restrictions, including the written clinical review criteria, readily accessible and conspicuously posted on its website to insureds, enrollees, health care professionals, and health care providers. Content published by a third party and licensed for use by an insurer or its designee utilization review organization may be made available through the insurer or its designee utilization review organization's secure, password-protected website if the access requirements of the website do not unreasonably restrict access to the content.

"Standardized electronic prior authorization transaction process" means a standardized transmission process, identified by the Director and aligned with standards that are nationally accepted, to enable prior authorization requests to be accessible, submitted by health care providers, and accepted by insurers or their designee utilization review organizations electronically through secure electronic transmissions with the goal of maximizing

administrative simplification, efficiency, and timeliness. The process must allow health care providers to supply clinical information under the standardized electronic prior authorization process. "Standard electronic prior authorization transaction process" does not include a facsimile.

The prior authorization requirements must be based on peer-reviewed clinical review criteria, which must do all of the following:

-- Take into account the needs of atypical patient populations and diagnoses.
-- Reflect community standards of care.
-- Ensure quality of care and access to needed health care services.
-- Be evidence-based criteria.
-- Be publicly available free of charge.
-- Be sufficiently flexible to allow deviations from norms when justified on a case-by-case basis.
-- The criteria must be evaluated and updated, if necessary, at least annually.

"Peer-reviewed" means the clinical review criteria that were approved by a committee comprised of clinicians, including licensed physicians or licensed pharmacists, or both, that meets regularly-scheduled intervals and evaluates, among other things, pharmaceutical literature or medical literature, or both, and scientific evidence to develop criteria that promote appropriate, safe, and cost effective drug utilization. "Evidence-based criteria" means criteria developed using evidence-based standards. "Evidence-based standards" means that term as defined in Section 3 of the Patient's Right to Independent Review Act: the conscientious, explicit, and judicious use of the current best evidence based on the overall systematic review of the research in making decisions about the care of individual patients.

Unless the criteria are developed as described below, it also must be developed by either a professional medical specialty society or an entity to which both of the following apply:

-- The entity works directly with clinicians, either within or outside the organization, to develop the criteria.
-- The entity does not have a financial stake in the outcome of the clinical care decisions made using the criteria.

In addition, for coverage other than prescription drug benefit coverage, before establishing or substantially or materially altering, its own written clinical review criteria, an insurer or designee utilization review organization must obtain input from actively practicing licensed physicians representing major areas of the specialty. For coverage of a prescription drug benefit, before establishing, or substantially or materially altering, its own clinical review criteria, an insurer or its designee utilization review organization must obtain input from actively practicing licensed pharmacists or actively practicing licensed physicians. If criteria are developed for a health care service provided by a health professional not licensed to engage in the practice of medicine under Part 170 (Medicine) or Part 175 (Osteopathic Medicine and Surgery) of the Public Health Code, an insurer or a designee utilization review organization must seek input from a health professional in the same profession as the health professional providing the health care service. "Health care provider" means any of the following: a) a health facility as that term is defined in Section 2006 of the Insurance Code (a health facility or agency licensed under Article 17 (Facilities and Agencies) of the Public Health Code), or b) a health professional. "Health professional means that term as defined in Section 2006 of the Insurance Code: an individual licensed, registered, or otherwise authorized to engage in a health profession under Article 15 (Occupations) of the Public Health Code.

An insurer must make available on its public website in a readily accessible format a list of all benefits that are subject to a prior authorization under the health benefit plan.

If an insurer implements a new prior authorization requirement or restriction, or amends an existing requirement or restriction the insurer must ensure that the new or amended requirement or restriction is posted on its public website before its implementation. For a benefit that does not involve coverage of a prescription drug, an insurer must notify contracted health care providers via the insurer's provider portal of the new or amended requirement or restriction at least 60 days before the requirement or restriction is implemented. For coverage of a prescription drug, an insurer must make available on its website or notify contracted health care providers via the insurer's provider portal of the new or amended requirement or restriction at least 45 days before the requirement or restriction is implemented unless any of the following apply:

-- The United States Food and Drug Administration (FDA) has done any of the following: a) issued a statement that calls into question the clinical safety of the drug; b) requires the manufacturers to conduct postmarket safety studies and clinical trials after drug is approved; c) issues any drug-safety-related labeling changes; or d) requires the manufacturers to implement special risk management programs.
-- The drug receives a new FDA approval and has become available.
-- The FDA has approved expanded use of the drug.

The initial review of information submitted in support of a request for prior authorization may be conducted and approved by a health professional.

Adverse Determination

For an adverse determination regarding a request for prior authorization for a benefit other than a prescription drug, the adverse determination must be made by a licensed physician. For an adverse determination of a health care service provided by a health professional that is not a licensed physician, a licensed physician may consider input from a health professional who is in the same profession as the health professional providing the health care service. The licensed physician must make the adverse determination under the general direction of the insurer's medical director who oversees the utilization management program. Medical directors must be licensed to engage in the practice of medicine or the practice of osteopathic medicine and surgery.

For an adverse determination regarding a request for prior authorization for a prescription drug, the adverse determination must be made by a licensed pharmacist or licensed physician. The licensed pharmacist or licensed physician must make the adverse determination under the general direction of the insurer's medical director who oversees the utilization management program. Medical directors must be licensed to engage in the practice of medicine or the practice of osteopathic medicine and surgery.

"Adverse determination" means that term as defined in Section 2213 of the Insurance Code. (Under that section, "adverse determination" means any of the following:

-- A determination by an insurer or its designee utilization review organization that a request for a benefit, on application of any utilization review technique, does not meet the insurer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness or is determined to be experimental or investigational and the requested benefit is therefore denied, reduced, or terminated or payment is not provided or made, in whole or in part, for the benefit.

-- The denial, reduction, termination, or failure to provide or make payment, in whole or in part, for a benefit based on a determination by an insurer or its designee utilization review organization of a covered person's eligibility for coverage from the insurer.
-- A prospective review or retrospective review determination that denies, reduces, or terminates or fails to provide or make payment, in whole or in part, for a benefit.
-- A rescission of coverage determination.
-- Failure to respond in a timely manner to a request for a determination.)

Denial of Prior Authorization; Appeal

If an insurer denies a prior authorization, the insurer or its designee utilization review organization, on issuing a medical benefit denial, must notify the health professional and insured or enrollee of the following:

-- The reasons for the denial and related evidence-based criteria.
-- The right to appeal the adverse determination.
-- Instructions on how to file the appeal.
-- Additional documentation necessary to support the appeal.

An appeal of the denial must be reviewed by a health professional to which all of the following apply:

-- The health professional does not have a direct stake or any financial interest in the outcome of the appeal.
-- The health professional has not been involved in making the adverse determination.
-- The health professional considers all known clinical aspects of the health care services under review, including a review of all pertinent medical records provided to the insurer or designee utilization review organization by the insured or enrollee's health care provider and any relevant records provided to the insurer or designee utilization review organization by a health care facility.
-- The health professional may consider input from a health profession who is licensed in the same profession as the health professional providing health care service or a licensed pharmacist if the adverse decision pertains to a prescription drug.

"Health professional" means an individual licensed, registered, or otherwise authorized to engage in a health professional under Article 15 (Occupations) of the Public Health Code or under laws of another state to engage in a health profession.

An insurer or its designee utilization review organization may not affirm the denial of an appeal unless the appeal is reviewed by a licensed physician who is board certified or eligible in the same specialty as the health care provider who typically manages the medical condition or disease or provides the health care service. However, if an insurer or its designee utilization review organization cannot identify a licensed physician who meets the requirements described above without exceeding the applicable time limits imposed under the bill, the insurer or its designee review organization may utilize a licensed physician in a similar general specialty as considered appropriate, as determined by the insurer or its designee utilization review organization.

Beginning June 1, 2023, through May 31, 2024, a prior authorization request that has not been certified as urgent by the health care provider is considered granted by the insurer or its designee utilization review organization if the insurer or the designee utilization review organization fails to grant the request, deny the request, or required additional information from the health care provider within nine calendar days after the date and time of submission or the prior authorization. After May 31, 2024, a prior authorization request that has not been

certified as urgent by the health care provider is considered granted by the insurer or its designee utilization review organization if the insurer or its designee utilization review organization fails to grant the request, denies it, or requires additional information of the health care provider within seven calendar days after the date and time of the submission.

Beginning June 1, 2023, through May 31, 2024, if additional information is requested by an insurer or its designee utilization review organization, the request is considered to have been granted by the insurer or its designee utilization review organization if the insurer or its designee utilization review organization fails to grant the request, deny it, or otherwise respond within nine calendar days the date and time of the submission of additional information. After May 31, 2024, if additional clinical information is requested and received by an insurer or its designee utilization review organization, the prior authorization request is considered granted by the insurer or its designee utilization review organization if the insurer or its designee utilization review organization fails to grant the request, deny it, or otherwise respond to the request of the health care provider within seven calendar days after the additional information is submitted.

"Urgent" means an insured is suffering from a health condition that may jeopardize seriously the insured's life, health, or ability to regain maximum function or could subject the insured or enrollee to severe adverse health consequences that cannot be adequately managed without the care or treatment that is the subject of the prior authorization.

Beginning June 1, 2023, a prior authorization request that has been certified as urgent by the health care provider is considered granted if the insurer or its designee utilization review fails to grant the request, deny it, or require additional information of the health care provider within 72 hours after the request is submitted. If additional information is requested by an insurer or its designee utilization review organization, the prior authorization request is considered to have been granted if the insurer or its designee utilization review organization fails to grant the request, deny it, or otherwise respond to the request within 72 hours after the additional information if submitted.

A prior authorization request is valid for at least 60 calendar days or for a duration that is clinically appropriate, whichever is later.

Report; Data Collection

By June 1, 2023, and each June 1 after that date, an insurer must report to the Department, on a form issued by the Department, the following aggregated trend data related to the insurer's prior authorization practices and experience for the prior plan year:

-- The number of prior authorization requests.
-- The number of prior authorization requests denied.
-- The number of appeals received.
-- The number of adverse determinations reversed on appeal.
-- Of the total number of prior authorization requests, the number of prior authorization requests that were not submitted electronically.
-- The top 10 services that were denied.
-- The top 10 reasons prior authorization requests were denied.

By October 1, 2023, and each October 1 after that date, the Department must aggregate and deidentify the data collected into a standard report and may not identify the name of the insurer that submitted the data. The report must be written in easily understandable language and posted on the Department's public internet website.

All of the following apply to any data, documents, materials, or other information described above that has not been aggregated, deidentified, and otherwise compiled into the standard report:

-- The data, documents, materials, or other information are considered proprietary and to contain trade secrets.
-- The data, documents, materials, or other information are confidential and privileged and is not subject to disclosure under the Freedom of Information Act.

Transparency

An insurer must adopt a program, developed in consultation with health care providers participating with the insurer, that promotes the modification of prior authorization requirements of certain prescription drugs, medical care, or related benefits based on any of the following:

-- The performance of the health care providers with respect to adherence to nationally recognized evidence-based medical guidelines, appropriateness, efficiency, and other quality criteria.
-- Involvement of contract health care providers with an insurer to participate in a financial risk-sharing payment plan, that includes downside risk.
-- Health provider specialty, experience, or other factors.

MCL 500.2212c & 500.2212e Legislative Analyst: Stephen P. Jackson

FISCAL IMPACT

The bill will have an indeterminate fiscal impact on State government and no fiscal impact on local units of government. The Department of Insurance and Financial Services may experience increased administrative costs related to monitoring insurers' compliance with the proposed requirements; however, many of these costs likely will be sufficiently funded by existing appropriations.

Fiscal Analyst: Jonah Houtz

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