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BILL ANALYSIS

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Senate Bill 247 (Substitute S-1)
Sponsor: Senator Curtis S. VanderWall
Committee: Health Policy and Human Services

Date Completed: 4-22-21

CONTENT

The bill would amend Chapter 22 (The Insurance Contract) of the Insurance Code to modify and delete various provisions pertaining to expedited review of a prior authorization request. The bill also would add Section 2212e to the Code to do the following:

- **Require an insurer that delivered, issued for delivery, or renewed in the State a health insurance policy that required a prior authorization with respect to any benefit to make available, by January 1, 2022, a standardized electronic prior authorization request transaction process.**
- **Require prior authorization requirements to be based on peer-reviewed clinical review criteria that met certain requirements.**
- **Require an insurer to post on its website if it implemented a new prior authorization requirement or restriction or amended 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 a licensed 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 practitioner to which certain requirements applied.**
- **Prohibit an insurer or its designee utilization review organization from affirming the denial of an appeal unless the appeal was reviewed by a licensed physician who met certain qualifications.**
- **Require an insurer to report annually to the Department of Insurance and Finical 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 transparent program that promoted the modification of prior authorization requirements based on the performance of the health care providers with respect to adherence to nationally recognized evidence-based medical guidelines and other quality criteria.**

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 policy, certificate, or contract requires prior authorization for prescription drug benefits. The bill would refer to a health benefit plan instead of a policy, certificate, or contract. "Health benefit plan" would mean 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.

The term also means an insurer issuing an expense-incurred hospital, medical, or surgical policy or certificate. Instead, the bill would refer to an insurer issuing or administering a health benefit plan.

"Prescription drug benefit" means 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 would mean 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. In order to designate a prior authorization request for expedited review, the prescriber must certify that applying the 15-day standard review period may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function. The bill would refer to a five-business day review period 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 policy, certificate, or contract requires prior authorization for prescription benefits. The bill would refer to a health benefit plan instead of a policy, certificate, or contract.

Section 2212c specifies that a prior authorization request that has not been certified for expedited review by the prescriber is considered to have been granted by the insurer if it fails 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 prescribes the conditions under which a request is considered granted if additional information is requested by an insurer. The bill would delete these provisions.

Section 2212c also specifies that a prior authorization request that has been certified for expedited review by the prescriber is considered to have been granted by the insurer if it fails 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 prescribes the conditions under which a prior authorization request is considered granted if additional information is requested by an insurer. The bill would delete these provisions.

Prior Authorization Requirements; Posting on Website

The bill creates Section 2212e, which specifies that for an insurer that delivered, issued for delivery, renewed, or administered a health benefit plan in the State, if the health benefit plan required a prior authorization with respect to any benefit, the insurer or its designee utilization review would have to make available, by January 1, 2022, 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" would mean 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 would include prescription drug benefits. "Prescription drug benefit" would mean that term as defined in Section 2212c.

"Prior authorization" would mean 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" would mean 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" would mean 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 would not include a facsimile.

Beginning January 1, 2022, an insurer or its designee utilization review organization and the health professional would have to perform a prior authorization using only a standard electronic prior authorization transaction process, which allows the transmission of clinical information, unless the health professional was unable to use the standard electronic prior authorization transaction process because of a temporary technological or electrical failure. The current prior authorization requirements would have to described in detail and written in easily understandable language. An insurer described in the bill or its designee utilization review organization would have to 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 could be made available through the insurer or its designee utilization review organization's secure, password-protected website if the access requirements of the website did not unreasonably restrict access to the content.

"Standardized electronic prior authorization transaction process" would mean 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 would have to allow health care providers to supply clinical information under the standardized electronic prior authorization process. "Standard electronic prior authorization transaction process" would not include a facsimile.

The prior authorization requirements would have to be based on peer-reviewed clinical review criteria, to which all of the following would apply:

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

"Peer-reviewed" would mean the clinical review criteria that was 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 promotes appropriate, safe, and cost effective drug utilization. "Evidence-based criteria" would mean criteria developed using evidence-based standards. "Evidence-based standards" would mean 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 were developed as described below, the criteria also would have to be developed by either a professional medical specialty society or an entity to which both of the follow applied:

-- The entity worked directly with clinicians, either within or outside the organization, to develop the criteria.
-- The entity did 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 would have to 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 would have to obtain input from actively practicing licensed pharmacists or actively practicing licensed physicians. If criteria were 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 would have to seek input from a health professional in the same profession as the health professional providing the health care service. "Health care provider" would mean 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 would mean 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 would have to make available on its public website in a readily accessible format a list of all benefits that were subject to a prior authorization under the health benefit plan.

If an insurer implemented a new prior authorization requirement or restriction, or amended an existing requirement or restriction, with respect to any benefit under a health benefit plan, the insurer would have to ensure that the new or amended requirement or restriction was posted on its public website before its implementation. For a benefit that was not a prescription drug benefit, an insurer would have to 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 was implemented. For coverage of a prescription drug, an insurer would have to 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 applied:

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

The initial review of information submitted in support of a request for prior authorization could be conducted and approved by a health professional who is qualified by education, experience, or knowledge.

Adverse Determination

For an adverse determination regarding a request for prior authorization for a benefit other than a prescription drug, the adverse determination would have to be made by a licensed physician. For an adverse determination of a health care service provided by a health professional that was not a licensed physician, a licensed physician could consider input from a health professional who was in the same profession as the health professional providing the health care service. The licensed physician would have to make the adverse determination under the clinical direction of one of the insurer's medical directors who was responsible for the provision of health care items and services provided to insureds or enrollees. Medical directors would have to be licensed to engage in the practice of medicine under Part 170 of the Public Health Code or the practice of osteopathic medicine and surgery under Part 175 of the Public Health Code.

For an adverse determination regarding a request for prior authorization for a prescription drug, the adverse determination would have to be made by a licensed pharmacist or licensed physician. The licensed pharmacist or licensed physician would have to make the adverse determination under the clinical direction of one of the insurer's medical directors who was responsible for the provision of health care items and services provided to insureds or enrollees. Medical directors would have to be licensed to engage in the practice of medicine under Part 170 of the Public Health Code or the practice of osteopathic medicine and surgery under Part 175 of the Public Health Code.

"Adverse determination" would mean 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 denied a prior authorization, the insurer or its designee utilization review organization, on issuing a medical benefit denial, would have to 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.
-- Instruction on how to file the appeal.
-- Additional documentation necessary to support the appeal.

An appeal of the denial would have to reviewed by a health practitioner to which all of the following applied:

-- The health practitioner did not have a direct stake or any financial interest in the outcome of the appeal.
-- The health practitioner had not been involved in making the adverse determination.
-- The health practitioner considered 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 practitioner could consider input from a health profession who was licensed in the same profession as the health professional providing health care service or a licensed pharmacist if the adverse decision pertained to a prescription drug.

"Health practitioner" would mean any of the following: a) a health professional; b) a pharmacists licensed in another state; or c) a physician licensed in another state.

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

A prior authorization request that had not been certified as urgent by the health care provider would be considered to have been granted by the insurer or its designee utilization review organization if the insurer or its designee utilization review organization failed to grant the request, denied it, or required additional information of the health care provider within five business days after the date and time of the submission. If additional information were requested by an insurer or its designee utilization review organization, the request would not be considered granted if the health care provider failed to submit the additional information within two business days the date and time of the request for additional information. If additional clinical information were requested and received by an insurer or its designee

utilization review organization, the prior authorization request would be considered granted by the insurer or its designee utilization review organization if the insurer or its designee utilization review organization failed to grant the request, denied it, or otherwise responded to the request of the health care provider within five business days after the date and time of the submission of additional information.

"Urgent" would mean 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.

A prior authorization request that had been certified as urgent by the health care provider would be considered granted by the insurer or its designee utilization review organization if the insurer or its designee utilization review failed to grant the request, deny it, or require additional information of the health care provider within two business days after the date and time of the submission of the request. If all additional clinical information were requested by an insurer or its designee utilization review organization, the prior authorization request would not be considered granted if the health care provided failed to submit the additional information within one business day after the date and time after the request for additional information. If additional information were requested by an insurer or its designee utilization review organization, the prior authorization request would be considered to have been granted by the insurer or its designee utilization review organization if the insurer or its designee utilization review organization failed to grant the request, deny it, or otherwise respond to the request within two business days after the date and time of the submission of additional information.

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

Report; Data Collection

By June 1, 2022, and each June 1 after that date, an insurer would have to report to 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, 2022, and each October 1 after that date, the Department would have to aggregate and deidentify the data collected into a standard report and could not identify the name of the insurer that submitted the data. The report would have to 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 had not been aggregated, deidentified, and otherwise compiled into the standard report:

-- The data, documents, materials, or other information would be considered proprietary and to contain trade secrets.

-- The data, documents, materials, or other information would be confidential and privileged and is not subject to disclosure under the Freedom of Information Act.

Transparency

An insurer would have to adopt a transparent program, developed in consultation with health care providers participating with the insurer, that promoted the modification of prior authorization requirements based on the performance of the health care providers with respect to adherence to nationally recognized evidence-based medical guidelines and other quality criteria.

MCL 500.2212c et al. Legislative Analyst: Stephen Jackson

FISCAL IMPACT

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

Fiscal Analyst: Steve Angelotti