Title 31 MARYLAND INSURANCE ADMINISTRATION

Subtitle 10 HEALTH INSURANCE — GENERAL

Chapter 51 Mental Health Benefits and Substance Use Disorder Benefits – Reports on Nonquantitative Treatment Limitations and Data

Authority: Insurance Article, §§2-109(a)(1) and 15-144, Annotated Code of Maryland

.01 Purpose

The purpose of this chapter is to adopt regulations to implement Insurance Article, §15-144, Annotated Code of Maryland to ensure uniform definitions and methodology for the reporting requirements established under this section.

.02 Scope

This chapter applies to carriers that deliver or issue for delivery a health benefit plan in Maryland.

.03 Definitions.

- A. In this chapter, the following terms have the meaning indicated.
- B. Terms Defined.
 - (1) "Analysis report" means the report required by Insurance Article, §15-144(c), Annotated Code of Maryland.
- (2) "As written" means as used in the development and design of a decision whether or not to apply a NQTL to a particular benefit, as reflected in the written policies, procedures and related documents, including medical necessity criteria or guidelines, used by the carrier and/or any entity delegated by the carrier to manage mental health, substance use disorder, or medical/surgical benefits on behalf of the carrier.
- (3) "Case management" means a program to assist a member in accessing necessary medical, substance use disorder, or mental health services, and may include:
 - (a) Coordinating access to care;
 - (b) Exploring service and funding source alternatives;
 - (c) Monitoring progress to established goals (set by a case manager and the patient);
 - (d) Assisting with coordinating discharge planning and follow-up; or
 - (e) Helping ensure the patient's benefits are used effectively.
- (4) "Concurrent Review" means any process used by the carrier or its private review agent to conduct utilization review for ongoing health care or for an extension of treatment beyond previously approved health care.
 - (5) "Data report" means the report required by Insurance Article, § 15-144(f), Annotated Code of Maryland.
- (6) "Emergency Services" means the treatment of a medical condition, including a mental health condition or substance use disorder, manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the lack of immediate medical attention could reasonably be expected to result in placing the health of the patient, or, in case of pregnancy, the unborn child in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part.
- (7) "Evidentiary standards" means the carrier's defined level and type of evidence necessary to evaluate whether a given factor is established, present, or utilized, which results in the determination to apply or not apply an NQTL to which that factor relates.
- (8) "Factor" means a circumstance, condition, fact, standard, criterion, influence, or any other consideration that contributes to the development, design, and/or implementation of a NQTL.
- (9) "Failure to Complete a Course of Treatment" means a patient's failure to follow a documented treatment plan prescribed or recommended by a healthcare professional, including on the Uniform Treatment Plan form when the treatment is for mental health or a substance use disorder.
- (10) "In operation" means as used in the implementation and application of NQTLs, including the administration of benefits.
- (11) "Measures" means the steps, plan, methods, or course of action taken by a carrier to assess compliance in the development and implementation of a NQTL when the carrier has delegated management of covered benefits to another entity. Measures include written policies, procedures, and guidelines, as well as operational controls, checks, audits, and safeguards.
- (12) "Medical/surgical benefits" has the meaning stated in Insurance Article, § 15-144(a)(4), Annotated Code of Maryland and may be abbreviated as "med/surg benefits" or "M/S benefits".
- (13) "Medical Necessity" means the definition, criteria, or guidelines used by the carrier and/or its private review agent to determine what is necessary, efficient, or appropriate for purposes of coverage of a service or benefit.
 - (14) "Mental health benefits" has the meaning stated in Insurance Article, § 15-144(a)(5), Annotated Code of Maryland.
 - (15) "MH/SUD" means mental health benefits and substance use disorder benefits as a combined category.
- (16) "NQTL" means a non-quantitative treatment limitation as defined in Insurance Article, § 15-144(a)(6), Annotated Code of Maryland.
 - (17) "Pharmacy services" means any of the following activities:
 - (a) Providing pharmaceutical care;
 - (b) Compounding, dispensing, or distributing prescription drugs or devices;

- (c) Compounding or dispending nonprescription drugs or devices;
- (d) Monitoring prescriptions for prescription and nonprescription drugs or devices;
- (e) Providing information, explanation, or recommendations to patients and health care practitioners about the safe and effective use of prescription or nonprescription drugs or devices;
 - (f) Identifying and appraising problems concerning the use or monitoring of therapy with drugs or devices;
- (g) Acting with the parameters of a therapy management contract, as provided under Subtitle 6A of the Health-Operations Article, Annotated Code of Maryland;
- (h) Administering vaccinations in accordance with Health-Occupations Article, § 12–508, Annotated Code of Maryland or self-administered drugs in accordance with Health-Occupations Article, § 12–509, Annotated Code of Maryland;
- (i) Delegating a pharmacy act to a registered pharmacy technician, pharmacy student, or an individual engaged in a Board approved pharmacy technician training program;
- (j) Supervising a delegated pharmacy act performed by a registered pharmacy technician, pharmacy student, or an individual engaged in a Board approved pharmacy technician training program;
- (k) Providing drug therapy management in accordance with Health-General Article, § 19–713.6, Annotated Code of Maryland; or
- (l) Prescribing and dispensing contraceptive medications and self-administrated contraceptive devices approved by the $U.S.\ Food\ and\ Drug\ Administration.$
- (18) "Plan documents" means all documents in which a carrier describes a requirement related to an NQTL, including a policy, certificate of coverage, medical policy, medical necessity criteria or guidelines, or provider manual. Plan documents also include any document reflecting analyses conducted or results from such analyses related to the comparability and stringency of an NQTL for MH/SUD benefits as compared to M/S benefits.
- (19) "Prescription Drug Formulary Design" means a continually updated list of prescription drugs approved for reimbursement, including both generic and specialty drugs.
- (20) "Prior authorization" means the process that a carrier or any entity delegated by the carrier to manage mental health, substance use disorder, or medical/surgical benefits on behalf of the carrier requires a member or provider to follow prior to the rendering of services to determine if coverage will be provided based on considerations such as medical necessity, level of care, appropriateness of health care services, provider type, geographic location, or diagnosis exclusions. Prior authorization includes, but is not limited to, preauthorization, precertification, prospective review, preadmission review, pretreatment review, utilization review, and any requirement that a member or provider notify the carrier or organization prior to receiving or delivering a health care service. Prior authorization includes reauthorization of services or benefits that had received preauthorization, but for which the approval period has lapsed. A request for prior authorization is one received during the reporting period, regardless of whether or when services are delivered or whether or when a claim is submitted.
- (21) "Process" means a series of actions or steps taken during the development, design or implementation/application of an NQTL.
- (22) "Process for Assessment of New Technology" means a systematic, scientific process to follow for evaluating medical and surgical treatments and mental health and substance use treatment in order to ensure that members under the carrier's health benefit plan have access to appropriate treatments not previously covered by the carrier.
 - (23) "Provider" means:
 - (a) A physician;
 - (b) Hospital;
 - (c) Facility;
 - (d) Practitioner; or
 - $(e) \ Other \ person \ who \ is \ licensed \ or \ otherwise \ authorized \ to \ provide \ health care \ services.$
 - (24) "Provider Credentialing and Contracting" means a carrier's:
 - (a) Processes;
 - (b) Procedures; and
- (c) Standards for determining which health care providers to contract with, either directly or through a subcontracting entity, to provide health care services to the carrier's enrollees under the carrier's health benefit plan.
- (25) "Reimbursement" means compensation or the amount allowed to a health care provider, member, or other person entitled to reimbursement by a carrier, or the combined amount of the carrier's payment and member's cost-sharing responsibility, for providing health care services, medications, or supplies to enrollees of the health benefit plan. "Reimbursement" includes, but is not limited to:
 - (a) Fee for service payments;
 - (b) Capitation payments;
 - (c) Bundled or global payments; and
 - (d) Bonuses or other incentive payments.
- (26) "Reimbursement rates" means the dollar amounts, fee schedules, or formulae to calculate the dollar allowed amounts under a value-based or other alternative payment arrangement, payable for a service or set of services.
- (27) "Restrictions for Provider Specialty" means, for services that are within the scope of practice for a health care provider, restrictions based on the licensure or certification of a health care provider that limit the scope or duration of benefits for services provided under the plan or coverage.

- (28) "Restrictions that Limit Duration or Scope of Benefits for Services" means non-numerical limits or restrictions based on geographic location, facility type, provider specialty, and other criteria, including exclusions of a specific or type of MH/SUD treatment, that limit the scope or duration of benefits for services provided under the plan or coverage.
 - (29) "Retrospective Review" means utilization review of health care that has been provided to an enrollee.
- (30) "Source" means the data, analyses, recommendation, requirement, meeting, or other information upon which a factor is based or from which a factor is derived or arises.
- (31) "Substance use disorder benefits" has the meaning stated in Insurance Article, § 15-144(a)(9), Annotated Code of Maryland.
 - (32) "Summary form" means the form required by Insurance Article, § 15-144(g)(5), Annotated Code of Maryland.

.04 Filing of Nonquantitative Treatment Limitation Comparative Analysis Report.

- A. For the five health benefit plans with the highest enrollment for each product offered by the carrier in the individual, small, and large group markets, a carrier that delivers or issues for delivery a health benefit plan in the State shall conduct a comparative analysis for each nonquantitative treatment limitation specified in the form required by the Commissioner, to demonstrate the carrier's compliance with the Parity Act. An analysis report shall be filed with the Commissioner using only the form developed by the Commissioner and posted on the Administration's website.
- B. Carriers shall prepare the analysis report in coordination with any entity the carrier contracts with to provide, manage, or administer MH/SUD benefits.
 - C. Carriers shall follow the instructions posted on the Administration's website to complete the analysis report.
- D. A complete analysis report shall include responses to each section of the standardized form, as described in the instructions posted on the Administration's website.
- E. Each analysis report shall contain a statement, signed by a corporate officer, attesting to the accuracy of the information contained in the analysis report.
- F. Failure to file a complete analysis report shall result in penalties described in Insurance Article, § 15-144 (j), Annotated Code of Maryland.
 - G. Complete Analysis Report.
- (1) The analysis required by Insurance Article, § 15-144(d), Annotated Code of Maryland shall have been performed for processes in place during the calendar year preceding the analysis report.
 - (2) A carrier shall analyze each NQTL separately for each classification and sub-classification (as applicable) of benefits.
- (3) If the carrier delegates administration or management of mental health, substance use disorder, or medical/surgical benefits to another entity (for example, a private review agent specializing in mental health and substance use disorder benefits or a pharmacy benefits manager), the analyses shall be conducted with close and coordinated involvement of both the carrier and the entity delegated by the carrier to manage mental health, substance use disorder, or medical/surgical benefits on behalf of the carrier. The carrier is responsible for providing all required information for the analyses, regardless of any delegation arrangement with a subcontracted entity.
 - (4) The analysis reports shall include the following information to be considered complete.
- (a) All of the information identified in Insurance Article, § 15-144(e), Annotated Code of Maryland in the manner and format specified in the standard reporting form and associated instructions provided on the Administration's website;
- (b) A response to each step listed in the reporting form, for each NQTL in each classification and sub-classification as applicable. If a particular item in a step is not applicable (for example, if none of the factors used to determine that the NQTL will apply to a benefit was given more weight than another), an explanation shall be provided as to why the item is not applicable;
- (c) A statement as to whether there is any variation in the application of a guideline or standard used by the carrier between MH/SUD and medical/surgical benefits, and, if so, a description of the factors and process used for establishing that variation. Specific definitions of factors, processes, or criteria used to establish or support any variation is required. Any practice guidelines that may be associated with the NQTL shall also be provided;
- (d) If the application of the NQTL turns on specific decisions in administration of the benefits, identification of the basis of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s), including expertise and specialty:
- (e) If the analyses rely upon any experts, an assessment of each expert's qualifications, expertise and specialty, and a description of the extent to which the carrier relied upon each expert's evaluations in setting recommendations regarding both MH/SUD and medical/surgical benefits. Any variation in the use of experts (e.g., specialty matching, licensure levels, etc.) for MH/SUD compared to M/S shall be defined and justified;
 - (f) A description of all exception processes available for each NQTL and when the exception may be applied;
- (g) An explanation of how much discretion is allowed in applying the NQTL and whether such discretion is afforded comparably for processing MH/SUD benefit claims and medical/surgical benefits claims;
- (h) Documentation of audits to check sample claims or other administrative data to assess how each NQTL operates in practice, and whether written processes are correctly carried out, including the results of the audits and reviews performed on the NQTLs identified in Insurance Article, § 15-144 (c)(2)(ii), Annotated Code of Maryland to conduct the comparative analysis required under Insurance Article, § 15-144 (d)(2), Annotated Code of Maryland as written, and in operation:

- (i) Citations to any documents, studies, testing, claims data, or reports that include factors, sources, evidentiary standards, or other evidence relied upon in developing the NQTL (for example, meeting minutes or reports showing how those considerations were applied), with copies of those items available on request; and
 - (j) A description of the consequences for failure to meet an NQTL standard.

.05 Filing of Data Report.

- A. For the five health benefit plans with the highest enrollment for each product offered by the carrier in the individual, small, and large group markets, a carrier that delivers or issues for delivery a health benefit plan in the State shall submit a data report for the immediately preceding calendar year for mental health benefits, substance use disorder benefits, and medical/surgical benefits by Parity Act classification.
- B. The data report shall be filed with the Commissioner using only the standardized form posted on the Administration's website.
 - C. Carriers shall follow the instructions posted on the Administration's website to complete the data report.
- D. A complete data report shall include responses to each applicable section of the standardized form and follow the instructions posted to the Administration's website.
- E. Each data report shall contain a statement, signed by a corporate officer, attesting to the accuracy of the information contained in the data report.
- F. Failure to file a complete data report shall result in penalties under Insurance Article, § 15-144 (J), Annotated Code of Maryland.

.06 Summary Form.

- A. A carrier subject to Insurance Article, § 15-144, Annotated Code of Maryland shall prepare a summary form using only the template form posted on the Administration's website.
- B. The summary form shall be made available to plan members and accessible to the public on the carrier's website no later than April 1, 2022 and April 1, 2024. The carrier shall make the summary form available to plan members in response to a written request within 30 days of the request.
- C. Carriers shall follow the instructions for completing the summary form using the instructions posted on the Administration's website.
- D. A complete summary form shall include responses to each applicable section of the standardized form, as described in the instructions posted on the Administration's website.

.07 Compliance Plan.

- A. If, as a result of the review of the reports described in regulations .02 and .03 of this chapter, the Commissioner finds that a carrier subject to Insurance Article, § 15-144, Annotated Code of Maryland failed to comply with provisions of the Parity Act, the Commissioner shall notify the carrier and require the carrier to submit a compliance plan pursuant to Insurance Article, § 15-144 (i), Annotated Code of Maryland to correct the noncompliance. The notice shall be in writing, but may be transmitted electronically.
- B. The carrier shall have 90 days to file a compliance plan following the date a notice of noncompliance is issued by the Commissioner.
 - C. The compliance plan shall include:
 - (1) An acknowledgement of the Commissioner's finding of noncompliance;
 - (2) A summary of action(s) taken by the carrier to correct the noncompliance prior to the notice from the Commissioner;
 - (3) A summary of future action(s) to correct the noncompliance and the time frame when the actions will be taken; and
 - (4) A summary of amounts owed to members or providers due to violations of the Parity Act, including:
 - (a) Any amounts owed to members and payment date(s);
 - (b) Draft correspondence to members;
 - (c) Any amounts owed to providers and payment date(s);
 - (d) Draft correspondence to providers; and
 - (e) Confirmation of amounts paid to members and providers.

08. Effective date

The regulations in this chapter are applicable for all reports filed after January 1, 2022.