

New language is underlined; deletions are ~~stricken~~.

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128.001: Scope and Purpose

105 CMR 128.000 applies to all carriers subject to the requirements of M.G.L. c. 176O. 105 CMR 128.000 establishes requirements for carriers in administering their internal grievance procedures and establishes the requirements for the conduct of external reviews of carriers' medical necessity adverse determinations. 105 CMR 128.000 also sets out requirements for continuity of care and referral to specialty care.

128.003: Authority

105 CMR 128.000 is promulgated pursuant to M.G.L. c. 111, § 217(a)(1) and M.G.L. c. 176O.

128.020: Definitions:

As used in 105 CMR 128.000 the following words shall have the following meanings:

Actively Practicing means that a health care professional regularly treats patients in a clinical setting.

Adverse Determination means a determination, based upon a review of information provided, by a carrier or its designated utilization review organization, to deny, reduce, modify, or terminate an admission, continued inpatient stay, or the availability of any other health care services, for failure to meet the requirements for coverage based on medical necessity, appropriateness of health care setting and level of care, or effectiveness.

Authorized Representative means an insured's guardian, conservator, holder of a power of attorney, health care agent designated pursuant to M.G.L. c. 210, family member, or other person authorized by the insured in writing or by law with respect to a specific grievance or external review, provided that if the insured is unable to designate a representative, where such designation would otherwise be required, a guardian, conservator, holder of a power of attorney, or family member in that order of priority may be the insured's representative or appoint another responsible party to serve as the insured's authorized representative. If the authorized representative is a health care provider, the insured must specify a named individual who will act on behalf of the authorized representative and a telephone number for that individual.

Carrier means an insurer licensed, or otherwise authorized to transact accident or health insurance under M.G.L. c.175; a nonprofit hospital service corporation organized under M.G.L. c. 176A; a nonprofit medical service corporation organized under M.G.L. c. 176B; a health maintenance organization organized under M.G.L. c. 176G; and an organization entering into a preferred provider arrangement under M.G.L. c. 176I, but not including an employer purchasing coverage or acting on behalf of its employees or the employees of one or more subsidiaries or affiliated corporations of the employer. “Carrier” shall not include any entity to the extent it offers a policy, certificate or contract that provides coverage solely for dental care services or vision care services.

Clinical Review Criteria means the written screening procedures, decisions, abstracts, clinical protocols and practice guidelines used by a carrier to determine the medical necessity and appropriateness of health care services.

Commissioner means the Commissioner of Public Health.

Complaint means:

- (1) any inquiry made by or on behalf of an insured to a carrier or utilization review organization that is not explained or resolved to the insured’s satisfaction within three business days of the inquiry; or
- (2) any matter concerning an adverse determination. In the case of a carrier or utilization review organization that does not have an internal inquiry process, a complaint means any inquiry.

Covered benefits or Benefits means health care services to which an insured is entitled under the terms of the health benefit plan.

Department means the Department of Public Health.

Evidence of Coverage means any certificate, contract or agreement of health insurance including riders, amendments, endorsements and any other supplementary inserts or a summary plan description pursuant to §104(b)(1) of the Employee Retirement Income Security Act of 1974, 29 U.S.C. §1024(b), issued to an insured specifying the benefits to which the insured is entitled.

Facility means a licensed institution providing health care services or a health care setting, including, but not limited to, hospitals and other licensed inpatient centers, ambulatory surgical or treatment centers, skilled nursing centers, residential treatment centers, diagnostic, laboratory and imaging centers, and rehabilitation and other therapeutic health settings.

Final Adverse Determination means an adverse determination made after an insured has exhausted all remedies available through a carrier’s formal internal grievance process.

Financial Affiliation means any financial interest in a carrier provided that the term financial affiliation shall not include revenue received from a carrier by a clinical reviewer for health services rendered to insureds.

Grievance means any oral or written complaint submitted to the carrier that has been initiated by an insured, or the insured's authorized representative, concerning any aspect or action of the carrier relative to the insured, including, but not limited to, review of adverse determinations regarding scope of coverage, denial of services, quality of care and administrative operations, in accordance with the requirements of 105 CMR 128.000 *et seq.*

Health Benefit Plan means a policy, contract, certificate or agreement entered into, offered or issued by a carrier to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services.

Health Care Professional means a physician or other health care practitioner licensed, accredited or certified to perform specified health services consistent with law.

Health Care Provider or Provider means a health care professional or facility.

Health Care Services means services for the diagnosis, prevention, treatment, cure or relief of a health condition, illness, injury or disease.

Inquiry means any communication by or on behalf of an insured to the carrier or utilization review organization that has not been the subject of an adverse determination and that requests redress of an action, omission or policy of the carrier.

Insured means an enrollee, covered person, insured, member, policy holder or subscriber of a carrier, including an individual whose eligibility as an insured of a carrier is in dispute or under review, or any other individual whose care may be subject to review by a utilization review program or entity as described under the provisions of M.G.L. c. 176O, 211 CMR 52.00 and 105 CMR 128.000.

Material Familial Affiliation means any relationship as a spouse, child, parent, sibling, spouse's parent, spouse's child, child's parent, child's spouse, sibling's spouse, domestic partner, aunt, uncle, foster parent or foster child.

Material Professional Affiliation means any physician-patient relationship, any partnership or employment relationship, a shareholder or similar ownership interest in a professional corporation, or any independent contractor arrangement that constitutes a financial affiliation.

Medical Necessity or Medically Necessary means health care services that are consistent with generally accepted principles of professional medical practice as determined by whether the service:

- (1) is the most appropriate available supply or level of service for the insured in question considering potential benefits and harms to the individual;
- (2) is known to be effective, based on scientific evidence, professional standards and expert opinion, in improving health outcomes; or
- (3) for services and interventions not in widespread use, is based on scientific evidence.

Office of Patient Protection means the office within the Department established by M.G.L. c.111, § 217 responsible for the administration and enforcement of M.G.L. c. 176O §§ 13, 14, 15, and 16 and 105 CMR 128.000.

Participating Provider means a provider who, under a contract with the carrier or with its contractor or subcontractor, has agreed to provide health care services to insureds with an expectation of receiving payment, other than coinsurance, copayments or deductibles, directly or indirectly from the carrier.

Same or Similar Specialty means that the health care professional has similar credentials and licensure as those who typically provide the treatment in question and has experience treating the same condition that is the subject of the grievance. Such experience shall extend to the treatment of children in a grievance involving a child where the age of the patient is relevant to the determination of whether a requested service or supply is medically necessary.

Service Area means the geographical area as approved by the Commissioner of Insurance within which the carrier has developed a network of providers to afford adequate access to members for covered health services.

Terminal Illness means an illness that is likely, within a reasonable degree of medical certainty, to cause one's death within six months, or as otherwise defined in section 1861(dd)(3)(A) of the Social Security Act (42 U.S.C. 1395x(dd)(3)(A)).

Utilization Review means a set of formal techniques designed to monitor the use of, or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of, health care services, procedures or settings. Such techniques may include, but are not limited to, ambulatory review, prospective review, second opinion, certification, concurrent review, case management, discharge planning or retrospective review.

Utilization Review Organization means an entity that conducts utilization review under contract with or on behalf of a carrier, but does not include a carrier performing utilization review for its own health benefit plans.

128.100: Clinical Decisions

The physician treating any insured shall make all clinical decisions regarding the medical treatment to be provided to the insured, including the provision of durable medical equipment and hospital lengths of stay:

- (1) Clinical decisions shall be made in accordance with generally accepted principles of professional medical practice and in consultation with the insured.
- (2) Nothing contained herein shall be construed as altering, affecting or modifying either the obligations of any third party payor or the terms and conditions of any agreement or contract between either the treating physician or the insured and any third party.
- (3) Carriers shall pay for health care services ordered by a treating physician or other practitioner acting within the scope of his or her practice if the services are a covered benefit under the insured's health benefit plan, and the services are medically necessary.

128.101: Carrier's Medical Necessity Guidelines

- (A) A carrier may develop guidelines to be used by the carrier in determining if services are medically necessary. Any such guidelines used by a carrier in determining if covered services are medically necessary shall be, at a minimum:
 - (1) developed with input from practicing physicians in the carrier's or utilization review organization's service area;
 - (2) developed in accordance with standards adopted by national accreditation organizations;
 - (3) updated at least biennially or more often as new treatments, applications and technologies are adopted as generally accepted professional medical practice;
 - (4) evidence based, if practicable; and
 - (5) applied in a manner that considers the individual health care needs of the insured.
- (B) In instances where the insured is enrolled in a health benefit plan where the carrier or utilization review organization provides only administrative services, the obligations of the carrier or utilization review organization related to payment as provided by M.G.L. c. 176O, §16 and 105 CMR 128.100 are limited to recommending to the third party payor that coverage should be authorized.

128.200: Internal Inquiry Process

- (A) A carrier or utilization review organization may maintain an internal inquiry process, in addition to the internal grievance process in 105 CMR 128.300 through 128.313.
- (B) The inquiry process is a process prior to the grievance process during which a carrier or utilization review organization may attempt to answer questions and/or resolve concerns communicated on behalf of an insured to the insured's satisfaction within three business days.
 - (1) This process shall not be used for review of an adverse determination, which must be reviewed through the internal grievance process set forth in 105 CMR 128.300 through 128.313.
 - (2) When this inquiry process fails to answer the insured's questions or resolve the insured's concerns to his/her satisfaction within three business days, the inquiry will, at the option of the insured, be subject to the internal grievance process.

- (C) When a carrier or utilization review organization provides an internal inquiry process, the following shall be included in that process:
- (1) the provision in writing to insureds of a clear, concise and complete description of the carrier's internal inquiry process;
 - (2) a protocol to receive and address an inquiry as expeditiously as possible, and to determine whether the insured's inquiry has been resolved to the insured's satisfaction;
 - (3) a protocol to provide written notice to an insured whose inquiry has not been explained or resolved to the insured's satisfaction within three business days of the inquiry, of the right to have the inquiry processed as an internal grievance under 105 CMR 128.300 through 128.313 at his/her option, including the rights to reduction of an oral inquiry to writing by the carrier, written acknowledgment and written resolution of the grievance as set forth in 105 CMR 128.300 through 128.313; and,
 - (4) a system for maintaining records of each inquiry communicated by an insured or on his behalf, and response thereto, for a period of two years, which records shall be subject to inspection by the Commissioner of Insurance and the Department.

128.300: Right to an Internal Grievance Process

A carrier or utilization review organization shall maintain an internal grievance process that provides for adequate consideration and timely resolution of grievances.

105 CMR 128.301: Information on Internal Grievance Process

The carrier or utilization review organization shall provide insureds with:

- (1) A clear, concise and complete written description of the carrier's internal grievance process.
- (2) A toll-free telephone number for assisting insureds in resolving such grievances and the consumer assistance toll-free number maintained by the Office of Patient Protection.
- (3) Notification about the availability of these resources.

128.302: Form and Manner of Request

- (A) There shall be a process to accept grievances by telephone, in person, by mail, or by electronic means, provided that an oral grievance made by the insured or the authorized representative shall be reduced to writing by the carrier and a copy thereof forwarded to the insured by the carrier or utilization review organization within 48 hours of receipt, except where this time limit is waived or extended by mutual written agreement of the insured or the insured's authorized representative and the carrier.
- (B) Any grievance filed pursuant to 105 CMR 128.300 through 128.313 that requires the review of medical records, shall include the signature of the insured, or the insured's

authorized representative on a form provided promptly by the carrier authorizing the release of medical and treatment information relevant to the grievance to the carrier or utilization review organization when necessary, in a manner consistent with state and federal law. The insured and the authorized representative shall have access to any medical information and records relevant to the grievance relating to the insured which is in the possession of the carrier and under its control. The carrier shall request said authorization from the insured when necessary for requests reduced to writing by the carrier and for any written requests lacking said authorization.

128.303: Records of Grievances

The carrier or utilization review organization shall establish a system for maintaining records of each grievance filed by an insured or on his behalf, and responses thereto, for a period of seven years, which records shall be subject to inspection by the Commissioner of Insurance and the Department.

128.304: Acknowledgment of Grievances

A written acknowledgment of the receipt of a grievance shall be sent to the insured or the insured's authorized representative, if any, within 15 business days of said receipt, except where an oral grievance has been reduced to writing by the carrier or utilization review organization pursuant to 105 CMR 128.302(A) or this time period is waived or extended by mutual written agreement of the insured or the insured's authorized representative and the carrier.

128.305: Time Requirements for Resolution of Grievances

- (A) A carrier or utilization review organization shall provide the insured or the insured's authorized representative, if any, with a written resolution of a grievance within 30 business days of receipt of the oral or written grievance.
- (B) When a grievance requires the review of medical records, the 30 business day period will not begin to run until the insured or the insured's authorized representative submits a signed authorization for release of medical records and treatment information as required in 105 CMR 128.302(B). In the event that the signed authorization is not provided by the insured or the insured's authorized representative, if any, within 30 business days of the receipt of the grievance, the carrier or utilization review organization may, in its discretion, issue a resolution of the grievance without review of some or all of the medical records.
- (C) For carriers that have an internal inquiry process, the 30 business day time period for written resolution of a grievance that does not require the review of medical records, begins:
 - (1) on the day immediately following the three business day time period for processing inquiries pursuant to 105 CMR 128.200, if the inquiry has not been addressed within that period of time; or

- (2) on the day the insured or the insured's authorized representative, if any, notifies the carrier or utilization review organization that s/he is not satisfied with the response to an inquiry under 105 CMR 128.200.
- (D) The time limits in 105 CMR 128.305 may be waived or extended by mutual written agreement of the insured or the insured's authorized representative and the carrier. Any such agreement shall state the additional time limits, which shall not exceed 30 business days from the date of the agreement.

128.306: Review of Grievances

- (A) Grievances shall be reviewed by an individual or individuals who are knowledgeable about the matters at issue in the grievance.
- (B) Grievances of adverse determinations shall be reviewed with the participation of an individual or individuals who did not participate in any of the carrier's prior decisions on the grievance. In at least one level of review of grievances of adverse determinations, these individuals shall be actively practicing health care professionals in the same or similar specialty who typically treat the medical condition, perform the procedure or provide the treatment that is the subject of the grievance.

128.307: Form of Written Resolution

- (A) A written resolution shall include identification of the specific information considered and an explanation of the basis for the decision.
- (B) In the case of a grievance that involves an adverse determination, the written resolution shall include a substantive clinical justification therefor that is consistent with generally accepted principles of professional medical practice, and shall at a minimum:
 - (1) identify the specific information upon which the adverse determination was based;
 - (2) discuss the insured's presenting symptoms or condition, diagnosis and treatment interventions and the specific reasons such medical evidence fails to meet the relevant medical review criteria;
 - (3) specify alternative treatment options covered by the carrier, if any;
 - (4) reference and include applicable clinical practice guidelines and review criteria; and
 - (5) notify the insured or the insured's authorized representative of the procedures for requesting external review, including the procedures to request an expedited external review.

(C) The carrier or utilization review organization must include with every final adverse determination a copy of the form prescribed by the Department for the request of an external review.

128.308: Opportunity for Reconsideration

- (A) The carrier or utilization review organization may offer to the insured or the insured's authorized representative, if any, the opportunity for reconsideration of a carrier's final adverse determination where relevant medical information:
- (1) was received too late to review within the 30 business day time limit; or
 - (2) was not received but is expected to become available within a reasonable time period following the written resolution.
- (B) When an insured or the insured's authorized representative, if any, chooses to request reconsideration, the carrier or utilization review organization must agree in writing to a new time period for review, but in no event greater than 30 business days from the agreement to reconsider the grievance. The time period for requesting external review shall begin to run on the date of the resolution of the reconsidered grievance.

128.309: Expedited Review of Grievances

A carrier or utilization review organization shall provide for an expedited resolution concerning a carrier's coverage or provision of immediate and urgently needed services, which shall include, but not be limited to:

- (1) A written resolution pursuant to 105 CMR 128.307 before an insured's discharge from a hospital if the grievance is submitted by an insured or the insured's authorized representative while the insured is an inpatient in a hospital. For the purposes of 105 CMR 128.309(1) only, and only while the insured is an inpatient, a health care professional or a representative of the hospital may be the insured's authorized representative without a written authorization by the insured.

If the expedited review process results in an adverse determination regarding the continuation of inpatient care, the written resolution must inform the insured or the insured's authorized representative of the opportunity to request an expedited external review pursuant to 105 CMR 128.401 and the opportunity to request continuation of services pursuant to 105 CMR 128.414.
- (2) ~~A written resolution pursuant to 105 CMR 128.307 Provisions for the automatic reversal of decisions denying coverage for services or durable medical equipment, pending the outcome of the internal grievance process, within 48 hours [or earlier for durable medical equipment at the option of a physician responsible for treatment or proposed treatment of the covered patient] of receipt of certification by said the physician responsible for the treatment or proposed treatment that is the subject of the grievance physician that, in the physician's opinion:~~
 - (a) ~~the service or use of durable medical equipment at issue in a grievance is medically necessary;~~

- (b) a denial of coverage for such services ~~or durable medical equipment~~ would create a substantial risk of serious harm to the patient; and
- (c) such risk of serious harm is so immediate that the provision of such services ~~or durable medical equipment~~ should not await the outcome of the normal grievance process.

~~(3) Provisions that require that, in the event a physician exercises the option of automatic reversal earlier than 48 hours for durable medical equipment, the physician must further certify as to the specific, immediate and severe harm that will result to the patient absent action within the 48 hour time period.~~

(3) A written resolution pursuant to 105 CMR 128.307 within less than 48 hours of the receipt of certification by the physician who ordered the use of the durable medical equipment that is the subject of the grievance, when such physician:

- (a) certifies that the use of the durable medical equipment is medically necessary;
- (b) certifies that a denial of coverage for such durable medical equipment would create a substantial risk of serious harm to the patient;
- (c) certifies that such risk of serious harm is so immediate that the provision of such durable medical equipment should not await the outcome of the normal grievance process;
- (d) describes the specific, immediate and severe harm that will result to the patient absent action within the 48 hour time period specified in 105 CMR 128.309(2); and
- (e) specifies a reasonable time period in which the carrier must provide a response.

(4) If the expedited review process set forth in 105 CMR 128.309(2) or (3) results in an adverse determination, the written resolution must inform the insured or the insured's authorized representative of the opportunity to request an expedited external review pursuant to 105 CMR 128.401 and, if the review involves the termination of ongoing services, the opportunity to request continuation of services pursuant to 105 CMR 128.414.

128.310: Expedited Process for Insured with Terminal Illness

- (A) When a grievance is submitted by an insured with a terminal illness, or by the insured's authorized representative on behalf of said insured, a resolution shall be provided to the insured or said authorized representative within five business days from the receipt of such grievance.
- (B) If the expedited review process affirms the denial of coverage or treatment to an insured with a terminal illness, the carrier shall provide the insured or the insured's authorized representative, if any, within five business days of the decision:

- (1) a statement setting forth the specific medical and scientific reasons for denying coverage or treatment; and,
 - (2) a description of alternative treatment, services or supplies covered or provided by the carrier, if any.
- (C) If the expedited review process affirms the denial of coverage or treatment to an insured with a terminal illness, the carrier or utilization review organization shall allow the insured or the insured's authorized representative, if any, to request a conference.
- (1) The conference shall be scheduled within ten days of receiving a request from an insured; provided however that the conference shall be held within five business days of the request if the treating physician determines, after consultation with the carrier's medical director or his designee, and based on standard medical practice, that the effectiveness of either the proposed treatment, services or supplies or any alternative treatment, services or supplies covered by the carrier, would be materially reduced if not provided at the earliest possible date.
 - (2) At the conference, the carrier shall permit attendance of the insured, the authorized representatives of the insured, if any, or both.
 - (3) At the conference, the insured and/or the insured's authorized representative, if any, and a representative of the carrier who has authority to determine the disposition of the grievance shall review the information provided to the insured under 105 CMR 128.310(B).
- (D) If the expedited review process set forth in 105 CMR 128.310 results in a final adverse determination, the written resolution must inform the insured or the insured's authorized representative of the opportunity to request an expedited external review pursuant to 105 CMR 128.401 and, if the review involves the termination of ongoing services, the opportunity to request continuation of services pursuant to 105 CMR 128.414.

128.311: Failure of Carrier to Meet Time Limits

- (A) A grievance not properly acted on by the carrier within the time limits required by 105 CMR 128.300 through 128.310 shall be deemed resolved in favor of the insured.
- (B) Time limits include any extensions made by mutual written agreement of the insured or the insured's authorized representative, if any, and the carrier.

128.312: Coverage or Treatment Pending Resolution of Internal Grievance

If a grievance is filed concerning the termination of ongoing coverage or treatment, the disputed coverage or treatment shall remain in effect at the carrier's expense through completion of the internal grievance process regardless of the final internal grievance decision, provided that the grievance is filed on a timely basis, based on the course of treatment. For the purposes of 105 CMR 128.312, ongoing coverage or treatment includes only that medical care that, at the time it was initiated, was authorized by the

carrier or utilization review organization [unless such care is provided pursuant to 105 CMR 128.309 (2)] and does not include medical care that was terminated pursuant to a specific time or episode-related exclusion from the insured's contract for benefits.

128.313: Confidentiality

No carrier or utilization review agency shall, except as specifically authorized by an appropriate release signed by an insured or authorized representative, release medical and treatment information or other information obtained as part of the internal inquiry or grievance process unless otherwise required or authorized by law.

128.400: External Review

Any insured or authorized representative of an insured who is aggrieved by a final adverse determination issued by a carrier or utilization review organization may request an external review by filing a request in writing with the Office of Patient Protection within 45 days of the insured's receipt of written notice of the final adverse determination.

128.401: Expedited External Review

- (A) An insured or the insured's authorized representative, if any, may request to have his or her request for review processed as an expedited external review.
- (B) Any request for an expedited external review shall contain a certification, in writing, from a physician, that delay in the providing or continuation of health care services that are the subject of a final adverse determination, would pose a serious and immediate threat to the health of the insured.
- (C) Upon a finding that a serious and immediate threat to the insured exists, the Office of Patient Protection shall qualify such request as eligible for an expedited external review.

128.402: Fees

- (A) An insured seeking a review shall pay a fee of \$25.00, which shall accompany the request for a review, to the Office of Patient Protection, ~~which shall accompany the request for a review~~.
- (B) The fee may be waived by said office if it determines that the payment of the fee would result in an extreme financial hardship to the insured.
- (C) The remainder of the cost for an external review shall be borne by the involved carrier. Upon completion of the external review, the Office of Patient Protection shall bill the involved carrier the amount established pursuant to contract between the

Department and the assigned external review agency minus the \$25 fee which is the insured's responsibility.

128.403: Consent to Release of Medical Information

- (A) Any request for a review pursuant to 105 CMR 128.400 *et seq.* shall include the signature of the insured, or the insured's authorized representative authorizing the release and forwarding of medical information and records relevant to the subject matter of the external review, in a manner consistent with state and federal law, to any external review agency assigned to conduct external reviews pursuant to 105 CMR 128.407.
- (B) In connection with any request for an external review, the carrier shall assure that the insured, and where applicable the insured's authorized representative, have access to any medical information and records relating to the insured, in the possession of the carrier or under its control.

128.404: Form and Manner of Request

Requests for review submitted by the insured or the insured's authorized representative shall:

- (1) be on a form prescribed by the Department;
- (2) include the signature of the insured or the insured's authorized representative consenting to the release of medical information;
- (3) include a copy of the written final adverse determination issued by the carrier; and,
- (4) include the \$25.00 fee required pursuant to 105 CMR 128.402.

128.405: Screening of Requests

- (A) The Office of Patient Protection shall screen all requests for external reviews to determine if they:
 - (1) comply with the requirements of 105 CMR 128.404;
 - (2) do not involve a service or benefit that has been explicitly excluded from coverage by the carrier in its evidence of coverage; and
 - (3) result from a carrier's issuance of a notice of final adverse determination.
- (B) Screening of requests for expedited reviews shall begin within 48 hours of receipt. Screening of all other requests shall begin within five business days of receipt.

128.406: Requests Ineligible for External Review – Notification

Notification of the rejection of a request for external review for failure to meet the requirements of 105 CMR 128.400 *et seq.* shall be issued by the Office of Patient Protection to the insured, the insured's authorized representative and the carrier within 72 hours of a receipt of a request for an expedited review and within ten business days of

receipt of all other requests. The notification shall set forth the specific reason why the request has been determined ineligible for an external review and any submitted fee shall be returned.

128.407: Assignment of Reviews

Upon the determination by the Office of Patient Protection that a request for review is eligible for an external review the case shall be assigned promptly to an external review agency by the Office of Patient Protection on a random basis. The Office of Patient Protection shall forward a copy of the insured's request for an external review together with any related documentation filed with said office by the insured or the carrier to the external review agency.

128.408: Notification of Assignment and Request for Information

Upon the referral of a request to an external review agency, the Office of Patient Protection shall notify the insured, the insured's authorized representative if applicable and the carrier, that the request has been referred and shall identify the selected external review agency, and where applicable, identify that the review is being considered on an expedited basis. A copy of the insured's written authorization for the release of medical records and information shall be included with notification sent to the carrier.

128.409: Medical Records and Information

(A) For non-expedited reviews, the carrier or utilization review organization shall forward the insured's medical and treatment records relevant to the review and created by or in the possession or control of the carrier and a copy of the carrier's evidence of coverage applicable to the insured, to the identified external appeal agency within three business days of receipt of the notification provided pursuant to 105 CMR 128.408.

Carriers shall make good faith efforts to obtain records relevant to the review and not in the possession of the carrier from providers.

(B) For expedited reviews, the carrier or utilization review organization shall furnish to the identified external agency the insured's medical and treatment records relevant to the review and created by or in the possession or control of the carrier, and a copy of the carrier's evidence of coverage applicable to the insured, within 24 hours of receipt of notification provided pursuant to 105 CMR 128.408. Carriers shall make good faith efforts to obtain records relevant to the review and not in the possession of the carrier from providers.

(C) The carrier or utilization review organization or the insured or his or her authorized representative shall have access to all information filed by any party with the external review agency including any information filed pursuant to 105 CMR 128.412.

(D) For the purposes of 105 CMR 128.409(A) and (B), “good faith efforts” shall be defined as no fewer than three documented attempts by the carrier to obtain the information from a provider or the provider’s designee.

128.410: Review Panel

Upon receipt of an external review referral the external review agency shall assign the review to a panel that is comprised of one or more clinical reviewers who did not participate in any of the carrier’s prior decisions on the grievance. These reviewers shall be actively practicing health care professionals in the same or similar specialty who typically treat the medical condition, perform the procedure or provide the treatment that is the subject of the external review.

128.411: Conflict of Interest

External review agencies shall insure that clinical reviewers assigned to any external review:

- (1) shall have no material professional affiliation, material familial affiliation or financial affiliation with any party that is the subject of said review;
- (2) shall have no material professional affiliation, material family affiliation or financial affiliation with any party that participated in the delivery of health care to the insured who is the subject of the review; and
- (3) shall not have participated as a clinical reviewer in connection with any medical necessity determination with respect to the insured who is the subject of the review.

128.412: Additional Information

The assigned ~~review panel~~ external review agency may request the carrier or the insured, or where applicable the insured’s authorized representative, to provide such additional information or documentation as the review agency deems necessary in order to render a decision. Such additional information shall be provided within 24 hours of the request in expedited review cases and within three business days for all other reviews.

- (1) Carriers shall make good faith efforts to obtain any such additional information requested by the external review ~~organization~~ agency that is not in the possession of the carrier.
- (2) Failure by the carrier to make good faith efforts to supply information requested pursuant to 105 CMR 128.409 or 128.412 may result in penalties to carriers including action by the Division of Insurance pursuant to 211 CMR 52.17. In addition, where a carrier has failed to make good faith efforts to supply information pursuant to 105 CMR 128.409 or 128.412, the external review agency may in its discretion order the grievance in dispute to be resolved in favor of the insured.

(3) For the purposes of 105 CMR 128.409 or 128.412, “good faith efforts” shall be defined as no fewer than three documented attempts by the carrier to obtain the information from a provider or the provider’s designee.

128.413: Informal Meeting

The ~~review panel~~ external review agency may, in its discretion, conduct an informal meeting with the parties in order to obtain information that it deems relevant to its decision making.

128.414: Continuation of Services

If the subject matter of the external review involves the termination of ongoing services, the insured may apply to the external review ~~panel~~ agency to seek the continuation of coverage for the terminated service during the period the review is pending. Any such request must be made before the end of the second business day following receipt of the final adverse determination. The ~~review panel~~ external review agency may order the continuation of coverage or treatment where it determines that substantial harm to the insured’s health may result absent such continuation or for such other good cause as the review ~~panel~~ agency shall determine. Any such continuation of coverage shall be at the carrier’s expense regardless of the final external review determination.

128.415: Decisions and Notice

- (A) The ~~review panel~~ external review agency shall determine whether the service that is the subject of the review is medically necessary and is a covered benefit as defined in 105 CMR 128.020.
- (B) The final decision of the ~~review panel~~ external review agency shall be in writing and set forth the specific medical and scientific reasons for the decision and shall be furnished to the insured, or where applicable the insured’s authorized representative, and the carrier.
- (C) For non-expedited reviews, a ~~review panel~~ an external review agency shall issue its final disposition within 60 business days from ~~the external review agency’s~~ its receipt of the referral from the Office of Patient Protection. If the review ~~panel~~ agency determines that additional time to fully and fairly evaluate the request for review is required:
 - (1) it may extend the time period for issuing a disposition for an additional period not to exceed 15 business days; and,
 - (2) shall provide notice of any said extension to the insured and the carrier or utilization review organization.
- (D) For expedited reviews, the ~~review panel~~ external review agency shall issue its final disposition within five business days from ~~the external review agency’s~~ its receipt of the referral from the Office of Patient Protection.

- (E) Nothing herein shall prohibit the parties from voluntarily proceeding with any informal efforts to resolve the matter under review prior to the issuance of a final decision.
- (F) The decision of the ~~review panel~~ external review agency shall be binding.
- (G) If the external review agency overturns a carrier's decision in whole or in part, the carrier shall issue a written notice to the insured within five business days of receipt of the written decision from the review agency. Such notice shall:
- (1) acknowledge the decision of the review agency;
 - (2) advise the insured of any additional procedures for obtaining the requested coverage or services;
 - (3) advise the insured of the date by which the payment will be made or the authorization for services will be issued by the carrier or utilization review organization; and
 - (4) advise the insured of the name and phone number of the person at the carrier who will assist the insured with final resolution of the grievance.

128.416: Confidentiality – External Review

No external review agency or reviewer shall, except as specifically authorized by an appropriate release signed by an insured or representative authorized by law, release medical and treatment information or other information obtained as part of an external review, except to the Department and as otherwise authorized or required by law.

128.500: Disenrollment of Primary Care Physician

Where a carrier allows or requires the designation of a primary care physician, the carrier shall in the event of disenrollment of a primary care physician for reasons other than those related to quality or fraud:

- (1) provide to any insured written notice of the disenrollment of the insured's primary care physician at least 30 days prior to any such disenrollment;
- (2) include in said notice a description of the procedure for choosing an alternate primary care physician; and,
- (3) permit the insured to be covered for health services, consistent with the terms of the carrier's evidence of coverage, provided by such primary care physician for at least 30 days after said physician is disenrolled.

128.501: Disenrollment of Providers of Care to Pregnant Women

Carriers shall allow any female insured who is in her second or third trimester of pregnancy and whose provider in connection with said pregnancy is involuntarily disenrolled for reasons other than those related to quality or fraud, to continue treatment

with said provider, consistent with the carrier's evidence of coverage, for a period up to and including the insured's first postpartum visit.

128.502: Disenrollment of Providers of Care to the Terminally Ill

Carriers shall allow any insured who is terminally ill, and whose provider in connection with the treatment of the insured's terminal illness is involuntarily disenrolled for reasons other than those related to quality or fraud, to continue treatment with said provider, consistent with the terms of the carrier's evidence of coverage, until the insured's death.

128.503: Coverage for the Newly Insured

- (A) A carrier shall provide coverage for health services to a newly insured provided by a physician who is not a participating provider in the carrier's network for up to 30 days from the effective date of coverage if:
- (1) the insured's employer only offers the insured a choice of carriers in which said physician is not a participating provider; and
 - (2) said physician is providing the insured with an ongoing course of treatment or is the insured's primary care physician.
- (B) With respect to an insured pregnant woman who is in her second or third trimester, coverage pursuant to 105 CMR 128.503(A) shall apply to services rendered through the insured's first postpartum visit.
- (C) With respect to an insured with a terminal illness, coverage pursuant to 105 CMR 128.503(A) shall apply to services rendered until the insured's death.

105 CMR 128.504: Carrier's Coverage Conditions

- (A) A carrier may condition coverage of continued treatment by a provider under 105 CMR 128.500 through 128.502, upon the provider's agreeing:
- (1) to accept reimbursement from the carrier at the rates applicable prior to the notice of disenrollment as payment in full;
 - (2) to not impose cost sharing with respect to the insured in an amount that would exceed the cost sharing that could have been imposed if the provider had not been disenrolled;
 - (3) to adhere to the quality assurance standards of the carrier and to provide the carrier with necessary medical information related to the care provided; and,
 - (4) to adhere to such carrier's policies and procedures, including procedures regarding referrals, obtaining prior authorization and providing treatment pursuant to a treatment plan, if any, approved by the carrier.
- (B) A carrier may condition coverage of treatment by a ~~provider~~ physician under 105 CMR 128.503 upon the ~~provider~~ physician's agreeing:
- (1) to accept reimbursement from the carrier at the rates applicable to participating providers as payment in full;

- (2) to not impose cost sharing with respect to the insured in an amount that would exceed the cost sharing that could have been imposed if the ~~provider~~ physician participated in the carrier's network;
 - (3) to adhere to the quality assurance standards of the carrier and to provide the carrier with necessary medical information related to the care provided; and
 - (4) to adhere to the carrier's policies and procedures, including procedures regarding referrals, obtaining prior authorization and providing treatment pursuant to a treatment plan, if any, approved by the carrier.
- (C) Nothing in 105 CMR 128.500 through 128.502 shall be construed to require the coverage of benefits that would not have been covered if the provider involved had remained a participating provider. Nothing in 105 CMR 128.503 shall be construed to require coverage of benefits that would not have been covered if the ~~provider~~ physician involved was a participating provider.

128.505: Standing Referrals

- (A) A carrier that requires an insured to designate a primary care physician shall allow such a primary care physician to authorize a standing referral for specialty health care, including mental health care, provided by a health care provider participating in such carrier's network when:
- (1) the primary care physician determines that such referrals are appropriate;
 - (2) the provider of specialty health care agrees to a treatment plan for the insured and provides the primary care physician with all necessary clinical and administrative information on a regular basis; and
 - (3) the health care services to be provided are consistent with the terms of the carrier's evidence of coverage.
- (B) Nothing in 105 CMR 128.505 shall be construed to permit a provider of specialty health care who is the subject of a referral to authorize any further referral of an insured to any other provider without the approval of the insured's carrier.
- (C) For the purposes of 105 CMR 128.505, "specialty health care" means health care services rendered by a provider other than a primary care physician.

128.506: Specialty Care Not Requiring Prior Authorization

- (A) No carrier that requires an insured to obtain referrals or prior authorizations from a primary care physician for specialty care shall require an insured to obtain a referral or prior authorization from a primary care physician for the following specialty care provided by an obstetrician, gynecologist, certified nurse-midwife or family practitioner participating in such carrier's health care provider network:
- (1) annual preventive gynecologic health examinations, including any subsequent obstetric or gynecological services determined by such obstetrician, gynecologist,

- certified nurse-midwife or family practitioner to be medically necessary as a result of such examination;
- (2) maternity care; and,
 - (3) medically necessary evaluations and resultant health care services for acute or emergency gynecological conditions.
- (B) No carrier shall require higher copayments, coinsurance, deductibles or additional cost sharing arrangements for such services provided to such insureds in the absence of a referral from a primary care physician.
- (C) Carriers may establish reasonable requirements for participating obstetricians, gynecologists, certified nurse-midwives or family practitioners to communicate with an insured's primary care physician regarding the insured's condition, treatment and need for follow-up care.
- (D) Nothing in 105 CMR 128.506 shall be construed to permit an obstetrician, gynecologist, certified nurse-midwife or family practitioner to authorize any further referral of an insured to any other provider without the approval of the insured's carrier.
- (E) For the purposes of 105 CMR 128.506, the term "specialty care" is limited to those services that are medically necessary and consistent with the terms of the carrier's evidence of coverage.
- (F) Nothing in 105 CMR 128.506 shall be construed to prohibit a carrier from applying all other applicable health plan requirements for preauthorization or other prior approval for admission to a facility or specific procedures for specialty care provided by an obstetrician, gynecologist, certified nurse-midwife or family practitioner.

128.507: Coverage of Pediatric Specialty Care

Carriers shall provide coverage of pediatric specialty care, including mental health care, by persons with recognized expertise in providing specialty pediatric care to insureds requiring such services.

128.508: Denial of Provider Application

Carriers shall provide health care providers who are applying to be participating providers and who are denied such status with a written reason or reasons for the denial of such application.

128.509: Provider Termination Without Cause Provisions

(A) Contracts between carriers and health care providers shall state that neither the carrier nor the provider has the right to terminate the contract without cause.

(B) Carriers shall provide a written statement to a provider of the reason or reasons for such provider's involuntary disenrollment.

128.510: Interpreter Services

Carriers shall provide insureds, upon request, interpreter and translation services related to a carrier's administrative procedures.

128.600: Reporting Requirements

(A) Carriers shall provide the following information to the Office of Patient Protection no later than ~~May 15th~~ April 1 of each year, with the exception of the materials required under 105 CMR 128.600(A)(5), which shall be submitted concurrent with their submission to the Division of Insurance.

- (1) a list of sources of independently published information assessing insureds' satisfaction and evaluating the quality of health care services offered by the carrier;
- (2) the percentage of physicians who voluntarily and involuntarily terminated participation contracts with the carrier during the previous calendar year for which such data has been compiled and the three most common reasons for voluntary and involuntary physician disenrollment;
- (3) the percentage of premium revenue expended by the carrier for health care services provided to insureds for the most recent year for which information is available;
- (4) a report detailing, for the previous calendar year, the total number of:
 - (a) filed grievances, grievances that were approved internally, grievances that were denied internally, and grievances that were withdrawn before resolution;
 - (b) external appeals pursued after exhausting the internal grievance process and the resolution of all such external appeals.

The report shall identify, for each such category, to the extent such information is available, the demographics of such insureds, which shall include, but need not be limited to, race, gender and age.

- ~~(5) A copy of the materials, if any, required to be submitted to the Commissioner of the Division of Insurance pursuant to M.G.L. c.176G, §14 and the applicable regulations of the Division of Insurance.~~
- ~~(6)~~ (5) A copy of the following which are required to be provided upon enrollment to at least one adult insured in each household residing in ~~the commonwealth~~ Massachusetts pursuant to M.G.L. c. 176O, §§ 6 and 7a:
 - (a) Evidence of coverage and any amendments thereto;
 - (b) A list of health care providers in the carrier's network, organized by specialty and by location and summarizing for each such provider the method used to compensate or reimburse such provider, provided, however, that disclosure of the specific details of any financial arrangements between a carrier and a provider is not required;
 - (c) A statement that physician profiling information, so-called, may be available from the board of registration in medicine;

- (d) A summary description of the process by which clinical guidelines and utilization review criteria are developed;
 - (e) The voluntary and involuntary disenrollment rate among insureds of the carrier;
 - (f) A statement that insureds have the opportunity to obtain health care services for an emergency medical condition, including the option of calling the local pre-hospital emergency medical service system, whenever the insured is confronted with an emergency medical condition which in the judgment of a prudent layperson would require pre-hospital emergency services; and
 - (g) A statement that the information specified in 105 CMR 128.600(A)(1) through (4) is available to the insured or prospective insured from the Office of Patient Protection.
- (B) Carriers shall provide to the Office of Patient Protection, concurrent with the submission to the Division of Health Care Finance and Policy pursuant to M.G.L. c. 118G, § 24, a copy of the health plan data and information set compiled for the National Committee on Quality Assurance or other information collected by the carrier and deemed to be similar or equivalent thereto. At the carrier's option, proprietary financial data may be excluded from this submission.
- (C) ~~Carriers~~ Each carrier shall provide to the Office of Patient Protection no later than ~~May 15th~~ April 1 of each year, ~~the name, telephone number and e-mail address of the person or persons within their organizations who will~~ information to assist the Office of Patient Protection in resolving appeals.
- (1) Each carrier shall provide the name, telephone number and e-mail address of the person or persons within its organization who will serve as the general contact for the Office of Patient Protection for appeals and grievances.
 - (2) Each carrier ~~Carriers~~ shall ~~also~~ provide the name, telephone number and e-mail address of the person or persons who have the authority to approve appeals and approve the payment of claims for all products and for all types of services.
 - (3) If any of this contact information changes, the carrier shall provide the new information in writing to the Office of Patient Protection within ten business days following the change.
- (D) The confidentiality of any information about a carrier or utilization organization which, in the opinion of the Office of Patient Protection in consultation with the Division of Insurance, is proprietary in nature shall be protected.
- (E) The Office of Patient Protection shall establish a site on the internet and through other communication media, make managed care information collected by the Office of Patient Protection readily accessible to consumers. The internet site shall, at a minimum, include:

- (1) the health plan report card developed pursuant to M.G.L. c. 118 G, § 24 by the Division of Health Care Finance and Policy;
- (2) a chart comparing the information obtained on premium revenue expended for health care services as provided pursuant to 105 CMR 128.600 (A)(3) for the most recent year for which information is available; and
- (3) data collected pursuant to 105 CMR 128.600(B).

REGULATORY AUTHORITY

105 CMR 128.000: M.G.L. c. 111, § 217(a)(1) and c. 176O.