958 CMR 11.00: Internal Appeals Process and External Review Process for Risk-Bearing Provider Organizations and Accountable Care Organizations

11.01: Scope and Purpose

958 CMR 11.00 applies to all Risk-bearing Provider Organizations and Accountable Care Organizations subject to the requirements of M.G.L. c. 176O § 24, M.G.L. c. 6D §§ 15 and 16. 958 CMR 11.00 establishes requirements for administering internal appeals processes and establishes the requirements for external review of appeals submitted by or on behalf of Patients of Risk-bearing Provider Organizations and Accountable Care Organizations.

11.02: Definitions

As used in 958 CMR 11.00 the following words shall have the following meanings:

Accountable Care Organization or ACO. An organization certified by the Commission as an Accountable Care Organization pursuant to M.G.L. c. 224 § 15.

ACO or RBPO Participant. A Health Care Provider or entity that participates, through billing, in the Accountable Care Organization's or Risk-bearing Provider Organization's Alternative Payment Contract(s).

Actively Practicing. A Health Care Professional who regularly treats patients in a clinical setting.

Alternative Payment Contract. Any contract between a Provider or Provider Organization and a Health Care Payer, employer or individual, which utilizes alternative payment methodologies, as defined under M.G.L. c. 6D § 1.

Authorized Representative. 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 may 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. An insurer licensed or otherwise authorized to transact accident and 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; or 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; provided that, unless otherwise noted, 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.

Commission. The Health Policy Commission established in M.G.L. c. 6D.

External Review Agency. An independent review organization, which is an entity or company under contract with the Commission to conduct independent reviews pursuant to 958 CMR 11.00. Each External Review Agency shall be accredited by a national accrediting organization.

Financial Affiliation or Financial Relationship. Any financial interest in a Carrier or RBPO or ACO provided that the term Financial Affiliation shall not include revenue received from a Carrier by a clinical reviewer for health services rendered to insureds.

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

Health Care Provider or Provider. A Health Care Professional or facility.

Material Familial Affiliation. 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. Any Health Care Professional-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.

Office of Patient Protection. The office within the Commission established by M.G.L. c. 6D, § 16.

Patient. An individual who chooses or is attributed to the Risk-bearing Provider Organization or Accountable Care Organization for medical or behavioral health care, and for whom such services are

paid under an Alternative Payment Contract with a Carrier, excluding Medicare, Medicare Advantage, and Medicaid patients.

Primary Care Provider. A Health Care Professional qualified to provide general medical care for common health care problems, who supervises, coordinates, prescribes, or otherwise provides or proposes health care services, initiates referrals for specialist care, and maintains continuity of care within the scope of his or her practice.

Provider Organization. Any corporation, partnership, business trust, association or organized group of persons, which is in the business of health care delivery or management, whether incorporated or not, that represents one or more Health Care Providers in contracting with health care payers for the payments of health care services; provided, however, that the definition shall include, but not be limited to, physician organizations, physician hospital organizations, independent practice associations, Provider networks, Accountable Care Organizations and any other organization that contracts with health care payers for payment for health care services.

Internal Reviewer. An individual directed by the RBPO or ACO to review internal appeals, who has a clinical background with an active license to practice and who was not involved in the decision about which the Patient appealed and is not under direct supervision of the individual who made the decision about which the Patient appealed.

Risk-bearing Provider Organization or RBPO. A Provider Organization that has obtained a Risk Certificate from the Division of Insurance pursuant to 211 CMR 155.00.

Same or Similar Specialty. 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.

Terminal Illness. 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 § 1861(dd)(3)(A) of the Social Security Act (42 U.S.C. 1395x(dd)(3)(A)).

Urgent Medical Need. The risk of serious harm to the Patient is so immediate that the provision of appealed services should not await the standard 14 day response time for an internal appeal or the standard 21 day response time for an external review. Urgent Medical Need may occur when a Patient is receiving emergency services, ongoing services, or the Patient has a Terminal Illness. Urgent Medical Need occurs where a delay may seriously jeopardize the health of the Patient or otherwise jeopardize the Patient's ability to regain maximum function.

11.03: Right to an Internal Appeal

(1) Risk-bearing Provider Organizations or Accountable Care Organizations shall maintain an internal appeal process that provides for adequate consideration and timely resolution of Patient concerns about denials, restrictions, or limitations of care.

(2) The internal appeals processes shall apply to decisions of the RBPO, ACO or the ACO or RBPO Participants relating to denials, restrictions or limitations of care regarding:

(a) Referrals to Providers not affiliated with the RBPO or ACO;

(b) The type or intensity of treatment or services;
(c) Timely access to treatment or services; and
(d) Other concerns related to the Patient's care provided by an RBPO or ACO or RBPO or ACO Participant that are related to Provider participation in an Alternative Payment Contract.

(3) The RBPO or ACO shall not:
(a) Require a Patient to submit such an appeal in writing.
(b) Prevent a Patient from seeking medical opinions outside of the RBPO or ACO.
(c) Terminate any medical or behavioral health services being provided to the Patient during the internal appeal or external review, including medical or behavioral health services which began prior to the Patient appeal and are the subject of the appeals process in 958 CMR 11.00; or
(d) Limit or restrict access to appeals process in 958 CMR 11.00.

(4) The RBPO or ACO shall inform any Patient of the right to authorize a representative to advocate on the Patient's behalf during the appeals process. An RBPO or ACO may require such authorization to be in writing.

11.04: Information on Internal Appeals

(1) The RBPO or ACO shall make information about its internal appeals process available to Patients and the public through the following means:
(a) Notice available in writing at all locations where Patients regularly seek care.
(b) Hard copy or electronic copy of the notice to Patients upon request.

(2) The RBPO or ACO, upon Primary Care Provider selection or Patient attribution, may provide notice by mail, email, website, and distributing the notice directly to Patients during an office visit.

(3) Notices shall include how to make an appeal. Such notices shall inform Patients of the right to authorize a representative to act on the Patient's behalf during the appeals process. The RBPO or ACO may require the Patient to authorize a representative in writing.

(4) Notices shall include the toll-free number, website, and email address maintained by the Office of Patient Protection.

11.05: Form and Manner of Request

(1) The RBPO or ACO shall adopt a process to accept appeals by telephone, in person, by mail, or by electronic means, provided that an oral appeal made by the Patient or the Patient's Authorized Representative shall be reduced to writing by the RBPO or ACO and a copy forwarded to the Patient or the Patient's Authorized Representative.

(2) Where an appeal requires review of a Patient's medical records such appeal shall include, if necessary, a form signed by the Patient or the Patient's Authorized Representative authorizing the release of medical and treatment information relevant to the appeal.

11.06: Risk-bearing Provider Organization and Accountable Care Organization Records of Appeals

Each RBPO or ACO shall establish a system for maintaining records of each appeal made by a Patient or on his or her behalf, and response thereto, for a period of seven years, which records shall be subject to inspection by the Commissioner of Insurance and the Office of Patient Protection.

11.07: Time Limits for Resolution of Internal Appeals

(1) The RBPO or ACO shall provide the Patient, or the Patient's Authorized Representative, with a written resolution of the appeal within 14 calendar days of receipt of the original appeal.

(2) The RBPO or ACO shall provide the Patient, or the Patient's Authorized Representative, with a written resolution of the expedited internal appeal concerning an Urgent Medical Need within 3 calendar days.

11.08: Internal Reviewers

(1) The RBPO or ACO shall ensure that an Internal Reviewer determines the resolution of the internal appeal.

(2) An Internal Reviewer shall determine whether the Patient has an Urgent Medical Need that warrants an expedited internal appeal. The Internal Reviewer determining Urgent Medical Need and the Internal Reviewer determining the resolution of the internal appeal may be the same individual.

11.09: Form of Written Resolution of the Internal Appeal

(1) Each written resolution of an internal appeal shall include a clear summary explanation of the basis for the decision, including a substantive clinical justification for the decision, and identification of the specific information considered.

(2) The written resolution on the Patient's appeal shall prominently provide information on the Patient's right to appeal the decision to the Office of Patient Protection and information on how to file a request for external review including but not limited to:

    (a) A paper copy of the form prescribed by the Office of Patient Protection for the request for external review, as well as instructions for locating the form on the Office of Patient Protection's website;
    (b) The toll-free number, website, and email address maintained by the Office of Patient Protection; and
    (c) A list of documents and information available to the Patient from the RBPO or ACO, including the Patient's medical records and other documents and information relied upon by the RBPO or ACO in the internal appeal. The RBPO or ACO shall include instructions for obtaining these documents.

11.10: External Review

A Patient or a Patient's Authorized Representative who is aggrieved by a denial or restriction by an RBPO or ACO and whose concerns were not resolved through the internal appeals process may request an external review of the internal appeal decision by filing a request in writing with the Office of Patient Protection within 30 calendar days of the Patient's receipt of the written resolution of the internal appeal decision.

11.11: Expedited External Review

(1) The Patient or Patient's Authorized Representative may apply to the External Review Agency to seek an expedited external review.

(2) The External Review Agency shall order the external review to be expedited where it determines that there is an Urgent Medical Need.

(3) A request for expedited external review by a Patient or the Patient's Authorized Representative shall be included in the external review request, on the external review request form issued by the Office of Patient Protection. Each request for an expedited review shall contain a description, in writing, from the Patient or Patient's Authorized Representative demonstrating the Patient's Urgent Medical Need and may include other information, including medical records, from the Patient or the Patient's Authorized Representative.

(4) The External Review Agency shall order that the external review be expedited within 24 hours of receiving the request for expedited external review from the Office of Patient Protection.

11.12: Fees

(1) The cost for an external review shall be borne by the involved RBPO or ACO. Upon completion of the external review, the Office of Patient Protection or the External Review Agency shall bill the involved RBPO or ACO the amount established pursuant to contract between the Commission and the assigned External Review Agency.

(2) There shall be no cost borne by the Patient requesting an external review.

11. 13: Consent to Release of Medical Information

(1) Any request for external review pursuant to 958 CMR 11.10 shall include the signature of the Patient or the Patient's Authorized Representative authorizing the release and forwarding of medical information and records relevant to the subject matter of the external review, in a matter consistent with state and federal law.

(2) In connection with any request for an external review, the RBPO or ACO shall assure that the Patient, and where applicable the Patient's Authorized Representative, has access to any medical information and records relating to the Patient, in the possession of the RBPO or ACO.

11.14: Form and Manner of Request for External Review

(1) Requests for external review submitted by the Patient or the Patient's Authorized Representative shall:
(a) Be on a form prescribed by the Office of Patient Protection;
(b) Include the signature of the Patient or the Patient's Authorized Representative consenting to the release of medical information; and
(c) Include a copy of the written resolution of the internal appeal issued by the RBPO or ACO.

11.15: Screening of Requests for External Review

(1) The Office of Patient Protection shall screen all Patient requests for external reviews to determine if they:
(a) Comply with the requirements of 958 CMR 11.00
(b) Do not involve an issue within the purview of the Patient's Carrier; and
(c) Result from an RBPO's or ACO's written resolution of the internal appeal upholding the decision that is the subject of the appeal; provided, however, that no written resolution is necessary where the RBPO or ACO has failed to comply with timelines for the internal appeals process.

11.16: Requests Ineligible for External Review – Notification

Notification of the rejection of a request for external review for failure to meet requirements in 958 CMR 11.15 shall be issued by the Office of Patient Protection to the Patient or the Patient's Authorized Representative within 72 hours of a receipt of a request for an expedited review and within 6 business days of a receipt of a request of all other requests. The notification shall set forth the specific reason why the request has been determined ineligible for an external.

11.17: Assignment of External Reviews

Upon the determination by the Office of Patient Protection that a Patient's request for review is eligible for external review, the external review request 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 Patient's request for an external review together with any related documentation filed with the Office by the Patient to the External Review Agency.

11.18: Notification of Assignment and Request for Information

(1) Upon the assignment of a request to an External Review Agency, the Office of Patient Protection shall notify the Patient, the Patient's Authorized Representative if applicable, and the involved RBPO or ACO that the request has been assigned 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 Patient's written authorization for the release of medical records and information shall be included with the notification.

(2) Upon receipt of an external review assignment, the External Review Agency shall assign the review to an external reviewer who did not participate in any of the RBPO's or ACO's prior decisions on the denial or restriction. The external reviewers shall be Actively Practicing Health Care Professionals in the Same or Similar Specialty who typically treat the medical or behavioral health condition, perform the procedure or provide the treatment that is the subject of the external review.

11.19: Medical Records and Other Information

(1) The RBPO or ACO shall forward the Patient's medical and treatment records relevant to the review and created by or in the possession or control of the RBPO or ACO, to the identified External Review Agency.
   a) In non-expedited review, any such information shall be forwarded within two business days of receipt of the notification provided pursuant to 958 CMR 11.18.
   b) In expedited review, any such information shall be forwarded within 24 hours of receipt of the notification provided pursuant to 958 CMR 11.18.

(2) The Patient or the Patient's Authorized Representative may submit additional medical evidence or other relevant information to the External Review Agency.
   (a) The Office of Patient Protection will notify the Patient or the Patient's Authorized Representative of the right to submit additional medical evidence or other relevant information in its communications with the Patient or Patient's Authorized Representative.
   (b) In a non-expedited review, any such additional medical evidence or other relevant information shall be reviewed by the External Review Agency if received within five calendar days from the date of notice from the Office of Patient Protection. Any such additional medical evidence or other relevant information may be reviewed by the External Review Agency if received more

than five calendar days from the date of the notice from the Office of Patient Protection but before the decision is rendered.

(c) In an expedited review, any such additional medical evidence or other relevant information shall be reviewed by the External Review Agency if received within 24 hours of the Patient's or Patient's Authorized Representative's filing of the request for expedited external review. Any such additional medical evidence or other relevant information may be reviewed by the External Review Agency if received more than 24 hours after the Patient's or Patient's Authorized Representative's filing of the request for expedited external review but before the decision is rendered.

11.20: Conflict of Interest

(1) External review agencies shall ensure that the External Review Agency and the external reviewers assigned to any external review:
   (a) Shall have no Material Professional, Material Familial, or Financial Affiliation with any party that is the subject of the review; and
   (b) Shall have no Material Professional, Material Familial or Financial Affiliation with any party that participated in the denial or restriction that is the subject of review.

(2) The Office of Patient Protection shall not contract with any External Review Agency which owns or controls, or is owned or controlled by a Carrier or utilization review organization or an RBPO or ACO, the sponsor of a group health plan, a trade association plans or issuers, or a trade association of Health Care Providers.

(3) Decisions by the External Review Agency regarding the hiring, compensation, termination, promotion, or other similar matters with respect to the external reviewer must not be based upon the likelihood that that the external reviewer will support the denial or restriction of care.

11.21: Decisions and Notice

(1) The External Review Agency shall determine whether the requested referral, treatment or service that is the subject of the review is likely to produce a more clinically beneficial outcome for the Patient than the referral, treatment or service recommended by the RBPO or ACO.

(2) The External Review Agency shall base its determination whether the requested referral, treatment or service is likely to produce a more clinically beneficial outcome for the Patient on a review of the following factors:
   (a) The Patient's clinical history, including prior clinical relationships;
   (b) The availability, within the RBPO or ACO, of a Health Care Professional with the appropriate training and experience to meet the particular health care needs of the Patient;
   (c) Generally accepted principles of professional medical practice;
   (d) The efficacy of the requested treatment or service, based on scientific evidence, professional standards and expert opinion, in improving health outcomes; and
   (e) Other factors the External Review Agency considers relevant to the Patient's ability to access the requested referral, treatment, or service.

(3) The final decision of the External Review Agency shall be in writing and shall contain the following information:
   (a) An analysis of the medical evidence and how the evidence supports the findings of the external reviewer;

(b) An explanation of why the requested referral, treatment or service was found or was not found to likely produce a more clinically beneficial outcome for the Patient than the referral, treatment or service recommended by the RBPO or ACO;
(c) A list of any medical literature or references relied upon in making the decision; and
(d) A statement that the decision is final and binding.

(3) The External Review Agency shall provide a final copy of the decision to the Patient, and the Patient's Authorized Representative and the RBPO or ACO. Where the Patient is a minor or person with a legal guardian, the External Review Agency shall provide the Patient's copy of the final decision to the Patient's parent or legal guardian.

(4) For non-expedited reviews, the External Review Agency shall issue its final disposition within 21 calendar days from its receipt of assignment from the Office of Patient Protection.

(5) For expedited reviews, the External Review Agency shall issue its final disposition within 72 hours of receipt of the assignment from the Office of Patient Protection.

(6) Each External Review Agency shall retain records of all external review requests, decisions, and notices for three years from the date of the final disposition, and shall make these records available upon request to the Office of Patient Protection upon request.

(7) The decision of the External Review Agency shall be binding on the RBPO and the Patient, or the ACO and the Patient.

(8) Upon a written request by the Patient, the Patient's Authorized Representative or the RBPO or ACO, and at the sole discretion of the Director of the Office of Patient Protection, the External Review Agency may be directed to retract and revise a decision only upon a finding of clear procedural or factual error which is evident on the face of the decision. Any such written request must be received by the Office of Patient Protection within seven calendar days of the date of the External Review Agency's final decision, in order to be considered.

(9) If the External Review Agency overturns an RBPO or ACO decision in whole or in part, the RBPO or ACO shall notify the Patient within two business days of receipt of the written decision from the review agency. Such notice shall:
(a) Acknowledge the decision of the review agency;
(b) Advise the Patient of any additional procedures for obtaining the requested services; and
(c) Advise the Patient of the name and phone number of the person at the RBPO or ACO who will assist the Patient with obtaining the referral, treatment or service.

(10) The RBPO or ACO shall comply with the External Review Agency's decision.

11.22: Confidentiality

No RBPO or ACO or External Review Agency or external reviewer shall, except as specifically authorized by an appropriate release signed by a Patient or a Patient's Authorized Representative authorized by law, release medical and treatment information or other information obtained as part of an internal appeal or external review, except to the Office of Patient Protection and as otherwise authorized or required by law.

11.23: Reporting Requirements

(1) Each RBPO or ACO shall provide the following information to the Office of Patient Protection no later than April 1 of each year. Such information shall be submitted in a manner specified by the Office of Patient Protection or using a template or form developed by the Office of Patient Protection.
   (a) A copy of the Patient notice used by the RBPO or ACO.
   (b) A summary report of the Patient appeals received by the RBPO or ACO. Summary reports shall not include any information identifying Patients, but shall include the number of appeals and the resolutions of such appeals. Appeals shall be classified into the following categories of denials, restrictions or limitations:
      1. Referrals to Providers not affiliated with the RBPO or ACO.
      2. Type or intensity of treatment or services.
      3. Denials or restrictions on timely access to treatment or services
      4. Other. For appeals categorized as "other," the RBPO or ACO shall include a brief description of the Patient's concern.
   (c) A description of the RBPO's or ACO's appeals process to resolve Patient appeals, including the title and clinical background of the Internal Reviewer(s);
   (d) A description or example of a written resolution of an appeal upholding the RBPO or ACO decision and a description or example of a written resolution of an appeal overturning the RBPO or ACO decision.
   (e) The name, telephone number and e-mail address of the person or persons within the RBPO or ACO who will serve as the general contact for the Office of Patient Protection for internal appeals and external reviews. If this contact information changes, the RBPO or ACO shall provide the new information in writing to the Office of Patient Protection within ten business days following the change.

(2) If a Patient concern is resolved at the point of care or service, either with clinical or administrative staff, then the RBPO or ACO is not required to report that concern as an internal appeal.

11.24: Severability

If any section or portion of a section of 958 CMR 11.00 or the applicability thereof is held invalid or unconstitutional by any court of competent jurisdiction, the remainder of 958 CMR 11.00 or the applicability thereof to other persons, entities, or circumstances shall not thereby be affected.

REGULATORY AUTHORITY

958 CMR 11.00: M.G.L. c. 176O § 24, M.G.L. c. 6D §§ 15 and 16.