958 CMR 12.00: DRUG PRICING REVIEW

Section

12.01: Scope and Purpose

958 CMR 12.00 governs the Commission's review of a Referred Manufacturer's pricing practices pursuant to M.G.L. c. 6D, § 8A and M.G.L. c. 118E, § 12A. 958 CMR 12.00 specifies the procedures by which the Commission may review information relative to a Referred Manufacturer's pricing practices and determine whether its pricing of a Drug is unreasonable or excessive in relation to the Drug's value.

12.02: Definitions

All defined terms in 958 CMR 12.00 are capitalized. As used in 958 CMR 12.00, these terms have the following meaning:

Attestation Form. A form, prescribed by the Commission, to be signed by a Referred Manufacturer, attesting that all information reported or provided is true and correct under pains and penalties of perjury.

Board. The governing board of the Commission established in M.G.L. c. 6D, §2(b).

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

Drug. A pharmaceutical product manufactured by a Manufacturer.

Executive Director. The Executive Director of the Commission.

Executive Office. The Executive Office of Health and Human Services established under M.G.L. c. 6A.

Manufacturer. An entity that manufactures a pharmaceutical product for which coverage is, or is reasonably anticipated to become, available from MassHealth for eligible members.

MassHealth. The medical assistance and benefit programs administered by the Executive Office pursuant to Title XIX of the Social Security Act (42 U.S.C. §§ 1396 et seq.), Title XXI of the Social Security Act (42 U.S.C. §§ 1397aa et seq.), M.G.L. c. 118E, and other applicable laws and waivers to provide and pay for medical services to eligible members.

Referred Manufacturer. A Manufacturer for which the Commission has received notice from the Executive Office pursuant to M.G.L. c. 118E, § 12A(g) identifying the Manufacturer as a Manufacturer of a Drug for which (i) negotiations with the Executive Office for a Supplemental Rebate have been unsuccessful and (ii) the Executive Office has determined to be a High-cost Drug pursuant to 101 CMR 801.00 et seq.

Standard Reporting Form. The form, as prescribed by the Commission, pursuant to 958 CMR 12.04.

Supplemental Rebate. As authorized by Section 1927 of the Social Security Act (42 U.S.C. §§ 1396r-8 et seq.), the value of payments by a Manufacturer for covered Drugs dispensed or administered for use by MassHealth members and included on claims paid by the Executive Office or a participating MassHealth managed care entity, which may be the result of a traditional or value-based arrangement, and which is in addition to the Manufacturer's mandated rebate under the Medicaid Drug Rebate Program as authorized by Section 1927 of the Social Security Act (42 U.S.C. §§ 1396r-8 et seq.).

12.03: Notice of Identification by the Executive Office

(1) The Commission shall provide written notice to each Referred Manufacturer. Such notice shall state that:

(a) the Commission has received notice from the Executive Office identifying the Referred Manufacturer as a Manufacturer of a Drug for which (i) negotiations with the Executive Office for a Supplemental Rebate have been unsuccessful and (ii) the Executive Office has determined to be a High-cost Drug pursuant to 101 CMR 801.00 et seq.;

(b) the Referred Manufacturer must provide the information specified in 958 CMR 12.04(1);

(c) any information disclosed by the Referred Manufacturer under M.G.L. c. 6D, § 8A or 958 CMR 12.00 et seq. shall be accompanied by a signed Attestation Form as specified in 958 CMR 12.04(6); and

(d) information disclosed by the Referred Manufacturer under M.G.L. c. 6D, § 8A or 958 CMR 12.00 et seq. shall not be a public record under M.G. L. c. 4, § 7 or M.G.L. c. 66 and shall remain confidential; provided, however, that the Commission may disclose the narrative submitted by a Referred Manufacturer pursuant to 12.04(3)(g) and may produce reports summarizing findings based on such records consistent with its responsibilities under M.G.L. c. 6D, § 8A. Such reports shall not identify specific prices charged for or rebate amounts associated with drugs of a Referred Manufacturer and shall not be presented in a manner that is likely to compromise the financial, competitive or proprietary nature of the information.

(2) The Commission shall include with the written notice the Standard Reporting Form, the Attestation Form and additional requests for information pursuant to 958 CMR 12.04(4).

12.04: Standard Reporting Form, Requests for Information, and Attestation Form

(1) Any Referred Manufacturer shall: provide its own estimation of the value of the Drug and supporting information, such as existing analyses; submit any additional data or documents that the Referred Manufacturer considers to be pertinent to the Commission's review; complete and submit a Standard Reporting Form; and respond to any requests for additional information within thirty (30) days of receipt of the written notice or request or such other timeframe as may be agreed upon, in writing, between the Referred Manufacturer and the Commission, through the Executive Director.

(2) The Standard Reporting Form shall be developed and updated from time to time by the Commission, with advance notice to and input from Manufacturers and other interested stakeholders, and shall be made publicly available on the Commission's website.

(3) The Standard Reporting Form shall include requests for information relating to the value and pricing of a Drug, including, but not be limited to:

(a) information on clinical efficacy, effectiveness and outcomes of the Drug, including clinical information submitted by the Referred Manufacturer to the US Food and Drug Administration or successor agency;

(b) a schedule of the Drug's wholesale acquisition cost and cost increases over the previous five (5) calendar years;

(c) information regarding the Drug's prices, net of rebates, internationally, nationally, and in Massachusetts;

(d) information to support the Referred Manufacturer's pricing of the Drug;

(e) information on utilization of the Drug;

(f) financial information for the Referred Manufacturer in the aggregate and for the Drug, using the best information available, including but not limited to:

i. the Referred Manufacturer's research and development budget and expenditures, including but not limited to, the Referred Manufacturer's aggregate, company-level research and development and other relevant capital expenditures, including facility construction, for the most recent year for which final audited data are available;

ii. the funding sources for the Referred Manufacturer's research and development expenditures, including identification of any public funding received;

iii. information regarding the Referred Manufacturer's acquisition cost if the Drug was acquired;

iv. the Referred Manufacturer's manufacturing, production and distribution budget and expenditures; and

v. the Referred Manufacturer's marketing budget and expenditures; and

(g) a written, narrative description, suitable for public release, of factors that contributed to reported changes in wholesale acquisition cost and prices net of rebates during the previous five (5) calendar years.

(4) The Commission may request additional information that it deems necessary to identify such Drug's proposed value or a proposed Supplemental Rebate and a determination of whether the pricing of a Drug is unreasonable or excessive in relation to its value.

(5) The Referred Manufacturer may submit to the Commission any additional data or information that the Referred Manufacturer considers to be pertinent to the Commission's review.

(6) All data and information provided by a Referred Manufacturer shall be accompanied by a signed Attestation Form.

12.05: Public Notice and Stakeholder Input

(1) Following notice to a Referred Manufacturer pursuant to 958 CMR 12.03, the Commission shall post a notice on its website regarding the identification by the Executive Office of the Referred Manufacturer.

(2) Interested stakeholders including, but not limited to patients, providers, provider organizations, clinical experts, and payers, may provide data or information to the Commission that they consider pertinent to the Commission's review of the Referred Manufacturer's pricing and the factors included in 958 CMR 12.06.

12.06: Identification of a Proposed Value

(1) Based on all available information, including information the Commission receives from MassHealth under M.G.L. c. 118E, § 12A, from the Referred Manufacturer under 958 CMR 12.04, and from any other interested stakeholders, the Commission may identify a proposed value for the Drug.

(2) In identifying a proposed value for a Drug, the Commission shall consider the Drug's benefits to the commonwealth and its residents and may consider factors including, but not limited to:

(a) information regarding the clinical efficacy, effectiveness and outcomes of the Drug;

(b) information relating to the pricing of the Drug, including, but not limited to, information relating to prices paid by other countries;

(c) the Drug's net price as compared to its therapeutic benefits, including, but not limited to, the seriousness and prevalence of the disease or condition that is treated by the Drug, and the extent to which the Drug addresses an unmet medical need or impacts affected patient subpopulations;

(d) the extent of utilization of the Drug or expected utilization of the Drug;

(e) the likelihood that the use of the Drug will reduce the need for other care or reduce caregiver burden, or enhance quality of life;

(f) whether there are therapeutic equivalents of the Drug, and the number of such equivalents available;

(g) characteristics of the Drug, including means and setting of administration, dosing frequency, duration of therapy, side effects, interactions and contraindications, and potential for misuse or abuse;

(h) analyses by independent third parties, provided that the Commission shall consider the methodologies and models underlying such analyses, any assumptions or limitations of research findings in the context of the results, and any outcomes for affected subpopulations that utilize the Drug, if applicable; and

(i) any other factors that the Commission considers relevant.

12.07: Identification of a Proposed Supplemental Rebate

(1) Based on all available information, including information the Commission receives from MassHealth under M.G.L. c. 118E, § 12A, from the Referred Manufacturer under 958 CMR 12.04 and from any other interested stakeholders, the Commission may identify a proposed Supplemental Rebate for the Drug.

(2) In identifying a proposed Supplemental Rebate for the Drug, the Commission

(a) shall consult the Executive Office and take into consideration any proposed Supplemental Rebate framework previously introduced in negotiations between the Executive Office and the Referred Manufacturer;

(b) may, as part of its consultation with the Executive Office, share information received from the Referred Manufacturer with the Executive Office; and

(c) may base the proposed Supplemental Rebate on a proposed value of the Drug as identified by the Commission.

12.08: Determination of Potentially Unreasonable or Excessive Pricing

After receiving the completed responses from the Referred Manufacturer pursuant to 958 CMR 12.04, the Commission shall make a determination to close review, and so notify the Referred Manufacturer, or, by a vote of the Board, shall make a determination that the Referred Manufacturer's pricing of the Drug is potentially unreasonable or excessive in relation to the value of the Drug as identified by the Commission and to continue review pursuant to 958 CMR 12.09. The Commission shall publicly post a summary of the rationale for determining that the Referred Manufacturer's pricing of the Drug is potentially unreasonable or excessive in relation to the value of the Drug and a list of any third-party cost-effectiveness analysis relied upon in identifying the proposed value.

12.09: Determination of Unreasonable or Excessive Pricing

(1) At least thirty (30) days prior to any determination by the Commission that the Referred Manufacturer's pricing of the Drug is unreasonable or excessive, the Commission, through the Executive Director:

(a) shall provide notice to the Referred Manufacturer that Commission has determined pursuant to 958 CMR 12.08 that Referred Manufacturer's pricing of the Drug is potentially unreasonable or excessive in relation to the value of the Drug as identified by the Commission and that the Commission intends to continue its review;

(b) shall provide to the Referred Manufacturer a copy of information, analyses or reports reviewed or used in identifying the proposed value of the Drug, and, to the

extent that the Commission engages with a third party to provide cost-effectiveness analysis or research related to the proposed value of the Drug, such information shall include:

i. a description of the methodologies and models used in such analysis;

ii. any assumptions and potential limitations of research findings in the context of the results; and

iii. any outcomes for affected subpopulations that utilize the Drug, if applicable;

(c) shall request that the Referred Manufacturer provide further information about the pricing of the Drug, including a justification for its pricing of the Drug, and any response to the information, analyses or reports provided pursuant to 958 CMR 12.09(1)(b);

(d) shall request information from other interested stakeholders, which may include, but not be limited to, patients, providers, provider organizations, clinical experts, and payers; and

(e) may conduct a public hearing pursuant to this section.

(2) The Referred Manufacturer must file such requested information, accompanied by the signed Attestation Form, within thirty (30) days of receipt of the request described in 958 CMR 12.09(1)(c) or such other timeframe as may be agreed upon, in writing, between the Referred Manufacturer and the Commission, through the Executive Director.

(3) Not later than sixty (60) days after receiving completed information from the Referred Manufacturer under 958 CMR 12.09(2), the Commission, by a vote of the Board, shall issue a determination on whether the Referred Manufacturer's pricing of a Drug is unreasonable or excessive in relation to the Commission's proposed value of the Drug and shall notify the Referred Manufacturer.

(4) Following a determination that the Referred Manufacturer's pricing of a Drug is unreasonable or excessive pursuant to 958 CMR 12.09(3), the Commission shall post a notice on its website stating the name of the Referred Manufacturer and the Drug reviewed, the Commission's proposed value for the Drug and that the Referred Manufacturer's pricing of a Drug is unreasonable or excessive in relation to the Commission's proposed value of the Drug.

12.10: Further Negotiations with the Executive Office

(1) Nothing in 958 CMR 12.00 shall preclude a Referred Manufacturer from engaging in further negotiations with the Executive Office pursuant to M.G.L. c. 118E, § 12A(b)

during the Commission's review of a Referred Manufacturer's Drug under 958 CMR 12.00 nor preclude the Executive Office from entering into a Supplemental Rebate agreement at a later date.

(2) The Commission may close review of a Drug, with notice to the Referred Manufacturer, upon receiving a written request from the Executive Office to withdraw its referral under M.G.L. c. 118E, § 12A(g).

12.11: Information Provided by the Executive Office in Connection with the Referral

Any information provided to the Commission by the Executive Office under M.G.L. c. 118E, § 12A(g) and 101 CMR 801.05(2) shall be considered a disclosure made for the express purpose of carrying out Title XIX of the Social Security Act (42 U.S.C. §§ 1396 et seq.) and shall only be used by the Commission for the purposes set forth in M.G.L. c. 6D, § 8A.

12.12: Confidentiality

Records disclosed by a Referred Manufacturer under 958 CMR 12.00 et seq. shall not be a public record under M.G. L. c. 4, § 7 or M.G.L. c. 66 and shall remain confidential; provided, however, that the Commission may disclose the narrative submitted by a Referred Manufacturer pursuant to 12.04(3)(g) and may produce reports summarizing any findings consistent with its responsibilities under M.G.L. c. 6D, § 8A. Such reports shall not identify specific prices charged for or rebate amounts associated with drugs of a Referred Manufacturer and shall not be presented in a manner that is likely to compromise the financial, competitive or proprietary nature of the information. The Commission shall develop and maintain policies and protocols to protect the confidentiality of records received from the Executive Office pursuant to M.G.L. c. 118E, § 12A(g) and 101 CMR 801.05(2) or disclosed by a Referred Manufacturer under 958 CMR 12.00 et seq.

12.13: Penalties

(1) The Commission may assess a civil penalty to a Referred Manufacturer of not more than $500,000 in each instance if it finds that the Referred Manufacturer has:

(a) Failed to timely provide information to the Commission.

(b) Knowingly obstructed the Commission's ability to issue a determination, including providing incomplete, false or misleading information to the Commission.

(2) The Commission shall determine whether to assess a penalty by vote of the Board.

(3) The Commission shall seek to promote compliance with 958 CMR 12.00 and shall only impose a civil penalty as a last resort.

(4) The Commission shall provide written notice to a Referred Manufacturer of the amount of the penalty, the reason(s) for assessing the penalty, and the right to request a hearing.

(5) The Commission shall not assess a penalty unless the Commission, through the Executive Director, has first afforded the Referred Manufacturer an opportunity for a hearing in accordance with M.G.L. c. 30A, §10.

(6) After the hearing, the Commission shall render a written decision and may assess a civil penalty pursuant to 958 CMR 12.13(1).

12.14: Applicability to Individual Patients

A determination of the value of a Drug pursuant to 958 CMR 12.00 et seq. is not intended to be a determination of the value of a Drug for any individual patient.

12.15: Severability

If any section or portion of a section of 958 CMR 12.00 or the applicability thereof is held invalid or unconstitutional by any court of competent jurisdiction, the remainder of 958 CMR 12.00 or the applicability thereof to other persons, entities, or circumstances shall not thereby be affected.

REGULATORY AUTHORITY

958 CMR 12.00: M.G.L. c. 6D, § 8A and M.G.L. c. 118E, § 12A.