101 CMR: EXECUTIVE OFFICE OF HEALTH AND HUMAN SERVICES

101 CMR 801.00: DRUG MANUFACTURER NEGOTIATIONS AND ACCOUNTABILITY

Section

801.01: General Provisions

(1) Scope and Purpose. 101 CMR 801.00 governs the process for direct negotiations between the Executive Office of Health and Human Services (EOHHS) and manufacturers for supplemental rebate agreements (SRAs), the public process for determining a drug's target value, and referrals of manufacturers to the Health Policy Commission (HPC).

(2) Administrative Bulletins. EOHHS may issue administrative bulletins to clarify its policy on and understanding of substantive provisions of 101 CMR 801.00.

801.02: Definitions

As used in 101 CMR 801.00, terms will have the meanings set forth in 101 CMR 801.02, except where the context clearly indicates otherwise.

Covered Drug. A pharmaceutical product for which coverage is, or is reasonably anticipated to become, available from MassHealth for eligible members.

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

Health Policy Commission (HPC). The commission established under M.G.L. c. 6D.

High-cost Drug. A covered drug projected by EOHHS to exceed a post-rebate cost per utilizer of $25,000 annually or an aggregate annual post-rebate cost to MassHealth of $10,000,000, based on factors including actual or expected utilization, prevalence of the disease or condition that is treated by the coved drug, dosing information, duration of therapy, and price of the covered drug after application of the manufacturer's mandated rebate under the MDRP.

Manufacturer. An entity that manufactures a covered drug.

MassHealth. The medical assistance and benefit programs administered by EOHHS 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.

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Medicaid Drug Rebate Program (MDRP). The program authorized by Section 1927 of the Social Security Act (42 U.S.C. §§ 1396r-8 *et seq*.) under which participating manufacturers are required to enter and have in place a national rebate agreement with the Secretary of the federal Department of Health and Human Services in exchange for state Medicaid coverage of most of the manufacturer's drugs, and under which such manufacturers are required to pay a rebate to states for such drugs paid for by the state's Medicaid program pursuant to a statutory formula.

Secretary. The Secretary of the Massachusetts Executive Office of Health and Human Services.

Supplemental Rebate Agreement (SRA). An agreement authorized by Section 1927 of the Social Security Act (42 U.S.C. §§ 1396r-8 *et seq*.) and in a format approved by the federal Centers for Medicare & Medicaid Services between EOHHS and a manufacturer memorializing the terms and conditions for payments by the manufacturer for covered drugs dispensed or administered for use by MassHealth members and included on claims paid by EOHHS or a participating MassHealth managed care entity, as applicable. The payment is in addition to the manufacturer's mandated rebate under the MDRP and may be structured as a traditional or value-based arrangement, as appropriate.

Third Party. An entity that is not:
(a) a manufacturer;
(b) EOHHS;
(c) another state department, agency, subdivision, office, board, commission, or institution of the executive, judicial, or legislative branches of the Commonwealth; or
(d) an individual employed by an entity described in 101 CMR 801.02: Third-party(a) through (c).

801.03: Direct Negotiations

(1) General.
(a) EOHHS may enter into direct negotiations with any manufacturer for an SRA for any covered drug(s) manufactured by the manufacturer. Such negotiations may be initiated by EOHHS or by the manufacturer, provided that nothing obligates EOHHS to engage in negotiations with any manufacturer.
(b) EOHHS will seek to prioritize direct negotiations in a manner that maximizes value to the Commonwealth, and will only enter into an SRA if EOHHS determines that doing so will maximize value to the Commonwealth in a manner consistent with the concept of "best value" as defined at 801 CMR 21.02: *Definitions* and consideration of the factors described in 101 CMR 801.03(3), as appropriate.
(c) Nothing precludes EOHHS from utilizing the processes described at 801 CMR 21.00: *Procurement of Commodities or Services, including Human and Social Services*, or any other process allowed under state law, to enter into an SRA as an alternative to a direct negotiation.

(2) Possible Outcomes.
(a) A direct negotiation is considered successful if it results in an executed SRA between EOHHS and the manufacturer.
(b) An actual or attempted direct negotiation is considered to have failed if:

1. EOHHS and the manufacturer do not execute an SRA as a result of the actual or attempted direct negotiation;
2. EOHHS has presented the manufacturer with an offer or counteroffer including, at minimum, the material SRA terms desired by EOHHS, and the manufacturer has had a reasonable opportunity to accept or reject such terms; and
3. EOHHS has provided written notice to the manufacturer of the agency's determination that the actual or attempted direct negotiation has failed, provided that such notice must be sent at least 30 days before EOHHS initiates the process described in 101 CMR 801.04, and provided further that EOHHS identifies in the notice if the covered drug is a high-cost drug eligible for the process described in 101 CMR 801.04.

(c) If neither the condition of 101 CMR 801.03(2)(a) nor the conditions of 101 CMR 801.03(2)(b) are satisfied, the direct negotiation is considered to be open, unless EOHHS notifies the manufacturer in writing of its withdrawal from the negotiation.

(3) Factors for Consideration.

(a) In determining whether to enter into direct negotiations with a manufacturer, or whether to enter into an SRA as a result of such negotiations, EOHHS may consider the following factors, as applicable, provided that EOHHS's consideration of such factors is consistent with the principles set forth in 801 CMR 21.01: *Purpose, Application and Authority*:

1. Information regarding the clinical efficacy, effectiveness, and outcomes of the covered drug;
2. Information relating to the pricing of the covered drug, including but not limited to information relating to prices paid in other countries;
3. The covered drug's post-rebate price to the Medicaid program 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;
4. The extent of utilization or expected utilization of the covered drug within the Medicaid population;
5. The likelihood that the use of the covered drug will reduce the need for other care, reduce caregiver burden, or enhance quality of life;
6. Whether there are therapeutic equivalents of the covered drug, and the number of such equivalents available;
7. Characteristics of the covered drug, including means and setting of administration, dosing frequency, duration of therapy, side effects, interactions and contraindications, and potential for misuse or abuse;
8. Analyses by independent third parties, provided that EOHHS will consider, as available, the methodologies and models used in the analysis, any assumptions and potential limitations of the analysis, and outcomes for specific subpopulations, if applicable;
9. The extent to which the manufacturer of the covered drug has entered into other SRAs;
10. Any information supplied by the manufacturer; and
11. Other appropriate measures or analysis related to the value, efficacy or outcomes of the covered drug.

(b) If EOHHS engages a third party to provide a cost-effectiveness analysis in evaluating whether to enter into an SRA, the analysis must include:

1. a description of the methodologies and models used in the analysis;
2. any assumptions and potential limitations of the analysis; and
3. outcomes for specific subpopulations, if applicable.

(c) EOHHS may, provided that doing so is consistent with its obligations under 101 CMR 801.03(1)(b), share with the manufacturer for review and input during the course of a direct negotiation any information, analyses, or reports regarding a covered drug relied on by EOHHS in developing an offer or counter offer for an SRA, and will consider any information provided by the manufacturer in response. Subject to 101 CMR 801.04(2)(e), nothing will compel EOHHS to share such information with the manufacturer during the direct negotiation process.

(4) Implications of Executed SRA. In the event EOHHS and the manufacturer execute an SRA for a covered drug, whether through the process described in 101 CMR 801.03 or otherwise, EOHHS will not subject the covered drug to the process described in 101 CMR 801.04 or a referral under 101 CMR 801.05 during the term of the SRA with the intent of securing an enhanced rebate for the covered drug from the manufacturer, provided that nothing prohibits EOHHS and the manufacturer from agreeing in good faith to amend or terminate the SRA as otherwise allowed under the terms of the SRA.

801.04: Determination of Target Value

(1) General. EOHHS may determine a target value for any covered drug that meets the following requirements:

(a) The covered drug must be a high-cost drug; and

(b) The covered drug must have been the subject of a failed direct negotiation under 101 CMR 801.03(2)(b).

(2) Process for Determining Target Value.

(a) EOHHS may publicly post a proposed target value for any covered drug that meets the requirements of 101 CMR 801.04(1).

(b) At least 30 days before finalizing the proposed target value, EOHHS will afford interested persons an opportunity to present data, views or arguments in regard to the proposed target value.

(c) At the sole discretion of the Secretary, EOHHS may hold a public hearing on the proposed target value, provided that EOHHS provides notice to the public at least 30 days prior to the hearing. Any testimony at the public hearing will be given under oath.

(d) In order to provide public notice of the opportunity to comment, and advertise a public hearing, if applicable, EOHHS will, on a dedicated location of the EOHHS website, post a notice including the following:

1. the proposed target value of the covered drug;
2. a summary of the rationale for the proposed target value;
3. a list of any third-party cost-effectiveness analysis relied on in setting the proposed target value;
4. the manner in which data, views, or arguments regarding the proposed target value may be submitted to the agency by any interested person, including the deadline for such comments; and
5. the time and place of a public hearing, if applicable.

EOHHS may file a copy of such notice with the Secretary of the Commonwealth for publication in the *Massachusetts Register*.

(e) Not later than concurrently with the posting of the public notice described in 101 CMR 801.04(2)(d), EOHHS will provide written notice to the manufacturer of its proposed target value, a copy of the public notice described at 101 CMR 801.04(2)(d), and will share with the manufacturer for review and input any information, analyses or reports regarding a covered drug relied on by EOHHS in developing the proposed target value described in 101 CMR 801.04(2)(a) and, if different, any information, analyses or reports regarding a covered drug relied on by EOHHS in developing any proposed supplemental rebate amount included in the offer or counteroffer described in 101 CMR 801.03(2)(b)(2).

(f) Prior to finalizing the proposed target value, EOHHS will consider any comments or testimony received by the specified deadline, including any comments, clarifications, or data submitted by the manufacturer of the covered drug, and will make updates to the proposed target value, as appropriate, and consider whether to reopen negotiations with the manufacturer under 101 CMR 801.04(a).

(g) After completion of the analysis described in 101 CMR 801.04(2)(f), and subject to 101 CMR 801.04(4), if applicable, EOHHS may post a final target value for the covered drug on a dedicated location of the EOHHS website, and also may file a copy of the target value with the Secretary of the Commonwealth for publication in the *Massachusetts Register*.

(3) Factors for Consideration.

(a) In establishing a target value for a covered drug, EOHHS may consider the following factors, as applicable:

1. Information regarding the clinical efficacy, effectiveness, and outcomes of the covered drug;
2. Information relating to the pricing of the covered drug, including but not limited to information relating to prices paid in other countries;
3. The covered drug's net price to the Medicaid program 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 benefits particular patient subpopulations;
4. The extent of utilization or expected utilization of the covered drug within the Medicaid population;
5. The likelihood that the use of the covered drug will reduce the need for other care, reduce caregiver burden, or enhance quality of life;
6. Whether there are therapeutic equivalents of the covered drug, and the number of such equivalents available;
7. 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;
8. Analyses by independent third parties, provided that EOHHS will consider, as available, the methodologies and models used in the analysis, any assumptions and potential limitations of the analysis, and outcomes for specific subpopulations, if applicable;
9. Any information supplied by the manufacturer or the public; and
10. Other appropriate measures or analysis related to the value, efficacy or outcomes of the covered drug.

(b) If EOHHS engages a third party to provide a cost-effectiveness analysis in establishing a target value, the analysis must include:

1. a description of the methodologies and models used in the analysis;
2. any assumptions and potential limitations of the analysis; and
3. outcomes for specific subpopulations, if applicable.

(4) Opportunity to Reopen Negotiations.

(a) At any time prior to posting a final target value for a covered drug under 101 CMR 801.04(2)(g), EOHHS may reopen direct negotiations with a manufacturer by presenting the manufacturer with an updated offer or counteroffer including, at minimum, the material SRA terms desired by EOHHS, provided that the manufacturer has a reasonable opportunity to accept or reject such terms.

(b) In the event that EOHHS and the manufacturer do not execute an SRA for the covered drug after direct negotiations are reopened under 101 CMR 801.04(4)(a), EOHHS may post a final target value for the covered drug under 101 CMR 801.04(2)(g).

(c) EOHHS may also initiate a request, or consider a request by a manufacturer to reopen direct negotiations at any time prior to referring a covered drug to the HPC under 101 CMR 801.05, provided that nothing obligates EOHHS to enter into such further negotiations.

801.05: Referral to the Health Policy Commission

(1) General.

(a) EOHHS may refer a manufacturer to the HPC for review of a covered drug under M.G.L. c. 6D, §8A, provided that the following conditions are met:

1. The covered drug meets the requirements of 101 CMR 801.04(1), and EOHHS and the manufacturer have not subsequently executed an SRA for the covered drug under 101 CMR 801.04(4) or otherwise;
2. EOHHS has posted a final target value for the covered drug under 101 CMR 801.04(2)(g) and not more than 180 days have passed since EOHHS has posted said final target value; and
3. The Secretary has provided written notice of the referral to the HPC, with a copy to the manufacturer.

(b) EOHHS may publicly post a copy of the referral notice on a dedicated location of the EOHHS website.

(2) Referral Contents.

(a) Upon referral of a manufacturer under 101 CMR 801.05(1), and notwithstanding 101 CMR 801.06, EOHHS may share or make available to the HPC any records that describe or relate to manufacturer's pricing of the covered drug, including any information shared with the manufacturer under 101 CMR 801.04(2)(e), and any information received from the manufacturer under 101 CMR 801.04(2)(f), provided that the status of any information subject to 101 CMR 801.06 will not be impacted by making such information available to the HPC.

(b) EOHHS considers any information shared with the HPC under 101 CMR 801.05(2)(a) to be a disclosure made for the express purpose of carrying out Title XIX of the Social Security Act (42 U.S.C. §§ 1396 *et seq*.).

(3) Opportunity to Reopen Negotiations.
(a) EOHHS may initiate a request, or consider a request by a manufacturer to reopen direct negotiations at any time after referring a covered drug to the HPC under 101 CMR 801.05, provided that nothing obligates EOHHS to enter into such further negotiations.
(b) The fact that EOHHS enters into direct negotiations with a manufacturer under 101 CMR 801.05(3)(a) will have no impact on the referral of that manufacturer to the HPC unless EOHHS withdraws the referral under 101 CMR 801.05(4).

(4) Withdrawal of Referral.
(a) At any time prior to the issuance of the determination described in M.G.L. c. 6D, §8A, subsection (h), EOHHS may withdraw the referral of a manufacturer to the HPC under 101 CMR 801.05(1)(a) upon written notice to the HPC, with a copy to the manufacturer.
(b) If EOHHS has publicly posted a copy of the referral notice under 101 CMR 801.05(1)(b), EOHHS will post a copy of the withdrawal notice on a dedicated location of the EOHHS website.

801.06: Confidentiality

Subject to 101 CMR 801.05(2), any non-public information shared with EOHHS by the manufacturer during the course of a direct negotiation under 101 CMR 801.03 or during the process for determining a target value under 101 CMR 801.04, or by the HPC under M.G.L. c. 6D, §8A, will not be a public record under M.G.L., c. 4, §7 or M.G.L. c. 66, and EOHHS will regard any records expressly designated as such by the manufacturer or HPC as confidential and proprietary.

801.07: Interaction with other Regulations

The application of any provision of 101 CMR 801.00, including the determination of a target value under 101 CMR 801.04, does not constitute a determination of medical necessity for a covered drug by the MassHealth agency for any individual MassHealth member, a determination that payment is available for a covered drug from the MassHealth agency to any MassHealth provider, or establish the rate of payment for any covered drug by EOHHS, and does not otherwise supersede any other applicable provision of another MassHealth or EOHHS regulation, including 130 CMR 450.000: *Administrative and Billing Regulations*, 130 CMR 406.000: *Pharmacy Services*, or 101 CMR 331.00: *Prescribed Drugs*.

801.08: Severability

The provisions of 101 CMR 801.00 are severable. If any provision or subprovision of 101 CMR 801.00 or the application of such provision or subprovision of 101 CMR 801.00 is held invalid or unconstitutional, such determination will not be construed to affect the validity or constitutionality of any other provision or subprovision of 101 CMR 801.00 or the application thereof.

REGULATORY AUTHORITY

101 CMR 801.00: M.G.L. c. 118E, § 12A.