957 CMR: Center for Health Information and Analysis

957 CMR 12.00: Pharmacy Benefit Manager Reporting

Section

12.01 General Provisions

(1) Scope and Purpose. 957 CMR 12.00 governs the reporting requirements for Pharmacy Benefit Managers to submit health care data and information to the Center for Health Information and Analysis to ensure uniform reporting of information in accordance with M.G.L. c. 12C.

(2) Applicability. 957 CMR 12.00 applies to Pharmacy Benefit Manager as defined in section 12.02.

(3) Authority. This regulation is issued pursuant to M.G.L. c. 12C, including but not limited to, §§ 3, 5, 10A, and 11.

12.02 Definitions

All defined terms in 957 CMR 12.00 are capitalized. Any other term used in this regulation but not defined herein shall have the meaning given to the term by M.G.L. c. 12C, other CHIA regulations, or Sub-Regulatory Guidance.

As used in 957 CMR 12.00, unless the context requires otherwise, the following words shall have the following meanings:

Adjudicatory Proceeding. A proceeding before an agency in which the legal rights, duties or privileges of specifically named persons or entities are required by constitutional right or by any provision of the General Laws to be determined after an opportunity for an agency hearing.

Administrative Fees. Administrative, service, or other fees that a Pharmacy Benefit Manager imposes on (1) Payers, for including, but not limited to, processing claims, managing drug Formularies, and other services; and (2) Pharmaceutical Manufacturing

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Companies, for including, but not limited to, administering rebates, providing data or analytic services, and other services.

Calendar Year. The period beginning January 1st and ending December 31st.

Carrier. An insurer licensed or otherwise authorized to transact accident or health insurance under chapter 175; a nonprofit hospital service corporation organized under chapter 176A; a nonprofit medical service corporation organized under chapter 176B; a health maintenance organization organized under chapter 176G; and an organization entering into a preferred provider arrangement under chapter 176I, but not including an employer purchasing coverage or acting on behalf of its employees or the employees of 1 or more subsidiaries or affiliated corporations of the employer; provided that, unless otherwise noted, the term "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.

CHIA or Center. The Center for Health Information and Analysis established under M.G.L. c. 12C.

Data Specification Manual. The Data Specification Manual contains data submission requirements including, but not limited to, required fields, file layouts, file components, edit specifications, instructions and other technical specifications.

Dispensing Fee. The fee paid, over and above the Ingredient Cost, to a pharmacy for dispensing drugs to Members.

Division. The Massachusetts Division of Insurance established under M.G.L. c. 175.

Formulary. A list of all drugs covered by the Pharmacy Benefit Manager on behalf of the Payer.

Health Plan Sponsor. An employer, union, association, trust, governmental entity, or other organization that establishes, maintains, or funds a health benefit plan for its employees, Members, or beneficiaries, whether by purchasing coverage from a Carrier or through a self-insured arrangement to the extent permitted by the Employee Retirement Income Security Act of 1974; provided, however, that Health Plan Sponsor shall not include an individual purchasing coverage on their own behalf.

Ingredient Cost. The price a pharmacy is paid for provisioning a drug, not including the Dispensing Fee.

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Maximum Allowable Cost (MAC). The per-unit amount that a Pharmacy Benefit Manager will reimburse a pharmacy for a drug, excluding the Dispensing Fee.

Member. A person whose primary residence is located in Massachusetts, as determined by the address on file with the Payer for coverage purposes during a given month, regardless of the location of the Member's employer or the Payer's principal place of business, covered by an individual contract or a certificate under a group arrangement contracted with a Payer.

National Drug Code (NDC). The numerical code maintained by the Food and Drug Administration that includes the labeler code, product code, and package code. A drug's NDC number consists of 11 digits and may be expressed in various formats (such as 5-4-2, 4-4-2, or other configurations) as determined by the Food and Drug Administration.

Payer. Any entity, other than an individual, that pays providers for the provision of health care services; provided, however, that Payer shall include both governmental and private entities; and provided further, that Payer shall include Carriers, Health Plan Sponsors, and self-insured plans to the extent allowed under the Employee Retirement Income Security Act of 1974.

Pharmacy Benefit Manager (PBM). A person, business, or other entity, however organized, licensed in Massachusetts by the Division, that directly or through a subsidiary provides Pharmacy Benefit Management Services for prescription drugs and devices on behalf of a Health Plan Sponsor, including but not limited to, a self-insurance plan, labor union or other third-party payer; provided however, that Pharmacy Benefit Manager shall not include a Health Plan Sponsor unless otherwise specified by the Division.

Pharmacy Benefit Management Services. Services performed by a Pharmacy Benefit Manager, including: (1) negotiating the price of prescription drugs, including negotiating and contracting for direct or indirect Rebates, discounts or other price concessions; (2) managing any aspects of a prescription drug benefit, including but not limited to, Formulary administration, mail-order pharmacy and specialty drug pharmacy services, clinical, safety and adherence programs for pharmacy service, the processing and payment of claims for prescription drugs, arranging alternative access to or funding for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to the prescription drug benefit, contracting with network pharmacies, controlling the cost of covered prescription drugs and managing or providing data relating to the prescription

drug benefit or the provision of services related thereto; (3) performance of any administrative, managerial, clinical, pricing, financial, reimbursement, data administration or reporting or billing service related to a health benefit plans' prescription drug benefit; and (4) such other services as the Division may define in regulation.

Pharmaceutical Manufacturing Company. An entity engaged in the: (1) production, preparation, propagation, compounding, conversion or processing of prescription drugs, directly or indirectly, by extraction from substance of natural origin, independently by means of chemical synthesis or by a combination of extraction and chemical synthesis; or (2) packaging, repackaging, labeling, relabeling or distribution of prescription drugs; provided however, that Pharmaceutical Manufacturing Company shall not include a hospital licensed under section 51 of chapter 111, a wholesale drug distributor licensed under section 36B of chapter 112 or a retail pharmacist registered under section 39 of said chapter 112.

Post-Sale Adjustment. Any exchange of funds between a PBM and a pharmacy occurring after the point-of-sale that affects the pharmacy's reimbursement, including but not limited to brand and generic effective rate reconciliations, performance-based adjustments, audit adjustments, and other types of claw backs.

Presiding Officer. The individual(s) authorized by law or designated by the Center to conduct an Adjudicatory Proceeding.

Rebate. Any rebate, discount, or price concession (including concessions from price protection and hold harmless contract clauses, volume-based discounts, market share incentives, Formulary placement fees, and outcome-based rebates) provided by a Pharmaceutical Manufacturing Company for dispensed drugs.

Rebate Aggregator. An entity, sometimes referred to as a group purchasing organization (GPO) or PBM GPO, that negotiates contracts with Pharmaceutical Manufacturing Companies related to pricing, Rebates, and other remuneration on behalf of Pharmacy Benefit Managers and Payers.

Spread Pricing. The practice in which a Pharmacy Benefit Manager retains the difference between the amount the PBM is paid by a Payer and the amount the PBM reimburses a pharmacy.

Sub Regulatory Guidance. An Administrative Bulletin, notice, manual, guide, or other document, including the *Data Submission Guide* or *Data Specification Manual*, that

specifies deadlines, technical submission requirements, or contains methodological explanations and examples to facilitate understanding of and compliance with adopted regulations. Such guidance shall be made publicly available and shall carry the force of this regulation, provided that it does not impose additional substantive obligations beyond those set forth in this regulation.

Wholesale Acquisition Cost. The cost of an individual prescription drug as defined in 42 U.S.C. 1395w-3a(c)(6)(B).

12.03 General Reporting Requirements

(1) Summary Information.
   (a) PBMs shall annually file the following contact information:
      1. Legal entity name, including, if applicable, any "doing business as" names;
      2. Business address; and
      3. Name, phone number, and email address of the filing entity's compliance officer.
   (b) If a PBM changes its contact information, it shall promptly notify the Center, within ten (10) business days, and provide updated contact information required in 957 CMR 12.03(1)(a).
   (c) PBMs shall also submit general information about their contracts for managing pharmaceutical benefits for Members, including but not limited to:
      1. A list of each contracted Payer;
      2. Summary data about total claims paid, fees paid and received, and total count of Members; and
      3. Information about the types of services provided to Payers and Members.

(2) PBMs that provide Pharmacy Benefit Management Services to 5,000 or more Members in the aggregate across all Payers, shall annually provide the Center the following information:
   (a) Basic drug information, such as:
      1. Drug product name;
      2. National Drug Code; and
      3. Drug category, such as specialty, brand, generic, and other categories as described in Sub-Regulatory Guidance.

(b) Utilization metrics, such as:
    1. Number of individual drug units;
    2. Number of prescriptions of individual drugs;
    3. Days' supply; and
    4. Number of Members with prescriptions.

(c) Payment or cost amounts per individual drug dispensed at pharmacies, such as:
    1. Wholesale Acquisition Costs;
    2. Dispensing Fees;
    3. Ingredient Costs;
    4. Total paid amount, including amounts paid by the PBM, Payer, and Member; and
    5. Any other fees, payments, or reimbursements related to the provision of prescriptions.

(d) Rebates, fees, and other amounts, including, but not limited to:
    1. Administrative Fees;
    2. The amount of Rebates a PBM:
        a. Retains based on its contractual arrangement with each individual Payer;
        b. Passes through to each individual Payer; and
        c. Passes through to the patient at the point of sale;
    3. Any other fees or amounts paid between the PBM and:
        a. Payers;
        b. Rebate Aggregators; and
        c. Pharmaceutical Manufacturing Companies.

(e) Information related to the PBM's practices of:
    1. Spread Pricing;
    2. Formulary placement; and
    3. Post-Sale Adjustments.

(f) For each Formulary:
    1. List of covered drugs that are considered preferred;
    2. List of covered drugs that are considered specialty;
    3. List of covered drugs by therapeutic category;
    4. Maximum Allowable Cost lists;
    5. Cost-sharing design and drug tiering options;

6. Information about utilization management options such as prior authorization, step therapy, quantity limits; and
7. Explanation of Formulary changes.

(g) Business information, including, but not limited to:

1. A narrative of the PBM's organizational structure; a detailed description of any material ownership interest(s) (defined as 10% or more) in any subsidiary, parent, affiliate, Rebate Aggregator, Payer, pharmacy, Pharmaceutical Manufacturing Company, consultant, or other person or entity whose business impacts the PBM; a description of the service area and pharmacy network; the roles, functions, responsibilities of, and interrelationships among pharmacies and the methods of pharmacy reimbursement and arrangements; unless the PBM reports such business information to the Division in a given reporting year.

(h) Any other information deemed reasonably necessary by the Center, issued through Sub Regulatory Guidance, to ensure uniform reporting of information in accordance with M.G.L. c. 12C.

12.04 Data Submission Procedures

(1) General. PBM shall submit data and information to CHIA in accordance with the procedures, deadlines, and schedules provided in 957 CMR 12.00 or Sub-Regulatory Guidance from the Center. In the event a data submission deadline falls on a Saturday, Sunday, or Commonwealth holiday, the data shall be due on the business day immediately thereafter.

(2) Sub-Regulatory Guidance. CHIA will issue Sub-Regulatory Guidance to clarify its requirements, policies, and procedures under 957 CMR 12.00 and to set forth the required technical information, such as: data file format, record specifications, data elements, definitions, code tables and edit specifications for data and information submitted pursuant to 957 CMR 12.00.

CHIA may also issue Sub-Regulatory Guidance to specify or amend data and information required to be submitted; to specify or amend the procedures for submitting data and information; and to specify or amend the timeframes for submitting data and information.

(3) Amended Data Submissions. PBM may amend data submissions, subject to the approval of CHIA, upon notice of the proposed amended data submissions, and the reasons for

such changes. Amended data submissions shall be made in accordance with the procedures provided in Sub-Regulatory Guidance.

(4) Data Review, Verification, and Resubmission. If necessary, PBM may be required to review, verify, or resubmit certain data and information previously submitted. CHIA will notify PBM of when such data and information must be reviewed, verified, or resubmitted and will provide to applicable PBM such health care data and information, or summary reports of such data and information, for review, verification, or resubmission.

(5) Additional Documentation. The Center may request that PBM submit additional documentation related to reported data and information through Sub-Regulatory Guidance or by written request.

(6) Accuracy. The PBM (i) certifies that an authorized representative of the PBM submitted information and data to the Center, and (ii) attests that information and data submitted to the Center is true, correct, and complete.

(7) Mergers. PBM must submit data for newly merged entities in accordance with Sub-Regulatory Guidance. CHIA must approve organizational reporting structure changes prior to implementation. The PBM must notify CHIA in writing as to any organization ID change, for approval, prior to a data submission.

(8) Extension Requests. CHIA may grant, for good cause, an extension in time to PBM to submit health care data and information.

12.05 Compliance and Penalties

The Center will provide written notice to PBM that fail to comply with the reporting deadlines established in 957 CMR 12.00.

(1) The Center will notify PBM that failure to respond within two weeks of the written notice, without just cause, may result in penalties. In accordance with M.G.L. c. 12C, § 11, PBM may be subject to a penalty of up to $25,000 per week for each week that they fail to provide the required data and information.

(2) Any remedy available under 957 CMR 12.00 is in addition to other sanctions and penalties that may apply under the provisions of other statutes and regulations.

(3) PBM that fail to comply with the requirements of 957 CMR 12.00 will be subject to all penalties and remedies allowed by law and the Center will take all necessary steps to enforce 957 CMR 12.00, including a petition to the Superior Court for an order enforcing the same.

(4) Before assessing a penalty, the Center shall notify the PBM that has failed to comply with the requirements of 957 CMR 12.00 that it has the right to request a hearing in accordance with M.G.L. c. 30A, § 10.

(5) If a hearing is timely requested in writing, the Center, including through a Presiding Officer, will conduct the hearing in accordance with 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedure*. After the hearing, the Center shall render a written decision and may assess a civil penalty pursuant to 957 CMR 12.05(1).

(6) After the issuance of a final decision, except where any provision of law precludes judicial review, a PBM aggrieved by such final decision may seek judicial review thereof in accordance with M.G.L. c. 30A, § 14.

12.06: Nonpublic Information

Except as specifically provided otherwise under M.G.L. c. 12C, data collected by the Center pursuant to 957 CMR 12.00 shall not be a public record under clause Twenty-sixth of section 7 of chapter 4 and section 10 of chapter 66. No such data shall be disclosed by the Center in a manner that is likely to compromise the financial, competitive or proprietary nature of such data and other information, or that may identify specific prices charged for drugs, the value of any Rebate amounts, individual drugs, or any Pharmaceutical Manufacturing Company.

12.07 Severability

The provisions of 957 CMR 12.00 are severable. If any provision or the application of any provision is held to be invalid or unconstitutional, such invalidity shall not be construed to affect the validity or constitutionality of any remaining provisions of 957 CMR 12.00 or the application of such provisions.

REGULATORY AUTHORITY

957 CMR 12.00: M.G.L. c. 12C