211 CMR 157.00: LICENSING AND REGULATION OF PHARMACY BENEFIT MANAGERS (PBMs)

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157.01: General

(1) Authority. 211 CMR 157.00 is promulgated pursuant to the authority granted by M.G.L. c. 176Y.

(2) Purpose. The purpose of 211 CMR 157.00 is to set forth rules and procedural requirements which the Commissioner deems necessary to implement the provisions of M.G.L. c. 176Y. A license may be granted only when the Division is satisfied that the entity possesses the necessary organization, background expertise, and financial integrity to supply the services sought to be offered.

(3) Applicability. No Person, business, or other entity shall establish or operate as a Pharmacy Benefit Manager (PBM), perform the functions of a PBM, or provide Pharmacy Benefit Management Services without obtaining a license from the Division in accordance with the provisions of 211 CMR 157.00.

157.02: Definitions

As used in 211 CMR 157.00 and the Division of Insurance's enforcement of M.G.L. c. 176Y generally, the following words mean:

Adverse Determination. A determination, based upon a review of information provided by a PBM or a Carrier or a designated Utilization Review Organization, to deny, reduce, modify, or terminate an admission, continued inpatient stay, or the availability of any other Health Care Services, including Pharmacy Services, for failure to meet the requirements for coverage based on Medical Necessity, appropriateness of health care setting and level of care, or effectiveness, including a determination that a requested or recommended Health Care Service or treatment is experimental or investigational. An Adverse Determination includes any denial of access to an out-of-Network Pharmacy where there is an oral or written assertion by a Covered Person or treating Health Care Professional that a Carrier's or PBM's preferred Network does not have Pharmacies that are able and available to dispense the patient's specific Prescription Drug and the preferred Network is therefore not adequate to deliver the needed Prescription Drug.

Affiliate or Affiliated. An Affiliate of, or Person affiliated with, a specific Person, is a Person that directly, or indirectly through one or more intermediaries, Controls or is Controlled by or is under common Control with the Person specified.

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Carrier. 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. For purposes of 211 CMR 157.00, a Carrier is also any entity, partially or fully funded or self-funded, that pays some or all of the costs of Pharmacy Services for a member of a Health Benefit Plan.

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

Commissioner. The Commissioner of Insurance, appointed pursuant to M.G.L. c. 26, § 6, or their designee.

Complaint.

(a) Any Inquiry made by or on behalf of a Covered Person to a Carrier or PBM that is not explained or resolved to the Covered Person's satisfaction within three business Days of the Inquiry;

(b) Any matter concerning an Adverse Determination; or

(c) In the case of a Carrier or PBM that does not have an internal Inquiry process, a Complaint means any Inquiry.

Control. Including Controlling, Controlled by and under common Control with, the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract other than a commercial contract for goods or non-management services, or otherwise, unless the power is the result of an official position with or corporate office held by the Person. Control shall be presumed to exist if any Person, directly or indirectly, owns, controls, holds with the power to vote, or holds proxies representing, 10% or more of the voting securities of any other Person. In the case of a Person that is a charitable or nonprofit organization subject to M.G.L. c. 180, Control shall be presumed to exist if any other Person shall, directly or indirectly, own, control or hold, more than 10% of the aggregate rights in any membership class or shall, directly or indirectly, have the right to appoint or elect more than 10% of the directors serving on the Person's board of directors.

Copay Accumulator. Any discount or free product vouchers that a retail Pharmacy or Carrier or health plan provides to a consumer in connection with a pharmacy service, item, or prescription transfer offer; or any discount, Rebate, product voucher, or other reduction in an individual's out-of-pocket expenses, including co-payments and deductibles.

Cost Sharing or Cost-sharing. Includes Covered Person's deductibles, coinsurance, copayments, or similar charges required of a Covered Person, but does not include premiums, balance billing amounts for out of-Network Pharmacies, or spending for non-Covered Benefits.

Covered Benefits or Benefits. Health Care Services to which a Covered Person is entitled under the terms of the Health Benefit Plan.

Covered Person. Persons covered under Health Benefit Plans.

Day or Days. Calendar days, unless otherwise specified in 211 CMR 157.00; provided, that computation of days specified in 211 CMR 157.00 begins with the first day following the referenced action, and provided further that if the final day of a period specified in 211 CMR 157.00 falls on a Saturday, Sunday or state holiday, the final day of the period will be deemed to occur on the next business day.

Division. The Division of Insurance established pursuant to M.G.L. c. 26, § 1.

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Finding of Neglect. A written determination by the Commissioner that the PBM has failed to make and file the materials required by M.G.L. c. 176Y or 211 CMR 157.00 in the form and within the time required.

Grievance. Any oral or written Complaint submitted to the PBM that has been initiated by an individual, Covered Person, or on behalf of a Covered Person with the consent of the Covered Person, concerning any aspect or action of the PBM relative to the individual or Covered Person including, but not limited to, review of Adverse Determinations regarding scope of coverage, denial of services, rescission of coverage, quality of care and administrative operations.

Group Purchasing Organization. An entity Affiliated with a PBM or a Pharmacy Benefit Plan or Pharmacy Benefit Program that uses purchasing volume aggregates as leverage to negotiate discounts and Rebates for covered Prescription Drugs with pharmaceutical manufacturers, distributors, and Wholesaler vendors.

Health Benefit Plan. A contract, certificate or agreement entered into, offered or issued to provide, deliver, arrange for, pay for or reimburse any of the costs of Health Care Services.

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

Health Care Services. Services for the evaluation, consultation, prescribing, diagnosis, prevention, treatment, management, cure or relief of a physical, behavioral, substance use disorder or mental health condition, illness, injury or disease.

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

Inquiry. Any communication by or on behalf of an individual that has not been the subject of an Adverse Determination and that requests redress of an action, omission, or policy of the PBM.

Mail-order Pharmacy. A Pharmacy whose primary business is to receive prescriptions by mail, telefax, or through electronic submissions, and to dispense medication to Covered Persons through the use of the United States mail, or other common, or contract carrier services.

Material Change. A modification to a PBM's organizational structures, procedures, or documents as reflected in the most recent licensing application or required reporting information pursuant to 211 CMR 157.00.

Maximum Allowable Cost or MAC. The per-unit amount that a PBM will reimburse a Pharmacy for a drug, excluding the dispensing fee.

Medical Necessity or Medically Necessary. Health Care Services that are consistent with generally accepted principles of professional medical practice as determined by whether:

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

NCQA. The National Committee for Quality Assurance.

Network or Pharmacy Network. A Pharmacy or group of Pharmacies that contracts to be part of a network of Pharmacies with a PBM.

Organization. An individual, corporation, partnership, business trust, association, organized group of Persons whether incorporated or not, or any line of business division, department, Subsidiary or Affiliate of any thereof and any receiver, trustee, or other liquidating agent of any of the foregoing while acting in such capacity.

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Person. An individual, a corporation, a partnership, an association, a joint venture, a joint stock company, a trust, an unincorporated Organization, any similar entity or combination of the foregoing.

Pharmacist or Registered Pharmacist. A registered pharmacist (R.Ph.) who, pursuant to the provisions of M.G.L. c. 112, § 24, is registered by the Massachusetts Board of Registration in Pharmacy to practice pharmacy.

Pharmacy. A physical or electronic facility under the direction or supervision of a Registered Pharmacist that is authorized to dispense Prescription Drugs.

Pharmacy Benefit Management Services. Services performed by a PBM or any Affiliated entity, including but not limited to:

(a) negotiating the price of Prescription Drugs, including negotiating and contracting for direct or indirect Rebates, discounts or other price concessions;

(b) 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 Services, 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;

(c) performance of any administrative, managerial, clinical, pricing, financial, reimbursement, data administration or reporting or billing service related to a Health Benefit Plan's Prescription Drug Benefit; and

(d) such other services as the Division may define in 211 CMR 157.00 or other regulation.

Pharmacy Benefit Manager or PBM. A Person, business or other entity, however organized, that directly or through a Subsidiary provides Pharmacy Benefit Management Services for Prescription Drugs and devices on behalf of a Health Benefit 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 Benefit Plan Sponsor unless otherwise specified by the Division. Persons, businesses, or entities performing any actions under this definition are subject to all licensure and enforcement requirements under 211 CMR 157.00 and M.G.L. c. 176Y.

Pharmacy Benefit Plan or Pharmacy Benefit Program or Program. A plan or program that pays for, reimburses, covers the cost of, or otherwise provides for Pharmacy Services under a Health Benefit Plan or Program.

Pharmacy Services. Products, goods, and services or any combination of products, goods, and services provided as part of the practice of pharmacy.

Pharmacy Services Administrative Organization or PSAO. An entity that provides administrative services to independent Pharmacies, including but not limited to administrative, contract, and payment efficiencies, and collective bargaining and contract negotiations with PBMs and Carriers.

Plan Sponsor or Sponsor. A group purchaser, an employer in the case of an employee Health Benefit Plan established or maintained by a single employer; or an employee organization in the case of a health plan established by or maintained by an employee organization, an association, joint board of trustees, a committee or other similar group that establishes or maintains the health plan.

Prescription Drug. Any substance prescribed by a properly licensed Health Care Professional and used for medicinal purposes. For purposes of 211 CMR 157.00, Prescription Drugs shall include biosimilars, biologics and vaccines.

Provider. Any professional Person, organization, Pharmacy, or other Person, entity, or institution subject to licensure for delivery or furnishing of Pharmacy Services.

Rebate. Any discount offered by a pharmaceutical manufacturer or PBM or related entity to a payer after a Prescription Drug is purchased, including but not limited to payers that may be Carriers, PBMs, employers, and Covered Persons. Rebate includes all payments that accrue to a PBM or its Pharmacy Benefit Plan or Program client or an Affiliated Group Purchasing Organization, directly or indirectly, from a pharmaceutical manufacturer, including, but not limited to, discounts, administration fees, credits, incentives, or penalties associated directly or indirectly in any way with claims administered on behalf of a Pharmacy Benefit Plan of program client. It includes any discount or other concession, or a payment that is

(a) based on utilization or a Prescription Drug and

(b) paid by a manufacturer or third-party, directly or indirectly, to a PBM, Pharmacy Services Administrative Organization, or Pharmacy, after a claim has been processed and paid at a Pharmacy. Rebate includes without limitation incentives, disbursement, and reasonable estimates of a volume-based discount.

Service Area. The geographical area within which the PBM has developed a Network of Pharmacies to afford adequate access for covered Pharmacy Services.

Specialty Drug. Specialty Drugs means a drug that provides treatment for serious, chronic, or life-threatening diseases that is covered under a patient's health plan or by a patient's carrier to which any of the following apply:

(a) the cost of the drug exceeds the drug cost threshold established by CMS under the Medicare Part D Program;

(b) the drug requires special administration, including, but not limited to, injection, infusion or inhalation;

(c) the drug requires unique storage, handling or distribution,

(d) the drug requires special oversight, intensive monitoring, complex education, and support or care coordination

Spread Pricing. The practice in which a PBM charges a Pharmacy Benefit Plan or Program or similar program a different amount for Pharmacy Services than the amount for Pharmacy Services that the PBM reimburses a Pharmacy for such Pharmacy Services.

Subsidiary. An Affiliate controlled by a Person directly or indirectly through one or more intermediaries.

Utilization Review. 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, including, for purposes of 211 CMR 157.00, Pharmacy Services.

Utilization Review Organization. An entity that conducts Utilization Review under contract with or on behalf of a Carrier or PBM, but it does not include a Carrier performing Utilization Review for its own Health Benefit Plans. A PBM is a Utilization Review Organization if it conducts Utilization Review.

Wholesaler. A Person or entity that sells and distributes prescription pharmaceutical products, including, but not limited to, a full line of brand-name, generic, and over-the counter pharmaceuticals, and which offers regular and private delivery to a Pharmacy.

157.03: Licensing

Pursuant to M.G.L. c. 176Y, no Person shall establish or operate as a Pharmacy Benefit Manager within the Commonwealth of Massachusetts without first obtaining a license from the Division in accordance with 211 CMR 157.00. In order to protect the interests of consumers, the Commissioner may refuse to issue or renew a license, or otherwise limit the conditions of licensure, if the Commissioner finds that the applicant is not competent, trustworthy, or financially responsible.

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(1) Application for Licensure. Each PBM or organization providing Pharmacy Benefit Management Services seeking licensure pursuant to M.G.L. c. 176Y and 211 CMR 157.00 for a three-year term effective beginning January 1, 2027 and thereafter is required to submit an application that contains at least the following information in a format specified by the Commissioner:

(a) Key Contact Information.

1. The name, address, and contact phone number of the applicant.

2. The name, address, phone number, email address, and title of the employee who will serve as the Division's primary contact for the applicant.

3. The name and address of the agent of the applicant for service of process in the Commonwealth or a power of attorney authorizing the Commissioner to accept service of process for any legal actions commenced against a PBM not domiciled in the Commonwealth of Massachusetts.

(b) Internal Operations Plan and Governance.

1. A copy of the basic organizational documents, such as articles of incorporation, articles of association, partnership agreement, trust agreement, or any other applicable document establishing the PBM and all amendments thereto, and other documents as necessary, including but not limited to:

a. the applicant's federal employer identification number;

b. proof that the applicant is registered with the Secretary of the Commonwealth; and

c. A copy of the bylaws, rules and regulations, or other similar documents regulating the conduct of the applicant's internal affairs.

2. A document signed by an authorized official of the applicant that indicates that no officer with management or control of the PBM has been convicted of a felony or has violated any of the requirements of state law applicable to PBMs, or, if the applicant cannot provide such a statement, a signed statement describing any relevant conviction or violation.

3. The name, address, official position, and professional qualifications of each individual who is responsible for the conduct of the affairs of the PBM, including all members of the board of directors, board of trustees, executive committee, other governing board or committee, the principal officers in the case of a corporation, the partners or members in the case of a partnership or association, including but not limited to the name, principal occupation, and employer of each such person.

4. Biographical affidavits (OMITTING SOCIAL SECURITY NUMBERS) for all officers, directors, trustees, and key managerial personnel of the applicant, in a manner consistent with the National Association of Insurance Commissioners' biographical affidavits.

5. A copy of the organizational chart with titles in the areas of marketing, administration, enrollment, Grievance procedures, quality assurance, contract negotiation, and financial matters.

6. If the applicant is a member of a holding company, an organizational chart displaying all parents, Subsidiaries, and Affiliates of the applicant.

7. A narrative of the applicant's organizational structure; a detailed description of any material ownership interest(s) (defined as 10% or more) in any Subsidiary, parent, Affiliate, aggregator, rebate aggregator, carrier, Pharmacy, drug manufacturer, 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, including but not limited to Maximum Allowable Cost appeal methodologies.

8. A statement signed by an authorized official of the applicant disclosing at least a 10% ownership interest, held either directly or indirectly or through an Affiliate, holding company, Subsidiary, or other Person or entity by any insurance carrier in the PBM, or any ownership interest, held either directly or indirectly or through an Affiliate, holding company, or Subsidiary by the PBM in an insurance Carrier.

9. Disclosure of any ownership interest, either directly or indirectly or through any Affiliate, holding company, or Subsidiary in a Pharmacy or Mail-Order Pharmacy that is part of the PBM's network.

10. A Certificate of Insurance of professional liability insurance of all officers and any employees; and

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11. A statement of insurance or self-funded insurance coverage for:
a. Protection against loss of property and liability of the PBM; and
b. Workers' compensation to protect against claims arising from work-related injuries; and
c. medical malpractice liability insurance of the PBM and Providers.

(c) Financial Plan.
1. Audited financial statements specific to the applicant, including but not limited to, audited financial reports, maintained and prepared in accordance with generally accepted accounting principles prescribed or permitted by the Commissioner, for at least the prior three fiscal years, if applicable, of the PBM's existence.
2. Financial statements as listed in 211 CMR 157.04(1)(a)2, which project the results of operations for the next three calendar years:
a. balance sheet;
b. statement of revenues and expenses;
c. statement of changes in capital;
d. cash flow;
e. capital expenditure; and
f. repayment schedule for existing or anticipated loans or alternative financing arrangements.
As applicable, the format shall be consistent with that specified for the information and reports required to be filed with the Commissioner pursuant to 211 CMR 157.04.
3. A statement of the applicant's accounting system and organization, management and internal controls, and processes and procedures to address customer service needs in the Commonwealth, including but not limited to those for addressing consumer Complaints in a timely and effective manner.
4. Certification that a PBM shall maintain adequate books and records about each purchaser for which the PBM provides Pharmacy Benefit Management Services, in accordance with prudent standards of record keeping, for the duration of the agreement between the PBM and the purchaser, and for three years after the PBM ceases to provide Pharmacy Benefit Management Services for the purchaser.
5. A statement and supporting analysis indicating when the PBM estimates that income from Massachusetts operations will equal or exceed related expenses, and analysis explaining in detail if the PBM does not estimate that such income will exceed related expenses.
6. All projections, estimates, reviews, and analyses must be accompanied by detailed statements of underlying assumptions used and the bases thereof, and further including, any independent evaluations and assessment of these statements.
7. A listing of shareholders or members or other equity holders or members with holdings of 10% or more of capital shares, partnership interest or other evidence of equity holdings, by name, address, number, and percentage of shares or other interest held and any other affiliations with the PBM.
8. Letters of financial support, credit, bond, or loan guarantee or other financial guarantee to the applicant and any supporting information and limitations thereon.
9. A statement of fidelity bond coverage of all officers and any employees entrusted with the handling of funds.
10. A list with names, address, phone number, and email contact information for each Carrier, Plan Sponsor, and workers' compensation insurance carrier that is a PBM client or contracted entity in the Commonwealth of Massachusetts, and a description of the projected number of enrollees and plan subscribers to be administered by the PBM in Massachusetts for each Carrier client or contracted entity, Plan Sponsor client or contracted entity, and workers' compensation insurance carrier client or contracted entity.

(d) Service and Utilization Plan.
1. A service and utilization plan consistent with Massachusetts law describing the following with respect to the PBM's operations in Massachusetts:
a. the Service Area of the PBM;
b. serviced health insurers or accounts serviced by the PBM;
c. the anticipated persons and population size to be serviced by the PBM;

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d. existing utilization rates for Pharmacy Services in the PBM's Massachusetts Service Areas; and

e. an up-to-date inventory of owned, operated, contracted, or participating pharmacies.

2. Description of the PBM's policies and procedures for validating that a Pharmacy satisfies the PBM's selection or credentialing requirements for participating in the PBM's Network, including but not limited to identification and explanation of the standards (*e.g.*, NCQA), the process and timelines for credentialing or recredentialing, and the PBM's documentation retention requirements for the process.

3. Documentation demonstrating the PBM's policies and procedures for adherence to Utilization Review requirements consistent with applicable state and federal law, including but not limited to 211 CMR 52.00: *Managed Care Consumer Protection and Accreditation of Carriers*.

4. If applicable, the total number and amount of all claims paid for Massachusetts residents for the most recent calendar year.

(e) Operational Reports. Each PBM or organization providing Pharmacy Benefit Management Services seeking licensure by the Division must demonstrate compliance with the reporting requirements set forth in 211 CMR 157.04(2) as follows, unless exempted in accordance with 211 CMR 157.04(3):

1. For new licensure applicants, initial submission of the reporting requirements.

2. For licensure renewal applicants, compliance with the reporting requirements.

(f) Quality Assurance and Standards. A detailed description of the quality assurance system, including but not limited to any quality certifications, or a certification that the description of the quality assurance system. Additionally, a PBM's application should explain its quality management and improvement systems and whether it meets applicable NCQA Standards for quality management and improvement.

(g) Signature and Certification. Completed signature and certification in a form as may be specified by the Commissioner. Such signature and certification shall include a certification signed by a corporate officer specifying compliance with the provisions of M.G.L. c. 176Y, 211 CMR 157.00, as well as all reporting or other applicable requirements of the Center for Health Information and Analysis and the Health Policy Commission, as provided in St. 2024, c. 342, and any related statute, regulation, or sub-regulatory guidance promulgated or issued by said agencies in implementation thereof.

(h) Miscellaneous.

1. Any other information deemed necessary and requested by the Commissioner.

2. The following documents may be requested by the Commissioner, but need not be submitted unless such request is made:

a. Current financial statements for guarantors of the PBM's contractual obligations;

b. Current financial statements for Persons or Providers or corporate entities which have contracted with the PBM for the provision of medical, administrative, or marketing services, audited if available; and

c. Copies of the PBM's contractual arrangements, including but not limited to a copy of the forms of group contracts with Carriers, a copy of the forms of group contracts with Pharmacies, and a copy of every contract form made or to be made between the applicant and any Providers of Pharmacy Benefit Management Services. For purposes of 211 CMR 157.03(1)(h)2.c., "contract form" means a single copy of each generic contract used for each type of Carrier, Pharmacy, or other applicable term, and not a copy of every individual contract signed between the PBM and each respective Carrier, Pharmacy, or other.

(i) Filing Fee. For licensure applications and renewals submitted in accordance with 211 CMR 157.03, a complete application shall include a non-refundable filing fee of $25,000.00.

(2) Material Changes. An applicant or PBM shall report to the Division any Material Change to the information contained in its application, certified by an officer of the PBM, within 30 Days of such a change.

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(3) Timeline and Review of Application. Renewal applications must be submitted by July 1st for a renewal date of January 1st of the subsequent year. Upon receipt of a complete application, the Commissioner shall review the submitted material to determine whether a license shall be granted or renewed. The organization must demonstrate evidence of meeting all requirements set forth in M.G.L. c. 176Y and 211 CMR 157.00. Unless otherwise determined by the Commissioner, the Division will notify all PBMs regarding the status of their PBM license applications by December 1st of the year in which a timely and complete application has been submitted.

(4) Approval of License. Each license issued in accordance with M.G.L. c. 176Y and 211 CMR 157.00 shall remain in effect for 36 months unless as otherwise specified by the Commissioner.

(5) Denial of License. If an application for a license is denied, the Commissioner shall notify the organization in writing, stating the reason(s) for the denial. The organization shall have the right to a hearing on its application within 30 Days of its receipt of such notice by filing a written request for a hearing within 15 Days of its receipt of such notice. The purpose of the hearing shall be to determine the reasonableness of the Division's action, and the hearing shall be held pursuant to M.G.L. c. 30A. Within 30 Days after the conclusion of the hearing, the Commissioner shall either grant a license or shall notify the organization in writing of the denial of a license stating the reason(s) for the denial. The organization shall have the right to judicial review of the Commissioner's decision in accordance with the provisions of M.G.L. c. 30A, § 14.

(6) Nonrenewal of License. If an application for a license renewal is denied, the Commissioner shall notify the organization in writing, stating the reason(s) for the nonrenewal. The organization shall have the right to a hearing on its application within 30 Days of its receipt of such notice by filing a written request for a hearing within 15 Days of its receipt of such notice. The purpose of the hearing shall be to determine the reasonableness of the Division's action, and the hearing shall be held pursuant to M.G.L. c. 30A. Within 30 Days after the conclusion of the hearing, the Commissioner shall either renew the license or shall notify the organization in writing of the nonrenewal of a license stating the reason(s) for the nonrenewal. The organization shall have the right to judicial review of the Commissioner's decision in accordance with the provisions of M.G.L. c. 30A, § 14.

(7) License Suspension, Revocation, Limitation, or Probation.

(a) The Commissioner may suspend, revoke, limit, or place on probation a license issued to a PBM under M.G.L. c. 176Y and 211 CMR 157.00, if the Commissioner finds any of the following conditions, upon examination or other evidence submitted to the Division, in the discretion of the Commissioner.

1. The PBM is required to have a license and fails to meet any qualification for issuance of a license or any other condition, including but not limited to the PBM failing to pay a renewal fee for a license;
2. The PBM's license has been suspended or revoked in another state;
3. The PBM is insolvent or is in an unsound financial condition;
4. The PBM's business policies or methods are unsound or improper;
5. The PBM's condition or management is such as to render its further transaction of business hazardous to the public or its customers, including but not limited to the Division receiving consumer complaints that justify an action to protect the health, safety and interests of consumers;
6. The PBM is not exercising good faith and fair dealing in the performance of contractual duties, or it is transacting business fraudulently, or it has been found to be engaging in fraudulent activity that is found by a court of law to be a violation of state or federal law;
7. The PBM or its officers, representatives, Affiliates, agents, or subcontractors have refused to timely file any report or produce any other information requested by the Commissioner or by the Center for Health Information and Analysis under M.G.L. c. 12C, § 10A;

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8. The PBM or its officers, representatives, Affiliates, agents, or subcontractors have failed to submit to an examination under M.G.L. c. 176Y, § 3, or to produce accounts, records, and files for an examination, or if any individual responsible for the conduct of affairs of the PBM has refused to give information with respect to its affairs, or if the PBM has refused to perform any other legal obligation as to an examination as required by the Commissioner;

9. Any individual responsible for the affairs of the PBM has been convicted of, or has entered a plea of guilty or nolo contendere, to any felony, including but not limited to situations where there is a withheld adjudication or the court does not formally enter a conviction;

10. The PBM has violated any lawful order of the Commissioner and any law of this Commonwealth applicable to the PBM; or

11. The PBM substantively fails to comply with the requirements of M.G.L. c. 176Y, 211 CMR 157.00, or any other provision of applicable law or regulation.

(b) Prior to taking any action pursuant to 211 CMR 157.03(7), the Commissioner shall notify the PBM in writing of his or her intention to take action and afford the PBM an opportunity for a hearing on the matter, pursuant to M.G.L. c. 30A.

(c) Following a hearing, the Commissioner shall notify the PBM in writing of any decision regarding the revocation or suspension of its license or of its license being limited or placed on probation. The PBM has the right to judicial review of the Commissioner's decision in accordance with the provisions of M.G.L. c. 30A, § 14.

157.04: Reporting

(1) Audited Annual Financial Reports. As a condition of licensure under M.G.L. c. 176Y and 211 CMR 157.00, all PBMs shall have an annual audit by a qualified, independent certified public accountant and shall file an audited financial report with the Commissioner, on or before June 1st for the preceding fiscal year. Extensions of the filing date may be granted by the Commissioner for 30-day periods upon a showing by the PBM or its independent certified public accountant of valid justification for such extension. The request for any extension must be received prior to the due date of the audited financial report and must contain sufficient detail to permit the Commissioner to make an informed decision with respect to the requested extension.

(a) The report shall include:

1. Opinion of the Independent Certified Public Accountant.

2. Audited Financial Statements, including:

a. balance sheet;

b. statement of revenues and expenses;

c. statement of cash flows;

d. statement of changes in capital; and

e. notes to financial statements.

f. In general, and except as otherwise provided herein, the financial statements filed pursuant to 211 CMR 157.04(1) should be prepared as follows:

i. The financial statements shall be comparative, presenting the amounts as of the last date of the current year and the amounts as of the year end immediately preceding.

ii. If the PBM is included in consolidated or combined financial statements, such financial statements must also be included in the filing of the audited financial report. A PBM may make written application to the Commissioner for approval, at the Commissioner's discretion, to file an annual audited consolidated or combined financial report in lieu of a separate annual audited financial report for the PBM. In such cases, and in cases of PBMs that have Subsidiaries that are consolidated, the annual audited financial report shall include a columnar consolidating or combining worksheet, as follows:

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(i) amounts shown on the consolidated or combined audited financial report shall be shown on the worksheet;
(ii) amounts for the PBM shall be stated separately;
(iii) non-PBM operations may be shown on the worksheet on a combined or individual basis; and
(iv) explanations of consolidating and eliminating entries shall be included.

iii. A reconciliation shall compare the amounts shown in the PBM columns of the worksheet with comparable amounts in the PBM's annual statement of financial condition.

3. Report of Significant Deficiencies in Internal Controls. In addition to the annual audited financial statements, each PBM shall furnish the Commissioner with a written report prepared by the accountant describing significant deficiencies in the PBM's internal control structure noted by the accountant during the audit. SAS No. 60, Communication of Internal Control Structure Matters Noted in an Audit (AU Section 325 of the *Professional Standards of the American Institute of Certified Public Accountants*) requires an accountant to communicate significant deficiencies (known as "reportable conditions") noted during a financial statement audit to the appropriate parties within an entity. No report need be issued if the accountant does not identify significant deficiencies. If significant deficiencies are noted, the written report shall be filed annually by the PBM with the Division. The PBM is required to provide a description of remedial actions taken or proposed to correct significant deficiencies, if such actions are not fully described in the accountant's report.

(b) Availability and Maintenance of Working Papers of the Independent Certified Public Accountant. The PBMs shall require the independent certified public accountant to make available for review by the Commissioner or the Commissioner's appointed agent, the work papers prepared in the conduct of the audit, which shall include the PBM's parent and Affiliates as they relate to the examination of the PBM. The PBM shall require that the accountant retain the audit work papers for a period of not less than five years after the period reported upon. The records of any such audit, examination, or other inspection, and the information contained in the records, reports, or books of a PBM reviewed by the Commissioner or the Commissioner's appointed agent shall be confidential pursuant to M.G.L. c. 176Y, § 3(e).

(c) Notification of Adverse Financial Condition. A PBM subject to 211 CMR 157.00 shall require the independent certified public accountant to immediately notify in writing an officer and all members of its Board of Directors of any determination by the independent certified public accountant that the PBM has materially misstated its financial condition as reported to the Commissioner for the fiscal year end immediately preceding. The PBM shall furnish such notification to the Commissioner within five Days of receipt thereof. If the accountant, subsequent to the date of the audited financial report filed pursuant to 211 CMR 157.04(1)(a)2, becomes aware of facts which would have affected the accountant's report, the Commissioner notes the obligation of the accountant to take such action as prescribed by Section 561 of the *Statement of Auditing Standards Number One* of the American Institute of Certified Public Accountants.

(2) Operational Reports. Unless otherwise reported to the Center for Health Information and Analysis, prior to and as a condition of continuing licensure, PBMs shall submit the following reports to the Commissioner on an annual basis, unless otherwise specified below:

(a) A detailed explanation, along with any supporting documentation, with respect to the following activities, as it pertains to the PBM's business in Massachusetts:

1. Spread Pricing, including but not limited to any related business where there is any difference between PBM payments to or from Pharmacies and PBM payments to or from contracted entities or Covered Persons;

2. A copy of the policies and procedures that demonstrate the PBM has established processes concerning Maximum Allowable Costs lists, including but not limited to appeal processes;

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3. Steering or steerage;
4. Prioritizing of particular drugs or groups of drugs with respect to any other PBM, Pharmacy, drug manufacturer or other Person or entity;
5. Exclusion of or limitation of particular drugs or groups of drugs with respect to any other PBM, Pharmacy, drug manufacturer or other Person or entity;
6. Contract or other provision whereby part of a Covered Person's copay goes back to PBM, including but not limited to claw backs;
7. Mid-year drug price changes of any kind during the previous 24 months;
8. Rebates to Subsidiaries, related entities, consultants, vendors, negotiating or cooperative organizations, drug manufacturers, PSAOs, contracted entities, or Covered Persons, including but not limited to incentive or other payments, paybacks, or negotiations related to other PBMs, Pharmacies, payers, drug manufacturers or other Person(s) or entity(s) to lower or raise the net cost of a drug or incentivize its inclusion on/exclusion from preferred formulary lists;
9. Copay accumulators;
10. Fees or remittances;
11. PBM right of first refusal to purchase Pharmacy;
12. Interactions, agreements, discussions, or collaboration with any other PBM.

(b) For the period of the prior three years, and on an annual basis thereafter, the following information on Rebates:
1. A statement of the aggregate amount of Rebates received by a PBM;
2. The aggregate amount of Rebates distributed by a PBM to an appropriate health care payer; and
3. The aggregate amount of Rebates passed on to an enrollee of each health care payer at the point of sale that reduced the enrollee's applicable deductible, copayment, coinsurance or other cost-sharing amount.

(c) For the period of the prior three years, and on an annual basis thereafter, the following information on reimbursement:
1. A statement of the individual and aggregate amount paid by a health care payer to the PBM for Pharmacy Services itemized by Pharmacy, product, and goods and services, including other Prescription Drug or device services; and
2. The individual and aggregate amount a PBM paid for Pharmacy Services itemized by Pharmacy, product, and goods and services, including other Prescription Drug or device services.

(d) On at least a semi-annual basis, a report including:
1. The overall aggregate amount charged to a health plan for all pharmaceutical claims processed by the PBM; and
2. The overall aggregate amount paid to Pharmacies for claims processed by the PBM.

(e) On at least an annual basis, a report including:
1. The aggregate wholesale acquisition costs from a manufacturer or wholesale distributor for each therapeutic category of drugs for the PBM's Massachusetts Plan Sponsors, net of Rebates and other fees and payments, direct or indirect, from all sources;
2. The aggregate amount of Rebates that the PBM received from all manufacturers for the PBM's Massachusetts Plan Sponsors. The aggregate amount of Rebates must include any utilization discounts the PBM receives from a manufacturer or wholesale distributor;
3. The aggregate amount of all fees that the PBM received;
4. The aggregate amount of Rebates that the PBM received from all manufacturers that were not passed through to Massachusetts health plans or insurers;
5. The aggregate amount of fees that the PBM received from all manufacturers that were not passed through to Massachusetts health plans, Carriers or insurers;
6. The aggregate retained Rebate percentage from business conducted in the state;
7. All of the following information attributable to patient use of Prescription Drugs covered by Massachusetts health plans:
a. the aggregate amount of Rebates and fees that the PBM received from manufacturers;

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b. the aggregate amount of Rebates and fees that the PBM received from manufacturers that were either passed through to Massachusetts health plans or enrollees at the point of sale of a Prescription Drug, or retained by the PBM; and

c. aggregate amount passed on to the enrollees of each healthcare payor at the point of sale that reduced the enrollees' applicable deductible, copayment, coinsurance, or other cost-sharing amount.

(f) On a quarterly basis, the PBM shall produce a report to the Commissioner of:

1. All drugs appearing on the national average drug acquisition cost list reimbursed 10% and below the national average drug acquisition cost; and

2. All drugs appearing on the national average drug acquisition cost list reimbursed 10% and above the national average drug acquisition cost.

For each drug listed in the quarterly report, a PBM shall include:

1. The month the drug was dispensed;
2. The quantity of the drug dispensed;
3. The amount the Pharmacy was reimbursed;
4. Whether the dispensing Pharmacy was an Affiliate of the PBM;
5. Whether the drug was dispensed pursuant to a government health plan; and
6. The average national drug acquisition cost for the month the drug was dispensed.

The quarterly report shall exclude drugs dispensed pursuant to 42 U.S.C. § 256b. A copy of the quarterly report shall be published on the PBM's publicly available website for a period of at least 24 months.

(3) Exemptions. Upon written application of any PBM, the Commissioner may grant an exemption from compliance with the requirements set forth in 211 CMR 157.04 or portions thereof if the Commissioner finds, upon review of the application, that compliance with 211 CMR 157.04 would constitute a financial or organizational hardship upon it or its independent certified public accountant. An exemption may be granted at any time for any specified period.

(4) Material Changes. All Material Changes to information reported pursuant to this section shall be submitted to the Commissioner on or before their effective dates. Failure to timely inform the Commissioner of a Material Change shall be considered a violation of M.G.L. c. 176Y and 211 CMR 157.00 and may result in fines being assessed against the PBM pursuant to M.G.L. c. 176Y, § 2(h).

(5) Additional Information or Reports. The Commissioner, if he or she so determines the need exists, may require the PBM to submit additional information or reports, other than, and in addition to, those reports specifically required by 211 CMR 157.04.

(6) Compliance. Failure to comply with any of the requirements 211 CMR 157.04 shall be considered a violation of M.G.L. c. 176Y and 211 CMR 157.00 and may result in fines being assessed against the PBM pursuant to M.G.L. c. 176Y, § 2(h).

157.05: Contracts between PBMs and Pharmacies.

Contracts between PBMs and Pharmacies shall contain the following provisions:

(1) Contracts between PBMs and Pharmacies shall incorporate all provisions of M.G.L. c. 175, § 226 and require that the PBM is in compliance with all such provisions, including but not limited to establishing an appeals process consistent with M.G.L. c. 175, § 226.

(2) A PBM shall not prohibit a Pharmacist from dispensing any Prescription Drug or over-the-counter medicinal product that is legally available within the Commonwealth.

(3) Termination of a Pharmacy or Pharmacist from a PBM Network shall not release the PBM from the obligation to make any payment due to the Pharmacy for Pharmacy Services properly rendered.

157.06: Contracts between PBMs and Carriers.

Beginning January 1, 2026, a Carrier may contract for Pharmacy Benefit Management Services in Massachusetts only with a Pharmacy Benefit Manager licensed by the Division. Contracts between PBMs and Carriers shall contain the following provisions:

(1) A PBM:
(a) may not sell a list of patients that contains information through which the identity of an individual patient is disclosed, unless the sale is permitted by and compliant with applicable law;
(b) shall maintain all data that identifies a Covered Person in a confidential manner that prevents disclosure to a third-party unless the disclosure is otherwise permitted by law or authorized by the Covered Person;
(c) 211 CMR 157.06 does not prohibit a PBM from:
1. engaging in general advertising about a specific pharmaceutical product or service; or
2. responding to the request and receipt by a person of information regarding
a. a specific pharmaceutical product or service,
b. the person's own records or claims, or
c. the person's dependent's records or claims.

(2) A PBM shall provide notice to employers and carriers about any changes to formularies included in plan Benefits.

157.07: Pharmacy Information, Network Information and Service Level Requirements.

(1) PBMs shall establish appropriate systems to collect, store, and maintain detailed information about each Pharmacy within their Pharmacy Network systems. The systems are to be developed in a manner that facilitates a Pharmacy's ability to update relevant information to the maximum extent feasible. PBMs shall ensure that Pharmacy Network lists include information for persons covered by plans providing services through Networks of Pharmacies about how they may obtain in Network care from an out of Network Pharmacy when an in Network Pharmacy is not available. The PBM shall ensure accessibility in the time and manner that a patient may obtain covered Pharmacy Services within a reasonable distance from a patient's residence. A Network shall not be comprised only of Mail-order Pharmacies but must have a mix of Mail-order Pharmacies and physical stores in Massachusetts. A Mail-order Pharmacy shall not be included in the calculations determining PBM Network adequacy.

(2) The detailed information that the PBM is required to collect, store, and maintain about Pharmacies which are a part of the PBM's Network, shall include at least the following information for each Pharmacy:
(a) operating hours for each location, including evenings and weekends;
(b) main phone number(s) available for use by Covered Persons;
(c) all languages understood or spoken by the Pharmacy personnel;
(d) whether the Pharmacy setting is ADA accessible and a description of the accommodations available to address physical, developmental, and intellectual disabilities;
(e) whether the Pharmacy has conditions, including the following:
1. if a Pharmacy is limited to hospital or facility inpatients;
2. for Pharmacies within clinics or community health centers, requiring that a patient receive other health care at the clinic or community health center; or
3. for Pharmacies at university or school health centers, requiring that patients are enrolled students in the university or school.

(3) PBMs shall ensure the accuracy of the required information on Pharmacies and Networks, and Pharmacy information should be audited to ensure accuracy on at least an annual basis, or as directed by the Commissioner. PBMs shall initiate these required audits no later than the start of the second calendar quarter after these regulations are promulgated in final form.

(4) PBMs will maintain files of all Pharmacy audits for no less than seven years from the completion of any audit so that they may be reviewed by Division staff upon request.

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(5) A PBM shall maintain a toll-free telephone number such that consumers may request and obtain information about applicable Pharmacy Networks and cost, including but not limited to cost-sharing, in a clear and accessible manner, in real time, and a consumer-facing website.

(6) In accordance with 211 CMR 157.07(3) and a schedule as determined by the Commissioner, a PBM shall file for each health plan that the PBM services in Massachusetts, a list describing the Network of Pharmacies that the PBM offers in Massachusetts. The PBM shall update an existing list whenever the PBM makes any Material Change to such a list. Accompanying the list, PBMs shall describe or demonstrate at least the following:

(a) The PBM's process for monitoring and assuring on an ongoing basis the sufficiency of the Network(s) to meet the needs of and protect consumers in its populations serviced in Massachusetts, including Network accessibility analyses (*e.g.*, GeoNetwork system analyses);

(b) The PBM's efforts to address the ability of the Network(s) to meet the needs of individuals serviced with limited English proficiency and illiteracy, with diverse cultural and ethnic backgrounds, or with disabilities;

(c) If, at any time, the PBM becomes aware of changes to the numbers of Pharmacies within its Network list that would cause the PBM to not meet its level of service in the Commonwealth, then within 30 Days of becoming aware the PBM will submit a corrective action plan for the Commissioner's review and approval that will identify the steps that the PBM will take to address the geographic areas where it is not meeting its service level requirement(s) and how the PBM plans to address access to care in those areas until Network changes are made so that the PBM can once again satisfy its service level requirement(s) for access to Pharmacy Services; and

(d) Any other information required by the Commissioner to determine compliance with the provisions of 211 CMR 157.07.

157.08: Conflicts of Interest

(1) A licensed PBM shall notify a Carrier in writing of any activity, policy, practice, contract, or arrangement of the PBM that directly or indirectly presents any conflict of interest with the PBM's relationship with or obligation to the Carrier, or which conflicts with duties imposed by 211 CMR 157.00 or the Commissioner.

(2) A PBM shall not make payments to a pharmacy benefit consultant or broker whose services were obtained by a Health Benefit Plan Sponsor to work on the Pharmacy benefit bidding or contracting process if the payment constitutes a conflict of interest, as determined by the Commissioner. For purposes of 211 CMR 157.08, payments from a PBM to a pharmacy benefit consultant or broker shall include, but not be limited to:

(a) shared Rebates from pharmaceutical manufacturers;

(b) per prescription fees;

(c) per member fees;

(d) referral fees;

(e) bonuses; or

(f) any other financial arrangement the Commissioner considers to be a conflict of interest, as may be specified in written policies or procedures.

157.09: Books and Records

Every PBM shall keep and maintain its books of account and other records on a current basis and within Massachusetts. In addition, every PBM shall make, or cause to be made, and retain books and records which accurately reflect:

(1) All contracts with Carriers requested by the Commissioner and all other contracts entered into by the PBM; and

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(2) Every PBM shall preserve for a period of not less than five years the books of account and other records required under the provisions of, and for the purposes of 211 CMR 157.00. After such books and records have been preserved for two years in an easily accessible place at the main offices of the PBM, they may be stored for the remainder of the five-year period subject to their availability to the Commissioner not more than five Days after he or she may request them.

157.10: Penalties

(1) If the Commissioner issues a Finding of Neglect on the part of a PBM, the Commissioner shall notify the PBM in writing that the PBM has failed to make and file the materials required by M.G.L. c. 176Y or 211 CMR 157.00 in the form and within the time required. The notice shall identify all deficiencies and the manner in which the neglect must be remedied. Following the written notice, the Commissioner shall fine the PBM $5,000 for each Day during which the neglect continues.

(2) Following notice and hearing, the Commissioner shall suspend the PBM's authority to do new business until all required reports or materials are received in a form satisfactory to the Commissioner and the Commissioner has determined that the Finding of Neglect can be removed.

(3) If a Person, business or other entity performs Pharmacy Benefit Management Services in violation of M.G.L. c. 176Y or 211 CMR 157.00, the Person, business or other entity shall be subject to a fine of $5,000 per Day for each Day that the Person, business or other entity is found to be in violation.

(4) A PBM that violates M.G.L. c. 176Y, 211 CMR 157.00, or any other rule or regulation promulgated pursuant to M.G.L. c. 176Y shall be subject to a fine of not less than $5,000 for each violation.

157.11: Severability

If any provision of 211 CMR 157.00 or application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions of 211 CMR 157.00 and, to that end, the provisions of 211 CMR 157.00 are severable.

REGULATORY AUTHORITY

211 CMR 157.00: M.G.L. c. 176Y, § 2(j).