

PHARMACY BENEFIT MANAGER LICENSURE APPLICATION CHECKLIST

This Checklist is not all-inclusive; it represents what information, at a minimum, a Pharmacy Benefit Manager (PBM) must submit when applying for licensure. The Department of Managed Health Care (Department) may request additional information as necessary during its review to make a finding under the Knox-Keene Health Care Service Plan Act of 1975, as amended.^{1, 2} The laws relating to PBMs may be found on the [Department's Pharmacy Benefit Manager Licensing page](#).

BACKGROUND:

A PBM³ must secure a license from the Department to engage in business as a PBM for a health care service plan licensed by the Department or health insurer licensed by the California Department of Insurance.^{4, 5} The Department requires the use of forms and processes similar to those required of health care service plan applicants, including Section 1351 and the forms and exhibits described in regulations, as amended, implementing that section, when determining whether to license a PBM. (Section 1385.009. See *also* Sections 1351, 1352, and Rule 1300.51.)

Address questions on whether any particular entity requires PBM licensure to:
PBM.Licensing@dmhc.ca.gov.

¹ Rule 1300.52.4 (a)(ii).

² California Health and Safety Code Sections 1340 et seq. (Act). References herein to “Section” are to Sections of the Health and Safety Code. References to “Rule” refer to the regulations promulgated by the Department, the California Code of Regulations, title 28. For PBM-specific provisions, see Article 6.1 of the Act.

³ “Pharmacy benefit manager” means a person, business, or other entity that, either directly or through an intermediary, affiliate, or both, acts as a price negotiator or group purchaser on behalf of a payer, or manages the prescription drug coverage provided by the payer, including, but not limited to, the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to prescription drug coverage, contracting with network pharmacies, or controlling the cost of covered prescription drugs. Section 1385.001(t)(1). See *also* Section 1385.001(t)(2)-(3), 1385.0034.

⁴ Section 1385.008.

⁵ References to “health care service plan” or “plan” in this Checklist have the same meaning as “payer” defined in Section 1385.001(m).

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GENERAL FILING INFORMATION:

- Application Submission: PBMs must submit filing information/documents/emails electronically through the Department's eFiling system. (See section below "Electronic Filing Requirements.")
- Application Fee: The PBM must reimburse the Department for the actual cost of processing the application, including overhead, up to an amount not to exceed twenty-five thousand dollars (\$25,000). Costs will be billed on a monthly basis and any payments are due within 30 days of the date of billing. The PBM will not be issued a license until the Department has received payment in full for all amounts charged in relation to application processing.⁶
- Improperly Filed Documents: The Department will not review improperly filed Applications and Exhibits. The PBM will be required to re-file and/or withdraw improperly filed Applications and Exhibits prior to review by the Department. (Section 1351.)
- Duration of Department Review: The duration of the Department's review will depend on the quality of the documents and information provided by the PBM, and the complexity of the filing. A complete, careful, and thorough initial application will limit delays. The PBM's ability to respond in a timely manner to requests from the DMHC for additional information, documentation and changes necessary to establish compliance may also impact the timeliness of the application process. The DMHC cannot guarantee licensure by a particular date.
- Confidentiality of Information. For an exhibit for which confidentiality is being requested (partial or entirely), the PBM must comply with Cal. Code Regs. tit. 28, § 1007, subd. (a), including submitting a separate, public Request for Confidentiality and filing the exhibit appropriately as public and confidential. (Please see the Request for Confidentiality Checklist posted in the eFiling system.) (Section 1385.0021, Rule 1007.)
- Designated Point of Contact. Once submitted, the filing will be assigned to an Office of Plan Licensing (OPL) attorney for review. This OPL attorney reviewer will be the filing's designated DMHC point of contact for the duration of the Department's review, unless the PBM is notified otherwise.

⁶ Section 1385.0016.

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ELECTRONIC FILING REQUIREMENTS:

- All filings, including the application for licensure, must be submitted electronically through the Department's eFile system pursuant to Rule 1300.41.8. This filing process is referred to as "eFiling."
- The PBM is required to provide the Department with the original hard copy of the Electronic Filing Signature Verification Contract form for a new "Signature Contract" only. This form verifies that prior to electronic submission, the PBM certifies, under penalty of perjury, that all statements within all documents filed electronically with the Department are true and correct.⁷ Electronic signatures may be used to sign a legally effective declaration under penalty of perjury.⁸
- Each PBM must assign an Administrator(s) who has the ability to provide web portal access by: Creating a New Account (add new staff), Edit Accounts (modify or delete existing accounts), Reset Accounts or monitor User Activity.
- To request an Electronic Filing Signature Verification Contract, or for more information on obtaining an eFiling Login and Password, please send an email to LicensingFiling@dmhc.ca.gov or call 916-324-9046.

PREPARING THE APPLICATION FOR FILING

- The application form and process requirements are set forth at Section 1385.009 and Rule 1300.51 and consist of exhibits requesting specific items of information from the PBM.⁹
- Submit one single application under filing type "Original Application for a PBM License." The Application description shall be titled "[PBM name] Application for Pharmacy Benefit Manager License."
- Each form and exhibit should be separately submitted within the same filing. In each exhibit, provide only information applicable to that exhibit. Do not bundle information and include in multiple exhibits.
- Submit each electronic exhibit under the correct exhibit title. If several exhibits are required under the same letter/number designation, add a sequential letter or Roman numeral as indicated in the following example.

⁷ Rule 1300.41.8(c)(2).

⁸ Rule 1300.41.8(c)(3).

⁹ Although Rule 1300.51 addresses applications for health care service plan or specialized health care service plan licenses, Section 1385.009 permits the Department to adopt these same forms and processes for PBM licensure.

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- Example: If Exhibit Q-1 calls for copies of the specified documents, an applicant employing three different documents would label them as follows: Exhibit Q-1-a; Exhibit Q-1-b; Exhibit Q-1-c.
- Include page numbers on all exhibits.
- Submit clearly legible electronic reproductions.
- The Department's eFiling system accepts the following electronic document types: .doc, .xls, .ppt, .rtf, .pdf, .jpg, .csv, .jpeg, .docx, .xlsx, .pptx, .txt, .gif, .wmv, .xml. There is a 15MB size limit per file and a 25MB total size limit when uploading multiple files.
- Review all proposed amendments prior to filing them to avoid errors and ensure consistency between exhibits.
- Amendments to the initial application must comply with Rule 1300.52, specifically, changes to the information previously filed must be redlined with both red-lined and clean versions submitted.
- This Checklist is provided for guidance and reference purposes only. The PBM is required to review and comply with the detailed requirements of the Knox-Keene Act and Title 28 Regulations and other applicable laws and Department guidance, such as DMHC All Licensee Letters (ALLs).

For questions concerning this checklist, please email PBM.Licensing@dmhc.ca.gov.

EXHIBITS TO FILE

This checklist is to assist a PBM applying for licensure as required by Section 1385.008. Specific requirements for each exhibit can be found within the Act and Rules (e.g., Sections 1351, 1385.009, 1385.0010 and Rule 1300.51).

Exhibit A-D: Execution Page

- A: Identification of PBM
- B: Type of Filing
- C: Type of PBM Contract(s)
- D: Contact Person

Exhibit D-2: Filings with Other Agencies

- If the PBM anticipates making or has made any related filing with any other state or federal agency, identify each agency, the nature, purpose, and date, or projected date, of each such filing.

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Exhibit E: Summary of Application

- E-1: Summary of eFiling Information** (Section 1385.009, Rule 1300.51(d)(E)(1).)
 - Within the Exhibit E-1:
 - List all exhibits within the “Exhibits to File” section of this checklist and indicate whether the PBM filed the exhibit. If the PBM omitted filing any exhibit, explain the omission next to the listed exhibit.
 - Summarize the PBM’s organizational structure and operations.
 - Provide the PBM’s legal name and any dba names.
 - Include the physical location (street address, city, state and country) of the PBM’s books and records related to corporate governance, claims, and accounting. Include the same information for books and records maintained by any entity performing claims and accounting services for the PBM.
 - Affirm the PBM's business practices and contracts comply with the applicable provisions of the Act and Rules, including the requirements of pharmacy benefit manager contracts and business practices set forth in Article 6.1 of the Act. (Section 1385.009(g).)
 - Affirm the PBM shall comply with all requirements for reporting data to the Department of Health Care Access and Information in accordance with this article and Chapter 8.5 (commencing with Section 127671) of Part 2 of Division 107. (Section 1385.009(h).)
- Subsequent and Amended Exhibits E-1: Summary of eFiling Information**
 - Any amendments to document(s) submitted in the initial application must be filed within the same open application filing for Department review. Submit the amended document(s) as the proper exhibit type. Each subsequent filing must also include an accompanying Exhibit E-1, as a separate exhibit, with any changes to the original Exhibit E-1 identified via highlight or strikeout, in accordance with Rule 1300.52(d).
- E-2: Business Plan** (Section 1385.009(i).)
 - Describe the PBM’s business operations, including its services, facilities and personnel.

Exhibit F: Organization and Affiliated Persons

- F-1: General Organization/Admin Info**

In the F-1, explain what form the legal entity is taking. The PBM is required to only submit forms related to the appropriate business structure of the PBM. Any forms are available in the Web Portal Download Section in eFiling.

 - **F-1-a-i: Articles of Incorporation** (Section 1385.009(a), Rule 1300.51(d)F(1).)
 - Include basic organizational documents, such as the articles of incorporation or other applicable documents, and all amendments to those documents.

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- **F-1-a-ii: Corporate Bylaws** (Section 1385.009(b), Rule 1300.51(d)F(1).)
 - Bylaws, rules and regulations, or similar documents regulating the conduct of the PBM's internal affairs.
- **F-1-a-iii: Corporation Information Form** (Section 1385.009(c), Rule 1300.51(d)F(1).)
 - Submit the related form, as applicable.
- **F-1-b-i: Partnership Agreement** (Section 1385.009(a), Rule 1300.51(d)F(1).)
 - Include basic organizational documents, such as the partnership agreement or other applicable documents, and all amendments to those documents.
- **F-1-b-ii: Partnership Information Form** (Section 1385.009(c), Rule 1300.51(d)F(1).)
 - Submit the related form, as applicable.
- **F-1-c: Sole Proprietor Information Form** (Section 1385.009(a), (b), (c), Rule 1300.51(d)F(1).)
 - Submit the related form, as applicable.
- **F-1-d: Misc Info Form** (Section 1385.009(a), Rule 1300.51(d)F(1).)
 - If the PBM is any other type of organization, include articles of association, trust agreement, or any other applicable documents, and any other organizational documents relating to the conduct of the internal affairs of the PBM.
- **F-1-f: Individual Information Sheet** (Section 1385.009(c), Rule 1300.51(d)F(1)(f).)
 - Anyone named in an F-1-a-iii, F-1-b-ii, F-1-c or F-1-d form must have a corresponding Individual Information Sheet.
- F-2-a: Affiliated Persons, Principal Creditors and Providers of Administrative Services** (Section 1385.009(c), Rule 1300.51(d)F(2).)
 - List of the names, addresses and official positions of persons who have loaned funds to the PBM for business operations.
- F-3: Other Controlling Persons** (Section 1385.009(c).)
 - Including any individual or entity not identified in any other exhibit that has any power, directly or indirectly, to manage, influence, administer the operations, or control the operations or decisions, of the PBM.
- F-4: Criminal, Civil & Administrative Proceedings** (Section 1385.009(d), Rule 1300.51(d)F(4).)
 - Statement whether, within the preceding 10 years, the PBM, its management company, an affiliate, a controlling person, officer, director, or other person occupying a principal management or supervisory position in the PBM, management company, or affiliate, or a person intended to

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hold that relationship or position, has been convicted of or pleaded nolo contendere to a felony, been held to have committed an act involving dishonesty, fraud, or deceit in a judicial or administrative proceeding to which the person was a party, or has had a license or certificate to operate as a PBM denied or revoked in another jurisdiction.

Exhibit G: Miscellaneous

- G-1: Form 1300.51.2 Consent Svc of Proc** (Section 1385.009(e).)
 - For PBMs not domiciled in California, complete the form found in Rule 1300.51.2, which is available in the Web Portal Download Section in eFiling. The form appoints the Department's director to accept service of process on the PBM's behalf.
- G-2: Disclosure of Financial Information** (Section 1385.0010.)
 - Complete the Customer Authorization of Disclosure of Financial Records form, which is available in the Web Portal Download Section in eFiling.

Exhibit EE: Actual and Projected Claims (Section 1385.0011(g).)

- EE-2: Actual and Projected Claims Count**
 - For operating PBMs, provide two years of actual claims count on a fiscal year basis and three years of projected claims count on a fiscal year basis.
 - For a new PBM, provide three years of projected claims count on a fiscal year basis.
- EE-3: Projections Assumptions & Sources**

Exhibit GG: Current Financial Viability

- GG-1: Financial Statements that demonstrate the PBM has adequate funding.**
 - **GG-1 -a: Audited Financial Statements** (Section 1385.009(f))
 - **GG-1 -b: Unaudited Financial Statements** (Section 1385.009(f))

Exhibit HH: Projected Financial Viability that is prepared in accordance with United States generally accepted accounting principles (also known to as "GAAP"). Projected financial statements include Balance Sheet, Income Statement, and Statement of Cash Flows

- HH-1: Pre-Operation Projection Fin Stmt** (Section 1385.009(f))
- HH-2: Pre-Operation Projection Fin Stmt** (Section 1385.009(f))
 - Monthly financial projections to be provided for the longer of one year or until the PBM reaches the break-even point.
 - Quarterly financial projections to be provided after the break-even point for one additional year.

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- The aforementioned financial projections, should be based on the actuarial report's top range adverse scenario utilization rates, cost per utilization unit, and per member per month costs.

HH-3: Substantiation of Projections

Include information to substantiate the assumptions and conclusions upon which the projected financial statements by Exhibit HH-1 and HH-2 are based:

- **HH-3-a: Feasibility Studies** obtained by PBM as normally required by conventional lending institutions, including at least the following: legal, marketing/enrollment, providers and financial. Best Practice: Complete this requirement prior to filing an application. (Section 1385.009(f))
- **HH-3-d: Projected Revenue and Expenses** (Section 1385.009(f))
- **HH-3-f-i: Capitol Arrangements/Credit Facility, Funding Arrangements, Subordinate Debt Agreements** (Section 1385.009(f))
 - Provide a detailed description of any measures taken or proposed to be taken by PBM to maintain solvency.
- **HH-3-f-ii: Creditor Financial Statements** (Section 1385.009(f))
 - If any funding obtained or to be obtained from an entity or individual other than a national bank or a bank incorporated under the laws of this state, attach as Exhibit HH-3-f-ii a copy of such entity or individual's most recent annual audited and quarterly unaudited financial statements.

HH-6: Legible copies of the actual policies of insurance to show coverage for malpractice, tort claims, facility loss, fidelity bond, and workers compensation (Section 1385.009(f))

- **HH-6-a: Errors & Omissions or Other Professional Liability Insurance**
- **HH-6-b: Coverage for Claims**
- **HH-6-c: Fire Insurance Policy**
- **HH-6-d: Director/Officer Fidelity Bond**
- **HH-6-e: Workers Compensation Policy**

HH-31 Misc.: Financial Documents – Public (Section 1385.009(f))

Note: For Exhibit HH-31, please file all appropriate documents that do not fit in other exhibit categories.

Exhibit H: Service Area

H-1: Service Area Description (Section 1385.009(j).)

- List all jurisdictions in which the PBM operates, including those where the PBM holds a license, registration, or certification as a PBM.

Exhibit I: Description of Health Care Arrangements (Sections 1385.004(a)(5), 1385.009(l), (m), (n).)

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I-7: Provider Group Correspondence

- Submit notice used by the PBM to inform pharmacists under contract with or subject to contracts with the PBM of the pharmacist's rights to submit complaints to the Department.

I-16: Pharmacies and Pharmacists

- List all health care providers, including pharmacies and pharmacists contracted or affiliated with the PBM.

I-17: Contracted Payers

- List each payer the PBM is affiliated with or has a contract for the provision of PBM services.
- For each payer:
 - Describe all services provided.
 - Provide the number of individual enrollees covered under the contract or contracts with each payer.

I-18: Supply Chain Entities

- List all contracted or affiliated pharmaceutical supply chain entities including drug manufacturers, wholesalers, and distributors.

Exhibit J: Internal System

J-9: Info on Utilization Management Program

- For each payer with which the PBM contracts, if the PBM has been delegated utilization management by a payer, clarify which entity's policies and procedures the PBM is using to conduct utilization management on behalf of that payer.

Exhibit K: Contracts with Providers

K-1: Template Copies of Contracts with Pharmacists, Pharmacies, or Contracting Pharmacy Agents/ Pharmacy Services Administration Organizations (Sections 1351, 1385.003, 1385.004, 1385.009, (l), (m), 1385.0026, 1385.0027(c), (f), 1385.0028, 1385.0029, 1385.0031, 1385.0032.)

- Submit each contract between the PBM and pharmacists, pharmacies, contracting pharmacy agents, pharmacy services administration organizations or pharmaceutical supply chain entities as an Exhibit K-1. Please cite by page and subsection to any contract language related to Article 6.1 requirements.

Exhibit K-3: Provider Contract Compensation Terms (Rule 1300.51(d)(K)(3).)

- Provide a copy of any contractual compensation provisions in any Exhibit K-1 submitted to the Department for review. Such compensation provisions should not be included in Exhibit K-1. (Section 1351(d), Rule 1300.51(d)(K)(3).) Exhibit K-3 is an automatically confidential exhibit; the

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PBM is not required to submit a Request for Confidentiality for an Exhibit K-3. (Rule 1300.67.8(a).)

- Exhibit K-3 must include copies of the following provisions or pages of the Provider Contract:
 - Title page.
 - Effective date of the contract.
 - Expiration date of the contract.
 - Execution page.
 - Compensation terms and terms describing any payment mechanisms.

Exhibit L: Organization Chart (Section 1385.009(k), Rule 1300.51(d)L.)

L-1: Organization Chart

- Include the PBM's organization chart(s) depicting the lines of responsibility and authority in the administration of the PBM's business.
 - Directors, trustees, principal officers (president or CEO, vice president, secretary, treasurer or CFO, or chairman of the board of a corporation, a sole proprietor, the managing general partner of a partnership), general partner, general manager or principal management person, and any persons occupying similar positions or performing similar functions.
 - Show committees and committee membership.

Exhibit M: Narrative Information

M-1: Description of Organization (Section 1385.009(k), Rule 1300.51(d)M(1).)

- Provide a narrative explanation of the Exhibit L-1 organization chart(s), including the responsibility and authority of each entity, board, committee, and position. Identify the persons who serve on the boards and committees and in those positions.

M-2: Key Management Names (Section 1385.009(c), Rule 1300.51(d)M(2)(a).)

- Provide a list of the names, addresses, and official positions of the persons who are to be responsible for the conduct of the affairs of the PBM, including all members of the board of directors, board of trustees, executive committee, or other governing board or committee, the principal officers, each shareholder with more than 5 percent interest in the case of a corporation, all partners or members in the case of a partnership or association, and each person who has loaned funds to the PBM for the operation of its business. This list should include any individuals who occupy a position specified in the Exhibit L-1 organization chart(s).

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- ❑ **M-3: Key Management Duties** (Section 1385.009(k), Rule 1300.51(d)M(2)(b).)
 - For each person named in the Exhibit M-2, provide a description of the principal responsibilities and authority in each position and the portion of the individual's time devoted to each principal function, including if they have responsibilities with affiliates, and if so, the percentage of time they will work for the PBM.

Exhibit N: Contracts for Administrative Services

- ❑ **N-1: Administrative Services Contracts** (Sections 1351(d), 1367.2075, 1385.003, 1385.004, 1385.008, 1385.009(g), 1385.0022, 1385.0027, 1385.0029, 1385.0031.)
 - Submit each contract between the PBM and a payer as an Exhibit N-1. Please cite by page and subsection to any contract language related to Section 1367.2075 or Article 6.1 requirements.
 - Submit each contract between the PBM and administrative services organizations not meeting the definition of a PBM.
- ❑ **N-2: Management Contracts**
 - Describe the PBM's administrative arrangements to monitor the proper performance of any agreements filed as an Exhibit N-1 or Exhibit N-3. Ensure the PBM identifies by page and subsection any provisions within the exhibits to protect the PBM's contracted health care service plans' enrollees in the event there is a failure of performance or if the contract is terminated.
- ❑ **N-3: Claims Processing Contracts**
 - File any contracts assuming any prescription drug claims processing functions.
- ❑ **N-5: Adm Services Monitoring Procedures**
 - File any monitoring policies and procedures used for any Exhibit N-1 or N-3 filed. Monitoring policies and procedure should include:
 - The key plan personnel responsible for oversight.
 - Procedures, mechanisms, and schedules for monitoring performance of each function.
 - Procedures, mechanisms and schedules for monitoring compliance with the applicable provisions of the Act associated with each function.
 - Procedures, mechanisms, and schedules for monitoring the financial conditions of any contracted entity.
 - Procedures, mechanisms, and schedules for resolving performance issues such as the development and implementation of corrective action plans.

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- Procedures, mechanisms and schedules to ensure resumption of functions on a long term and short term basis if the contracted entity fails to perform appropriately.

N-6: Compensation of Admin Contracts

- Provide a copy of any contractual compensation provisions in any Exhibit N-1 or N-3 submitted as an Exhibit N-6. Such compensation provisions should not be included in Exhibits N-1 or N-3. (Sections 1351(d), 1385.0021.)
- Exhibit N-6 must include copies of the following provisions or pages of any Exhibit N-1 or N-3:
 - Title page.
 - Effective date of the contract.
 - Expiration date of the contract.
 - Execution page.
 - Compensation terms and terms describing any payment mechanism.
- If the PBM is requesting confidential treatment for information contained with the Exhibit N-6, the PBM must comply with Rule 1007, including submitting a separate, public Request for Confidentiality and filing the exhibit appropriately as public and confidential. (Section 1385.0021, Rule 1007.)

N-7: PBM-to-Manufacturers/Supply Chain Entities Contracts (Sections 1351, 1385.009(g), 1385.0027, 1385.0029, 1385.0032.)

- Submit contracts between the PBM and manufacturers or other supply chain entities as an Exhibit N-7. Please cite by page and subsection to any contract language related to Article 6.1 requirements.

Exhibit O: Separation of Medical and Fiscal Services

O-1: Description of Separation (Section 1385.009(o).)

- Describe how the PBM will keep medical and clinical decision making separate from fiscal and administrative management to ensure medical and clinical decisions will not be unduly influenced by fiscal and administrative management. Include any controls the PBM has in place to ensure this separation.

Exhibit P: PBM Contracts

P-7: PBM-to-PBM Contracts (Sections 1351(d), 1385.0029.)

- File each contract between the PBM and any other PBM. Please cite by page and subsection to any contract language related to Article 6.1 requirements. If the contract contains any performance bonuses, provide

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the pinpoint citation and language to any provisions containing performance bonuses in the cover page to the contract.

Amending an Application Prior to Licensure:

In addition to complying with Rule 1300.52, an amendment to a pending application shall comply with the following:

- Any amendments to document(s) submitted in the initial application must be filed within the same open application filing for Department review. Submit the amended document(s) as the proper exhibit type.
- Each subsequent filing must also include an accompanying single Exhibit E-1, as a separate exhibit, with any changes to the original Exhibit E-1 identified via highlight or strikeout, in accordance with Rule 1300.52(d).
- Nonmaterial changes to the information previously submitted in connection with an application (as amended to date) may be accumulated and shall be submitted as an amendment to the license application monthly or within 30 days (or other period requested by the Director) of each such change.
- Financial statements with an application (as amended to date) shall be updated by an amendment to the license application which shall consist of quarterly financial statements (see Section 1385.0011(b)) as of the closing date of such quarter and shall be filed within 45 days after the close of each quarter of PBM's fiscal year.
- Amendments to license applications pursuant to Section 1352(a) shall be filed by exhibit and item as set forth in Section 1385.009 and Rule 1300.51(d) and shall comply with the following:
 - The amendment must describe under Exhibit E-1 the purpose of the amendment and the nature of the changes.
 - The amendment must include the pages of the exhibits changed by the amendment.
 - All changes to previously filed material must be highlighted by strikeout, underline, or other method in accordance with Rule 1300.52(d).