

From: DMHC Licensing eFiling
Subject: APL 19-017 (OPL) - Requirements Pursuant to AB 315 Pharmacy Benefit Management
Date: Friday, October 11, 2019 11:58:00 AM
Attachments: APL 19-017 (OPL) - Requirements Pursuant to AB 315 Pharmacy Benefit Management
Exhibit A_DMHC 10-242 PBM Registration Form

Dear Health Plan Representative,

Please see the attached All Plan Letter regarding requirements pursuant to AB 315: Pharmacy Benefit Management.

Thank you.



Gavin Newsom, Governor
State of California
Health and Human Services Agency
DEPARTMENT OF MANAGED HEALTH CARE
980 9th Street, Suite 500
Sacramento, CA 95814
Phone: 916-324-8176 | Fax: 916-255-5241
www.HealthHelp.ca.gov

ALL PLAN LETTER

DATE: October 11, 2019

TO: All Health Care Service Plans

FROM: Phuc Nguyen
Acting Deputy Director
Office of Plan Licensing

SUBJECT: APL 19-017 (OPL) Requirements Pursuant to AB 315: Pharmacy Benefit Management

The Department of Managed Health Care (DMHC) issues this All Plan Letter (APL) to inform health care service plans (Plans) and pharmacy benefit managers (PBMs) of the requirements of Assembly Bill 315 (Wood, Ch. 905, Stats. 2018), including Article 6.1 of the Health and Safety Code (commencing with Section 1385.001).¹ Specifically, this APL addresses the requirements of Sections 1385.003 through 1385.005, including required Plan disclosures, PBM registration, and other PBM requirements. Plans are asked to disseminate this APL to contracted PBMs.

I. BACKGROUND

Assembly Bill 315 added Section 4441 to the Business and Professions Code, and Sections 1368.6, 1385.001, 1385.002, 1385.003, 1385.004, 1385.005, 1385.006, and 1385.007 to the Health and Safety Code.

Business and Professions Code section 4441 requires, in part, PBMs to notify a purchaser in writing of any of its activities, policies, or practices that present a conflict of interest. PBMs are also required to disclose, on a quarterly basis, certain information with respect to prescription product benefits specific to the purchaser, including the aggregate wholesale acquisition costs from a pharmaceutical manufacturer or labeler for certain therapeutic drugs and any administrative fees received from a pharmaceutical manufacturer or labeler.

¹ All further statutory references (unless otherwise noted) are to sections of the California Health and Safety Code, and all regulatory references (unless otherwise noted) are to sections of California Code of Regulations, title 28.

Section 1385.003 prohibits a Plan from including in a contract with a pharmacy provider, or its contracting agent, a provision that prohibits the provider from informing a patient of a less costly alternative to a prescribed medication.

Section 1385.004 provides a Plan that contracts with PBM(s) for management of prescription drug coverage must require its contracted PBM(s) to register with the DMHC. Section 1385.005 outlines the information that these contracted PBMs must provide to the DMHC.

Section 1385.007 directs the DMHC to establish a Task Force on Pharmacy Benefit Management Reporting from July 1, 2019, through February 1, 2020, to determine what information related to pharmaceutical costs, if any, the DMHC should require Plans or contracted PBMs to report.²

Section 1368.6 establishes a pilot project in Riverside and Sonoma counties from January 1, 2020, through January 1, 2023, to assess the impact of Plan and PBM prohibitions on the dispensing of certain amounts of prescription drugs by network retail pharmacies. Plans in those counties are required to report annually to the DMHC information relating to the pilot project.

II. PLAN AND PBM REQUIREMENTS

A. Plan Filing Requirements Due November 8, 2019³

Sections 1385.003 and 1385.004 require Plans that contract with PBMs for management prescription drug coverage to have those contracted PBMs register with the DMHC. To comply, Plans offering a pharmacy benefit must submit a compliance filing on or before November 8, 2019.⁴ The filing should be submitted via eFiling as an **Amendment** filing titled “APL 19-017: Compliance with H&S Code Sections 1385.003 and 1385.004,” and must contain the information identified below in an Exhibit E-1:

1. State the filing is submitted to demonstrate compliance with APL 19-017 and Sections 1385.003 and 1385.004, effective January 1, 2020.
2. Explain how the Plan and its delegates, including pharmacy providers and PBMs and their subcontractors, will comply with Section 1385.003, subdivision (a) regarding disclosure of the prescription drug information detailed in Section 1363.03, subdivision (a) effective January 1, 2020.

² The first PBM Taskforce meeting was held on July 31, 2019, and a copy of the agenda and related documents are available on the [DMHC's public website](#).

³ This APL does not apply to plans with only Medicare Advantage lines of business.

⁴ Plans that do not offer a pharmacy benefit and/or do not contract with a PBM for prescription drug coverage management are not required to make a compliance filing.

3. State either:

The Plan's contracts with pharmacy providers and/or the pharmacy provider's contracting agent do not contain a provision that prohibits providers from informing an enrollee of a less costly alternative to a prescribed medication.

OR

The Plan's contracts with pharmacy providers and/or the pharmacy provider's contracting agent contains provisions that conflict with Section 1385.003, but affirms the Plan will provide a proposed contract amendment within 30 days to cure the conflict and demonstrate compliance by the January 1, 2020 effective date of Section 1385.003.

4. And state either:

The Plan's contracts with PBMs contain provisions that require the PBMs' compliance with Section 1385.004 and do not contain provisions that conflict with Section 1385.004.

OR

The Plan's contracts with PBMs do not contain provisions that require the PBMs' compliance with Section 1385.004, and/or contain provisions that conflict with Section 1385.004, but affirms the Plan will provide a proposed contract amendment within 30 days to demonstrate compliance by the January 1, 2020 effective date of Section 1385.004.

B. PBM Registration Requirement Due January 1, 2020

Section 1385.005 requires PBMs contracted with a Plan to register with the DMHC. To comply, PBMs contracted with Plans must register on or before January 1, 2020, by submitting the attached fillable Application Form for Pharmacy Benefit Manager Registration form. (DMHC 10-242). The DMHC will accept PBM Registration Applications beginning October 14, 2019.

The PBM's submission must contain the following information and documents:

1. Cover Letter.

- State the PBM is submitting the PBM Registration Application to register as a PBM with the DMHC pursuant to Section 1385.005, effective January 1, 2020.
- Provide a brief narrative introduction of the PBM.

2. Completed PBM Registration Application (DMHC 10-242).

- The Application Form for Pharmacy Benefit Manager Registration is attached as Exhibit A to this APL.
- The Application Form for Pharmacy Benefit Manager Registration is also available for download online at the [DMHC's public website](#).
- Submit the completed Application Form for Pharmacy Benefit Manager Registration, cover letter, and related documents to the DMHC via electronic mail or US Mail to the address identified below.

For electronic submissions:

TO: PBM.Registration@dmhc.ca.gov

SUBJECT: PBM Registration Application for <insert PBM Name>

For US Mail submissions:

DMHC-Office of Plan Licensing

ATTN: PBM Registration

980 9th Street, Suite 500

Sacramento, CA 95814

3. Initial Registration Application Fee of \$3,500.

- The DMHC will begin review of the original PBM Registration Application upon receipt of the \$3,500 flat filing fee. The DMHC will bill for time spent reviewing the PBM's responses and changes requested by the DMHC at a variable hourly rate, depending on the reviewer's classification, up to \$500. The fees to review an initial PBM Registration Application are capped at \$4,000.
- Fees are payable to the DMHC via check payable to the "Department of Managed Health Care." Submit checks by mail to the Office of Plan Licensing:

DMHC - Office of Plan Licensing

ATTN: PBM Registration

980 9th Street, Suite 500

Sacramento, CA 95814

Please note: if there is a change in any information disclosed to the DMHC in the initial PBM Registration Application, the PBM must notify the Department of that change in writing within 30 days of that change pursuant to Section 1385.005, subdivision (g). DMHC 10-242, the Application Form for Pharmacy Benefit Manager Registration may be used to submit the change by selecting the appropriate check box on page one of the form.

When disclosing the change(s), the PBM should submit an amended PBM Registration Application and describe the specific changes in a cover letter. The DMHC will bill the PBM at a variable hourly rate, depending on the reviewer's classification, for the hour(s) spent reviewing the changes, and any of the PBM's responses and changes requested by the DMHC. There is no cap on fees for the DMHC's review of an Amendment to Application Form for Pharmacy Benefit Manager Registration.

III. PILOT PROJECT (SONOMA AND RIVERSIDE COUNTIES)

Section 1368.6 establishes a pilot project within Sonoma and Riverside counties to assess the impact of Plan and PBM prohibitions on the dispensing of certain amounts of prescription drugs by network retail pharmacies, effective January 1, 2020 through January 1, 2023. This APL addresses only the filing requirements associated with Sections 1385.003, 1385.004 and 1385.005. Additional guidance regarding the pilot project's annual reporting requirements pursuant to Section 1368.6, subdivision (e) is forthcoming in a separate APL.

The DMHC does not intend to issue guidance regarding the Plans' implementation and processes for administering the pilot project requirements pursuant to Section 1368.6, subdivisions (a) through (d).

IV. QUESTIONS OR CONCERNS

Questions or concerns regarding this APL from Plans should be directed to the Plan's assigned Office of Plan Licensing reviewer.

Questions or concerns regarding this APL from PBMs should be directed to the Office of Plan Licensing at 916-324-9046 or at PBM.Registration@dmhc.ca.gov.

OFFICIAL USE ONLY
FEE PAID:

**APPLICATION FORM FOR PHARMACY BENEFIT MANAGER REGISTRATION
CALIFORNIA HEALTH AND SAFETY CODE SECTION 1385.005¹
KNOX-KEENE HEALTH CARE SERVICE PLAN ACT**

Dated:

Original Application Form for Pharmacy Benefit Manager Registration

The Department of Managed Health Care (DMHC) will begin review of the original Application Form for Pharmacy Benefit Manager² Registration upon receipt of the \$3,500 flat filing fee. The DMHC will bill for time spent reviewing the PBM's responses and changes requested by the DMHC at a variable hourly rate, depending on the reviewer's classification, up to \$500. The fees to review an initial Application Form for PBM Registration are capped at \$4,000. [See Section 1385.005(f)].

Amendment to Application Form for Pharmacy Benefit Manager Registration

Pharmacy Benefit Manager Registration Number:

After a PBM is registered with the DMHC, a PBM submitting changes to the DMHC pursuant to Section 1385.005(g) will be billed at a variable hourly rate, depending on the reviewer's classification, and any of the PBM's responses and changes requested by the DMHC. The fees to review an amendment to Application Form for PBM Registration are not capped. [See Section 1385.005(f)].

Date of the most recently submitted Application Form for Pharmacy Benefit Manager Registration:

Note: A Pharmacy Benefit Manager Registration obtained pursuant to Section 1385.005 is not transferable. [See Section 1385.005(b)].

1. Legal name of the PBM (Person or Entity) [See Section 1385.005(c)(1)]:

¹ California Health and Safety Code sections 1340 et seq. (the "Act"). References herein to "Section" are to sections of the Act.

² Pharmacy Benefit Manager (PBM) is defined at Section 1385.001.

Fictitious name(s) used in connection with the operation of the PBM [See Section 1385.005(c)(1)]:

If none, specify "N/A"

2. Address of the PBM [See Section 1385.005(c)(2)]:

Street Address or PO Box Number

City, State and Zip Code

Mailing Address, if different [See Section 1385.005(c)(2)]:

Street Address or PO Box Number

City, State and Zip Code

Phone Number of PBM (include area code) [See Section 1385.005(c)(2)]:

Email Address of PBM:

3. Identify by legal name and dba each health care service plan³ with which the PBM contracts in the state of California. (If space is insufficient, please file an attachment to the application form and title the attachment "Response to Item 3").

³ Health care service plan is defined at Section 1345(f).

4. Identify all of the health care service plans' product lines for which the PBM contracts in the state of California. Check all that apply.

EPO Individual	EPO Large Group	EPO Small Group
HMO Individual	HMO Large Group	HMO Small Group
HSP Individual	HSP Large Group	HSP Small Group
Medi-Cal	POS Individual	POS Large Group
POS Small Group	PPO Individual	PPO Large Group
PPO Small Group	IHSS	Cal-MediConnect
Healthy Kids	MCAP (AIM)	Medicare
MRMIP	Other (please specify)	

5. Name of the PBM's agent for service of process in the state of California [See Section 1385.005(c)(3)]:

Address of the PBM's agent for service of process in the state of California [See Section 1385.005(c)(3)]:

Street Address or PO Box Number

City, State and Zip Code

Mailing Address, if different [See Section 1385.005(c)(3)]:

Street Address or PO Box Number

City, State and Zip Code

6. Name and address of each person beneficially interested⁴ (Person or Entity) in the PBM, but limit to including those persons who own the five largest interests in the PBM. (The DMHC reserves the right to request the names and addresses of all persons beneficially interested.). If there are fewer than five persons beneficially interested, the PBM need not use all of the fields provided below. [See Section 1385.005(c)(4)]:

a.i. Name of person beneficially interested [See Section 1385.005(c)(4)]:

Full Name - First, Middle, and Last Name or Entity

a.ii. Address [See Section 1385.005(c)(4)]:

Street Address or PO Box Number

City, State and Zip Code

a.iii. Mailing Address, if different:

Street Address or PO Box Number

City, State and Zip Code

b.i. Name of person beneficially interested [See Section 1385.005(c)(4)]:

Full Name - First, Middle, and Last Name or Entity

⁴ For purposes of this section, "person beneficially interested" with respect to a PBM means and includes the following [See Section 1385.005(h)]:

1. If the PBM is a partnership or other unincorporated association, each partner or member [See Section 1385.005(h)(1)].
2. If the PBM is a corporation, each of its officers, directors, and stockholders, provided that a natural person shall not be deemed to be beneficially interested in a nonprofit corporation [See Section 1385.005(h)(2)].
3. If the PBM is a limited liability company, each officer, manager, or member [See Section 1385.005(h)(3)].

b.ii. Address [See Section 1385.005(c)(4)]:

Street Address or PO Box Number

City, State and Zip Code

b.iii. Mailing Address, if different:

Street Address or PO Box Number

City, State and Zip Code

c.i. Name of person beneficially interested [See Section 1385.005(c)(4)]:

Full Name - First, Middle, and Last Name or Entity

c.ii. Address [See Section 1385.005(c)(4)]:

Street Address or PO Box Number

City, State and Zip Code

c.iii. Mailing Address, if different:

Street Address or PO Box Number

City, State and Zip Code

d.i. Name of person beneficially interested [See Section 1385.005(c)(4)]:

Full Name - First, Middle, and Last Name or Entity

d.ii. Address [See Section 1385.005(c)(4)]:

Street Address or PO Box Number

City, State and Zip Code

d.iii. Mailing Address, if different:

Street Address or PO Box Number

City, State and Zip Code

e.i. Name of person beneficially interested [See Section 1385.005(c)(4)]:

Full Name - First, Middle, and Last Name or Entity

e.ii. Address [See Section 1385.005(c)(4)]:

Street Address or PO Box Number

City, State and Zip Code

e.iii. Mailing Address, if different:

Street Address or PO Box Number

City, State and Zip Code

7. Names and addresses of the five key persons with management or control over the PBM. (The DMHC reserves the right to request the names and addresses of all persons with management or control over the PBM). If there are fewer than five key persons, the PBM need not use all of the fields provided below. [See Section 1385.005(c)(5)]:

a.i. Name of person with management or control over PBM [See Section 1385.005(c)(5)]:

Full Name - First, Middle, and Last Name or Entity

a.ii. Address [See Section 1385.005(c)(5)]:

Street Address or PO Box Number

City, State and Zip Code

a.iii. Mailing Address, if different:

Street Address or PO Box Number

City, State and Zip Code

b.i. Name of person with management or control over PBM [See Section 1385.005(c)(5)]:

Full Name - First, Middle, and Last Name or Entity

b.ii. Address [See Section 1385.005(c)(5)]:

Street Address or PO Box Number

City, State and Zip Code

b.iii. Mailing Address, if different:

Street Address or PO Box Number

City, State and Zip Code

c.i. Name of person with management or control over PBM [See Section 1385.005(c)(5)]:

Full Name - First, Middle, and Last Name or Entity

c.ii. Address [See Section 1385.005(c)(5)]:

Street Address or PO Box Number

City, State and Zip Code

c.iii. Mailing Address, if different:

Street Address or PO Box Number

City, State and Zip Code

d.i. Name of person with management or control over PBM [See Section 1385.005(c)(5)]:

Full Name - First, Middle, and Last Name or Entity

d.ii. Address [See Section 1385.005(c)(5)]:

Street Address or PO Box Number

City, State and Zip Code

d.iii. Mailing Address, if different:

Street Address or PO Box Number

City, State and Zip Code

e.i. Name of person with management or control over PBM [See Section 1385.005(c)(5)]:

Full Name - First, Middle, and Last Name or Entity

e.ii. Address [See Section 1385.005(c)(5)]:

Street Address or PO Box Number

City, State and Zip Code

e.iii. Mailing Address, if different:

Street Address or PO Box Number

City, State and Zip Code

8. Indicate whether the PBM is structured as any of the following entities [See Section 1385.005(d)]:

Partnership

Other unincorporated association

Limited Liability Company

Corporation

Other – please describe

9. Does the PBM have more than 5 partners, members, or stockholders? [See Section 1385.005(d)]:

Yes

If yes, please provide the name, address, usual occupation, and professional qualifications of each of the five partners, members, or stockholders who own **the 5 largest interests** in the PBM's entity in the fields provided below [See Section 1385.005(d)].

No

If no, please provide the DMHC with the name, address, usual occupation, and professional qualifications of **each** of the partners, members, or stockholders in the fields provided below. Please note, if PBM is responding no, the PBM need not use all of the fields provided below [See Section 1385.005(d)].

a.i. Name of partner, member, or stockholder [See Section 1385.005(d)]:

Full Name - First, Middle, and Last Name or Entity

a.ii. Address [See Section 1385.005(d)]:

Street Address or PO Box Number

City, State and Zip Code

a.iii. Mailing Address, if different:

Street Address or PO Box Number

City, State and Zip Code

a.iv. Usual Occupation [See Section 1385.005(d)]:

a.v. Professional Qualifications [See Section 1385.005(d)]:

b.i. Name of partner, member, or stockholder [See Section 1385.005(d)]:

Full Name - First, Middle, and Last Name or Entity

b.ii. Address [See Section 1385.005(d)]:

Street Address or PO Box Number

City, State and Zip Code

b.iii. Mailing Address, if different:

Street Address or PO Box Number

City, State and Zip Code

b.iv. Usual Occupation [See Section 1385.005(d)]:

b.v. Professional Qualifications [See Section 1385.005(d)]:

c.i. Name of partner, member, or stockholder [See Section 1385.005(d)]:

Full Name - First, Middle, and Last Name or Entity

c.ii. Address [See Section 1385.005(d)]:

Street Address or PO Box Number

City, State and Zip Code

c.iii. Mailing Address, if different:

Street Address or PO Box Number

City, State and Zip Code

c.iv. Usual Occupation [See Section 1385.005(d)]:

c.v. Professional Qualifications [See Section 1385.005(d)]:

d.i. Name of partner, member, or stockholder [See Section 1385.005(d)]:

Full Name - First, Middle, and Last Name or Entity

d.ii. Address [See Section 1385.005(d)]:

Street Address or PO Box Number

City, State and Zip Code

d.iii. Mailing Address, if different:

Street Address or PO Box Number

City, State and Zip Code

d.iv. Usual Occupation [See Section 1385.005(d)]:

d.v. Professional Qualifications [See Section 1385.005(d)]:

e.i. Name of partner, member, or stockholder [See Section 1385.005(d)]:

Full Name - First, Middle, and Last Name or Entity

e.ii. Address [See Section 1385.005(d)]:

Street Address or PO Box Number

City, State and Zip Code

e.iii. Mailing Address, if different:

Street Address or PO Box Number

City, State and Zip Code

e.iv. Usual Occupation [See Section 1385.005(d)]:

e.v. Professional Qualifications [See Section 1385.005(d)]:

10. Has the PBM been convicted of a felony or violated any of the provisions of Article 6.1? [See Section 1385.005(e)]:

No

Yes

If yes, state the violation or describe the reason(s) that prevent the PBM from being able to comply with the requirements [See Section 1385.005(e)]:

11. PBM affirmations. Check below to affirm:

a. The PBM exercises good faith and fair dealing in the performance of its contractual duties to a health care service plan. [See Section 1385.004(a)(3)].

Yes

No

If no, explain:

b. The PBM complies with the requirements of Chapter 9.5 (commencing with Section 4430) of Division 2 of the California Business and Professionals Code, as applicable. [See Section 1385.004(a)(4)].

Yes

No

If no, explain:

- c. The PBM informs all pharmacists under contract with or subject to contracts with the PBM of the pharmacist's rights to submit complaints to the DMHC under Section 1371.39 and of the pharmacist's rights as a provider under Section 1375.7. [See Section 1385.004(a)(5)].

Yes

No

If no, explain:

- d. The PBM will notify a health care service plan in writing of any activity, policy, or practice of the PBM that directly or indirectly presents a conflict of interest that interferes with the discharge of the PBM's duty to the health care service plan to exercise good faith and fair dealing in the performance of its contractual duties. [See Section 1385.004(b)].

Yes

No

If no, explain:

12. Identify the name, title, address and telephone number of representative who may be contacted concerning this Application Form for Pharmacy Benefit Manager Registration:

Contacts Name:

Contacts Full Name - First, Middle, and Last Name

Contacts Title:

Title

Mailing Address:

Street Address or PO Box Number

City, State and Zip Code

Phone Number (include area code):

Name of Person/Entity Filing Application Form for Pharmacy Benefit Manager Registration:

Full Name - First, Middle, and Last Name or Entity

Signed By:

Full Name - First, Middle, and Last Name

Title:

Application Form for Pharmacy Benefit Manager Registration Declaration

I certify (or declare) under penalty of perjury under the laws of the State of California that I have read the information contained in this Application Form for Pharmacy Benefit Manager Registration including its attachments and know the contents thereof and that the statements therein are true and correct.

I further declare hereby that the PBM will notify in writing the DMHC within 30 days of a change in any of the information disclosed to the DMHC in the Application Form for Pharmacy Benefit Manager Registration. [See Section 1385.005(g)].

PBM Name:

Signature of Authorized Person:

Printed Name and Title of Authorized Person:

Executed at (City and State):

Date: