

PROPOSED ACTION ON REGULATIONS

1062

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Latonya B. Dargan, Executive Administrative Law Judge, Deputy Director of Quality Assurance, Office of Administrative Hearings, 11101 Gilroy Road, Hunt Valley, MD 21031, or call 410-229-4172, or email to latonya.dargan@maryland.gov, or fax to 410-229-4244. Comments will be accepted through December 20, 2021. A public hearing has not been scheduled.

.16 Postponements.

A.—C. (text unchanged)

D. Documentation of the reasons for the postponement shall be required from the party making the request.

[D.] E.—[E.] F. (text unchanged)

CHUNG K. PAK
Chief Administrative Law Judge

Title 31
MARYLAND INSURANCE
ADMINISTRATION

Subtitle 10 HEALTH INSURANCE —
GENERAL

Notice of Proposed Action

[21-193-P]

The Insurance Commissioner proposes to amend:

- (1) Regulations .02 and .03 under COMAR 31.10.46 Pharmacy Benefits Managers—Maximum Allowable Cost;
(2) Regulations .02 and .03 under COMAR 31.10.47 Cost Pricing and Reimbursement Other than MAC; and
(3) Regulations .02—.05 under COMAR 31.10.48 Pharmacy Benefits Managers—Informational Filing of Contracts and Amendments.

Statement of Purpose

The purpose of this action is to revise existing regulations to conform to recent changes to Insurance Article, Title 15, Subtitle 16, Annotated Code of Maryland, which were enacted during the 2020 and 2021 legislative sessions. Specifically, H.B. 601, enacted as Chapter 358, Acts of 2021, amended the definition of "purchaser" and added a new definition of "carrier", which altered the scope of this subtitle. The bill also amended Insurance Article, §§15-1628, Annotated Code of Maryland, to change the PBM contract filing requirement to an informational filing. H.B. 1307, enacted as Chapter 455, Acts of 2020, amended Insurance Article, §15-1628, Annotated Code of Maryland, to prohibit certain fees for credentialing a pharmacy to participate in a PBM's network. The bill also amended Insurance Article, §15-1628.3 to prohibit certain reimbursement practices of PBMs. Previously, PBMs were only required to provide a certain notice to pharmacies before engaging in these reimbursement practices. The action also corrects some outdated cross-references.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact. There will be a decrease in administrative costs to both PBMs and the MIA based on the change in the PBM contract filing requirements to reflect an informational filing instead of a file and review process.

Table with 3 columns: Impact, Revenue (R+/R-), Expenditure (E+/E-), and Magnitude. Rows include A. On issuing agency, B. On other State agencies, C. On local governments, D. On regulated industries or trade groups, E. On other industries or trade groups, F. Direct and indirect effects on public.

III. Assumptions. (Identified by Impact Letter and Number from Section II.)
A. There should be a slight decrease in administrative costs for the MIA as the PBM contract filing requirements will require an informational filing rather than a file and review process.
D. There should be a slight decrease in administrative costs for the MIA as the PBM contract filing requirements will require an informational filing rather than a file and review process.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Lisa Larson, Director of Regulations, Maryland Insurance Administration, 200 St. Paul Place, Suite 2700, Baltimore, MD 21202, or call 410-468-2007, or email to insuranceregreview.mia@maryland.gov, or fax to 410-468-2020. Comments will be accepted through December 20, 2021. A public hearing has not been scheduled.

31.10.46 Pharmacy Benefits Managers—
Maximum Allowable Cost

Authority: Insurance Article, §§15-1601, 15-1604, 15-1605, 15-1607, 15-1609, 15-1628, 15-1628.1, and 15-1642, Annotated Code of Maryland

.02 Definitions.

A. (text unchanged)

B. Terms Defined.

(1)—(2) (text unchanged)

(3) "Carrier" [means:

(a) An insurer;

(b) A nonprofit health service plan; or

(c) A health maintenance organization.] *has the meaning stated in Insurance Article §15-1601, Annotated Code of Maryland.*

(4) (text unchanged)

(5) "Contracted pharmacy" has the meaning stated in Insurance Article, [§15-1628.1,] §15-1601, Annotated Code of Maryland.

[(6) "Fee or performance-based reimbursement related to an adjudicated claim or incentive program" means any downward adjustment of an adjudicated claim and includes, but is not limited to, using the application of the following:

(a) Refill rates of generic, brand name, or preferred drugs;

(b) Comparison of dispensing rates of a pharmacy or pharmacist to another pharmacy or pharmacist; or

(c) Combined—aggregate—overall—percentage—discounts applied to all adjudicated claims.]

[(7)] (6)—[(11)] (10) (text unchanged)

[(12)] (11) "Participating pharmacy contract" means a contract filed with the Commissioner that is:

(a) (text unchanged)

(b) Filed at least 30 days before the contract or an amendment to the contract is to become effective;]

[(c)] (b)—[(e)] (d) (text unchanged)

[(13)] (12)—[(21)] (20) (text unchanged)

.03 Disclosures to a Contracted Pharmacy.

A.—B. (text unchanged)

[C. Except as provided in §§D and E of this regulation, a contracted pharmacy may not be charged a fee or held responsible by a purchaser or PBM for:

(1) A fee or performance-based reimbursement related to an adjudicated claim; or

(2) An incentive program.

D. A PBM, whether its contract is directly with a pharmacy or indirectly with a pharmacy through a PSAO or group purchasing organization, shall disclose any fee or performance-based reimbursement that relates to the adjudication of a claim or incentive program by stating:

(1) The specific dollar amount of a fee or alternative reimbursement; or

(2) The specific percentage of the potential adjustment relating to reimbursement of a claim.

E. The disclosure described in §D shall be:

(1) Provided during claims processing; or

(2) Described in detail on the initial remittance advice.]

[F.] C. (text unchanged)

31.10.47 Cost Pricing and Reimbursement Other than MAC

Authority: Insurance Article, §§15-1601, 15-1604, 15-1605, 15-1607, 15-1609, 15-1628, 15-1628.2, 15-1630, and 15-1642, Annotated Code of Maryland

.02 Definitions.

A. (text unchanged)

B. Terms Defined.

(1)—(2) (text unchanged)

(3) "Carrier" [means:

(a) An insurer;

(b) A nonprofit health service plan; or

(c) A health maintenance organization.] *has the meaning stated in Insurance Article, §15-1601, Annotated Code of Maryland.*

(4)—(6) (text unchanged)

(7) "Contracted pharmacy" has the meaning stated in Insurance Article, [§15-1628.1,] §15-1601, Annotated Code of Maryland.

(8) (text unchanged)

[(9) "Fee or performance-based reimbursement related to an adjudicated claim or incentive program" means any downward adjustment of an adjudicated claim and includes, but is not limited to, using the application of the following:

(a) Refill rates of generic, brand name, or preferred drugs;

(b) Comparison of dispensing rates of a pharmacy or pharmacist to another pharmacy or pharmacist; or

(c) Combined aggregate overall percentage discounts applied to all adjudicated claims.]

[(10)] (9) "Participating pharmacy contract" means a contract filed with the Commissioner that is:

(a) (text unchanged)

(b) Filed at least 30 days before the contract or an amendment to the contract is to become effective;]

[(c)] (b)—[(e)] (d) (text unchanged)

[(11)] (10)— [(20)] (19) (text unchanged)

.03 Disclosures to a Contracted Pharmacy.

A. (text unchanged)

[B. Except as provided in §§C and D of this regulation, a contracted pharmacy may not be charged a fee or held responsible by a purchaser or PBM for:

(1) A fee or performance-based reimbursement related to an adjudicated claim; or

(2) An incentive program.

C. A PBM, whether its contract is directly with a pharmacy or indirectly with a pharmacy through a PSAO or group purchasing organization, shall disclose any fee or performance-based reimbursement that relates to the adjudication of a claim or incentive program by stating:

(1) The specific dollar amount of a fee or alternative reimbursement; or

(2) The specific percentage of the potential adjustment relating to reimbursement of a claim.

D. The disclosure described in §C shall be:

(1) Provided during claims processing; or

(2) Described in detail on the initial remittance advice.]

[E.] B. (text unchanged)

31.10.48 Pharmacy Benefits Managers — Informational Filing of Contracts and Amendments

Authority: Insurance Article, §§2-109, 12-203(d)(2), 15-1628, and 15-1642, Annotated Code of Maryland

.02 Definitions.

A. (text unchanged)

B. Terms Defined.

(1)—(2) (text unchanged)

[(3) "Filing entity" means a pharmacy benefits manager or PBM, pharmacy services administration organization or PSAO, or group purchasing organization or GPO required to file a contract or amendment to a contract under this chapter.]

[(4)] (3) (text unchanged)

[(5)] (4) "Participating pharmacy contract" has the meaning stated in Insurance Article, [§15-1601(h)(1),] §15-1601, Annotated Code of Maryland.

[(6)] (5) (text unchanged)

PROPOSED ACTION ON REGULATIONS

1064

.03 Submission Requirements.

A. Pursuant to the requirements of Insurance Article, §15-1628(b), Annotated Code of Maryland, a [filing entity] *PBM* shall submit to the Commissioner *as an informational filing* [all] *each* participating pharmacy [contracts] *contract form* and *each* [amendments] *amendment to a* [contracts.] *contract form at least 30 days before the contract form or amendment to the contract form is to become effective.*

B. *The Commissioner is not required to review the informational filing to evaluate whether a contract form or amendment to a contract form is in violation of Maryland law at the time the informational filing is made.*

[B.] C. Unless it is disapproved by the Commissioner, a [filing entity] *PBM* may [not] use a *contract form* or amendment to a *contract form* [unless:] *after*

[(1) It] *it* has been filed with the Commissioner and 30 days have passed since the filing was acknowledged by the Commissioner in writing as having been received-]; or

(2) Subject to the filing corrections under §C of this regulation, a filing entity receives written notice that the contract or amendment to a contract may be used in Maryland and at least 30 days have passed since the initial filing was acknowledged by the Commissioner in writing as having been received.

C. A filing entity that receives written notice from the Commissioner that its contract or amendment to a contract contains defects and is disapproved may resubmit the filing indicating the corrections made].

D. [Except under the circumstances in §C of this regulation, a filing entity] *A PBM* may not file a *contract form* or amendment *form* that has been previously disapproved by the Commissioner.

E. (text unchanged)

F. The filing shall include a cover letter which includes the following:

(1) A list of the [contracts] *contract forms* and [amendments] *amendment forms* included in the submission; and

(2) A brief description of the purpose of each *contract form* and amendment *form* included in the submission.

G. (text unchanged)

H. A filing made under this chapter shall include a signed certification from a responsible officer of the [filing entity] *PBM* that, to the best of the officer's knowledge and belief, the [contracts] *contract forms* and [amendments] *amendment forms* comply with applicable statutes and regulations.

I. A *PBM* may not file a *contract form* or amendment *form* before the *PBM* has successfully registered as a *PBM* with the Commissioner.

.04 Noncompliant Contract Terms.

A. A [filing entity] *PBM* may have a *contract form* or amendment to a *contract form* disapproved *at any time after the contract form or amendment to a contract form has been submitted as part of an informational filing* if the *contract form* or amendment *form* contains or uses any language that:

(1)—(5) (text unchanged)

[(6) Other than a provider fee allowed under Insurance Article, §15-112, Annotated Code of Maryland, requires a pharmacy or pharmacist to pay a licensing fee or other fee to participate in the provider panel;]

[(7)] (6)—[(8)] (7) (text unchanged)

B. (text unchanged)

.05 Use of Noncompliant Contract or Amendment.

A. If a *PBM* uses a *contract form* or amendment *form* which becomes effective and the *contract form* or amendment *form* is subsequently found by the Commissioner to be noncompliant, the Commissioner may:

(1)—(2) (text unchanged)

B.—C. (text unchanged)

KATHLEEN A. BIRrane
Insurance Commissioner