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 Gitney 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
[21-193-3]
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 The action also corrects some outdated cross-references.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>
<thead>
<tr>
<th>Revenue (R+/R-)</th>
<th>Expenditure (E+/E-)</th>
<th>Magnitude</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. On issuing agency: Administrative costs (E-)</td>
<td>NONE</td>
<td>Minimal</td>
</tr>
<tr>
<td>B. On other State agencies: NONE</td>
<td>NONE</td>
<td>Minimal</td>
</tr>
<tr>
<td>C. On local governments: Benefit (+) Cost (-)</td>
<td>NONE</td>
<td>Minimal</td>
</tr>
<tr>
<td>D. On regulated industries or trade groups: NONE (+)</td>
<td>NONE</td>
<td>Minimal</td>
</tr>
<tr>
<td>E. On other industries or trade groups: NONE</td>
<td>NONE</td>
<td>Minimal</td>
</tr>
<tr>
<td>F. Direct and indirect effects on public: NONE</td>
<td>NONE</td>
<td>Minimal</td>
</tr>
</tbody>
</table>

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.
B. 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 insurancecregiverview.min@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

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

.03 Disclosures to a Contracted Pharmacy.
A. (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. (text unchanged)

31.10.47 Cost Pricing and Reimbursement Other than MAC


.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.
.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)] If 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