PCMA

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Re: Regulation of the Secretary of Health for the Regulation of the Administrators of Pharmacy Benefits and Services in Puerto Rico

Dear Assistant Secretary Nuñes Marrero:

I am writing to provide the Pharmaceutical Care Management Association (PCMA) comments on the Secretary of Health's proposed rule dealing with pharmacy benefit manager (PBM) licensure and regulation. PCMA is the national trade association for the PBMs, which manage prescription drug benefits on behalf of health plans, large and small employers, labor trusts and government programs. Our goal is to ensure that the final rule is clear, understandable, and it provides fair notice to PBMs on how to comply.

At the outset, we note that the Fiscal Oversight Board of Puerto Rico is currently questioning the legality of Act 82 of 2019. We believe it is premature to enact a regulation implementing a statute that is currently being questioned in court. If Act 82 is ultimately revoked, the administrative and economic burdens to the government, pharmacies, plan sponsors, and PBMs, all of which are subject to this Act, would have been futile. We are submitting comments for purposes of record but respectfully suggest that the rulemaking be put on hold until the case related to the legality of Act 82 is resolved by the court.

Regarding our comments below, they are based on an unofficial translation of the proposed regulation. In some areas of the regulation, there is a disconnect between the statutory sections and the regulatory sections. The regulations should correspond directly to the statutes they are clarifying, and to those only. We noted areas of concern below. In addition, we've provided detailed comments on other concerns with the proposed rule and have included suggestions and proposed amendments in italics below each comment.

We are happy to have further discussions on any of these issues.

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Chapter II – Purpose

Article 2.02 – Applicability

1. Article 2.02 provides the Secretary with broad authority to "establish additional requirements to those set forth herein to all [PBMs]....when they are necessary in the interest of the health and safety of the individuals who may be affected directly or indirectly for the costs of medications...." The authority should specifically indicate that any additional regulations on PBMs are directly relevant to the enforcement of the statute. Any further requirement would be inconsistent with the underlying law.

   PCMA requests the following amendment:

   The Secretary may establish additional requirements to those set forth herein to all Pharmacy Benefit Managers, Pharmacy Services Managers, and related entities that provide services as PBAs in Puerto Rico, when they are necessary to enforce the existing authority provided under the Act. ~~necessary in the interest of the health and safety of the individuals who may be affected directly or indirectly for the costs of medications and treatments negotiated between the Pharmacy Benefit Managers, Pharmacy Services Managers, related entities, pharmaceutical companies and third-party payers.~~

Chapter III – Definitions

Article 3.01 – Definitions

1. Subsection (b) defines "Pharmacy Benefit Administrator or Manager." The proposed definition is vague and does not qualify related entities to be limited to those providing PBA services in Puerto Rico. This definition appears to contemplate primarily the client/plan side services only (e.g., eligibility, claims adjudication, etc.) whereas the definition of "Pharmacy Services Manager" in subsection (t) focuses on the PBM services that are focused on management of pharmacy services as well as network contracting, contracting with manufacturers, actuarial service, customer service and call centers, etc. Furthermore, the definition of PBA does not include a person providing services pursuant to the contract between the PBA and the contracted pharmacy, which is an essential service of PBM or PBA. We are unclear as to the need for two definitions in the rule and believe that "Pharmacy Benefit Administrator or Manager" and "Pharmacy Services Manager" should be combined into one definition for the purposes of the rule.

   PCMA recommendations:

   PCMA requests clarification and distinction between a PBA and PSM in subsection (t), if there is such a distinction. If not, we would ask that the Secretary use only the statutory definition of "Pharmacy Services Manager" (also referred to as "Pharmacy Benefits Manager") and clarify that it includes related entities that provide services as a pharmacy benefit administrator in Puerto Rico:

"Pharmacy Services Manager – also known as "Pharmacy Benefit Managers or PBM" -- means a person, legal person, entity or organization dedicated to providing management services, administration, review, advice on prescription drug benefits for sponsors ("Plan sponsors") such as employers, self-insured employers, health service organizations, health plans, third-party administrators, union groups and other persons who contract such services to perform one or more of the following activities, among others: administer services or sponsor pharmacy coverage, prescription and claim processing, medication service benefit management, "Drug adherence management"), drug interaction program, medication utilization program, medication form, committee and advice on medication forms and their management, programs for the use of generics and incentives; analysis of medical and medication data, medication ("Drug utilization review"), medication pre-authorization services, medication repetition program management, ("medical therapy management" or "MTM"), wellness management , network contracting of pharmacy service providers, call and customer service centers, handling of pharmacy services by mail, contracting with drug manufacturers and third parties related to their services, reports, actuarial services, computer services and processing , management of disease medicine therapy and advice and use of clinical pharmacists. Reference may be made in this Act as PBM and include related entities that do not call or identify themselves as PBM <u>but provide pharmacy benefit administrative services in Puerto Rico</u>. The definition also includes any person or entity offering the services and products that the PBM contracted with the pharmacy.

2. Subsection (e) defines "Cost of Dispensing." While this definition is consistent with the statute, this language deviates from a typical definition of *dispensing* costs, to what appears to be a definition of a *drug* cost. We think this should be clarified to ensure the term refers to the cost of dispensing a drug rather than the cost of the actual drug.

   PCMA requests the following amendment:

   Cost of Dispensing - means the reimbursement paid to the Pharmacy for dispensing the Medication. This reimbursement reflects the cost of the Pharmacist's professional services and the cost of dispensing the Medicines to a beneficiary. <u>The cost of dispensing</u> ~~Pharmaceutical costs~~ include<u>s</u>~~, but are not limited to,~~ reasonable costs related to the time spent in obtaining information on medical coverage, review of the patient profile, use of medications, prescription interpretation, dose verification, review of the list of Medications of the medical plan, compose the mixture of the Medication, labeling, review of bottles used, guidance and pharmaceutical counseling and delivery, among other related processes.

3. Subsection (k) defines "pharmacy," but within the proposed rule, the term "pharmacy service provider is used." We believe that the term "pharmacy" should be the favored term, because it is the defined term in the rule.

   PCMA suggestion for clarity:

   Where we have offered amendments in other areas in this comment letter, we've suggested correcting the term "pharmacy service provider" to "pharmacy," but for clarity and consistency with the definition, all use of "pharmacy service provider" in the rule should be changed to "pharmacy."

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4. Subsection (m) defines "Medication Forms." The phrase "and related entities" is contained within this definition and throughout the proposed rule. The reason for these additional words is unclear, as the definitions of PBA and PSM already define which entities are to be regulated under this authority. Without a reason for additional words, PCMA suggests consistency with the statute.

   PCMA requests the following amendment[1]:

   Medication Forms - means the Covered Drug Forms (FMC) established by the PBMs or PBAs ~~and related entities~~ for the pharmacy benefits coverage of health insurance plans. They include physical health, mental health and dental medications for the holistic treatment of patients.

5. Subsection (q) defines "Inspection." The statute calls for the ability of the Regulatory Commissioner to examine or audit, not "inspect." When a new term is introduced, it implies that there are different meanings to the words used. Therefore, for clarity and consistency, we request that the term used in the rule match the statute. Additionally, within the definition, it is unclear what is meant by "facility" for the purposes of PBM operations as it doesn't seem to fit the business model of PBMs. PBMs do not have brick-and-mortar facilities where they treat patients or provide clinical services, unlike other types of health care facilities (e.g., hospitals, doctors' offices, clinics, etc.). Thus, we are seeking clarification as to what it means or requesting to remove the term entirely.

   PCMA requests the following amendment:

   Examination ~~Inspection~~ - means the process by which a designated officer of the Department physically verifies the fact that any ~~health facility or~~ PBA or PSM ~~facility~~, subject to the laws and regulations that the Department administers, complies with its provisions.

   We also request that the definition of "Inspector" be amended to "Examiner" for consistency with the statute.

6. Subsection (t) defines "Pharmacy Services Manager." The Act provides the Secretary with broad authority to "establish additional requirements to those set forth herein to all [PBMs]....when they are necessary in the interest of the health and safety of the individuals who may be affected directly or indirectly for the costs of medications...." The rule should specifically indicate that any additional regulations on PBMs are necessary to enforce the statute. Any further requirement would be inconsistent with the underlying law. As noted in comment 1 above, it is not clear why there is a need for two different definitions – both of which define what a PBM is – and we suggest only using the definition of "Pharmacy Services Manager" as drafted in comment 1 for consistency with the statute.

[1] We request the removal of "and related facilities" or "related entities" in the following articles as well: 3.01(r) (definition of "inspector"); 4.03 (functions and powers of the Regulatory Commissioner); 4.03(b); 4.03(d); 5.03(b)(3) (information required for license application); 6.01(b) (inspection powers of the Regulatory Commissioner); 7.01(f) (MAC lists); 8.02(c) (claim and reimbursement process); 8.02(d); 8.02(e); 10.06(a) (review of request for audit reconsideration); 10.06(b); 12.01 (drug changes); 13.01 (termination); 14.01 (prohibitions).

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7. Subsection (z) defines "Health Insurance Organization or Issuer." The proposed definition does not provide a clear exemption for ERISA plans or Medicare plans as programs or contracts for which the Office of the Commissioner of Insurance does not have jurisdiction.

   PCMA requests the following amendment:

   Health Insurance Organization or Insurer - means an entity subject to the laws and regulations of insurance in Puerto Rico or subject to the jurisdiction of the Office of the Commissioner of Insurance, who hires or offers to hire to provide, supply, processing or pay the costs of services of care of health or refund, including any for or non-for profit corporation that provides hospital and health services, health services organizations and any other entity that provides benefit plans, services or health care. Such term does not include health coverage provided through an employee benefit plan under the Employee Retirement Income Security Act of 1974, 29 U.S.C. Sec. 1001, et seq., or Medicare.

Chapter IV – Office of the Regulatory Commissioner

Article 4.01 – Creation of the Office of the Regulatory Commissioner

1. Subsection (c) includes "inspect" and "cite witnesses" to the powers of the Regulatory Commissioner. However, the statute, at Article 6(c) states the Commissioner will have power to "investigate, audit, or examine the operations, transactions, accounts, files, documents and capital of the PBMs, PBAs..." The reason for the additional words in the proposed rule is unclear, and it is furthermore unclear what "cite witnesses" means. PCMA suggests consistency with the statute.

   PCMA requests the following amendment:

   The Office of the Regulatory Commissioner shall have the power to investigate, ~~inspect, cite witnesses~~, approve and adopt the necessary rules to make the purposes of these Regulations viable.

Article 4.03 – Functions and Powers of the Regulatory Commissioner

1. Subsection (c) includes enforcement of prompt pay requirements for pharmacy reimbursement within the functions and powers of the Regulatory Commissioner. PCMA does not object to the 30-day timeline, but the proposed rule should specify that the 30-day clock starts with the receipt of a clean claim, which would track with the statutory language.

   PCMA requests the following amendment:

   The Regulatory Commissioner shall ensure that PBMs~~,~~ or PBAs~~, or related entities~~ comply with payments to pharmacy providers in a term not exceeding thirty (30) calendar days for clean claims with an actionable claim for payment pursuant to 26 L.P.R.A. § 3001 et. seq.

2. Subsection (d) includes vague references to "capital" and the aforementioned "or related entities." We do not know the purpose of this language and suggest clarifications to ensure consistency with the statute.

   PCMA requests the following amendment:

   It is incumbent upon the Regulatory Commissioner to investigate or audit the operations, transactions, accounts, files, documents, and public financial disclosures ~~capital~~ of the PBMs and PBAs ~~or related entities~~ specific to operations in Puerto Rico pursuant to Chapter X of these Regulations.

Chapter V – Licenses

Article 5.02 – License Cost

1. We recognized that this article is mis-numbered in the proposed regulation. It should be 5.03, and the rest of this chapter should be renumbered.

2. Subsection (b) includes information on how the fees collected from licensees will be used. We think it is critical to specify, as delineated in the statute, for what purpose the licensure fees will be used.

   PCMA requests the following amendment:

   The referred payment corresponds to the annual cost to have a license to operate as a PBM, PBA or related entity in Puerto Rico. It does not constitute a limitation to require additional amounts for certain purposes, as determined by the Secretary, as necessary to enforce this Act.

Article 5.03 – License Application

1. Subsection (b)(6) includes required information that must be included in the license application for a license to operate as a PBA or PBM, including an audited financial statement of the PBM or PBA. PCMA suggests that consolidated financial statements provide sufficient information to the Commissioner, and thus proposes that the language be amended to allow for the submission of consolidated financial statements.

   PCMA requests the following amendment:

   Certified copy of the audited consolidated financial statements of the entity of the previous year.

2. Subsection (b)(10) broadly requests "any other document that the Secretary considers necessary to carry out the complete evaluation of the corresponding request." We believe that only *relevant* documents pertaining to the application should be required to be provided in order to process the application.

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PCMA requests the following amendment:

Any other relevant document that the Secretary considers necessary to carry out the complete evaluation of the corresponding request.

Article 5.07 – Restrictions

1. Subsection (a) includes a criterion for fraud, for which a PBM or PBA license may be revoked. We think the language here could be strengthened to provide greater clarity to regulated entities.

   PCMA requests the following amendment:

   The licensed entity has been convicted of ~~committed~~ fraud in any process related to these Regulations.

2. Subsection (d) includes a criterion for financial crimes, for which a PBA or PBM license may be revoked. Listing "fraud" in this section is redundant to subsection (a) above, and it is unclear what "ideological" means in this context. We think the language here could be strengthened to provide greater clarity to regulated entities.

   PCMA requests the following amendment:

   The licensed entity has ~~committed~~ been convicted of crimes related to illegal appropriation, embezzlement, ~~fraud and ideological~~ or document falsification.

Chapter VI – Inspections

Article 6.01 – Inspection Powers of the Office of the Regulatory Commissioner

1. Subsection (a) discusses the enforcement and compliance powers of the Regulatory Commissioner. We believe this chapter should be retitled and amended throughout to mirror the statute which discusses "examinations" and not inspections. Additionally, some of the language does not appear in the statute, which we think should be removed, as it vague and goes beyond what is statutorily permitted.

   PCMA requests the following amendment:

   The Office of the Regulatory Commissioner shall have the power to enforce and monitor compliance with the provisions of these Regulations, including the jurisdiction to investigate, ~~inspect, cite witnesses,~~ audit or examine, ~~approve~~ and adopt the necessary rules to ensure compliance herewith.

2. Subsection (b)(2) provides an unclear criterion for PBA or PBM contracts with pharmacy service providers that the Regulatory Commissioner must verify: "That the reimbursement for the medication and the cost for dispensing are consistent with the standards and criteria

prevailing in the Puerto Rican market." Without additional specificity on the standards and criteria, regulated entities have not been given adequate notice on how to comply with the rule.

PCMA recommendation:

The Secretary should specify what will be used to indicate what is "consistent" with the standards and criteria of the Puerto Rican market. To that end, we encourage the Secretary to establish objective metrics, standards, or criteria, provided through rulemaking. Providing adequate notice and opportunity to comment on the proposal is necessary to ensure a fair process and provide clarity on how to comply.

3. Subsection (b)(3) provides an unclear criterion for PBA or PBM contracts with pharmacy service providers that the Regulatory Commissioner must verify: "That any reduction in the amount of the reimbursement will not be done in a unilateral, arbitrary or discriminatory way or based on unfair business practices." It is unclear what would constitute "unilateral, arbitrary or discriminatory." In addition, the nature of a PBM-pharmacy contract and the Act is such that it may allow for changes in reimbursements without the need for pharmacy to affirmatively consent to the changes. For example, the Act requires a PBM to update its MAC list every seven days. MAC lists include reimbursement rates for generic drugs, which are a commodity and pricing on them may change due to market forces. If the reimbursement rate goes down to reflect current market rates, a pharmacy can check the reimbursement rate through the PBM electronic portal. The pharmacy is aware that reimbursement may change with the updating of the list and can access the relevant list or specific drug reimbursement rate as needed. This is the framework for the MAC reimbursement methodology that the pharmacy has contractually agreed to and the Act contemplates. It defies logic to think that the Act contemplates pharmacies having to sign new contracts—potentially every 7 days—if the reimbursement rate changes on any one of thousands of generic drugs. and it's unclear if this satisfies the requirement here.

   PCMA recommendation:

   The Secretary should provide context around what constitutes "unilateral." Regulated entities need more information about what exactly is prohibited to ensure that they can stay in compliance with the law.

4. Subsection (b)(4) provides the following criterion for PBA or PBM contracts with pharmacy service providers that the Regulatory Commissioner must verify: "That the payment of the reimbursement for drugs is not below the acquisition cost, provided that the pharmacy service provider serves proof of purchase of the dispensed drug." However, to reflect the true acquisition cost, the pharmacy should be required to provide information on any volume or other discounts not reflected on the invoice so that a determination of the pharmacy's actual net acquisition cost can be made.

   PCMA requests the following amendment:

   That the payment of the reimbursement for drugs is not below the <u>net</u> acquisition cost, provided that the pharmacy ~~service provider~~ serves proof of purchase of the dispensed drug,

as well as information on volume or other discounts or rebates not reflected on the invoice, so as to indicate the pharmacy's actual net acquisition cost.

Article 6.02 – Inspection Process

1. Our general comment throughout this section is that, as currently drafted, the proposed regulation appears to be more appropriate for a health care facility that provides actual medical care, like a hospital, not a PBM, which is an administrative organization that typically operates from a standard office. We recommend a more appropriate regulatory oversight process that is less like an "inspection" and more like a market conduct exam, market survey, or desk audit, which is consistent with the statute, which gives the commissioner authority to "investigate, audit, or examine..." (*see* Article 6 (b)). We also believe that it is important to ensure that all information reviewed be held confidential and not subject to any open record public requests.

   PCMA requests the following amendments:

   Article 6.02 – ~~Inspection~~ Examination Process

   New Subsection (h):
   All information reviewed by the Regulatory Commissioner is to remain confidential and not subject to public disclosure under Puerto Rican open records laws.

2. Per our comments above, PCMA requests the following amendments to subsection (a):

   At the beginning of each fiscal year, the Regulatory Commissioner will present to the Secretary, for its approval, an Examination ~~Inspection~~ Plan, which will contain, among others, the number of entities that will be included as part of the examination ~~inspection and monitoring~~ process during said fiscal year.

3. Per our comments above, PCMA requests the following amendments to subsection (b):

   The license renewal examinations, if necessary, ~~inspections~~ will be made during the term of validity of each license, with the purpose of determining the compliance with the provisions laid down in this Regulation. Should the inspection not be performed during the term of validity of the license, it must be performed once (1) every two (2) years.

4. Per our comments above, PCMA requests the following amendments to subsection (c):

   The examinations ~~inspections~~ may be initial, general, follow-up, or as part of the process of investigating a complaint or incident related to the services they provide.

5. Subsections (c) and (d) appear to be the same examination. We would appreciate the Secretary providing clarity on what difference, if any, there is between the two examinations. If there is no substantive difference between these two examinations, we recommend that (d) be stricken to avoid confusion.

6. Per our comments above, PCMA requests the following amendments to subsection (e):

   ~~Inspections~~ Examinations shall be carried out by inspectors duly authorized by the Secretary, through the Office of the Regulatory Commissioner. They must always be identified and will show their identification to any person who requests it.

7. Per our comments above, PCMA requests the following amendments to subsection (f):

   Any person holding a License under the provisions of these Regulations, must provide any examination ~~inspection~~ required by the Office of the Regulatory Commissioner.

8. Per our comments above, PCMA requests the following amendments to subsection (g):

   Examinations ~~Inspections~~ of entities ~~establishments~~ regulated by these Regulations may be carried out without prior notice during the regular hours of operation of the establishment. ~~The fact that the owner or principal is not present at the establishment will not be a reason or justification to prevent such inspection from taking place.~~

Article 6.03 – Authority to Enter Licensed Entities

1. As noted in our comments for article 6.02 above, our general comment in this section is that, as currently drafted, the proposed regulation appears to be more appropriate for a health care facility, like a hospital, not a PBM operation, which is typically just a standard office. We recommend a more appropriate regulatory oversight process that is less like an "inspection" and more like a market conduct exam, market survey, or desk audit, which is consistent with the statute. Furthermore, the scope of an examination or audit should be *relevant* documents.

   PCMA requests the following amendments:

   The Department of Health and the Office of the Regulatory Commissioner and its authorized representatives or inspectors shall carry out the examinations ~~inspections~~ or investigations they deem necessary, and may review ~~any~~ relevant documents necessary to determine compliance with the Act and this regulation of the licensed entity or in the process of licensing in such a way that compliance with each of the requirements established in this regulation.

Article 6.04 – Inspection Visits

1. As noted in our comments for article 6.02 above, our general comment in this section is that, as currently drafted, the proposed regulation appears to be more appropriate for a health care facility, like a hospital, not a PBM operation, which is typically just a standard office. We recommend a more appropriate regulatory oversight process that is less like an "inspection" and more like a market conduct exam, market survey, or desk audit, which is consistent with the statute. Furthermore, the scope of an examination or audit should be *relevant* documents.

   PCMA requests the following amendments:

   Article 6.04 – ~~Inspection Visits~~ Examinations

2. Following our comments above, PCMA requests the following amendments to subsection (a):

   The Examiner ~~Inspector~~ visiting a licensed entity, as part of the examination of the entity ~~inspection of the establishments~~ to which this Regulation applies, may perform, among others, the following functions:

3. Per our comments above, PCMA requests the following amendments to subsection (a)(1):

   Examine relevant records, documents, inventories, assets, premises, properties, transactions, businesses or any other materials or activities related to the administration of pharmacy benefits or the management of pharmacy services specific to operations in Puerto Rico, necessary to ensure compliance with this regulation.

4. Per our comments above, PCMA requests the following amendments to subsection (b):

   Every examination ~~inspection~~ process must contain an entry conference and an exit conference. In the entry conference, examiners ~~inspectors~~ will introduce themselves to the personnel designated by licensed entity, they will communicate the purpose of the visit of ~~inspection~~ examination and will indicate the process to be carried out. During the departure conference, the examiners ~~inspectors~~ will communicate to the licensed entity's staff the preliminary findings found, and the receipt of the Deficiencies Report and the corrective plan.

5. As drafted, the language in subsection (c) would permit the Regulatory Commissioner to interview clients as part of an examination; we believe that that is outside the scope of the statute.

   PCMA requests the following amendments:

   The examiners ~~inspectors~~ of the Office of the Regulatory Commissioner shall have access to the licensed entity, and to relevant ~~any~~ requested information and documentation, ~~as well as to be able to interview clients~~, employees and administrators of the licensed entity.

6. As drafted, the language in subsection (e) would permit the Regulatory Commissioner to "obtain" documents during an examination, but it is customary that during a market conduct exam or audit, for example, regulators make copies of the relevant documents and notify the custodian of which documents they made copies.

   PCMA requests the following amendments to subsection (e):

   In the case of documents obtained by the examiners ~~inspectors~~, which are deemed by them as unnecessary for the examination ~~inspection~~ as is provided in this Regulation, shall be returned to its owner or legal custodian from whom they were obtained. If the document is relevant to the examination, the examiners may make copies but the examiner must notify the legal owner or custodian of which documents they are copying.

Article 6.05 – Complaints

1. Subsection (b) discusses investigations of PBAs and PBMs in the event of a complaint. We believe the language in the proposed rule can be clarified to distinguish these types of investigations from the types of market conduct exams or audits as described in earlier articles.

   PCMA requests the following amendments:

   At the beginning of an investigation ~~inspection~~ for a complaint, a summary of the statements contained in the complaint will be delivered to the administration or person in charge of the PBA, PBM or related entity.

2. Subsection (c) would provide the Regulatory Commissioner with vast discretion to talk to "third parties," including contractors—completely at the Commissioner's discretion—about a PBM's business. The statute does not grant the Regulatory Commissioner the authority to talk to third parties about private contract agreements. PCMA requests that this subsection be deleted as this is vague and attempts to grant new authority to the Regulatory Commissioner related to confidential and proprietary contracts not subject to the statute.

Article 6.06 – Inspections Report and Corrections Plan

1. As noted above, the Regulatory Commissioner's authority extends to "investigations, audits, and examinations" of PBMs/PBAs (*see* Article 6 (c)). As we suggested above, PCMA suggests that the term "inspection" in this article be changed to "examination" in all relevant sections, which includes (a), (b), (c), (g), and (h).

2. Subsection (f) provides for extensions of the deadline to submit a corrections plan. The statute is silent on a time period. PCMA understands that the information should be provided in a timely manner but believes 5 working days is too short of a timeframe to comply and believes 10 working days is a more reasonable timeframe.

   PCMA requests the following amendment:

   Extensions of no more than ~~five (5)~~ ten (10) additional working days will be granted to submit a corrections plan, to those entities that, by written evidence, submit a duly justified request.

3. Subsection (g)(1) allows for examination and photocopying of documents related to an inspection under certain conditions. This subsection indicates that information cannot be examined unless "the person or institution or entity consents in writing to grant the information and release..." It is unclear to whom the regulation is referring in this context and more clarity is needed.

   PCMA recommendation:

   The Secretary should use defined terms here. It is not clear who has to provide the consent. We believe that it should be the PBA or PSM.

PCMA

Chapter VII – Maximum Allowable Cost (MAC) Lists Permitted

Article 7.01 – MAC List

1. Subsection (a) establishes what MAC lists are. The regulation should clarify that MAC lists relate to generic drugs only, as intended by the statute. In addition, "pharmacies" and "pharmacists" are defined terms and should be used consistently throughout the regulation. Finally, "Cost of Acquisition" is a defined term and it should be used in this Article instead of other phrases intended to mean the same.

   PCMA requests the following amendments:

   Any PBM, PBA or any related entity will develop and implement a MAC list. Such MAC list shall establish the amounts to be paid or reimbursed to pharmacies ~~providers of pharmaceutical services~~ for the ~~acquisition~~ cost of acquisition paid to ~~by~~ those pharmacies ~~providers~~ for generic medications.

2. Subsection (f) would require PBMs and PBAs to send MAC lists to the Office of the Regulatory Commissioner each time they are updated. This process would be incredibly difficult to comply with considering the lists can vary depending on the client and the fact that there are thousands of generic drugs on MAC lists. Furthermore, it would inundate the Regulatory Commissioner with unnecessary information that is continuously changing, possibly more often than every seven days.

   PCMA requests the following amendments:

   All PBMs and PBAs must make available, upon request of the Office of the Regulatory Commissioner, the relevant MAC list requested with the information that follows: ~~All PBMs, PBAs, or related entities must also send their updated MAC list to the Office of the Regulatory Commissioner. They may be submitted electronically to the Office of the Regulatory Commissioner in the format designated for these purposes. They should include the following information for each medicine included on the MAC list:~~

   1. *The National Drug Code (NDC)*
   2. *The classification of the medication according to subsection (c) of this article*
   3. *The updated prices of the list, which should be ~~reviewed~~ updated every seven (7) calendar days.*

3. Subsection (f)(3) establishes how often MAC lists should be updated, as is the intent of the statute. However, the regulation simply provides that the MAC lists should be "reviewed" every seven days, which appears to conflict with various provisions in the statute and proposed regulation. We think the Secretary should revise the proposed rule to align with statutory intent and other provisions of the proposed rule.

   PCMA requests the following amendment:

   The updated prices of the list, which should be updated ~~reviewed~~ every seven (7) calendar days.

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Article 7.02 – Update of MAC Lists

1. Subsection (a) would require PBMs and PBAs to send MAC lists to the Office of the Regulatory Commissioner each time they are updated. As discussed above, this process would be incredibly difficult to comply with considering the lists can vary depending on the client. Furthermore, it would inundate the Regulatory Commissioner with unnecessary information that is constantly changing, possibly more often than every seven days.

   PCMA requests the following amendments:

   The price updates corresponding to each drug on the MAC list must be reviewed every seven (7) calendar days. ~~They may be submitted electronically to the Office of the Regulatory Commissioner in the format designated for these purposes.~~

2. Subsection (b) provides further instruction on the updates of MAC lists. We suggest a procedure for posting a MAC list that is consistent with current market practices. This would ensure that there is little disruption in process but also would provide transparency for pharmacies.

   PCMA requests the following amendments:

   The updates of the drugs subject to the MAC list, the prices corresponding to each drug, and the GPI are available for the pharmaci~~es~~y ~~service providers, both at the electronic site designated by the Office of the Commissioner Regulator and~~ on the website owned by each PBM or PBA.

3. Subsection (c) concerns licensure and is misplaced. We request deleting this language.

Chapter VIII – Drug Payment Reimbursement

Article 8.02 – Claim and Reimbursement Process to PBMs, PBAs, or Related Entities

1. As we noted in our comments to Article 6.01(b)(4) above, the "cost of acquisition" should reflect the pharmacy's true acquisition cost, which would be net of any discounts or rebates, which often are not reflected on the invoice. As we suggested in the definitions, we propose that the language in subsection (c) be revised to require the pharmacy to submit information indicating any applicable discounts so that the PBM can determine whether it has reimbursed at least cost of acquisition. In addition, we believe that the words "service provider" after "pharmacy" are unnecessary, since the term "pharmacy" is a defined term in the regulations (*see* 3.01(k)).

   PCMA requests the following amendments:

   The claim request of a pharmacy ~~service provider~~ submitted to a PBM, or PBA ~~or related entity~~ must include a copy of the commercial invoice of the Distributor or Wholesaler

indicating the ~~acquisition~~ cost of acquisition of the drug and any other documentation to demonstrate any applicable discounts the pharmacy received that reduced the pharmacy's net cost to purchase the drug.

2. As we noted above, the "cost of acquisition" should reflect the pharmacy's true acquisition cost, which would be net of any discounts or rebates. We suggest that the language in subsection (j) be revised to require the pharmacy to submit information indicating any applicable discounts so that the PBM can determine whether it has reimbursed at least cost of acquisition.

   PCMA requests the following amendments:

   The complaint before the Office of the Regulatory Commissioner must include a copy of the commercial invoice of the Distributor or Wholesaler and any other documentation demonstrating discounts not reflected on the invoice that reduced the pharmacy's net cost to purchase the drug~~indicating the cost of acquisition of the drug~~.

Chapter IX – Quarterly Reports on Reimbursements of Payments and Medicines Denied

Article 9.01 – Quarterly Reports

1. The English translation of subsection (a) appears to require quarterly reports on denied pharmacy reimbursements (see **bolded** language): (a) "Every PBM, PBA or related entity shall be required to submit quarterly reports on **refunds of payments and medications denied to pharmacy service providers** to the Office of the Regulatory Commissioner."

   PCMA recommendation:

   We ask the Secretary to clarify which PBM activities this is referencing. We believe it means that the report is to contain only information regarding pharmacy reimbursement matters but are seeking further guidance.

2. Subsection (b) requires PBMs to submit quarterly reports to the Office of the Regulatory Commissioner within the first 15 days of the month following the quarter to be included in the report. The statute is silent on time period. PCMA understands that the information should be provided in a timely manner but believes 15 days is too short of a timeframe to comply and believes 30 days is a more reasonable timeframe.

   PCMA requests the following amendments:

   Every PBM or PBA ~~or related entity~~ must submit each quarterly report to the Office of the Regulatory Commissioner within the first ~~fifteen (15) days of the month~~ thirty (30) days following the quarter included in the report.

3. The English translation of subsections (f)(v)-(vi) appears to require quarterly reports on denied pharmacy reimbursements.

PCMA

PCMA recommendation:

We ask the Secretary to clarify which PBM activities are required to be included in this report. We believe it relates to pharmacy reimbursement matters but are seeking further guidance.

Chapter X – Audits

Article 10.05 – Request for Audit Reconsideration

1. Subsection (c) establishes a procedure for a pharmacy to request administrative review on a PBM audit. The proposed rule does not have a timeline attached to this review process, and we suggest including such information that is consistent with the statutory requirements.

   PCMA requests the following amendments:

   In the event that the PBM~~,~~ or PBA ~~or related entity~~ does not issue a determination on the audit reconsideration request within thirty (30) calendar days, it may then request, within the next thirty (30) calendar days, an administrative review before the Office of the Regulatory Commissioner to issue a final determination.

Chapter XII – Changes of Medicines

Article 12.01 – Drug Changes

1. Subsections (a) and (b) establish a procedure for a PBM or PBA to provide information to covered individuals of changes to the prescription drug formulary. The provisions on disclosures regarding changes to the formulary should be clearer so as not to confuse patients who are not taking a drug that is affected by a formulary change.

   PCMA requests the following amendments:

   a) *Any entity regulated by Law 82-2019, including insurance companies, PBMs or PBAs, ~~or related entities,~~ that decides to remove a maintenance medication from their pharmacy coverage must send a notification to inform said removal to all patients that are ~~could be~~ affected.*

   b) *The notification of removal may be made by mail or by electronic means provided it can be evidenced that the information on the removal was sent to all patients who are ~~might be~~ affected.*

PCMA

Chapter XIII – Termination or Nonrenewal of Services to Pharmacy Service Providers

Article 13.01 – Termination

1. As noted above, we believe that consistent terminology is important throughout the regulation. As such, we recommend that this chapter be retitled "Termination or Nonrenewal of Services to Pharmacies," since "pharmacy" is defined in the statute and the regulation.

2. The proposed rule is unclear as to what would be considered "just cause" for terminating a contract. PCMA seeks clarification regarding when a contract agreement may be terminated for just cause and suggests the following language changes for clarity.

   PCMA requests the following amendments:

   Any termination, cancellation or non - renewal of a contract or agreement between a PBM~~,~~ or PBA ~~or entity~~ and a pharmacy related to the Health Plan of the Government of Puerto Rico ~~one provider of services of pharmacy~~ should be for just cause, except in the cases of suspected fraud, abuse and waste ~~related to the Health Plan of the Government of Puerto Rico~~.

   In the case of ~~A~~any termination, cancellation or non-renewal of a contract between a PBM~~,~~ or PBA ~~or related entity~~ with a pharmacy ~~service provider~~, the PBM~~,~~ or PBA ~~or related entity~~ will be required to issue a written notification to the pharmacy ~~service provider~~ not less than ninety (90) calendar days in advance, prior to the date established for termination or cancellation, stating the specific causes for it.

Chapter XIV – Prohibited Practices to PBMs, PBAs and Related Entities

Article 14.01 – Prohibitions

1. Subsection (g) prohibits PBMs from failing to update the price of medications every seven (7) days when an increase or decrease occurs, notifying pharmacies and adjusting these prices in their systems. For clarity, this section should reference drugs that are on the maximum allowable cost list, since it is those drugs that have regular price fluctuations and where the statute (Article 7(d)(2)) requires the change.

   PCMA requests the following amendment:

   g) Skip updating the price of medications on the maximum allowable cost list every seven (7) days when an increase or decrease occurs, notifying pharmacies and adjusting these prices in their systems.

2. Subsection (j) prohibits "billing pharmacies for the service of issuing [pharmacy] payments or withholding any amount of payment according to [a pharmacy's] volume of business or payment methods chosen."

PCMA

PCMA recommendation:

It is unclear to what practice this subsection is referring, and we would appreciate clarification on this provision.

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Thank you for the opportunity to provide feedback on the proposed regulation. Please contact me at 202-756-5743 or aalexander@pcmanet.org if you have any questions about our comments.

Sincerely,

April C. Alexander

April C. Alexander
General Counsel and Vice President, State Regulatory Affairs