PCMA

March 2, 2018

The Honorable Neal Foster Chair
House Finance Committee
Alaska State Legislature
Juneau AK 99801

Re: Concerns re: HB 240 – Pharmacy Benefit Managers

Dear Chairman Foster:

On behalf of the Pharmaceutical Care Management Association (PCMA), I am writing to you regarding HB 240. PCMA is the national association representing pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million Americans with health coverage provided through large and small employers, health insurance plans, labor unions, state and federal employee benefit plans, and government programs. As requested by the Committee during the February 14th hearing on HB 240, I am writing to share our concerns with HB 240.

I. PBM Registration Provisions: §§ 21.27.901 – 905 Are Unnecessary

The registration requirements in sections 21.27.901 – 905 are unnecessary because the Division of Insurance already has jurisdiction over the pharmacy benefits of insured plans and the ability to enforce those requirements on the plans providing those benefits in Alaska. PBMs, through their contracts with health plans, cannot do anything that would bring the client out of compliance with Alaska law. Thus, PBMs are required to comply with the same consumer protections governing utilization review, prior approval, and dispute resolution systems, among others.

II. Pharmacy Audit Provisions: §§ 21.27.910 – 940 May Encourage Fraudulent Activity

Sections 21.27.910 – 21.27.940 may have the unintended consequence of opening the door to fraud, abuse, and wasteful spending in health care. Health plans and employers that choose to use PBMs for pharmacy benefits rely on audits of network pharmacies to recoup monies incorrectly paid for claims with improper quantity, days' supply, and coding; duplicative claims; and other irregularities. The State of Alaska's own RFP for PBM services specifically requires a "robust process for tracking and monitoring fraud/abuse." Audits also have a patient safety aspect in that they verify if pharmacies are complying with board of pharmacy rules such as the proper storage of prescription drugs and posting of required signs. Specifically:

a. Section 21.27.910(b) requires entities to provide pharmacies with an advanced written notice 10 business days before an audit. This would give individuals ample time to hide evidence of fraudulent activities or evade authorities altogether.

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org

PCMA

b. Section 21.27.910(c)(3) limits the number of prescriptions available to audit to 250, which is simply not a large enough sample size to do an effective audit. Auditors look for errors, irregularities, and suspicious patterns over time, and compare claims with historical information and with similarly situated pharmacies. Substantial changes in claim volume or the dollar amounts from pharmacies can indicate fraudulent activity.

c. Section 21.27.910 (d)(1) and (2) require a pharmacist licensed in AK to conduct the audit. Since this could limit the ability to conduct full and fair audits, we recommend requiring an audit be conducted (1) by a licensed pharmacist or (2) in consultation with a licensed pharmacist.

d. Section 21.27.920 (b)(2) and (b)(3) prohibit recoupments of mailed payments as well as payments based on a percentage.

e. Section 21.27.935 states that when conducting an audit, clerical or computer errors must be intentional. However, section 21.27.940 states that activities under sections 21.27.907-955 do not apply in cases of suspected fraud.

f. Section 21.27.940 should clarify that the requirements of AS 21.27.901 - 21.27.955 do not apply to federal programs or payers.

Audit procedures are contained in PBM-pharmacy contracts and PBMs supply pharmacies with provider manuals that contain information about audits and examples of fraud, waste, and abuse. Additionally, some PBMs also distribute provider tip sheets quarterly which may contain additional information related specifically to what audits entail. These protections are sufficient.

III. Payment for Generic Drugs: §§ 21.27.945 – 950 Create a State-Mandated Pricing Scheme

Sections 21.27.945 – 955 would create a pricing scheme that would limit or delay the ability of plan sponsors and consumers to benefit from the dramatic cost savings associated with the use of generic drugs. Maximum allowable cost (MAC) is the PBM or plan payment for the unit ingredient costs for generic drugs, and a MAC list creates a standard reimbursement amount for identical products. A MAC list is a common cost management tool that is developed from a proprietary survey of wholesale prices existing in the marketplace, taking into account market share, existing inventory, expected inventories, reasonable profits margins, and other factors. The purpose of the MAC list is to ensure that the pharmacy and/or their buying groups are always motivated to seek generic drugs at the lowest possible price. The MAC list ensures that the PBM, on behalf of their clients (primarily employers), are paying a fair price for widely available generic drugs. States adopted MAC lists for their Medicaid programs after audits showed that Medicaid reimbursements for generic drugs far exceeded a pharmacy's acquisition costs. Employers have similar concerns and goals to protect against overpaying for generic drugs.

PCMA

a. Section 21.27.945(1) requires PBMs to provide proprietary information to pharmacies.

Section 21.27.945(1) requires PBMs to provide the "*methodology* and sources used to determine the drug pricing list" (emphasis added). While providing sources gives the pharmacies insight into where the PBM is gathering the market data to create the list, each PBM has its own confidential methodology in creating a MAC list. These methodologies are one way PBMs compete and should not be exposed.

b. Section 21.27.945(b)(2) limits drugs allowed on a MAC list.

Section 21.27.945(b)(2) in coordination with the definition of "multi-source generic drug" in Section 21.27.955 (6) limits the generic drugs that can be included on a MAC list to only drugs that have two or more "multi-source generic drugs" available in the marketplace. By prohibiting the use of MAC reimbursement for drugs during the generic exclusivity period (right after the brand counterpart goes off patent), the number of drugs that can be dispensed at discounted generic drug rates significantly decreases. Thus, pharmacies would be allowed to purchase these drugs at a competitive rate (the price of the exclusive generic as opposed to the price of the brand name drug), but payers would be forced to reimburse pharmacies at excessive brand prices, benefitting pharmacies at the expense of consumers.

c. Section 21.27.950 guarantees profits for pharmacies.

Section 21.27.950(c), stating that PBMs "shall grant an appeal" in specified circumstances prescribes specific pharmacy reimbursement terms by requiring that pharmacies are reimbursed at the "cost" of the drugs to the pharmacy, even if the cost was inflated or not truly reflected on the invoice—ensuring pharmacy profit at the expense of consumers.

MAC provides an incentive for the pharmacy to shop for the lowest price of a generic drug. The risk that a pharmacy may be reimbursed at something less than it paid its supplier places an incentive on the pharmacy to manage its inventory efficiently and leverage buying power to result in the lowest possible acquisition cost. Poor purchasing practices, negligence in research, and inadequate management of inventory can cause pharmacies to fail to acquire a drug at a price less than or equal to the MAC list price. These inefficient practices should not be rewarded.

Academics have opined that there are dangers in reimbursing pharmacies based on their invoiced drug acquisition cost.[1] Dr. Hyman reports that this type of cost-based reimbursement system will "effectively function as a 'guaranteed profits' term," because the pharmacies will be "guaranteed they will be paid at least that amount, and likely more. And because of rebates and discounts [that pharmacies receive from their suppliers], invoiced prices may not reflect actual drug acquisition costs—further inflating the guaranteed profits."[2] In addition, he indicates that legislation mandating cost-based reimbursement is likely to cause:

- Increased spending on pharmaceuticals and the cost of pharmaceutical coverage
- Reduced competition at the wholesaler and manufacturer level;

[1] David A. Hyman, Professor of Medicine, University of Illinois, The Adverse Consequences of Mandating Reimbursement of Pharmacies Based on Their Invoice Drug Acquisition Costs, January 2016.
[2] Id. at 1.

PCMA

- Increased use of off-invoice discounting
- Guaranteed profits for pharmacies, irrespective of their actual efficiency
- Reduced consumer welfare.

The State of Washington considered a pharmacy "reimbursement at cost" requirement for PBMs, and found that the fiscal impact would be between a 1 percent increase and 10 percent increase in pharmacy costs paid for by the State—up to $113 million annually. The state's Office of Financial Management fiscal analysis done on the original version of the bill it analyzed indicated that "if PBMs pay more for pharmaceuticals, the inventory management for pharmacies may also change. Removing price limits, such as those created by MAC lists, reduce the incentive for pharmacies to purchase pharmaceuticals at the lowest cost possible; demand for lower cost pharmaceuticals may be reduced."[3]

d. Section 21.27.950(d)(2) requires PBMs to provide information they do not have.

Section 21.2.950(d)(2) requires PBMs, upon denial of an appeal, to identify a drug "that has been purchased" by a network pharmacy at a particular price. Although PBMs have information about *average prices in the marketplace* and through MAC reimbursement methodology, encourage pharmacies to purchase efficiently, PBMs do not know where a specific pharmacy *has purchased* a drug *at a particular price*. This section is unworkable because of these issues.

e. Section 21.27.950(d)(3) is unclear.

This section requires a PBM, upon denial of an appeal, to provide the name of a wholesaler "who operates in the state in which the drug may be purchased." This is unclear drafting. If it means that PBMs must provide the name of a wholesaler from which a drug may be purchased at a particular price, it is inappropriate for PBMs to direct pharmacies to specific suppliers of drugs.

f. Section 21.27.950 authorizes director to interfere in private contracts.

Sections 21.27.950(e) and (f) would give the Division Director the ability to supersede any arbitration agreements between PBMs and pharmacies. Arbitration agreements are used regularly in contracting because they provide an alternative forum for resolving disputes outside of the courtroom, and they are widely used in the healthcare industry. Parties negotiate contracts in good faith, anticipating potential disagreements and drafting terms that outline the rights and responsibilities of each party in the event of conflict. These arbitration agreements sometimes provide for appeal rights to the court system, in the event resolution by arbitration fails. This section appears to authorize the Director's Office to render binding judgment on the parties, inserting itself in the midst of an agreed-upon process—something that is unheard of for other health care entities. This is unnecessary and a government overreach into private contracting.

[3] Washington State Office of Financial Management, "Multiple Agency Fiscal Note 5857 SSB Full" 3-8-2015, page 3, available at: http://app.leg.wa.gov/billinfo/summary.aspx?bill=5857&year=2015.

PCMA

We greatly appreciate the opportunity to provide the Committee with our perspectives and look forward to further discussion. Please let me know if you have any questions about our concerns. Thank you.

Sincerely,

April C. Alexander

April C. Alexander
Assistant Vice President, State Affairs

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org

PBM BEST PRACTICES

PBMs work to deliver the lowest net cost of drugs for their clients and improve patient health outcomes.

PBMs offer their clients programs that facilitate timely patient appeals to help ensure appropriate medication use.

PBMs provide clients with audit rights in their contracts.

PBMs perform drug utilization reviews to help reduce drug-drug interactions, increase patient safety, and improve appropriate use.

PBM clients are entitled to negotiate all client contractual terms, including rebate arrangements ranging from 100% pass-through to shared savings.

PBMs offer network options that include high quality, credentialed pharmacies.

PBMs provide clients with programs to protect against drug manufacturer price inflation.

PBMs provide patients 24-7 access to pharmacists or other clinicians.

PBMs utilize independent clinical experts and specialists to develop formularies and clinical programs to help ensure patients have access to clinically appropriate treatments.

PBMs guarantee financial terms and service levels to maximize overall contract value.

What is Maximum Allowable Cost (MAC)?

- The methodology for establishing contracted reimbursement rates for brand-name drugs is different from that used for generic drugs. Maximum allowable cost (MAC) is one of the most common methodologies used in paying pharmacies for dispensing generic drugs.

- By definition, MAC is the maximum allowable reimbursement by a pharmacy benefit manager (PBM) for a particular generic drug that is available from multiple manufacturers and sold at different prices.

- Each manufacturer has its own price for a particular generic drug and these prices can differ extensively by manufacturer. The purpose of MAC pricing is to standardize the reimbursement amount for identical products from various manufacturers, regardless of each manufacturer's price.

- A MAC list is a common cost management tool that is developed from a survey of wholesale prices existing in the marketplace, taking into account: market share, existing inventory, expected inventories, reasonable profits margins and other factors. Each PBM develops and maintains its own confidential MAC list derived from its specific proprietary methodologies.

- The purpose of a MAC list is to incentivize pharmacies to negotiate more competitive rates for generic drugs with manufacturers and wholesalers in order to keep overall prices down.

- PBMs use MAC lists to balance fairly compensating pharmacies with being able to provide a cost-effective drug benefit plan to their health plan and employer clients.

- MAC pricing is used by 79% of private employer prescription drug plans for retail generic prescriptions. Forty-five state Medicaid programs now use MAC lists. States adopted MAC lists after government audits showed that Medicaid reimbursements for generic drugs far exceeded a pharmacy's acquisition costs.

- Independent pharmacies join buying groups and/or Pharmacy Services Administration Organizations (PSAOs) to earn discounts and rebates from preferred suppliers of drugs and other products. The typical PSAO represents thousands of pharmacies, giving these groups access to pooled purchasing power, negotiating advantages, and contracting strategies.

- Any legislative proposals that restrict a PBM's ability to place lower cost, generic drugs on a MAC list will increase costs for any plan sponsor that uses a PBM to manage their drug benefit. This includes the state plan, Medicaid, employer plans, union plans, workers' compensation plans, etc.

KEEPING GENERIC DRUGS AFFORDABLE

The Value of Maximum Allowable Cost (MAC) Lists

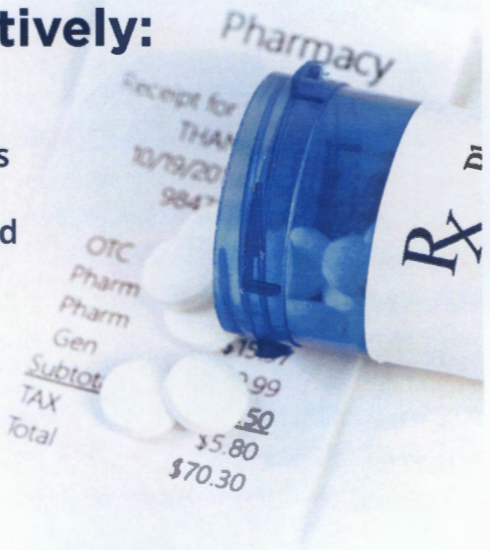
What is a MAC list?

- A MAC list specifies the most a PBM will reimburse a pharmacy for a particular generic drug
- Identical generic drugs can be made by several manufacturers and listed at different prices
- PBMs set and regularly update MAC lists at a level that reflects the average acquisition cost of a well-run pharmacy
- MAC lists encourage pharmacies to purchase generics at the lowest possible cost, driving competition among wholesalers and generic drug manufacturers

MAC lists help PBMs fairly compensate pharmacies and provide cost-effective drug benefits to health plan and employer clients.

MAC lists are effectively:

- ✓ Increasing and maintaining high generic dispensing rates
- ✓ Ensuring pharmacies are paid fairly but not overpaid for dispensing generics
- ✓ Making the generic market more competitive and more efficient



Who uses MAC lists?

79% of private employers[1]

45 State Medicaid[2] Programs

Medicare Part D Plans

Unions

1 Express Scripts. (2016). Available at: http://lab.express-scripts.com/lab/insights/drug-options/mac-pricing-incents-more-affordable-rx

2 Office of the Inspector General, Department of Health and Human Services. *Medicaid Drug Pricing in State Maximum Allowable Cost Programs.* (July 2013).

Generic drugs are driving significant savings in commercial insurance, Medicare, and Medicaid

$111.5
billion in commercial insurance savings

$32.7
billion in Medicaid savings

$67.6
billion in Medicare savings

Generic drugs saved U.S. consumers
$207
billion in 2015.

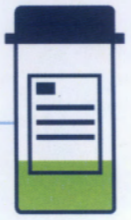
Increased generic drug dispensing rates
=
more money in the pocket of consumers through lower copays and premiums

If the use of generic drugs and MAC lists are restricted:

A 2015 analysis of more than 800 affected generic prescriptions found that restrictions on MAC lists could:

- Increase costs by **31% to 56%** for affected generic prescriptions
- Increase expenditures nationally by up to **$6.2 billion** annually

Generic drugs account for
89%
of filled prescriptions and account for only
27%
of drug expenditures



Reference: IMS Institute for Health Informatics, for the Generic Pharmaceutical Association. (2016).

PCMA

Audit Legislation – Issues and Concerns

- Often, legislation that appears or is intended to help pharmacies can actually have the unintended consequence of opening the door to fraud, abuse, and wasteful spending in health care.

- Health plans and employers with pharmacy benefit plans rely on audits of their network pharmacies to recoup monies incorrectly paid for claims with improper quantity, improper days-supply, improper coding, duplicative claims, and other irregularities.

- Health plans and employers should have the right to ensure that the pharmacy claims they are paying for are legitimate. In a time of rising health care costs, preventing fraudulent activity is an important tool to keeping health care costs down.

- This legislation severely restricts the ability of health plans and employers to make sure they are getting what they pay for. Auditing is part of the cost of doing business. That goes for any type of business – pharmacies should not be an exception to the rule.

- On behalf of healthcare purchasers, Pharmacy Benefit Managers (PBMs) look for errors, irregularities, and suspicious patterns over time. Claims are compared with historical information as well as claims submitted by similarly situated pharmacies. Substantial changes in the volume of claims or the dollar amount of claims from particular pharmacies can indicate fraudulent activity.

- In addition to detecting fraud, audits also have a patient safety aspect. Auditors ensure that pharmacies are complying with Board of Pharmacy rules including the proper storage of prescription drugs or posting of required signs.
- Audit and appeals procedures are already contained in contracts between PBMs and pharmacies. PBMs also supply pharmacies/pharmacists with provider manuals, which contain information about audits and examples of fraud, waste, and abuse. Additionally, some PBMs also distribute provider tip sheets quarterly which may contain additional information related specifically to what audits entail.

- "Health care fraud is a pervasive and costly drain on the U.S. health care system. In 2008, Americans spent $2.34 trillion dollars on health care. Of those trillions of dollars, the

Federal Bureau of Investigation (FBI) estimates that between 3 and 10 percent was lost to health care fraud." [1]

- In 2013 alone, a joint health care fraud prevention effort between the Department of Justice and the Department of Health and Human Services resulted in the recovery $4.3 billion in taxpayer dollars. Some of the recovered money came from uncovering pharmacy fraud schemes that included fraudulent billing practices and illegal dispensing of medications. [2]

[1] National Health Care Anti-Fraud Association, "Combating Health Care Fraud in a Post-Reform World: Seven Guiding Principles for Policymakers," October 2010, available at http://www.nhcaa.org/eweb/docs/nhcaa/PDFs/Member%20Services/WhitePaper_Oct10.pdf.

[2] U.S. Department of Health and Human Services & U.S. Department of Justice, "Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2013," February 2014, available at https://oig.hhs.gov/publications/docs/hcfac/FY2013-hcfac.pdf