DIGESTIVE HEALTH
PHYSICIANS ASSOCIATION®

DHPA Toolkit for State Regulation of Pharmacy Benefit Managers:

Reining in Abusive PBM Practices Impacting Independent GI Practices and their Patients

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I. Introduction

Since its inception in 2014, the mission of the Digestive Health Physicians Association (DHPA®) has been to promote and protect the high quality, cost-efficient care furnished by independent gastroenterology practices. For more than eight years, DHPA has engaged legislators and regulators at the federal level on significant health policy issues affecting the more than 2,400 physicians in DHPA's 104 independent GI practices and the millions of patients DHPA's practices serve. And DHPA has supported its member practices on significant health policy issues arising at the State level that pose threats to—or create opportunities to enhance—independent GI practices' ability to deliver accessible, high quality, cost-efficient care to patients.

A Need for State-Level Regulation of PBMs: PBMs Are Negatively Affecting GI Practices and Their Patients

In speaking with our member practices, we have heard increasing concern about the effect that pharmacy benefit managers (PBMs) are having on independent GI practices and their patients.

PBMs are powerful intermediaries who sit between patients and health plans. The three largest PBMs—CVS Caremark, Express Scripts, and Optum Rx—control prescription-drug benefits for more than 268 million Americans, which amounts to over 85% of all Americans with health insurance.

PBMs are under no obligation to act in the best interests of the plans and patients that they purport to serve—and sometimes they do not. PBMs have steered patients to PBM-affiliated, mail-order pharmacies, imposed first-to-fail and step-therapy requirements that have harmed patients, forced pharmacists to substitute drugs that will secure for the PBMs the greatest profit margin, even if that prescription is not what the doctor expressly ordered, and inhibited the ability of medical practices to engage in in-office dispensing.

Notably, PBMs are largely unregulated by the federal government, and the U.S. Supreme Court recently recognized the autonomy of the States to regulate PBMs in a case called *Rutledge v. Pharmaceutical Care Management Association*, 141 S. Ct. 474 (2020). And even before the Supreme Court decided *Rutledge*, the federal government, forty-five States, and the District of Columbia filed briefs with the Supreme Court arguing that States have robust authority to regulate PBMs.

As a result, there has been a recent surge of State-level regulation of PBMs, and the push for such regulation has straddled the political divide. Blue States and Red States—from California to Texas—have either enacted or are considering legislation to further regulate PBMs.

Overview of this Toolkit and How to Use It to Bring About Change

This toolkit is divided into four parts. The first part discusses at a high level the types of State laws that regulate PBMs, and it includes links to two compendiums of State PBM laws throughout the country. Second, we provide an overview of the State-level regulators with oversight of PBMs. Third, we identify other stakeholders with an interest in PBM regulation. Finally, the toolkit includes model letters that DHPA member practices and their patients can tailor as the deem

appropriate for use in working to secure legislative and regulatory reforms of the PBM industry most relevant to your practices and patients.

There are three types of model letters in this toolkit: (1) a letter for member practices to send to State legislators, (2) a letter that patients may send to State legislators, and (3) a letter that member practices can send to their State medical societies.

The letters directed to legislators should be sent to legislative committees with jurisdiction over PBMs. As explained in further detail in this toolkit, there are up to four such committees in the House and Senate of most State legislatures: (1) the healthcare committee, (2) the insurance committee, (3) the finance committee, and (4) the committee with jurisdiction over professional licensing. Most State legislatures have a website that identifies these committees, their chairs and ranking members, and addresses where the letters can be sent.

In addition, the letters can be adapted to add information about your practice; we've added brackets where this information can be added. We would also encourage you to include anecdotes to the extent they are appropriate that further demonstrate PBM abuses that adversely impact your practice and patients. Your experience matters—and it can move legislators to do the right thing!

* * *

In preparing this toolkit, we owe many thanks to DHPA's legal counsel, Howard Rubin, and his partner, Robert T. Smith, who is one of the leading lawyers in the country on State authority to regulate PBMs. We hope you find this Toolkit useful as your independent GI group considers ways to ensure that your practice's voice is heard in the formation of health policy in your State.

Sincerely,

Latha Alaparthi, M.D.
DHPA President

Scott R. Ketover, M.D.
DHPA Chair, Health Policy

II. Overview of State Laws Regulating PBMs

State have enacted—or have contemplated enacting—a variety of laws that regulate PBMs. Those laws can be broken down into five main categories:

- First, most States have enacted registration and licensing requirements for PBMs to offer pharmacy benefit management services to State residents.

- Second, many States have enacted laws regulating a PBM's interaction with pharmacies and other providers who dispense prescription drugs ultimately covered by the PBM. These include laws regulating the rates that PBMs reimburse pharmacies and providers; banning gag clauses that PBMs use to prevent pharmacists from disclosing to patients situations where a patient might save money by not processing a claim through the PBM; restricting PBMs from steering patients to PBM-affiliated pharmacies; preventing PBMs from reimbursing PBM-affiliated pharmacies more than unaffiliated pharmacies; regulating the performance standards that PBMs impose on pharmacies; and restricting PBM practices that mandate step therapies or the substitution of prescribed drugs.

- Third, some States have begun regulating the relationship between PBMs and the health plans and insurers that PBMs purport to serve. For example, some States have enacted laws imposing on PBMs an obligation to act in the best interests of the plans they serve, requiring PBMs to disclose conflicts of interest, and mandating that PBMs pass along to plans rebates and other remuneration that PBMs receive from drug manufacturers.

- Fourth, virtually all States regulate the relationship between PBMs and the State's Medicaid plan.

- Finally, virtually all States regulate the relationship between PBMs and the State's public employee health plan.

Two outside organizations have prepared compendiums that purport to summarize how various States regulate PBMs. The National Conference of State Legislatures (NCSL), a bipartisan organization that counsels State legislatures, has a very thorough compendium of State laws regulating PBMs: https://www.ncsl.org/research/health/state-policy-options-and-pharmacy-benefit-managers.aspx. In addition, the National Community Pharmacists Association (NCPA), a trade association that advocates on behalf of independent pharmacies, has prepared a spreadsheet (and PDF of the spreadsheet) summarizing various State PBM laws: https://ncpa.org/how-states-protect-pharmacy-and-patients-pbm-abuses.

State PBM laws are rapidly changing, and as a result, these resources may not be fully up to date, but they should give DHPA member practices a place to start in determining the state of the law in various jurisdictions throughout the country.

III. Key Government Actors Shaping PBM Policy at the State Level

In developing a plan for effective Steve-level advocacy, it is important to be aware of the various government actors who can have a profound impact on shaping PBM policy. We highlight those players here and discuss the importance of building relationships with these policymakers more generally.

Key Legislators/Legislative Committees. State legislatures might have up to four committees in each legislative chamber with jurisdiction over issues impacting PBMs—a Health Committee, a Finance Committee, an Insurance Committee, and a Professional Licensing Committee. Most health policy issues will go through Health Committees, although the committees with jurisdiction over health policy issues are sometimes the same committees that also tackle other topics such as education and the environment. We flag this because it means that the legislators on those committees with jurisdiction over multiple topics might be less educated about (or engaged on) health policy issues. At times, an important health policy issue—such as the controlling of health care costs in a consolidating health care market—might be taken up by multiple committees (e.g., Health and Finance Committees). In addition, as States grapple with how to regulate PBMs, an increasing number of jurisdictions are turning to their insurance departments, which are overseen by the legislature's Insurance Committees. And some States have granted State boards of pharmacy authority to regulate PBMs, and as a result, a legislature's Professional Licensing Committees might have jurisdiction over PBM issues as well.

Secretaries/Commissioners of Departments of Health and Insurance: Health policy initiatives often are developed within a State's Executive Branch—most commonly within Departments of Health and Insurance. It is valuable to educate front office officials—the Secretary/Commissioner, Deputy Secretaries/Commissioners, Chiefs of Staff—about the important role that independent GI (and other specialty) practices play in delivering high quality, affordable care to patients in the State, and about the adverse effects that PBMs might be having on your practices and patients.

State Boards of Pharmacy. An often-overlooked player in the shaping of health policy at the State level is the pharmacy licensing board. Often referred to as the State Board of Pharmacy, it may be responsible for licensing PBMs, and it may be responsible for policing the PBMs' relationship with pharmacies and providers. The Board also may have the authority to receive complaints about PBM misconduct and bring enforcement actions. Members of the Board of Pharmacy are typically appointed by the Governor and consist of licensed pharmacists and, in some instances, non-pharmacist health policy specialists.

State Attorneys General. Finally, some States vest their Attorney General with enforcement authority over PBM practices. This can include receiving complaints about and investigating PBM misconduct.

IV. Other Stakeholders Relevant to State-Level PBM Policy

It is important to understand which stakeholders influence health policy in your State—those who might be aligned with your practice's policy objectives as well as those who might be opposed to your positions. Many of these assessments will be dependent on the particular policy issue, but there are certain stakeholders that commonly play a significant role in influencing the development of health policy in the legislature and State executive agencies. We expect that the following organizations will play a role in shaping legislation to rein in PBM abuses.

State medical societies are among the most active organizations lobbying on health policy issues. In many instances, the State medical society will represent the interests of all physicians, regardless of medical specialty or site of service. Although physicians in different practice settings are often competitors, and medical societies tend to not weigh in on issues that divide physicians, virtually all physicians are likely aligned in their views of how State legislation and regulation can be used to curb PBM abuses. Because of the importance of State medical societies in helping to influence health care policy, we have included a model letter for member practices to send to their State medical societies.

Pharmacy organizations are a natural ally in seeking legislative and regulatory reform targeted at PBMs. Many of the negative PBM practices affecting GI practices and their patients—*e.g.*, step therapies and substitution—also have a negative effect on pharmacy. Indeed, the only potential point of nonalignment would focus on PBM restrictions of in-office dispensing—where physicians and pharmacies are competitors. But even there, PBMs place similar restrictions on retail pharmacy—forcing patients to use PBM-controlled mail-order pharmacies. As a result, there may be ways for GI and other physician practices to find common ground with pharmacists in seeking PBM regulations.

Patient advocacy organizations have grown in stature in recent years—particularly organizations advocating on behalf of patients with complex and difficult-to-treat diseases. These patients often suffer when PBMs impose mail-order restrictions and step-therapy requirements. So patient organizations active in your State are natural allies to GI and other practices seeking reforms of PBM business practices.

Large commercial payors and trade associations representing these payors are typically significant players in shaping health policy at the State level, particularly with respect to issues affecting payment policy. It is unlikely that any major health policy initiatives in a State will be developed and come to fruition without input from the payor community. And due to significant vertical integration—the largest insurers are now vertically integrated with the largest PBMs—it is likely that large commercial payors and their trade associations will oppose PBM reforms.

Business and their trade associations are split on PBM regulation. At the local level, many business organizations view pharmacies as a classic example of a small business. But at the national level, business organizations tend to reflexively oppose any kind of State regulation. As a result, State-level business organizations have sometimes avoided weighing in on PBM regulations, whereas the U.S. Chamber of Commerce has actively opposed efforts at PBM reform. In addition, because some businesses sponsor employee health plans, they may have divergent views on the need for PBM reform.

Model Letter 1:
GI Practice Letter to State Legislative Committees with Jurisdiction over PBMs

[Date]

[Name of Chair]
[Name of Ranking Member]
[Committee Name]

Dear Chair[man/woman Name] and Ranking Member [Name]:

I am a physician [and board-certified gastroenterologist]. [Describe practice, location, and total number of patients for which your practice cares per year].

I write about a critical issue facing my practice and my patients—the abusive practices of pharmacy benefit managers (PBMs). I ask that you explore meaningful reforms of the PBM industry.

As you likely know, PBMs are powerful intermediaries who sit between patients and health plans. The three largest PBMs—CVS Caremark, Express Scripts, and Optum Rx—control the prescription-drug benefits for more than 268 million Americans, which amounts to over 85% of all Americans with health insurance.

In recent years, PBMs have jeopardized my ability to deliver critical care to my patients. For example, many gastroenterologists offer in-office dispensing of certain prescription drugs and biologics. This allows clinical staff to supervise patients (and advise on medications, including injectables, that can be difficult to self-administer), speak about side-effects, and offer a convenient option for patients that promotes adherence to medications. And yet, some PBMs have restricted the ability of patients to receive medications directly from their physicians. Instead, these PBMs have forced patients to use PBM-owned, mail-order pharmacies. On top of this, there are prominent examples where PBMs have not taken basic precautions to ship temperature-sensitive medications or have failed to ship necessary medications in a timely manner.

As another example, doctors now have at their disposal a variety of prescription drugs (branded and generic) and biologics (including biosimilars) to treat particular ailments. At the same time, patients often respond positively to a specific drug or biologic. Without regard for any of this, PBMs have forced patients to switch treatments—not based on any sound medical judgment—but because the PBM has negotiated a rebate with a specific pharmaceutical manufacturer. I then have to demonstrate to the PBM that the PBM's favored product is not in the best interest of my patient.

It's also disturbing that the hidden rebates that PBMs receive—and other undisclosed conflicts of interest they harbor—are *increasing* the costs of life-saving prescriptions. One pharmaceutical executive testified before Congress that PBMs *punished* his company for *lowering* drug prices—because it meant there was less room for the PBMs to demand hidden rebates from the manufacturer. And when the State of Ohio audited the PBMs administering its Medicaid plan, it determined that the PBMs had realized undisclosed profits of *$224.8 million in a single year*.

Although PBMs are national players in the healthcare space, they are virtually unregulated by the federal government, and the U.S. Supreme Court recently affirmed the States' role in regulating PBMs in a case in 2020 called *Rutledge v. Pharmaceutical Care Management Association*. The Court held in a unanimous decision that States are free to regulate the relationship between PBMs and pharmacies—and between PBMs and patients—without triggering concerns about preemption under federal law. And even before the Supreme Court decided *Rutledge*, the federal government, forty-five States, and the District of Columbia filed briefs with the Supreme Court arguing that States have robust authority to regulate PBMs.

As a result, there has been a surge of State-level regulation of PBMs, and the push for such regulation has straddled the political divide. Blue States and Red States—from California to Texas—have enacted laws regulating PBMs. I urge our State to do the same to address PBM abuses that are harming my practice and my patients.

Sincerely,

[Signature]

Model Letter 2:
Patient Letter to State Legislative Committees with Jurisdiction over PBMs

[Date]

[Name of Chair]
[Name of Ranking Member]
[Committee Name]

Dear Chair[man/woman Name] and Ranking Member [Name]:

As a constituent and a patient, I write to encourage the committee to take up legislation regulating pharmacy benefit managers (PBMs).

As you likely know, PBMs are powerful intermediaries who sit between patients and health plans. The three largest PBMs—CVS Caremark, Express Scripts, and Optum Rx—control the prescription-drug benefits for over 268 million Americans, which amounts to over 85% of all Americans with health insurance.

In recent years, PBMs have adopted a number of business practices that are harming patients like me. For example, my treating physician offers in-office dispensing as an option for treating certain ailments. For me, this is a great convenience—it saves a trip to the pharmacies—and I can speak with my physician and his staff about side-effects and adherence. Yet, some PBMs have restricted the ability of patients to receive medications directly from their physicians. Instead, these PBMs have forced patients to use PBM-owned, mail-order pharmacies. On top of this, there are prominent examples where PBMs have not taken basic precautions to ship temperature-sensitive medications or have failed to ship necessary medications in a timely manner.

As another example, PBMs have employed drug-substitution and first-to-fail policies that have forced patients to switch treatments—not based on any sound medical judgment—but because the PBM has negotiated a rebate with a specific pharmaceutical manufacturer. Patients like me then have to endure weeks of discomfort while they work with their physician to get the PBM to approve the prescription that my doctor prescribed to me.

Worse still, the hidden rebates that PBMs receive—and other undisclosed conflicts of interest—are *increasing* the costs of life-saving prescriptions. One pharmaceutical executive testified before Congress that PBMs *punished* his company for *lowering* drug prices—because it meant there was less room for the PBMs to demand hidden rebates from the manufacturer. And when the State of Ohio audited the PBMs administering its Medicaid plan, it determined that the PBMs had realized undisclosed profits of *$224.8 million in a single year*.

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Sincerely,

[Signature]

Model Letter 3:
GI Practice Letter to State Medical Society About PBM Reform

[Date]

[Name of Medical Society President]
[Name of Medical Society]

Dear [Name]:

I am a physician [and board-certified gastroenterologist]. [Describe practice, location, and total number of patients for which your practice cares per year]. [IF TRUE, INCLUDE THE FOLLOWING SENTENCE – My colleagues and I are long-standing members of [NAME STATE MEDICAL SOCIETY]].

I write about a critical issue facing my practice and my patients—the abusive practices of pharmacy benefit managers (PBMs). I ask that the [name of Medical Society] promote State-level reforms to curb PBM abuses that are inhibiting my practice and harming my patients.

As you likely know, PBMs are powerful intermediaries who sit between patients and health plans. The three largest PBMs—CVS Caremark, Express Scripts, and Optum Rx—control the prescription-drug benefits for over 268 million Americans, which amounts to over 85% of all Americans with health insurance.

Unfortunately, PBMs have encroached upon the [name of Medical Society]'s core interest in promoting the practice of medicine. For example, many gastroenterologists offer in-office dispensing of certain prescription drugs and biologics. This allows clinical staff to supervise patients (and advise on medications, including injectables, that can be difficult to self-administer), speak about side-effects, and offer a convenient option for patients that promotes adherence to medications. And yet, some PBMs have restricted the ability of patients to receive medications directly from their physicians. Instead, these PBMs have forced patients to use PBM-owned, mail-order pharmacies. On top of this, there are prominent examples where PBMs have not taken basic precautions to ship temperature-sensitive medications or have failed to ship necessary medications in a timely manner.

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Sincerely,

[Signature]