No. 18-540

IN THE

Supreme Court of the United States

LESLIE RUTLEDGE, IN HER OFFICIAL CAPACITY AS ARKANSAS ATTORNEY GENERAL,
Petitioner,

v.

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Eighth Circuit

BRIEF OF *AMICI CURIAE* COMMUNITY ONCOLOGY ALLIANCE, INC.; FLORIDA CANCER SPECIALISTS & RESEARCH INSTITUTE, LLC; NORTH SHORE HEMATOLOGY-ONCOLOGY ASSOCIATES, P.C. D/B/A NEW YORK CANCER AND BLOOD SPECIALISTS; REGIONAL CANCER CARE ASSOCIATES, LLC; TENNESSEE ONCOLOGY, PLLC; TEXAS ONCOLOGY, PA; AND QUALITY CANCER CARE ALLIANCE, LLC, IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether the Employment Retirement Income Security Act of 1974 preempts Arkansas's statute regulating pharmacy benefit managers and the rate at which pharmacy benefit managers reimburse pharmacies.

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INTEREST OF *AMICI* ONCOLOGY CARE PROVIDERS[1]

Amici Community Oncology Alliance, Inc.; Florida Cancer Specialists & Research Institute, LLC; North Shore Hematology-Oncology Associates, P.C. d/b/a New York Cancer and Blood Specialists; Regional Cancer Care Associates, LLC; Tennessee Oncology, PLLC; Texas Oncology, PA; and Quality Cancer Care Alliance, LLC have a compelling interest in protecting the health and well-being of their oncology patients and oncologists' ability to render the most effective oncology care without interference by pharmacy benefit managers (PBMs). Many states, including Arkansas, have taken steps to address PBM reimbursement that is below a provider's acquisition cost. PBMs routinely rely on the doctrine of preemption, including under the Employment Retirement Income Security Act of 1974 (ERISA), to avoid state regulation. The Eighth Circuit's broad ruling on ERISA preemption interferes with the States' ability to regulate PBM conduct and directly interferes with oncologists' relationships with their patients thereby harming cancer patients throughout the country.

INTRODUCTION AND SUMMARY OF ARGUMENT

Cancer care is changing in ways relevant to this case. Recent pharmacologic advancements and innovations have created more options for oncologists to effectively treat cancer with oral chemotherapy and related anti-cancer and supportive care oral drugs

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[1] Pursuant to Rule 37.3(a), all parties consented to the filing of this brief. Pursuant to Rule 37.6, no counsel for any party in this case authored this brief in whole or in part. No person or entity, other than *amici* and their members, made a monetary contribution intended to fund the preparation or submission of this brief.

(collectively referred to as "oral cancer drugs"). Unlike their intravenously infused predecessors, which were historically administered in-office under direct oncologist supervision and covered and paid for by insurers and self-insured employers (collectively "payors") as a "medical benefit," these self-administered oral cancer drugs are dispensed on an outpatient basis and paid for under the pharmacy benefit. Brand oral cancer drugs are very expensive, and thus offer a very lucrative market for PBMs that promise payors their ability to manage the costs of oral cancer drugs. In doing so, PBMs have effectively inserted themselves between oncologists and their patients by changing the way cancer treatment is delivered. Using predatory reimbursement pressure, combined with market power, PBMs have adversely impacted cancer care. Especially as PBMs have merged with insurers, this new and unwanted negative involvement has and will continue to result in harm to cancer patients unless states like Arkansas are permitted to act within their traditional roles as regulators of healthcare within their borders. Act 900, which the Eighth Circuit held was preempted by ERISA, is precisely the kind of legislation states must be able to pass to protect patient wellbeing. Because this Court's precedents establish the States' right to protect the health and well-being of their respective citizens, and because PBMs are contractors, and not ERISA plans themselves, the Court should reverse the Eighth Circuit and find that ERISA does not preempt Arkansas's regulation of PBMs.

In the past decade, PBMs have taken steps that have negatively impacted cancer care. More specifically, PBMs effectively control the "network" of oncology providers that can dispense oral cancer drugs to cancer patients. A PBM "provider network" is a collection of providers assembled by a PBM to provide pharmacy

services to a plan sponsor's members—if a provider is excluded from a PBM network it cannot fully and effectively care for that network's member patients. Thus, oncologists' access to PBM networks is critical for cancer patient care given the increasing use of oral cancer drugs in cancer treatment. In some cases, PBMs restrict oncologists from providing oral cancer drugs directly to their patients and instead require that the PBM's affiliated mail-order specialty pharmacy ("mail-order pharmacy") deliver drugs to patients. In other cases, PBMs will "low-ball" reimbursement for drugs to oncologists, such that the reimbursed amount is lower than the oncologist's cost of the drug. This in effect ultimately forces use of the PBM's mail-order pharmacy because oncologists providing oral cancer drugs on a regular basis when the drug cost is greater than the reimbursement is not financially viable. PBMs profit either way when they "low-ball" reimbursement or force oral cancer drugs to be delivered to the patient by their mail order pharmacy. The problem with this is that it adversely impacts cancer care as cancer patients routinely experience delays, denials, and incorrect drugs and/or dosages when delivered by a PBM mail-order pharmacy. Also, because of the bifurcation of care, costs increase with drug waste when the PBM mail-order pharmacy delivers a drug that has been dose modified or discontinued.

The Eighth Circuit's broad ruling on ERISA preemption as applied to PBMs threatens to interfere with cancer patients' relationships with their oncologists by permitting PBMs to freely reimburse oncologists below their acquisition cost for medications that treat cancer. Such a broad ruling will embolden PBM efforts to direct patients away from oncologists providing oral cancer drugs at the site-of-care in close coordination with patients' overall treatment. Because

Arkansas's Act 900 does not make reference to ERISA plans and does not have an impermissible connection with ERISA plans, it is not preempted. Moreover, because "Our Federalism" has traditionally placed the healthcare of citizens under the auspices of states, which are in the best position to recognize and respond to their citizens' needs, this Court should find that broad preemption is disfavored, and reverse the Eighth Circuit.

DISCUSSION

I. BACKGROUND OF COMMUNITY ONCOLOGY PRACTICES

Oncology is a branch of medicine that deals with the prevention, diagnosis, and treatment of cancer. Patients have a uniquely intimate relationship with their oncologists. This often stems from the challenging circumstances under which a cancer patient is first introduced to an oncologist. A central component of the oncologist-patient relationship and optimal cancer patient treatment requires that oncologists have the ability to not only administer intravenous chemotherapy (medical benefit), but also dispense oral cancer medications (pharmacy benefit) directly to patients at the site-of-cancer care in a coordinated and integrated manner as part of a cancer patient's overall treatment plan.[2]

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[2] Nancy J. Egerton, *In-Office Dispensing of Oral Oncolytics: A Continuity of Care and Cost Mitigation Model for Cancer Patients*, Am. J. Manag. Care Vol. 22, Supp. No. 4, S100 (2016) (citing American Association for Cancer Research, Medicines in development for cancer: a report on cancer (2015), https://www.ncoda.org/wp-content/uploads/bp-attachments/7218/ajmcpan032016inofficedispensingcontinuityofcarebynancyegerton.pdf); *see also* Jason Hoffman, PharmD, RPh, *In-House Specialty Pharmacies*

Oncologists, specifically those in independent oncology practices (as opposed to hospitals), dispense oral cancer drugs to patients under one of two practice models based on state board of pharmacy regulations and restrictions. One type of physician practice is known as a "Dispensing Physician Practice," which is a physician practice that dispenses medication pursuant to the physician's plenary medical license as permitted by state and federal law.[3] These types of practices do not hold a pharmacy license. The State of New York, for example, permits oncologists to dispense medication directly to patients as part of their medical license. N.Y. Educ. Law § 6807(2)(a)(8). The other type is a practice known as "Physician-Owned Pharmacy," which include practices that dispense all types of drugs, including oral cancer drugs, through a licensed retail pharmacy in the practice.[4] In this instance, the licensed retail pharmacy may be the same entity as the medical practice. This model is similar to a Dispensing Physician Practice with the exception that the physician-owned pharmacy is independently licensed as a pharmacy by the applicable state board of pharmacy and follows all requirements necessary to operate as a licensed pharmacy. The State of Texas is one example of a state that permits oncologists to own

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Improve Quality of Care, Feb. 24, 2020, https://www.cancertherapyadvisor.com/home/cancer-topics/supportive-care/in-house-specialty-pharmacies-improve-quality-of-care/.

[3] *See, e.g.*, Drug Topics, *Physician in-office dispensing of Rx drugs*, (2014), https://www.drugtopics.com/hse-business-management/physician-office-dispensing-rx-drugs.

[4] Frier Levitt, *Pharmacy Benefit Managers' Attack on Physician Dispensing and Impact on Patient Care*, Community Oncology Alliance, 17 (Aug. 7, 2016), https://directscripts.com/wp-content/uploads/2016/09/COA-Frier-Levitt-PBM-Attack-Physician-Dispensing.pdf.

and operate a pharmacy. *See* Tex. Occ. Code Ann. § 102.003 (permitting medical business arrangements falling within federal safe harbors). As used throughout this Brief, the term "Community Oncology Practices" refers broadly to both Dispensing Physician Practices and to Physician-Owned Pharmacies. Community Oncology Practices provide a majority of cancer treatment in the United States, with the largest practice consisting of over 400 oncologists. Due to the increased availability and use of oral cancer drugs, most practices now dispense these drugs under one of the models described herein.

A. Patients Benefit from Direct Administration of Treatment from Oncologists

Chemotherapy and related cancer medications (often categorized as "specialty drugs") are among the most complex medications in the country.[5] They often have serious, and potentially life-threatening side effects. Thus, oncologists need to directly supervise patients' cancer medications directly at the site-of-care. Oncologists, as well as specialized oncology nurses, educate patients on the special handling requirements of oral cancer drugs and the importance of taking these medications as instructed.[6] Patient compliance with oral cancer drug therapy is shown to be higher when provided directly by an oncologist at the site-of-care

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[5] Robert Barnett, Jr., Commonly Used Drugs Account For Disproportionate Share Of Total Costs, Wolters Kluwer Health Law Daily, May 23, 2019.

[6] T. Lambourne *et al.*, Optimizing Patient Education of Oncology Medications: A Patient Perspective, *J Canc Educ* 34, 1024–1030 (2019), https://doi.org/10.1007/s13187-018-1406-9 (concluding patients would like to receive more quantitative information including prevalence of side effects and expected effect of treatment on the disease).

as opposed to a separate pharmacy.[7] Patients also need to understand the potential toxicity of these medications if taken improperly. Oral cancer drugs have serious potential side effects and patients need to understand how these side effects can be addressed.[8] Oncologists working at these practices can monitor and react to patient side effects in real time, avoid conflicting instructions to patients, and reduce the time to care.[9] When states are unable to control PBM conduct, their tactics interfere with oncologists providing their patients with highly coordinated care, and education, at the site-of-care.

Another reason site-of-care administration is essential for oncology patients is because many cancer medications cannot be self-administered by the patient and require an oncologist's expertise to ensure the medication is properly administered. This is the case with intravenous cancer medications but, even with oral cancer drugs, studies show that receiving medication directly from a patient's oncologist improves patient outcomes.[10] In many cases "patients now receive

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[7] *See*, *e.g.*, American Society of Clinical Oncology, *In-House Specialty Pharmacy at Cancer Center Improves Quality of Care, Reduces Medical Errors* (Feb. 27, 2017), https://www.asco.org/about-asco/press-center/news-releases/house-specialty-pharmacy-cancer-center-improves-quality-care ("Along with a delay in access to medication, researchers found more errors when patients filled their prescriptions elsewhere.").

[8] Egerton, *supra*, at S101.

[9] *Id.* at S101; *see also* Avalere Health, *Oral Oncolytics: Addressing the Barriers to Access and Identifying Areas for Engagement*, Community Oncology Alliance, Feb. 1, 2010, https://communityoncology.org/oral-oncolytics-addressing-the-barriers-to-access-and-identifying-areas-for-engagement/.

[10] *Id.* at S102.

combination chemotherapy consisting of intravenous and oral drugs within the same regimen or as single therapies administered sequentially through multiple lines of therapy."[11] As a practical matter, oral cancer drugs are not typically stocked by independent and chain stand-alone retail pharmacies due to their expense, specialized nature, and handling requirements.[12] Community Oncology Practices provide coordinated, integrated cancer treatment to their patients. When PBMs deliver oral cancer drugs through their mail-order pharmacies they bifurcate care to the detriment of the cancer patient. The purpose of the PBM doing this is based solely on financial gain to the PBM, not the best interests of the patient. State laws, under attack by the Pharmaceutical Care Management Association (PCMA), which sole function is to advocate for PBMs, not cancer patients, are instrumental in addressing PBMs' abusive tactics, such as predatory "low-ball" reimbursement that results in cancer patient hardship.

II. THE ADVENT OF ORAL CANCER MEDICATIONS COMBINED WITH A HIGHLY CONSOLIDATED PBM LANDSCAPE JEOPARDIZES PATIENT CANCER CARE

PBMs have become extremely consolidated, resulting in only a few PBMs throughout the country managing the majority of prescriptions. These few PBMs have

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[11] *Id.* at S99.

[12] Oncology Practice Management, *Specialty Pharmacy Services: An Overview for Oncology Practices*, Innovations In Oncology Management, Vol. 2 No. 2, http://oncpracticemanagement.com/special-issues/innovations-in-oncology-management-vol-2-no-2/586-specialty-pharmacy-services-an-overview-for-oncology-practices.

almost complete control over reimbursement within their provider networks, effectively functioning as monopolies on a state or regional basis. Consequently, Community Oncology Practices must contract with these PBMs on whatever terms the PBMs offer, often resulting in reimbursement that is below the drug acquisition cost. Moreover, congruent to their rise in market power, PBMs have aggressively entered the oral cancer drug "market," which provides huge profit potential for them in what are increasingly very expensive specialty drugs. This has resulted in PBMs providing "low-ball" reimbursement and/or requiring oral drug dispensing through the PBM mail-order pharmacy to increase profits.

A. Extreme Consolidation of PBMs has forced Community Oncology Practices to Accept PBM Contract Terms

Three PBMs control nearly 85 percent of the United States' pharmacy marketplace: CVS Caremark, Express Scripts, Inc. (ESI) and OptumRx.[13] Each PBM shares common ownership with a major insurer: CVS Caremark is owned by CVS Health, which also owns Aetna[14] and SilverScript[15] insurance companies, and CVS retail and specialty pharmacies.[16] Health insurer

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[13] *See e.g.*, Council of Economic Advisors, Reforming Biopharmaceutical Pricing at Home and Abroad, 10 (Feb. 2018), https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf.

[14] CVSHealth, A New Path to Better Health, https://cvshealth.com/aetna.

[15] SilverScript, About SilverScript Insurance Company, https:// www.silverscript.com/about-us.

[16] CVSHealth, Retail Pharmacy, https://www.cvshealth.com/about/our-offerings/retail-pharmacy, CVSHealth, Specialty Phar-

Cigna and the PBM, ESI, recently merged,[17] and ESI operates its own mail-order pharmacy[18] and Accredo Health, Inc. which operates Accredo Specialty Pharmacy.[19] Insurance company UnitedHealth Group owns OptumRx,[20] which in turn owns OptumRx Specialty Pharmacy (formerly Briova).[21]

These vertically integrated models enable PBMs to dominate the pharmaceutical supply chain, and force Community Oncology Practices to contract into their networks, as patients have no other choice but to participate in a plan that chooses to use one of these PBMs to manage its pharmacy benefit. This means that Community Oncology Practices are forced not only to accept reimbursement below acquisition cost, but patients are in many cases forced to use PBMs' wholly owned mail-order pharmacies. This prevents patients from receiving medication directly from their oncologists at the site-of-care.

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macy, https://cvshealth.com/about/our-offerings/cvs-specialty (last visited February 24, 2019).

[17] Bruce Japsen, *Cigna-Express Scripts Merger's A Done Deal*, Forbes, Dec. 19, 2018, https://www.forbes.com/sites/brucejapsen/2018/12/19/cigna-express-scripts-merger-a-done-deal-by-thursday/#261d98a55688).

[18] Express Scripts, express-scripts.com ("We manage your pharmacy plan, and we're a pharmacy.").

[19] Express Scripts, Specialty Pharmacies: FAQs, express-scripts.com.

[20] UnitedHealth Group, Optum Products & Services, https://www.unitedhealthgroup.com/businesses/optum.html.

[21] Optum, Specialty Pharmacy, https://specialty.optumrx.com/.

B. Advent of Oral Oncology Medications Enables PBMs to Dispense Oral Cancer Drugs to the Detriment of Patients' Wellbeing

A recent and significant development in oncology that has catalyzed PBMs' shifting of patients from Community Oncology Practices to PBM-owned mail order pharmacies is the increased development, availability, and use of oral cancer drugs.[22] This is significant because PBMs *cannot* provide or administer *intravenous* treatments because a PBM is not a licensed medical practice with licensed physicians. *Only* licensed physicians can "administer" intravenous cancer treatments as part of their plenary medical license. However, PBMs *may* "dispense" oral cancer drugs under the pharmacy benefit through their wholly-owned or associated pharmacies, whether it be a wholly owned mail order pharmacy or specialty pharmacy.

This distinction between "administering" and "dispensing," and PBMs' ability to do one but not the other, has led PBMs to find ways to capitalize on the increase in oral, rather than intravenous, cancer drugs. In so doing, PBMs drive oncology "business" to PBM affiliates, thereby increasing profits attributable to oncology medications. The methods PBMs employ include reimbursing Community Oncology Practices at prices at or below their drug acquisition cost, which when done without limitation, requires some Community Oncology Practices to cease participation in PBM networks, despite having the legal right to be in the network.[23] Where PBMs can make providing oral

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[22] Egerton, *supra*, at S99.

[23] Frier Levitt, *supra*, at 13.

cancer drugs at the site-of-care not viable financially for Community Oncology Practices, PBMs are able to successfully divert the dispensing of oral cancer drugs away from the site-of-care, coordinated with patients' total cancer treatment, to their own wholly-owned pharmacies. Community Oncology Practices simply cannot afford to dispense these expensive drugs at a substantial and unsustainable financial loss.[24] Additionally, PBMs often require that PBM mail-order or specialty pharmacies exclusively dispense and deliver the medications, thus overtly diverting patients away from their oncologists' coordinated care and to their own pharmacies.[25] *State law is invaluable in helping preserve the relationship between oncologist and patient.*

C. Unsustainable PBM Reimbursement Causes Patients to Lose Access to the Providers of Their Choice

The issues of reimbursement and network access are inherently intertwined. Through their contracts, PBMs dictate the terms and conditions of network access. In most instances, PBM contracts permit the PBM to unilaterally determine whether to admit a provider into the network and to terminate providers even after admission, with or without cause.[26] If a provider takes issue with reimbursement at the initial contracting stage, the PBM will likely deny the provider access to the network. In the case of cancer care, that means the Community Oncology Practice would be unable to dispense oral chemotherapy to their

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[24] *Id.* at 30.

[25] *Id.* at 26.

[26] *See*, *e.g.*, OptumRx Provider Manual 2020, 1st Ed., 115-16, https://learn.optumrx.com/content/dam/orx-rxmicros/pharmacy-manual/OptumRxProviderManual2020V1.2.pdf.

patients covered by that PBM. When reimbursement becomes an issue following a provider's admission into a PBM network, a provider that raises the issue of reimbursement risks termination without cause. Once a Community Oncology Practice is terminated, it may no longer provide the patient with oral cancer drugs for that PBM, which risks negative treatment outcomes and limits patients' choice of provider.

To ensure complete control over reimbursement, PBMs often draft contracts of adhesion that unilaterally set reimbursement rates for oral cancer drugs at prohibitively low levels. Community Oncology Practices are forced to accept these contracts, and accept whatever reimbursement PBMs will provide, with little recourse other than state law. The use of PBM adhesion contracts is well documented. *See*, *e.g.*, *Park Irmat Drug Corp. v. Express Scripts Holding Company*, 911 F.3d 505, 513 (8th Cir. 2018); *see also Crawford Professional Drugs, Inc. v. CVS Caremark Corp.*, 748 F.3d 249, 264 (5th Cir. 2014); Eugene A. DePasquale, *Bringing Transparency & Accountability to Drug Pricing* (Dec. 11, 2018), at 6, 10-16; Al Redmer, Jr., *Maryland Insurance Administration Pharmaceutical Services Workgroup Report* (Jan. 11, 2018), at 5. However, the impact PBM adhesion contracts have on providers is less documented due in large part to strict confidentiality requirements, mandatory private arbitration, and little federal or state oversight of these PBM contracts. As Pennsylvania's Auditor General noted in his special report on PBMs, because PBMs are often deemed "subcontractors . . . not direct contractors . . . their contracts are not required to be open for any entity[.]"[27] Thus, PBMs incorporate various addenda,

[27] Eugene DePasquale, *Bringing Transparency & Accountability to Drug* Pricing, Pennsylvania Auditor General, 6 https://

terms, and conditions that unilaterally permit them to dictate reimbursement.[28] These contracts can only be checked by state and federal oversight.

One example of terms PBMs force on Community Oncology Practices are fees referred to as "Direct and Indirect Remuneration Fees" (DIR Fees). These DIR Fees are typically assessed by PBMs as network participation fees and/or as quality performance programs and are assessed retroactively on Community Oncology Practices, typically irrespective of whether the practices have any oral cancer drug claims subject to the reporting and "quality" measurement criteria.[29] Moreover, PBMs refuse to include these in contracts as upfront price concessions, likely because they would otherwise pose unreasonable reimbursement terms in violation of applicable Medicare guidance, by plainly reimbursing well below actual, available acquisition costs.[30] Nevertheless, these DIR Fees do in fact reduce

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www.paauditor.gov/Media/Default/Reports/RPT_PBMs_FINAL.pdf.

[28] *Id.* at 12-15.

[29] Frier Levitt, *"Performance" Based DIR Fees: A Rigged System with Disparate Effect on Specialty Pharmacies, Medicare Part D Beneficiaries and the U.S. Healthcare System*, Community Oncology Alliance, 11 (March 1, 2017), https://communityoncology.org/wp-content/uploads/2018/06/NASPWhitePaperonDIRFees.pdf.

[30] *See id.* at 35 (stating "CMS has expressly noted that pharmacy reimbursement rates are part of the terms and conditions that must also be 'reasonable and relevant' in accordance with the Federal [Any Willing Provider Law as codified at 42 U.S.C. § 1395w-104(b)(1)(A); 42 C.F.R. 423.120(a)(8)(i)], and that 'offering pharmacies unreasonably low reimbursement rates for certain "specialty" drugs may not be used to subvert the convenient access standards.'").

oral cancer drug reimbursement below acquisition cost for Community Oncology Practices.

The result of reimbursement below cost is inevitable: Community Oncology Practices are unable to dispense oral cancer drugs on a long-term basis, despite having the statutory right to do so, because they cannot dispense medications that result in unsustainable losses. Consequently, cancer patients are forced into the PBMs' own pharmacies, rather than receiving their drugs at the site-of-care integrated into and coordinated with their total cancer care. Patients receiving their oral cancer drugs from a PBM pharmacy often encounter delays and denials from PBM pharmacies, as well as the incorrect drug or dosage, as has been well documented in the press and by the Community Oncology Alliance.[31]

D. Required Use of PBM Pharmacies Causes Waste

Mail-order pharmacies are designed to dispense large quantities of oral medications—typically 90-day supplies. When PBM mail-order pharmacies dispense a 90-day supply of an oral cancer drug, without having first assessed patient outcomes, it can harm patients

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[31] *See*, *e.g.*, Community Oncology Alliance, Horror Stories [The Real-Life Patient Impact of PBMs vols I-V], https://community oncology.org/category/horror-stories/?_sf_s=PBM; Marty Schladen, *Cancer patient on PBMs: 'It's scary when you're in the hospital and they say, "denied"'*, Columbus Dispatch, May 12, 2019, https://www.dispatch.com/news/20190512/cancer-patient-on-pbms-its-scary-when-youre-in-hospital-and-they-say-denied-; Carmen George, *Cancer patients are being denied drugs, even with doctor prescriptions and good insurance*, The Fresno Bee, August 2, 2019, https://www.fresnobee.com/news/local/article232478212.html.

and cause substantial waste.[32] For example, if a patient recognizes after five days that a particular medication is having intolerable side effects, or an oncologist determines that the medication is not effective, the remaining 85-days' supply is wasted; it cannot be returned and neither the patient nor the insurer or self-insured employer is reimbursed for the unused medication. If the patient is forced by the PBM to use the PBM's mail-order pharmacy, these adjustments cannot be made quickly, which means the patient will go without proper medication until the patient can see the oncologist and the oncologist can address the issue. Cancer care under this model is detrimental to patients.

As opposed to PBM mail-order pharmacies, Community Oncology Practices have access to patient medical and pharmacological information in real time, enabling the oncologist to evaluate the titration of a given cancer medication, permitting the oncologist to adjust the administration of medications based on patients' unique individual responses.[33] Throughout the entire treatment period, the patient directly interacts with their oncologist and provides feedback.[34] This greatly benefits the patient by improving the quality of care. This focus on patient care and outcomes at the granular level cannot be duplicated by a PBM mail

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[32] Egerton, *supra*, at S100-S101.

[33] Barnes et al., Oral Oncolytics: Addressing the Barriers to Access and Identifying Areas for Engagement, Avalere Health 2-3 (Feb. 2010), https://communityoncology.org/wp-content/uploads/2018/08/avalere-coa-oral-oncolytics-study-summary-report.pdf.

[34] *Ibid.*

order pharmacy with limited, at best, patient-care information.[35]

Moreover, the waste caused by excessive dispensing of oral cancer drugs is profound. When PBM mail-order pharmacies dispense oral cancer drugs that the patient can no longer take, it is the PBM and their mail order pharmacy that retain payment for the drugs—which is paid for by the federal government, state governments, or insurers or self-insured employers—even though the remaining medication is wasted. Given that one bottle of an oral cancer drug can cost $12,000 or more, a PBM's involvement in over-dispensing oral cancer drugs results in substantial waste.[36] Preserving state law will help reduce waste in the healthcare system by regulating PBM bad behaviors.

III. STATE REGULATION OF PBMS IS WITHIN THE TRADITIONAL LEGISLATIVE ROLE OF THE STATES

An American Medical Association (AMA) Board member recently noted that, "[b]ecause of market concentration and lack of transparency, patients and physicians are essentially powerless in the face of

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[35] Bill Wimbiscus, *The Benefits of Medically Integrated Dispensing for Cancer Drugs*, Targeted Oncology, Jan. 17, 2019, https://www.targetedonc.com/news/the-benefits-of-medically-integrated-dispensing-for-cancer-drugs.

[36] Community Oncology Alliance, The Real-life Patient Impact of PBMs: Volume I (2017), https://communityoncology.org/the-real-life-patient-impact-of-pbms-volume-i/; *see also* National Community Pharmacists Association, Waste Not, Want Not, Examples of mail order pharmacy waste, https://www.ncpanet.org/pdf/leg/sep11/mail_order_waste.pdf.

PBM pricing and coverage decisions."[37] Given this market dominance and the fact that "PBMs' role in managing drug benefits now resembles the typical role of insurers," the AMA found "they should be treated as such by regulators. . . ."[38] Thus, the AMA adopted recommendations at its 2019 Annual Meeting that included precisely the kind of regulations enacted by Arkansas with Act 900.[39] However, if the Eighth Circuit's decision is upheld, the regulations recommended by the AMA and supported by oncologists would be preempted by ERISA.

States recognize that PBM practices adversely impact stand-alone retail pharmacies and increasingly Community Oncology Practices, especially in terms of negatively effecting how cancer patients are treated. Thus, states have taken reasonable steps to protect patients from harm caused by certain PBM practices. When PBMs control reimbursement rates, network access, and engage in patient steering, they take treatment out of the hands of physicians. Many states, including Arkansas, have identified the various abuses and have enacted or are considering legislation to curtail these practices, but these laws are in jeopardy under the broad preemption articulated by the Eighth Circuit.

This Court has forcefully defended the States' rights to safeguard the health of their citizens, declaring the "structure and limitations of federalism . . . allow the

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[37] Kevin O'Reilly, *Time to scrutinize PBMs' outsized role in Rx decision-making*, American Medical Association (June 10, 2019) https://www.ama-assn.org/delivering-care/public-health/time-scrutinize-pbms-outsized-role-rx-decision-making.

[38] *Ibid.* (internal quotation omitted).

[39] *Ibid.*

States great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006) (quotation marks and citation omitted); *see also Barsky v. Bd. of Regents*, 347 U.S. 442, 449 (1954) ("It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of a state's police power."). The Court has consistently reinforced the foundational principal that "the regulation of health and safety matters is primarily, and historically, a matter of local concern," *Hillsborough Cnty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985), and specifically, "the field of health care" as "a subject of traditional state regulation." *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 387 (2002). Absent a "clear and manifest purpose of Congress" to undermine matters so historically bound to state provenance, the Court has rightfully deferred to the individual healthcare policies of each state. *Id.* at 365. This is a case where such deference to states, which also regulate the scope of oncologists' licensure and pharmacy practices, is due.

A. Several Other States Have Taken Action Similar to Arkansas to Regulate PBMs

States have begun identifying and addressing PBM predatory and abusive practices. By way of example, following an extensive investigation, the Pennsylvania Solicitor General released a special report on the role of PBMs in Pennsylvania entitled "Bringing Transparency & Accountability to Drug Pricing: A Special Report on the Role of Pharmacy Benefit Managers."[40] The report succinctly shows many of the

[40] *See generally*, DePasquale, *supra*.

problematic practices utilized by PBMs, which create significant obstacles for Community Oncology Practices. The practices discussed in the report include spread pricing, pharmacist "gag rules," disparate reimbursement and issues pertaining to a general lack of oversight and transparency.[41] The report noted that Pennsylvania was not alone in experiencing these issues and identified several other states experiencing similar challenges including Maryland, North Dakota, Ohio, South Dakota, and West Virginia.[42]

Thus, in addition to Act 900, other states have enacted laws that may be affected by the overbroad preemption rule announced in the Eighth Circuit. Primary among these laws includes recent legislation in North Dakota. In April 2017 North Dakota enacted Senate Bills 2258 and 2301. *See* S.B. 2258, 2017 Leg., 65th Sess. (ND 2017); S.B. 2301, 2017 Leg., 65th Sess. (ND 2017). Among other things, the legislation sought to remedy "perceived self-dealing and abusive practices on the part of PBMs." *Pharm. Care Mgmt. Ass'n v. Tufte*, 326 F. Supp. 3d 873, 879 (D.N.D. 2018). Relevant to Community Oncology Practices, the legislation included provisions that prohibit PBMs from enforcing "pharmacy accreditation standards or recertification requirements inconsistent with, more stringent than, or in addition to federal and state requirements for licensure as a pharmacy in this state"; requiring irrelevant exclusionary standards as prerequisite for participation in-network; utilizing proprietary—rather than unbiased—performance standards for participation; and charging post-point of sale fees. Very notably, the law "prohibits PBMs from having an

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[41] *See generally ibid.*

[42] *Id.* at 9.

ownership interest in patient assistance programs or mail-order specialty pharmacy unless the PBM agrees 'to not participate in a transaction that benefits the [PBM] . . . instead of another person owed a fiduciary duty.'" *Tufte*, 326 F. Supp. 3d at 880. The outcome of this case will have a substantial effect upon North Dakota's law.

Indeed, PCMA brought an action in district court seeking preliminary and permanent relief against the enforcement of North Dakota's law, but the court denied such relief, instead granting the State's motion for summary judgment. *Ibid.* Ultimately, because the North Dakota law did not "change how ERISA plans are administered," *id.* at 887, the court found it was not preempted. North Dakota's law is preeminent in the protections it affords pharmacies, including Community Oncology Practices. Specifically, the provisions disallowing accreditation and performance standards incongruent with national accreditation standards aids Community Oncology Practices—and ultimately patients—by disallowing PBMs from creating insurmountable hurdles for access to specialty networks. This kind of legislation ensures access for patients to their provider of choice which, in the case of cancer care, is their oncologist providing oral cancer drugs.

Other states have passed laws directly regulating PBMs' abilities to divert cancer patients to their own pharmacies. On January 1, 2020, Georgia's Pharmacy Anti-Steering and Transparency Act became effective.[43] In enacting the legislation, Georgia's Assembly expressly stated that PBM practices of referring patients to affiliate pharmacies presented a "potential conflict of

[43] HB 233, 2019-2020 Regular Session (GA 2019).

interest" that may "limit or eliminate competitive alternatives," cause overutilization of services, increase costs, adversely affect quality, disproportionately harm rural and underserved patients, and were "against the public policy of th[e] state." O.C.G.A. § 26-4-119(b). Georgia's policy statement demonstrates precisely its strong interest in "protecti[ng] the lives, limbs, health, comfort, and quiet of all persons" in Georgia. *Gonzales*, 546 U.S. at 270. Reversing the Eighth Circuit's decision will preserve the State's right to enforce its policy.

In addition to the foregoing, several states are in various stages of enacting new legislation aimed at mitigating PBMs' deleterious behavior. Colorado's House recently passed HB20-1078, prohibiting a PBM from reimbursing independent pharmacies less than it reimburses its affiliates and from retroactive reduction of payments (i.e., DIR fees).[44] Florida's Legislature is considering a bill which would address multiple PBM abuses, including among others spread pricing, arbitrary denial for participation in-network, overbroad accreditation standards, and self-referrals.[45] These bills and many others at various stages of the legislative process would likely be entirely preempted under the Eighth Circuit's broad standard, as each regulates entities whose customers "by definition[] include" ERISA plans. *Pharm. Care Mgmt. Ass'n v. Rutledge*, 891 F.3d 1109, 1112 (8th Cir. 2018).

Furthermore, broad preemption has an undue chilling effect on state lawmakers. There are currently 128 bills pending in state legislatures which, if

[44] HB20-1078, 2020 Regular Session (CO 2020).

[45] HB961, 2020 Regular Session (FL 2020).

enacted, would regulate PBMs.[46] Expansive ERISA preemption has already begun to chip away at such state legislative efforts. For example, on December 26, 2019, New York's Governor vetoed S6531, a bill that would have imposed fiduciary-like duties on PBMs, mitigating the kinds of harm to patients that results from PBMs denying access to Community Oncology Practices.[47] In the veto memorandum the Governor cited to ERISA preemption as the primary reason for his veto.[48] This demonstrates the chilling effect the specter of overbroad ERISA preemption has upon lawmakers.

Legislators have also allowed ERISA preemption to unduly interfere in legitimate legislation. New Jersey recently enacted a law that disallows post point-of-sale fees.[49] Among those excepted from that Act are PBMs that provide services for sponsors of ERISA plans.[50] The legislative history makes it clear that although ERISA plans were initially not exempt, the bill was amended to exempt them.[51] Other states have also unnecessarily exempted ERISA-related matters from pending or enacted legislation regulating PBMs. *See*, *e.g.*, *Md. Code Ann., Ins.* § 15-1601 (West 2020); *N.C. Gen. Stat. Ann.* § 58-56A-4 (West 2020); *Nev. Rev. Stat. Ann.* § 683A.177 (West 2020); *Ohio Rev. Code Ann.* § 3959.111 (West 2020) *W. Va. Code Ann.* § 33-51-8

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[46] National Academy for State Health Policy, 2020 State Legislative Action to Lower Pharmaceutical Costs, Feb. 18, 2020, https://nashp.org/rx-legislative-tracker/.

[47] Cuomo, Veto Memorandum #286, Dec. 26, 2019.

[48] *Ibid.*

[49] NJ Sess. Law Serv. ch. 274 (West 2020).

[50] *Ibid.*

[51] NJ Assem. Floor State., A.B. 3717, June 20, 2019.

(West 2020); *Mo. Ann. Stat.* § 376.387 (West 2020) (carving out ERISA plans "to the extent th[e] section may be preempted" by ERISA); *Miss. Code. Ann.* § 73-21-153 (West 2020) (same). These unnecessary exemptions demonstrate how the Eighth Circuit's decision has unduly reinforced the erroneous perception that ERISA preemption extends to regulation of PBMs.

IV. THE EIGHTH CIRCUIT'S DECISION IMPERMISSIBLY NULLIFIES STATES' EFFORTS TO REGULATE PBMS DESPITE THE STATES' RESERVED RIGHT TO REGULATE PUBLIC HEALTH

The Eighth Circuit's Decision nullifies states' efforts to regulate PBM behavior that threatens patient health, thus abrogating the states' historical power to protect the health and welfare of their citizens. The Court has emphasized the need to "avoid[] the [preemption] clause's susceptibility to limitless application." *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 943 (2016). Under the Eighth Circuit's limitless interpretation in this case, state regulations, including those that expressly permit and encourage Community Oncology Practices to provide oral cancer drugs to patients directly at the site-of-care, as well as those that govern fair reimbursement, would be nullified. The Eighth Circuit's decision goes too far in expanding the scope of ERISA preemption, and the Court should reverse and instead hold that because PBMs are not ERISA "plans," states are permitted to regulate them without invoking ERISA preemption.

A. The Court's Federalism Jurisprudence Establishes the States' Right to Regulate PBMs

This Court has long honored the principle of "Our Federalism," properly reserving to the states their sovereign powers. Justice Frankfurter once opined, "due regard for our federalism, in its practical operation, favors survival of the reserved authority of a State over matters that are the intimate concern of the State unless Congress has clearly swept the boards of all State authority, or the State's claim is in unmistakable conflict with what Congress has ordered." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 241 (1947) (FRANKFURTER, J., dissenting). This Court manifested this sentiment in *Rush Prudential*, stating, "the field of health care [is a] subject of traditional state regulation . . .," 536 U.S. at 387, and in accord with Justice Frankfurter's statement in *Rice*, found these "historic police powers of the States were not to be superseded by [a] Federal Act unless that was the clear and manifest purpose of Congress." *Id.* at 365. States' rights to control the scope of an oncologist's license, and the ability to dispense to patients, should be protected by state law.

A state's legislative policy choices regarding healthcare, the welfare of its citizens, and the regulation of PBMs is precisely the "intimate concern of the State" this Court has jealously safeguarded through the principle of "Our Federalism." *Younger v. Harris*, 401 U.S. 37, 44 (1971); *see*, *e.g.*, *Alden v. Maine*, 527 U.S. 706, 748 (1999) ("Although the Constitution grants broad powers to Congress, our federalism requires that Congress treat the States in a manner consistent with their status as residuary sovereigns and joint participants in the governance of the Nation.") (KENNEDY,

J., concurring); *see also New York v. United States*, 505 U.S. 144, 188 (1992) ("States are not mere political subdivisions of the United States. . . . The Constitution instead 'leaves to the several States a residuary and inviolable sovereignty. . .' reserved explicitly to the States by the Tenth Amendment.") (quoting The Federalist No. 39, p. 245 (C. Rossiter ed. 1961)). These principles must apply, if at all, to states' efforts to curb PBM abuse, and protect the wellbeing of cancer patients and preserve the full spectrum of how oncologists' practice medicine, including providing oral cancer drugs integrated and coordinated with a patients' overall cancer treatment.

Patients' wellbeing the States, and Amici, seek to defend through the legislative process are safeguarded by the same "inviolable sovereignty" this Court has upheld throughout the course of the Republic. *Ibid.* Regulation of PBMs is thus delegated to the States and is not preempted by ERISA. Indeed, states have vigorously regulated the business and practice of medicine, making clear policy choices regarding their citizens' wellbeing in areas that include, among others, cancer care. States have thus promoted Community Oncology Practices for their citizens' welfare, yet PBMs have sought to override such state policy considerations by denying network access, diverting patients to their own mail-order pharmacies, and "low-balling" reimbursement to Community Oncology Practices, as discussed herein more fully, *supra*.

State authority that permits Community Oncology Practices to dispense oral cancer drugs to their patients should be recognized and protected. This practice is currently permitted in 47 states, with many specifically announcing their intent to encourage

dispensing for oncologists.[52] In New York, for example, although the Legislature initially restricted in-office dispensing to a 72-hour supply, it quickly enacted an amendment allowing for dispensing beyond 72 hours, if pursuant to an oncological protocol. *Compare* 1989 N.Y. Sess. Law Serv. 777 with 1990 N.Y. Sess. Law Serv. 18. *See also* N.J.S.A. 45:9-22.11(d) (allowing prescribing for greater than 72 hours when the prescriber dispenses drugs pursuant to an oncological protocol); *Utah Code Ann.* § 58-17b-805 (West 2020) (allowing dispensing of a cancer drug regimen by oncologists in outpatient setting where such treatment is "in the best interest of the patient or provides better access to care for the patient"). Thus, as a matter of policy, states have already largely decided to allow and, indeed, encourage the practice of Community Oncology Practices providing oral cancer drugs at the site-of-care. To protect those policy decisions, states must be permitted the ability to regulate PBMs when they engage in practices that jeopardize these legislative choices.

B. States Can Regulate PBMs Because They Are Not ERISA Plans

PBMs are not ERISA plans and, therefore, state efforts to regulate them are not subject to ERISA preemption. As observed by the First Circuit, state regulation of PBMs does not bear any "connection with" or "reference to" ERISA plans because PBMs are essentially third-party contractors and not plans at all. *See generally Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 303 (1st Cir. 2005). In *Rowe*, the First Circuit recognized that while state regulation may lead ERISA plans to "re-evaluate their working relationships with the PBMs if they wish," they are not

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[52] Community Oncology Pharmacy Association, State laws, http://www.coapharmacy.com/states/.

compelled to do so. *Ibid.* Thus, as providers of benefits services, but not plans themselves, PBMs are subject to state regulation notwithstanding their tangential relationship to ERISA plans. Because they are dispensable subcontractors, which a plan can choose to do without, PBMs are not subject to ERISA preemption.

A state law bears "reference" to ERISA plans if it "acts immediately and exclusively *upon ERISA plans*" or if "the existence of *ERISA plans* is essential to the law's operation." *California Div. of Labor Standards Enforcement v. Dillingham Constr., N. A., Inc.*, 519 U.S. 316, 325 (1997) (emphasis added). A state law has an "impermissible 'connection with' *ERISA plans*" if it "'governs . . . a central matter of plan administration' or 'interferes with nationally uniform plan administration.'" *Gobeille*, 136 S. Ct. at 943 (citation omitted). "A state law also might have an impermissible connection with ERISA plans if 'acute, albeit indirect, economic effects' of the state law 'force an ERISA plan to adopt a certain scheme of substantive coverage or effectively restrict its choice of insurers.'" *Ibid.* But PBMs are not plans, and so Act 900 cannot act either immediately or exclusively upon them impermissibly. The existence of ERISA plans is not essential to Act 900 because Act 900 regulates PBMs, not plans.

PBMs are merely sub-contractors with which ERISA plans may or may not contract, subject to various economic considerations falling outside the scope of the *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 668 (1995) standard of "acute" but "indirect" economic effects. As the *Rowe* Court observed, those relationships are subject to "re-evaluat[ion]" by ERISA plans. 429 F.3d at 303. Indeed, a health care plan can choose not to contract with a PBM whatsoever, as several state

Medicaid programs have chosen.[53] Given the choice between contracting with PBMs as regulated by the states or any other option for servicing pharmacy benefits, plans remain "right where they would be in any case, with the responsibility to choose the best overall coverage for the money." *Travelers*, 514 U.S at 662. That is, PBMs are dispensable to ERISA plans, which have the option of not contracting with PBMs at all.

Providing these subcontractors with ERISA preemptive protection from state laws would be "a result 'that no sensible person could have intended.'" *Egelhoff v. Egelhoff*, 32 U.S. 141 (2001) (SCALIA, J., concurring)(quoting *Dillingham Constr.*, 519 U.S. at 336. Indeed, expanding ERISA preemption to subcontractors of plans pushes the outer limits, not only of the preemption doctrine, but even of Congressional authority, essentially "prohibit[ing] States from applying a host of generally applicable civil laws to ERISA plans." *Gobeille*, 136 S. Ct. at 948 (THOMAS, J., concurring).

States require the ability to regulate PBMs, and Congress never intended to abrogate the States' ability to do so. PBMs offer a benefit that plans can utilize by choice. As discussed above, PBMs cause considerable harm to the wellbeing of oncology patients and unduly interfere with Community Oncology Practices. ERISA plans do not require PBMS. PBMs in many cases are harmful to oncology patients and,

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[53] *See*, *e.g.*, Tracey Walker, *Michigan's Medicaid Program Plans to Save Millions By Eliminating PBMs*, Managed Healthcare Executive, October 21, 2019, https://www.managedhealthcareexecutive.com/news/michigans-medicaid-program-plans-save-millions-eliminating-pbms (reporting Michigan planned to eliminate PBMs for Medicaid and noting West Virginia had done so in 2017).

consequently, subject to the police power of states. Accordingly, PBM regulation is not preempted by ERISA.

CONCLUSION

Community Oncology Practices must be permitted to use their full scope of licensure to treat cancer patients using both medical and pharmaceutical protocols and having the option, in consultation with their patients, to choose the best treatment methods. PBMs endanger patient wellbeing when they deny network access to oncologists, provide unsustainable reimbursement and force patients away from their Community Oncology Practices and toward PBM pharmacies. States have begun to exercise their right to police these abuses by passing laws like Act 900 in Arkansas. These laws are not preempted by ERISA, because PBMs are subcontractors who provide services that plans can choose not to utilize. In order to preserve the principles of federalism and ensure states' ability to protect patient wellbeing, this Court should reverse the Eighth Circuit's decision, and should hold that ERISA preemption does not extend to PBMs.

Respectfully submitted,

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