Pharmacy Benefit Managers' Attack on Physician Dispensing and Impact on Patient Care: Case Study of CVS Caremark's Efforts to Restrict Access to Cancer Care

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1 Executive Summary

Physician dispensing has been a critical part of the American healthcare system for decades, and dispensing physician practices have participated as in-network providers for various Medicare Part D pharmacy networks since the implementation of the Medicare Part D program in 2006. There is good reason for this. Receiving medication directly from a patient's treating physician has been routinely proven to increase adherence,[1] ensure timely receipt of medication,[2] and improve patient health outcomes.[3] This has been particularly true in oncology, where intense cancer treatments can span many years, requiring regular physician visits for chemotherapy and checkups. Keeping patients close to their oncologists lessens the burden of this devastating disease. With millions of Americans relying on medication dispensed from and provided by their physicians at the point of care, it is imperative that the vitality of the community healthcare delivery system be preserved, including physician dispensing.

Physician dispensing can take place in a variety of forms, depending on the State laws of the physician's jurisdiction. For example, some States permit a physician to dispense directly to a patient from his or her medical practice under the physician's medical license. In other jurisdictions, physicians are permitted to dispense medications to patients through licensed physician-owned pharmacies, that operate similarly to traditional retail pharmacies. The benefits of physician dispensing – including integration of medical records, direct to patient dispensing at the point of care, and continuous coordination of care and monitoring of treatment – apply equally to dispensing practices and physician-owned pharmacies.

Despite the many positive benefits of physician dispensing, and the proven outcomes data highlighting the importance of the practice within the American healthcare system, pharmacy benefits managers ("PBMs") have begun a disturbing trend of systematically and surgically limiting access by patients to continue to obtain their outpatient medications from their dispensing physicians. Through a variety of mechanisms, PBMs have embarked on an increasing trend of limiting patient access to specialty drugs, by shifting the dispensing of these drugs to mail order pharmacies owned or associated with PBMs, despite the deleterious effects this has on patient care and access.

The impact of PBM action on patient care cannot be overstated. All Medicare Part D payments are made to providers through PBMs. Currently, only five PBMs control network access for more than 80% of the covered lives in the United States.[4] With only five PBMs, network access to each is critical for pharmacies and dispensing healthcare providers. The power of PBMs to restrict the classes of "in-network" providers will thus alter patient care and the healthcare landscape.

The impact of PBM action to limit access by dispensing physicians is even more pronounced in the specialty drug marketplace, where dispensing physicians frequently treat Medicare cancer patients. More than two-thirds of the growth in overall medicine spending is attributable to specialty medicine.[5] In 2015, 37% of the total United States spending on drugs was attributed to specialty medications, and specialty

[1] Pauline W. Chen, *When Patients Don't Fill Their Prescriptions*, N.Y. Times (May 20, 2010), *available at* http://www.nytimes.com/2010/05/20/health/20chen.html?_r=0.
[2] Lee Schwartzberg et al., *Abandoning Oral Oncolytic Prescriptions at the Pharmacy: Patient and Health Plan Factors Influencing Adherence* (2010), *available at* http://www.communityoncology.org/pdfs/asco-poster-handout.pdf.
[3] Michael A. Fischer et al., *Primary Medication Non-Adherence: Analysis of 195,930 Electronic Prescriptions*, 25 J. Gen. Intern. Med. 284 (Apr. 2010), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2842539/pdf/11606_2010_Article_1253.pdf.
[4] Michael Hiltzik, *Soaring Prescription Prices Cause a Nasty Divorce in the Healthcare Market*, L.A. Times (March 22, 2016), *available at* http://www.latimes.com/business/hiltzik/la-fi-hiltzik-anthem-express-20160322-snap-htmlstory.html.
[5] Tor Constantino, *Specialty Medicine Innovation Drives Growth, Partially Offset by Price Concessions from Manufacturers*, IMS Health (Apr. 14, 2016), http://www.imshealth.com/en/about-us/news/ims-health-study-us-drug-spending-growth-reaches-8.5-percent-in-2015.

medications are projected to account for 50% of total drug spend by 2018.[6] Dispensing physicians comprise about 46% of the specialty medical spend,[7] and, according to a 2014 study conducted by the University of Utah, 14% of *all* prescriptions purchased by participating consumers were dispensed directly by a physician.[8] In addition, the cancer prevalence in the Medicare population is much higher, at nearly 9% versus less than 1% in the commercial population.[9]

PBMs have taken a variety of actions aimed at capturing increased specialty pharmacy business and the profits associated with specialty drug spending. All major PBMs, including Prime Therapeutics, OptumRx, Express Scripts and CVS Caremark, have acquired or launched their own specialty pharmacies in an attempt to gain market share in the growing specialty drug space. CVS Caremark has just announced that it has opened a new 112,000 square foot specialty pharmacy facility in Orlando,[10] in order to handle its continually increasing specialty drug volume. These recent efforts are positive for shareholders, but negative for physicians and Medicare patients.

The clear and overarching trend in healthcare generally, and for Medicare oncology patients specifically, is towards integration and coordination of care focused on the physician as the primary clinician responsible for patient outcomes. One example supporting physician dispensing to Medicare patients comes directly from CMS itself. Medicare's new Oncology Care Model ("OCM") focuses on physician-led care, and explicitly contemplates not only physician-administered drugs billed under Medicare Part B, but also outpatient prescription drugs dispensed by physicians and billed under Medicare Part D. Yet, it is this very type of "physician dispensing" that CVS Caremark erroneously considers "out-of-network." Exclusion of dispensing physicians from Medicare Part D networks is in direct opposition to this new healthcare paradigm, and negatively affects physicians' ability to properly manage patient care.

The last few years have seen a shift in the treatment of cancer patients from physician-administered chemotherapy – traditionally covered under Medicare's Part B medical benefit – to oral oncolytics – which are typically paid for by Medicare under the Part D pharmacy benefit. In fact, recent studies show that of the 836 anti-cancer drugs currently in clinical development, 25% are oral oncolytics.[11] By eliminating competition in the form of physician dispensing, PBMs, via their own specialty pharmacies, seek to capture the lucrative market for this new regime of prescription drugs. This is done without regard to clinical care, and puts profits over patients.

The decision to terminate dispensing physicians is financially motivated, and is not justified under the law. Principally, physician dispensing is permitted under Federal law, so long as physician dispensing is permitted in the State where the physician is located. Physician dispensing is also widely permitted under applicable State law. Almost all States either explicitly permit physicians to dispense medications to their

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[6] Express Scripts, Inc., *Drug Trend Report: The Strength of Practicing Pharmacy Smarter*, http://lab.express-scripts.com/lab/drug-trend-report (last visited Jul. 8, 2016).

[7] *See id.*; *see also* Katie Holcomb and Justin Harris, Milliman Research Report, *Commercial Specialty Medication Research: 2016 Benchmark Projections* (Dec. 28, 2015), *available at* http://www.milliman.com/uploadedFiles/insight/2016/commercial-specialty-medication-research.pdf.

[8] *See* Mark Munger et al., *Emerging Paradigms: Physician Dispensing*, Presentation to the Nat'l Ass'n of Bds. of Pharmacy (May 20, 2014), *available at* https://www.nabp.net/system/rich/rich_files/rich_files/000/000/338/original/munger-202.pdf.

[9] *See* Kathryn Fitch, Pamela M. Pelizzari, and Bruce Pyenson, *Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data 2004-2014*, Milliman, Inc. (April 2016), *available at* http://www.communityoncology.org/pdfs/studies/Trends-in-Cancer-Costs-White-Paper-FINAL-20160403.pdf.

[10] CVS Health Corp., *Specialty Pharmacy Facility Opens in Orlando* (July 14, 2016), *available at* http://cvshealth.com/about/our-offerings/cvs-specialty/specialty-pharmacy-orlando.

[11] 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, S99 (2016) (citing American Association for Cancer Research, *Medicines in development for cancer: a report on cancer* (2015), *available at* http://phrma.org/sites/default/files/pdf/oncology-report-2015.pdf).

patients, or are otherwise silent on the topic, and therefore, permissive, in regards to physician dispensing by placing no limitations on the practice. Thus, with very limited exceptions, Federal and State laws do not justify recent PBM actions.

On the contrary, Federal law protects dispensing physicians and physician-owned pharmacies against termination from Medicare networks. The Centers for Medicare and Medicaid Services ("CMS") clearly requires that Part D sponsors comply with the Medicare "Any Willing Provider" requirements. A PBM's refusal to contract with any provider that is willing to comply with their terms and conditions is a violation of these Federal statutes.

In addition to the laws protecting providers against termination, Federal law also protects the freedom of patients to select a provider of their choice. Blocking network access to dispensing physicians and physician-owned pharmacies run afoul of the Medicare freedom of choice laws, which provide that a Medicare beneficiary may obtain health services (including prescription drug services) from "*any institution, agency, or person*" qualified to participate under Medicare."[12] Patient choice, particularly when it comes to Medicare oncology care, should be honored with even stricter vigilance.

Exclusion of dispensing physicians from Medicare Part D networks flouts the spirit and intent of the Medicare program, and violates PBM obligations as a sponsor and administrator under the Part D program. PBM conduct must also be considered against the backdrop of Federal healthcare laws, including the Federal Anti-Kickback Statute. Such Federal laws are, in part, designed to protect patients and avoid profit motives from interfering with providers' decisions. PBMs, in conjunction with their retail/specialty pharmacies, are also providers (in addition to being payors and plan administrators). The vast clinical benefits of physician dispensing are wholly overlooked when the entire class of trade is excluded from continuing to service Medicare patients, and ultimately, if left unchecked, these exclusions run the risk of causing lowered medication adherence and patient harm.

Against this backdrop, we look at one particular example of conduct by one of the nation's largest PBMs – CVS Caremark. This year, CVS Caremark has announced that it will terminate dispensing physicians from its Medicare Part D networks as of January 1, 2017, due to a new "interpretation" of existing Medicare Part D regulations. While no other PBM yet shares this interpretation of Federal law, this serves as a concrete example of the current trend of limiting patient access to specialty drugs, by shifting the business to mail order pharmacies associated with PBMs.

Throughout this White Paper, we have utilized CVS Caremark's recent actions as a "case study" to demonstrate the impact of the PBM's actions on patient care. Ultimately, if CVS Caremark is successful, it will usher in a sea change in the way cancer care is provided. Again, with virtually all Medicare Part D payments being made through only five PBMs that control 80% of the covered lives in the United States,[13] the loss of access to so many "in-network" providers with CVS Caremark would be disastrous for patients and physicians alike.

As will be explored in this White Paper, if CVS Caremark (or any other PBM) is permitted to exclude dispensing physicians, Medicare patients lose, the cost of treating Medicare patients will rise, and CVS Caremark will have been successful in limiting competition while benefiting its wholly owned retail and specialty pharmacies. Not only must CVS Caremark reverse its stated intention and permit dispensing physicians to remain "in-network" for Medicare Part D, but the industry as a whole must recognize the importance of dispensing physicians as an essential piece of the cancer care continuum.

[12] 42 U.S.C. § 1395a (emphasis added).
[13] *See* Hiltzik, *supra* note 4.

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2 Introduction

Medicare. Established more than fifty years ago, Medicare provides health coverage for more than 50 million Americans today.[14] To get Medicare prescription drug coverage, beneficiaries must join a plan approved by CMS to offer Medicare drug coverage. Medicare offers prescription drug coverage to eligible enrollees either through a Medicare Advantage prescription drug plan that offers both medical and pharmacy coverage, or through the Medicare Part D program, which offers only a drug benefit.[15] As of February 2016, approximately 40.8 million of the 56.2 million Medicare-eligible beneficiaries were enrolled in a Part D plan. Part D plans are administered by private companies – known as Plan Sponsors – that contract with CMS to offer prescription drug coverage.[16] Beneficiaries generally then obtain Part D drugs from providers that are "in-network" for their particular plan.

PBMs operate as agents for the ultimate payors (beneficiaries, employers, and the Federal Government) – contracting with manufacturers and pharmacies, designing drug benefit plans, and reimbursing drug costs to pharmacies on behalf of these ultimate payors (principals). The economic literature recognizes that agents, such as PBMs, may pursue objectives that differ from those of the principals, such as Medicare.[17] Opportunistic self-dealing is one way in which an agent (the PBM) can pursue its own interests at the expense of the principal (Medicare) while it is representing the Government and/or the beneficiaries.

One example of opportunistic self-dealing can be seen in CVS Health Corporation,[18] which owns CVS Specialty[19] and CVS Pharmacy chains, and is a Medicare Plan Sponsor. CVS Health Corporation also owns CVS Caremark, the company's PBM arm. CMS has contracted with CVS Caremark as a PBM to administer prescription drug benefits for Medicare patients.

CVS Health (as the parent company) not only profits from Medicare by providing PBM services (through CVS Caremark), but also profits from dispensing drugs to Medicare beneficiaries as a pharmacy provider,

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[14] U.S. Department of Health and Human Services ["HHS"], Centers for Medicare & Medicaid Services ["CMS"], *National Medicare Handbook*, at 3 (Sept. 2015), *available at* https://www.medicare.gov/pubs/pdf/10050.pdf.

[15] *Id.*

[16] HHS, Office of Inspector General ["OIG"], *Memorandum Report: Part D Plans Generally Include Drugs Commonly Used By Dual Eligibles*, at 3 (June 29, 2016), *available at* http://oig.hhs.gov/oei/reports/oei-05-16-00090.pdf.

[17] *See* Bengt Holmstrom, *Moral Hazard and Observability*, Bell J. of Econ., 74-91 (1979); *see also* Jean Jacques Laffont and Jean Tirole, *A Theory of Incentives in Procurement and Regulation* (MIT Press 1994).

[18] As stated in its latest quarterly Report, CVS Health's business includes a "Pharmacy Services Segment". According to CVS, their "Pharmacy Services business generates revenue from a full range of pharmacy benefit management ("PBM") solutions, including . . . Medicare Part D services, mail order, specialty pharmacy . . . . As a pharmacy benefits manager, we manage the dispensing of prescription drugs through our mail order pharmacies, specialty pharmacies, long-term care pharmacies and a national network of more than 68,000 retail pharmacies, consisting of approximately 41,000 chain pharmacies (which includes our CVS Pharmacy® stores) and 27,000 independent pharmacies, to eligible members in the benefit plans maintained by our clients . . . ." CVS Health Corp., Quarterly Report (Form 10-Q) (May 3, 2016).

[19] CVS also states that "[o]ur specialty pharmacies support individuals who require complex and expensive drug therapies. Our specialty pharmacy business includes mail order and retail specialty pharmacies that operate under the CVS Caremark®, CarePlus CVS Pharmacy ™, Navarro® Health Services and Advanced Care Scripts® ("ACS") names. . . . In addition, through [the] SilverScript Insurance Company subsidiary, [CVS Health is] a national provider of drug benefits to eligible beneficiaries under the federal government's Medicare Part D program. The Pharmacy Services Segment operates under the CVS Caremark® Pharmacy Services, Caremark®, CVS Caremark®, CarePlus CVS Pharmacy ™, Accordant®, SilverScript®, Coram®, CVS Specialty ™, NovoLogix®, Navarro® Health Services and Advanced Care Scripts® names. " *Id.*

through the company's retail, mail order and specialty pharmacies (operated by CVS Pharmacy, CVS Caremark, and CVS Specialty, respectively). These pharmacy providers also participate in CVS Health's PBM networks (managed by CVS Caremark), and directly compete with independent providers, including dispensing physicians. Despite the obvious conflict of interest inherent in this arrangement, CVS Caremark is also the gatekeeper of network access to providers authorized to dispense Part D medication to Medicare beneficiaries. As such, when CVS Health unilaterally wields the power to eliminate network access of a competing class of trade, the motive and legal authority must be questioned.

PBMs' Roles as Medicare Pharmacy Providers. Virtually every major PBM company (i.e., Express Scripts, CVS Caremark, OptumRx, Prime Therapeutics) not only operates a pharmacy benefits management component, but also owns and operates licensed pharmacy providers of some kind, whether retail, mail order and/or specialty pharmacies. The PBMs that are also pharmacy providers compete directly with dispensing physicians for prescription volume within the pharmacy networks that they manage in their role as PBMs.

This same concept applies to CVS Caremark. As noted above, CVS Health Company (the parent company, as distinguished from CVS Caremark) not only operates a PBM, but owns and operates licensed retail, mail order and specialty pharmacies. According to the 2015 "CEO's Shareholder Letter," "[t]hroughout 2015, [CVS] continued to capture an outsized share of the specialty market, the industry's fastest-growing sector. Our CVS Specialty business is the nation's largest, and our growth has outpaced both the industry overall and that of our nearest competitor. In 2015, revenues from the specialty drugs we dispensed and managed across the enterprise totaled nearly $40 billion, increasing 32% over the prior year."[20]

CVS Specialty directly competes with dispensing physicians for prescription volume within the pharmacy networks that CVS Caremark manages. As CVS Caremark is now the biggest player in the industry, its recent adverse actions against dispensing physicians will change the course of medicine and patient care, particularly for Medicare's vulnerable cancer patient population.

PBMs Limit Competition by Controlling "Network Access." One of the methods utilized by PBMs to build the prescription volume is by limiting "network access" by competing providers and forcing patients to use the companies' wholly owned mail order and specialty pharmacies. This is an example of opportunistic self-dealing accomplished using the PBM's power to limit network access at the expense of patients. Network access is the ability of a pharmacy or dispensing physician to dispense a prescription drug to a Medicare patient in a PBM's Medicare Part D network and receive payment from the PBM. If a PBM could eliminate competitors from filling specialty prescriptions to Medicare patients, that PBM would enjoy a significant economic benefit by capturing additional prescription volume. This approach has been effective for numerous PBMs, such as CVS Health.

For example, when Medicare beneficiaries under CVS Caremark's plan want to obtain their prescription drug, they are limited to those "in-network" pharmacies permitted by CVS Caremark to fill prescriptions in CVS Caremark's network. Because CVS Health also owns the nation's largest chain of pharmacies[21] and the nation's largest specialty pharmacy, CVS Health inherently competes with all other providers in its network. CVS Health is therefore attempting to significantly limit network access (and, by proxy, competition) by eliminating a segment of providers that compete with CVS Health for the specialty drug market – dispensing physicians – by declaring them "out-of-network" and therefore ineligible to fill

[20] CVS Health Corp., *Letter to Shareholders from President and Chief Executive Officer Larry J. Merlo* (Feb. 9, 2016), *available at* http://investors.cvshealth.com/2015-in-review/ceo-shareholder-letter.
[21] *See* CVS Health Corp., https://cvshealth.com/about (last visited Jul. 8, 2016).

Medicare prescriptions. Again, this is done without regard to the impact on patient outcomes, and is motivated purely by business interests.

CVS Caremark Has Limited the Network Access of Competing Dispensing Physicians by Unjustifiably Reinterpreting CMS Regulations. As described in greater detail in Section 4 below, in early 2016, CVS Caremark undertook to re-interpret longstanding CMS regulations in such a way as to effectively cut out physicians from continuing to dispense medications to their Medicare Part D patients. Citing their "ongoing regulatory review," CVS Caremark has taken the position that beginning January 1, 2017, dispensing physicians will no longer be included in CVS Caremark's Medicare Part D networks. Instead, CVS Caremark now takes the position that CMS Medicare Part D rules define a "sponsor" network as a pharmacy only network, and therefore, considers physician dispensing facilities to be "out-of-network."[22]

CVS Caremark has further stated that it will hold dispensing physicians subject to "the same treatment under out-of-network rules."[23] CVS Caremark therefore intends to cease reimbursing dispensing physicians for prescription medication dispensed to Medicare beneficiaries. This serves as perhaps the most blatant example of PBMs' efforts to improperly limit dispensing physician access to Part D plans, at the expense of patients.

The scope of CVS Caremark's recent action is likely to expand beyond exclusion of just dispensing physicians. CVS Caremark has also made pronouncements suggesting that many physician-owned pharmacies would no longer meet the PBM's terms and conditions for participation in the "retail pharmacy" networks contained in the Provider Agreement and Provider Manual. Thus, this action applies not just to Medicare Part D networks, but also impacts commercial plans as well.

In short, dispensing physicians and physician-owned pharmacies are being denied network access for Medicare Part D beneficiaries and are being considered "out-of-network," and CVS Caremark is effectively seeking to shut out all physician dispensing and physician-owned pharmacies from dispensing medications to CVS Caremark's Medicare patients.

CVS Caremark currently stands alone in this interpretation. No other PBM or major payor has taken these positions or interpretations of CMS regulations and no other PBM has taken the position that dispensing physicians are "out-of-network." This is especially significant given that dispensing physicians and physician-owned pharmacies make up a substantial portion of the total provider population.[24] It seems, therefore, that CVS Health seeks merely to capture a greater percentage of the specialty drug market, and is using its PBM to effectuate that business objective by curtailing network access.

White Paper Goal. Through this "White Paper," our goal is to assist patient and provider advocacy groups in educating lawmakers, regulators, CMS, Plan Sponsors, Medicare Beneficiaries, and the public at large as to the value of physician dispensing, using CVS Caremark's recent actions as a case study. This White Paper explores the financial and economic motives of PBM limitation of physician dispensing, through the lens of CVS Caremark's actions, and analyzes the Federal and State legal issues involved.

White Paper Scope. In setting the context for the discussion, this White Paper draws upon the background of the specialty pharmacy industry (including the consolidation of PBMs and payors and the resulting influence on CVS Caremark's decision); thoroughly explains CVS Caremark's recent actions; explores the

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[22] CVS Health Corp., *Letter to Congressman Ed Whitfield from Senior Vice President of Government and Public Affairs Melissa A. Schulman* (Feb. 19, 2016) ["CVS-Whitfield Letter"].

[23] *Id.*

[24] *See* Express Scripts, Inc., *Lower Rx Costs With a New Site of Care* (Jun. 23, 2016), http://lab.express-scripts.com/lab/insights/specialty-medications/lower-rx-costs-with-a-new-site-of-care*; see also* Holcomb and Harris, *supra* note 7; Munger et al., *supra* note 8.

legal concepts impacted by PBMs' actions to limit network access (including the legality of physician dispensing and the error of CVS Caremark's recent interpretation of CMS regulations); and elucidates the clinical and economic benefits of physician dispensing. We have addressed these issues by providing references to industry standards and practices, citations to applicable laws and regulations, analysis of administrative guidance, and case studies involving real world examples.

Oncology Context. While many PBM actions – including those of CVS Caremark – will impact dispensing physicians and physician-owned pharmacies of all kinds, to illustrate some of the more direct and severe effects of this action, we largely discussed physician dispensing in the oncology context. We have chosen examples from this field because of the unique nature of the medications dispensed to treat oncology patients, and the crucial role that dispensing physicians play in this space. Oncology lends itself well to illustrating the issues at play with physician dispensing, particularly as oral oncolytic agents dispensed to patient for self-administration are an increasingly important component of cancer therapy.

Ultimately, through this White Paper, we intend to demonstrate how PBM action to limit network access by dispensing physicians – including specifically, CVS Caremark's "reinterpretation" of CMS regulations – is plainly wrong, and how, based on the history, custom and practice of physician dispensing, the rights of dispensing physicians (in addition to physician-owned pharmacies) must be appropriately safeguarded, particularly in the Medicare Part D context.

3 Background

3.1 What Is Physician Dispensing and How Does It Differ From Traditional Pharmacy Dispensing?

Physician dispensing occurs when physicians provide their patients with medication directly at the point of care, instead of providing a patient with a prescription to be taken to and filled at a pharmacy. In some limited circumstances, patients will also have their medication delivered to their home, but the initial fill is typically at the time and point of care.

Physician dispensing has become increasingly popular in the United States, and has expanded to include a variety of medications in both the retail and specialty space. This increased popularity has largely benefited overall patient care, as studies have shown that patient compliance with drug therapy is 60% to 70% higher from a dispensing physician than a pharmacy.[25] The many clinical benefits of physician dispensing are discussed in greater detail in Section 6.1 below. Additionally, as the physician's practice can directly access the dispensing records, and in some cases actually consolidate the information into the EHR, the physician is in a better position to assure patient compliance with their drug regimen. Moreover, in-office physician dispensing saves the patient time, as the patient no longer needs to fill a prescription at a pharmacy, and also saves the physician time, as in-office dispensing greatly reduces the need for pharmacy callbacks.

Another common form in the oncology context is the physician-owned pharmacy, which is when a physician or physician group wholly owns an in-office pharmacy. This model is very similar to a dispensing physician framework, with the exception that the physician-owned pharmacy is independently licensed as a pharmacy by the applicable Board of Pharmacy and follows all of the requirements applicable to licensed pharmacies (including the use of a pharmacist-in-charge).

[25] William Shell, *The History of Physician Dispensing*, Complete Claims Processing, Inc., http://www.ccpicentral.com/history-of-physician-dispensing.php (last visited Jul. 8, 2016).

While dispensing physicians oftentimes dispense retail medication, at times they also dispense specialty medicine. While there is no clear or standardized legal definition of "specialty medicine," they typically have one or more of the following characteristics: (1) high cost, (2) special handling processes, (3) treat a rare disease, (4) require ongoing assessment of a patient's response, (5) require patient administration training, (6) require a prior authorization from an insurance company, and/or (6) are part of a Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategies (REMS) program.

Additionally, a number of specialty medications administered by physicians and physician-owned pharmacies require special handling and storage techniques. Specifically, the handling of specialty medications often requires a capital intensive storage facility, along with special and costly packaging and close coordination with patients to ensure proper administration and storage of the medicine once delivered.

Close communication with patients is essential for dispensing physicians and physician-owned pharmacies dispensing specialty medications. Physicians must have proper procedures in place in order to remain cognizant of any changes in the patient's condition and to ensure patient adherence. Physician dispensing of drugs (either directly by the physician or via a physician-owned pharmacy), especially oncology drugs, provides this and is therefore critical to the healthcare system.

The relationship between oncologists and their patients promotes medication adherence and is far superior to PBM's mail order method. The consolidation of PBMs and payers, as well as PBM ownership of specialty pharmacies and the economic motives of CVS Health, now combine to challenge the significant patient benefits of physician dispensing.

3.2 Consolidation of PBMs and Payors, and the Resulting Influence on Recent PBM Actions

Before outlining the history of PBM consolidation, it is critical to understand that in the Medicare Part D context, all Medicare payments are made to providers through PBMs. The power of PBMs to decide what classes of providers are "in-network" has the ability to alter patient care and the healthcare landscape.

Medicare's Payment Framework. Dispensing physicians and physician-owned pharmacies rely on payments under a Medicare patient's prescription drug insurance benefit from PBMs and contract with PBMs through various pharmacy networks. A PBM is a third-party administrator of prescription drug programs covered by a Plan Sponsor (i.e. health insurance company, union, self-insured employer group, or a governmental health program, such as Medicare). A PBM is primarily responsible for processing and paying prescription drug claims submitted by participating providers on behalf of covered beneficiaries. A PBM's role is not limited to processing and paying prescription drug claims. Rather, PBMs also provide bundled services related to the administration of pharmaceutical benefits, including formulary design, formulary management, negotiation of branded drug rebates, and controlling network access of participating pharmacies.

PBMs play a critical role in the administration of prescription drug programs. However, over the past ten years, the PBM marketplace has transformed considerably. Changes include both horizontal and vertical integration among insurance companies, PBMs, chain pharmacies, specialty pharmacies, and long term care pharmacies. As a result, a smaller number of large companies now wield nearly limitless power and influence over the prescription drug market.

With only five PBMs, network access to each is critical. Over 80% of the PBM marketplace (or 80% of the covered lives in the United States) is comprised of only five PBMs.[26] The lack of competition in the market place stems, in large part, from a series of mergers, integrations, and consolidations. This consolidation and integration is undoubtedly a factor leading PBMs, such as CVS Caremark, to push dispensing physicians "out of network," as the PBMs recognize the potential increased revenue and market share associated with specialty medicine often dispensed by physician practices (especially in the oncology market). As such, it seems clear that the push to make dispensing physicians "out-of-network" has more to do with economic self-dealing by PBMs, such as CVS Caremark, than it does with a legitimate interpretation of Federal and State law.

Vertical Consolidations. To understand the implications of CVS Caremark's recent push to make dispensing physicians "out-of-network," a brief review of the industry consolidation is relevant. It began with a series of vertical consolidations in which some PBMs acquired pharmacies and other PBMs acquired insurance companies. In 2007, the shareholders of Caremark Rx, one of the nation's largest PBMs at the time, approved a $26.5 billion takeover of CVS Pharmacy, which effectively created the first vertically integrated retail pharmacy and PBM.[27] Vertical integration of the industry continued in 2011, as Blue Cross Blue Shield of North Carolina, one of Medco's largest customers, began shifting its PBM business away from Medco and to Prime Therapeutics,[28] a PBM that is wholly owned by a group of thirteen Blue Cross plans across the country. Thereafter, in 2012, UnitedHealthcare ("United"), the nation's largest insurance company, began migrating the administration of its plans from Medco Health Solutions to OptumRx, United's wholly owned PBM.[29] As such, the nation's largest insurer now has its own vertically integrated PBM. With fewer PBMs, a provider's network termination means that a provider is unable to service a large percentage of the patient population. Due to its size and market share, termination from any one PBM – including particularly CVS Caremark – often spells irreparable harm for a provider seeking to participate in the Medicare Part D program.

Horizontal Consolidation and the Race to Be the Largest. Consolidation of the PBM and payor space has not been limited to vertical integration. In 2011, two of the nation's then-largest PBMs – Medco Health Solutions, Inc. and Express Scripts, Inc. – announced a $29 billion merger. After a contentious regulatory approval process, the Federal Trade Commission ultimately approved the merger in 2012.[30]

Thereafter, the industry continued consolidation both horizontally and vertically. In 2013, a regional PBM – SXC Corporation – agreed to buy another regional PBM – Catalyst, Inc. – for $4.4 billion to form a national PBM, known as Catamaran Corp.[31] In July 2015, Catamaran was acquired by United, OptumRx's parent company, for $12.8 billion. The two PBMs are now integrating operations and operate under one name, OptumRx. In 2015, Rite Aid acquired the PBM – EnvisionRx – for approximately $2 billion.[32] Later that

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[26] Hiltzik, *supra* note 4.

[27] Evelyn M. Rusli, *Caremark Approves CVS Merger*, Forbes (Mar. 16, 2007, 4:59 PM), http://www.forbes.com/2007/03/16/caremark-approves-update-markets-equity-cx_er_0316markets29.html.

[28] Jon Kamp, *Medco Faces Loss of Blue Cross Customer*, Wall St. J. (Aug. 3, 2011, 6:04 PM), http://www.wsj.com/articles/SB10001424053111903454504576486653127464070.

[29] Anna Wilde Mathews, *UnitedHealth's Answer to Express Scripts-Medco Merger?*, Wall St. J. (Jul. 21, 2011, 8:34 AM), http://blogs.wsj.com/deals/2011/07/21/unitedhealths-answer-to-express-scripts-medco-merger/.

[30] Reed Abelson and Natasha Singer, *F.T.C. Approves Merger of 2 of the Biggest Pharmacy Benefit Managers*, N.Y. Times (Apr. 2, 2012), http://www.nytimes.com/2012/04/03/business/ftc-approves-merger-of-express-scripts-and-medco.html.

[31] Michael J. De La Merced, *SXC Health Solutions to Buy Catalyst Health for $4.4 Billion*, N.Y. Times, (Apr. 18, 2012, *as updated* 3:07 PM), http://dealbook.nytimes.com/2012/04/18/sxc-health-solutions-to-buy-catalyst-for-4-4-billion/.

[32] *Rite Aid Completes Acquisition of Leading Independent Pharmacy Benefit Manager EnvisionRx*, Bus. Wire (Jun. 24, 2015, 10:23 AM), http://www.businesswire.com/news/home/20150624005906/en/Rite-Aid-Completes-Acquisition-Leading-Independent-Pharmacy.

year, Walgreens announced its intention to acquire Rite Aid and EnvisionRx for $9.4 billion.[33] That merger is pending. Also in 2015, Aetna, the nation's third largest insurer, announced its intention to acquire Humana, the nation's fourth largest insurer, as well as Humana's wholly owned PBM, Humana Pharmacy Solutions, for $37 billion.[34] Finally, in 2015, Anthem announced its agreement to buy Cigna (including its PBM arm) for $48 billion, which would result in, yet again, fewer players in the space.[35] However, on July 21, 2016, the Justice Department filed lawsuits to block both the Aetna-Humana and Anthem-Cigna mergers, asserting that the mergers would quash competition, leading to higher prices and reduced benefits.[36] While these mergers (which would bring the number of major insurers down to three) may be blocked, much of the damage is already done, as there are still only five major insurers handling the majority of patients in the United States.

Exclusion from a PBM's Medicare Network Is an Insurmountable Blow to Dispensing Physicians. It is not difficult to understand why exclusion from a particular PBM's Medicare network (including CVS Caremark's) could put a provider out of business. When that provider is an oncology practice serving the vulnerable Medicare patient population, the call to reverse CVS Caremark's decision should be especially strong.

As more consolidation over time has yielded fewer payors, the number of standalone Medicare Part D prescription drug plans offered in 2016 has fallen precipitously – by 42% since 2007.[37] Particularly alarming is the fact that about two-thirds of all Medicare Part D Prescription Drug Plan ("PDP") enrollees are concentrated in networks across just three payors: United, CVS Caremark, and Humana.[38] Fewer payors exponentially increases the importance of network access for providers (including dispensing physicians) for each individual PBM. Exclusion from one PBM with a market share of 35% means that the provider loses out on a major portion of the patient population.

PBM Mergers and Consolidations in Last Five Years

2011	medco	EXPRESS SCRIPTS	PRIME THERAPEUTICS	SXC Health Solutions, Inc.	Catalyst	OPTUMRx	CVS CAREMARK

[33] Dana Mattioli, Michael Siconolfi, and Dana Cimilluca, *Walgreens, Rite Aid Unite to Create Drugstore Giant*, Wall St. J. (Oct. 27, 2015, 9:01 PM), http://www.wsj.com/articles/walgreens-boots-alliance-nears-deal-to-buy-rite-aid-1445964090.

[34] *Aetna to Acquire Humana for $37 Billion, Combined Entity to Drive Consumer-Focused, High-Value Health Care*, Bus. Wire (Jul. 3, 2015, 2:08 AM), http://www.businesswire.com/news/home/20150702005935/en/Aetna-Acquire-Humana-37-Billion-Combined-Entity#.VZYpMeTD9OI.

[35] Michael J. De la Merced and Chad Bray, *Anthem to Buy Cigna Amid Wave of Insurance Mergers*, N.Y. Times (Jul. 24, 2015), http://www.nytimes.com/2015/07/25/business/dealbook/anthem-cigna-health-insurance-deal.html.

[36] Leslie Picker, *U.S. Sues to Block Anthem-Cigna and Aetna-Humana Mergers*, N.Y. Times (Jul. 21, 2016), http://www.nytimes.com/2016/07/22/business/dealbook/us-sues-to-block-anthem-cigna-and-aetna-humana-mergers.html.

[37] The Kaiser Family Foundation, *Medicare Prescription Drug Benefit Fact Sheet* (Oct. 13, 2015), http://kff.org/medicare/fact-sheet/the-medicare-prescription-drug-benefit-fact-sheet/.

[38] Adam J. Fein, *Medicare Part D 2016: 75% of Seniors in a Preferred Pharmacy Network (PLUS: Which Plans Won and Lost)*, Drug Channels (Jan. 20, 2016), http://www.drugchannels.net/2016/01/medicare-part-d-2016-75-of-seniors-in.html.

2013	EXPRESS SCRIPTS	PRIME THERAPEUTICS	catamaran	OPTUMRx	CVS CAREMARK
2015	EXPRESS SCRIPTS	PRIME THERAPEUTICS	OPTUMRx		CVS CAREMARK

This rapid evolution of pharmacy benefits and payor industry shows how a limited number of corporations wield an outsized level of control and influence in the prescription drug coverage marketplace. Eliminating physician dispensing from the Medicare (and all CVS Caremark's) network will only exacerbate the control PBMs exert over dispensing decisions, which is a dangerous situation for vulnerable patient populations, including the cancer population.

3.3 Because Physician Dispensing Comprises Nearly One-Half of the Specialty Drug Spend, Excluding It Will Have a Profound and Irreversible Impact on Both Providers and Patients

Over the past five years, drug spending, and especially spending on specialty medications, has grown exponentially. Indeed, more than two-thirds of the growth in overall medicine spending is attributable to specialty medicine.[39] In 2015, 37% of the total United States spending on drugs was attributed to specialty medications, and specialty medications are projected to account for 50% of total drug spend by 2018.[40] By 2020, specialty drug spend is projected to total about $400 billion, representing about 9.1% of national health spending.[41] Moreover, dispensing physicians comprise about 46% of the specialty medical spend[42] and, according to a 2014 study conducted by the University of Utah, 14% of *all* prescriptions purchased by participating consumers were dispensed directly by a physician.[43] As a result, PBMs have adjusted their business models to capture profits associated with specialty drug spending. All major PBMs, including Prime Therapeutics, OptumRx, Express Scripts, and CVS Caremark, have acquired or launched their own specialty pharmacies in an attempt to gain market share in the growing specialty drug space.

Ultimately, the PBM industry's quest to capture specialty medicine profits has been overwhelmingly successful. Estimates indicate that the industry's three largest players – Express Scripts, CVS Caremark, and Walgreens – collectively control about 63% of specialty drug revenue.[44] As profits in the specialty

[39] Constantino, *supra* note 5.
[40] Express Scripts, Inc., *supra* note 6.
[41] UnitedHealth Center for Health Reform & Modernization, *The Growth of Specialty Pharmacy: Current Trends and Future Opportunities* (Apr. 2014), *available at* http://www.unitedhealthgroup.com/~/media/uhg/pdf/2014/unh-the-growth-of-specialty-pharmacy.ashx.
[42] *See* Express Scripts, Inc., *supra* note 6; *see also* Holcomb and Harris, *supra* note 7.
[43] *See* Munger et al., *supra* note 8.
[44] Adam J. Fein, *Six Factors Driving New Specialty Pharmacies*, Pharm. Commerce (Mar. 3, 2014), http://pharmaceuticalcommerce.com/opinion/six-factors-driving-new-specialty-pharmacies/.

medicine realm continue to soar, so do the profits for the industry's largest PBMs. In 2011, Express Scripts reported over $14.5 billion in revenue associated with home delivery and specialty pharmacy segments. In 2015, the number had grown to more than $40.8 billion,[45] and as evidenced by 2016 Second Quarter Results, specialty pharmacy claims grew as a percentage of overall claims processed.[46] Furthermore, evidence indicates that the industry's largest players will continue to benefit from specialty drug spend. Indeed, on May 3, 2016, Larry Merlo, CVS Health Corporation's President and Chief Executive Officer, stated that "[i]n the first quarter, specialty revenues increased 23%, and [CVS's] volumes continued to outpace the market."[47] Meanwhile, CVS Health touts itself as having "the largest U.S. specialty pharmacy with $40 billion in revenue."[48] It is expected that the specialty drug market will continue to see increased profits, but the question remains whether those profits will only be realized by the largest players in the industry. CVS Caremark's expulsion of dispensing physicians from the Medicare Part D network is designed simply to increase the company's share of the specialty drug market.

3.4 Conversion from Intravenous Oncology Drugs, Reimbursable Under Part B Medical Insurance, to Oral Oncolytics, Reimbursable Under Part D by PBMs

The last few years have seen a shift in the treatment of cancer patients from physician-administered (i.e. infused or injected) chemotherapy – traditionally covered under Medicare's Part B medical benefit – to oral oncolytics – which are typically paid for by Medicare under the Part D pharmacy benefit. PBMs, seeking to exclude competition and capture the lucrative market for this new regime of prescription drugs, have taken note. Recent conclusions – like CVS Caremark's – that dispensing physicians are "out-of-network" is one of the PBMs' business strategies to capture this business segment.

Treatment of cancer continues to improve as research yields results in treating specific cancers. Among the recent developments is an increased focus on oral oncolytics. In fact, recent studies show that of the 836 anti-cancer drugs currently in clinical development, 25% are oral oncolytics.[49]

While oral chemotherapy has existed for decades, oral oncolytics are becoming more popular than intravenous chemotherapy for numerous reasons. Primarily, oral oncolytics are more convenient for patients. Instead of traveling to the hospital or outpatient center, or receiving home intravenous treatment, patients can self-administer their chemotherapy at home in oral pill form. Importantly, recently approved and available oral oncolytics have hit the marketplace, and are more targeted to disrupt specific biologic processes in specific types of cancer cells. This targeted approach to treatment exhibits a higher degree of safety and effectiveness as compared to traditional chemotherapies, because traditional chemotherapy impacts both cancer and rapidly growing healthy cells. However, even these advanced treatments can be very toxic and can have severe patient side effects if not monitored closely and dynamically.

[45] Stock Analysis on Net, https://www.stock-analysis-on.net/NASDAQ/Company/Express-Scripts-Holding-Co/Analysis/Revenues (last visited Jul. 8, 2016).
[46] Express Scripts Announces 2016 Second Quarter Results, http://phx.corporate-ir.net/phoenix.zhtml?c=69641&p=irol-newsArticle&ID=2187940 (last visited Aug. 10, 2016).
[47] Yahoo Fin., *Edited Transcript of CVS earnings conference call or presentation 3-May-16 12:30pm GMT* (May 3, 2016, 6:32 PM), http://finance.yahoo.com/news/edited-transcript-cvs-earnings-conference-223253578.html.
[48] CVS Health Corporation, *CVS Health at a Glance*, https://cvshealth.com/about/facts-and-company-information (last visited Jul. 8, 2016).
[49] Egerton, *supra* note 11.

These developments have resulted in an increasing volume of chemotherapy drugs for which reimbursement falls under Part D rather than the traditional Part B. This shift in the industry has resulted in dispensing physicians, whose services were previously covered under Part B, becoming increasingly reliant on participation in Medicare Part D networks, as a replacement to the Medicare Part B direct billing and fee-for-service framework. This shift has provided the PBMs with an opportunity for a new avenue of service to oncology patients, whereas before, this particular area of business was reserved to physicians administering injectable chemotherapy in their clinics and billing under Part B. CVS Caremark is obviously exploiting this new opportunity to exclude physician competition from Medicare Part D networks.

4 Case Study: CVS Caremark's Attempt to Push Dispensing Physicians "Out-of-Network"

As mentioned above, while this White Paper seeks to address all problems with PBMs attempting to improperly direct business to their wholly-owned specialty pharmacies, we utilize CVS Caremark's recent actions as a striking and particularly egregious example of these negative PBM efforts.

Starting in early 2016, CVS Caremark "re-interpreted" longstanding CMS regulations in such a way that will effectively cut out physicians from continuing to dispense medications to their Medicare Part D patients. Ostensibly, CVS Caremark has taken the position that beginning January 1, 2017, the physician dispensing class of trade will no longer be included in CVS Caremark's Medicare Part D network. CVS Caremark has made this decision in accordance with their recent interpretation of the CMS Medicare Part D rules that define a "sponsor" network as a "pharmacy only" network, and therefore, considers physician dispensing facilities to be "out-of-network" and subject to "the same treatment under out-of-network rules."

CVS Caremark has begun communicating this new position in a variety of ways. Most prominently, CVS Caremark began communicating this position in correspondence to dispensing physician practices (and their representatives) in early 2016.[50] In this correspondence to a Congressman representing a dispensing physician practice, CVS Caremark stated:

> [CVS Caremark's] ongoing regulatory review … made clear that CMS considers such physician dispensing facilities as out-of-network providers. CMS Medicare Part D rules define "sponsor networks" as pharmacy only networks, and "retail pharmacy" is defined as a licensed pharmacy from which enrollees can purchase a drug without being required to receive medical services.

CVS Caremark further took the position that CMS had allegedly agreed that covered Part D drugs that are appropriately dispensed and administered in a physician's office will be subject to the same treatment under "out-of-network access" rules. CVS Caremark – despite having credentialed, contracted, and paid dispensing physicians as "in-network" Medicare Part D providers for over a decade – seemingly unilaterally took the position that Dispensing Physicians are "out-of-network providers" under Medicare Part D and now subject to network exclusion. No other PBM or major payor has taken this position or interpretation.

CVS Caremark's recent interpretation appears at first blush to impact only dispensing physician practices (as opposed to physician-owned and licensed retail pharmacies), and appears to apply to Medicare Part D networks only. However, other statements and actions by CVS Caremark strongly suggest a broader application and impact. In fact, in that same February 2016 letter, CVS Caremark took a new position that

[50] *See* CVS-Whitfield Letter, *supra* note 22.

the two-physician practice apparently did not meet the PBM's terms and conditions to be a retail pharmacy provider, based on a variety of factors. These "factors" apply with equal measure and logic to all dispensing physician practices (even those participating in commercial networks). Thus, CVS Caremark's true actions are to exclude dispensing physicians and, ostensibly, physician-owned pharmacies, from all CVS Caremark networks – governmental or private.[51] This is being done under the guise of not meeting CVS Caremark's "definition" of a retail pharmacy.

4.1 Financial and Economic Motives of CVS Caremark

Industry consolidation, along with the massive success of CVS Caremark's aggressive strategy to limit network access for independent specialty pharmacies, has led to CVS Caremark developing ever-evolving strategies to acquire yet a greater share of the specialty pharmacy market. CVS Caremark's new action serves as a prime example of recent PBM conduct that, if left unchecked, poses an immense threat to Medicare patients and to the overall healthcare system.

CVS Caremark's latest tactic is to reinterpret laws and regulations to effectively eliminate its competition in the oral oncolytic market. However, CVS Caremark's unilateral reinterpretations of existing laws and regulations come at the expense of patient choice and fair competition,[52] and are not supported by Federal and State law.

Frankly, CVS Caremark's recent reinterpretation of "community retail pharmacy" and determination that physician dispensing facilities are to be treated as out-of-network providers under Medicare illustrates CVS Caremark's assault on competing providers in the industry. CVS Caremark's self-serving reinterpretation of "community retail pharmacy" will lead to hundreds of thousands of Medicare cancer patients alone having to switch providers to obtain their oncology medications. The action will similarly result in dispensing physicians losing the vast majority of their patient population, as CVS Caremark manages the benefits for a critical percentage of patients utilizing physician dispensing services. While those patients could theoretically switch to any in-network pharmacy, CVS Caremark will likely employ a number of strategies to capture that business. More specifically, CVS Caremark has often utilized "specialty networks" and "Preferred Cost Sharing Networks"[53] to route prescriptions to narrow networks of "preferred providers."[54] Among those "preferred providers" would be CVS Health's retail and specialty pharmacies, further ensuring that this business is captured. Notably, CVS Caremark routinely creates "specialty pharmacy" networks where its own CVS Specialty pharmacy is one of only a few (if not the only) participating providers enjoying nearly exclusive access to specialty claims. To the extent these narrow networks are utilized, CVS Caremark will only further strengthen its grip on the retail and specialty market.

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[51] While this White Paper addresses only the impact on dispensing physician practices and physician-owned pharmacies, CVS Caremark's actions potentially encompass a much larger range of providers not meeting the PBM's strict interpretation of "retail pharmacy," such as specialty pharmacies, mail order pharmacies, long term care pharmacies, closed door pharmacies, etc.

[52] *See*, *e.g.*, James Langenfeld & Robert Maness, *The Cost of PBM "Self-Dealing" Under A Medicare Prescription Drug Benefit* 30-31 (2003), *available at* http://www.ncpanet.org/pdf/pbm-selfdealing090903.pdf (study concluding that self-dealing by PBMs would cost the U.S. Government and Medicare beneficiaries billions of dollars during the period 2004-2013); *see also* Carol Ukens, *PBM Mail Order Would Up Medicare Rx Cost, Study Finds*, Drug Topics (Oct. 6, 2003), at 34, *available at* http://www.drugtopics.com/drugtopics/article/articleDetail.jsp?id=111109 (discussing the same study which found that "letting PBMs favor their own mail-order pharmacies would increase the cost of a Medicare Rx benefit by between $14.5 billion and $29 billion over a 10-year period, compared with the cost of using independent mail-order pharmacies.").

[53] Pursuant to The Social Security Act [*codified at* 42 U.S.C. 1395w-104], Medicare Part D plans are permitted to create "Preferred Cost Sharing Networks," which consist of sub-networks of preferred providers that offer lower cost sharing to their beneficiaries.

[54] *See* PBM Watch, *Part D Reform Information Center*, http://www.pbmwatch.com/part-d-reform-information-center.html (last visited July 8, 2016).

These profit-driven actions by CVS Caremark (whose parent company owns the nation's largest pharmacy chain and specialty pharmacies) are not supported by the applicable law and regulations.

5 Legal Concepts

5.1 Physician Dispensing Is Legal and Permitted by Federal Law and the Majority of States

Notwithstanding CVS Caremark's suggestions to the contrary, physician dispensing is completely legal under Federal and State law, and, in fact, is specifically permitted and even encouraged in many contexts. This section of the White Paper seeks to describe the overall practice and explain the importance within the context of relevant laws and regulations.

"Physician dispensing," where a physician dispenses drugs directly from their office rather than a retail pharmacy, is an alternative to having a full retail pharmacy attached to the oncology practice. Physician dispensing is clearly permitted on a Federal level, and is generally permitted at the State level, especially in the oncology context, as discussed in detail below.

5.1.1 Federal Law Permits, and the Medicare-Sponsored Oncology Care Model Encourages, Physician Dispensing

Generally speaking, physician dispensing is permitted under Federal law, so long as physician dispensing is permitted in the State where the physician is located. While there is no specific Federal guidance for non-controlled substances, DEA regulations allow a registered practitioner to "engage in those activities that are authorized under state law for the jurisdiction in which the practice is located."[55] This would, therefore, give registered physicians the right to dispense controlled substances where otherwise permitted by State law.

In addition, the Federal Trade Commission ("FTC") has written opinions on the practice of physician dispensing, in relation to State law restrictions. The FTC supports physician dispensing, finding that it "maximizes consumers' option in the purchasing of prescription drugs."[56] "Dispensing by physicians benefits consumers by maximizing the number of qualified sources from which they may purchase prescription drugs, and by enabling consumers to avoid making a separate trip to a pharmacy."[57] Thus, even the FTC has strongly supported the importance of dispensing physicians within a robust and competitive marketplace.

Physician Dispensing Is Permitted by the Stark Law. The Federal prohibition against physician self-referral, commonly known as the Stark Law (42 U.S. Code § 1395nn), prohibits a physician from referring Medicare and Medicaid patients for certain "designated health services" ("DHS") to an entity with which he or she (or an immediate family member) has a financial relationship, unless the relationship fits within an exception. DHS is defined to include, among other products and services, outpatient prescription drugs

[55] U.S. Department of Justice ["DOJ"], Drug Enforcement Administration ["DEA"], Office of Diversion Control, *Practitioner's Manual: An Informational Outline of the Controlled Substances Act*, at 7 (2006), *available at* http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf.

[56] U.S. Federal Trade Commission ["FTC"], *Letter to the California Assembly from Director of Bureau of Competition Jeffrey I. Zuckerman*, *available at* https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-hon.tim-leslie-concerning-california.b.1732-restrict-ability-physicians-dispense-prescription-drugs-their-patients/p874680.pdf (last visited Jul. 12, 2016).

[57] FTC, *Letter to Maryland State Board of Medical Examiners from Director of Bureau of Competition Jeffrey I. Zuckerman* (Dec. 31, 1986), *available at* https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-maryland-state-board-medical-examiners-concerning-practice-and-regulation/af-47.pdf.

covered under Medicare Part D.[58] Physician dispensing falls within the ambit of the Stark Law, as it is a referral within the same entity, owned by the physician, for DHS. However, this arrangement can be deemed compliant, and a physician may lawfully refer patients to a pharmacy that he or she owns, provided the arrangement fits within one of the "Exceptions" to the Stark Law.

Here, the In-Office Ancillary Services exception to the Stark Law applies. It contains certain supervision, building, and billing requirements, all of which have several options which may be satisfied.[59] The In-Office Ancillary Services Exception treats DHS delivered in a physician's office as an integral part of the patient encounter and not a wholly separate service, even though the DHS can be billed as a separate encounter. Generally, these statutory exceptions and safe harbors have been promulgated by the government out of a belief that protected conduct supports a beneficial public policy concern. Here, the dispensing physician is personally furnishing the prescriptions, in their own office where they perform other services, and the prescriptions are billed directly by such physician, satisfying the requirements of the Exception. As such, physician dispensing is clearly and explicitly permitted by the Stark Law.

Physician Dispensing Is Permitted by the Anti-Kickback Statute. Likewise, the Anti-Kickback Statute prohibits individuals from knowingly or willfully offering, paying, soliciting, or receiving any remuneration directly or indirectly, in cash or in kind, (A) "in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program" (which include Medicare and Medicaid), or (B) "in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal healthcare program."[60] Thus, an arrangement whereby a physician dispenses directly to his or her own patients creates potential Anti-Kickback Statute implications, as the physician may receive remuneration in the form of the profits made by the billing of the prescription claim as a result of the referrals. However, there are certain explicit Exemptions and Safe Harbors to this statute, and physician dispensing does not violate the Anti-Kickback Statute if structured appropriately.

Where an arrangement fulfills all of the requirements of an Exemption or Safe Harbor, the arrangement or transaction will qualify for protection from prosecution under the Anti-Kickback Statute. It should be noted, regarding both the Stark Law and Anti-Kickback Statute, that the exceptions and Safe Harbors exist to allow physicians to take part in arrangements that would otherwise be prohibited. The existence of the exceptions to these laws is an indication that certain practices are considered permissible, and a recognition that there are certain "legitimate and beneficial activities,"[61] such as physician pharmacy ownership, that should be protected from scrutiny, as long as certain safeguards are in place.

Similar to the Stark Law's In-Office Ancillary Services exception, the Anti-Kickback Statute contains a Safe Harbor that includes ancillary services provided by a "group practice,"[62] which excepts from remuneration generated as a result of general investment interests in the physician's own practice or group practice (provided certain standards are met).[63] Among the chief requirements, the practice or group must be wholly-owned by licensed healthcare professionals who practice in the practice or group, and the practice

[58] *See* 42 C.F.R. § 411.351, *et seq*.
[59] *See generally* 42 U.S.C. § 1395nn, *et seq*.
[60] 42 U.S.C. § 1320a–7b(b).
[61] H.R. Rep. No. 100-85, at 27 (1987).
[62] 42 U.S.C. § 1395nn(h)(4).
[63] 42 C.F.R. § 1001.952(p).

must be a unified, centralized business as it relates to physician dispensing.[64] As such, physician dispensing is permitted under the Anti-Kickback Statute so long as it meets this exception.

The Medicare-Sponsored Oncology Care Model Encourages Physician Dispensing. A recently announced initiative by the U.S. Department of Health and Human Services ("HHS") on cancer care for Medicare beneficiaries lends direct Federal support for physician dispensing. Specifically, CMS' Innovation Center's ("CMMI") announced on June 29, 2016 that it has selected 200 physician group practices and 17 health insurance companies to participate in a care delivery model that supports and encourages higher quality and more coordinated cancer care.[65] As described in greater detail below, the Medicare-sponsored Oncology Care Model ("OCM") focuses on physician-led care, and providing patients with timely, coordinated diagnostic and treatment services. Importantly, the Model explicitly contemplates that participants in the program will include not only patients receiving physician-administered drugs billed under Medicare Part B, but also oral chemotherapy drugs dispensed under Part D, and are thus considered "physician dispensing." As such, current Medicare programs operating under Federal law fully contemplate physicians dispensing products to their patients. Medicare's OCM program stands in direct opposition to CVS Caremark's expulsion of dispensing physicians from the Medicare Part D network.

Thus, it is clear from both the Stark Law and the Anti-Kickback Statute, which contain exceptions that directly track the mechanics of the practice, as well as Medicare's own initiative, that physician dispensing has been directly contemplated and found permissible under Federal authorities.

5.1.2 State Law Widely Permits Physician Dispensing

Physician dispensing is also widely permitted under applicable State law. Many States either explicitly permit physicians to dispense medications to their patients, or are otherwise silent on the topic, and therefore, permissive, in regards to physician dispensing by placing no limitations on the practice.

In the many States where physician dispensing is expressly permitted, a physician is generally permitted to prescribe, dispense and charge for prescriptions dispensed to his or her own patients, so long as the physician obtains specific licensure with the State for dispensing. For example, in Virginia, physicians are explicitly allowed to dispense medication provided they are "licensed by the Board [of Pharmacy] to sell controlled substances."[66] Notably, many of the States that require physicians to be licensed to dispense medications, cause the physician to be licensed by the *Board of Pharmacy* (as opposed to the Board of Medical Examiners) to do so; this is an important distinction.

More specifically to oncology drugs, State law in some jurisdictions additionally considers physician dispensing of oncology drugs to be especially appropriate, even if it limits physician dispensing in other contexts. For example, while New York allows only a 72-hour supply of a drug to be dispensed by a physician and New Jersey limits to a seven-day supply, both of these States have express exceptions, which include "drugs dispensed pursuant to an oncological or AIDS protocol," allowing for regular dispensing of these drugs, in recognition of the distinct needs of these groups of patients.[67]

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[64] *See id*. This section references the in-office ancillary services exception to the Stark Law, *as codified at* 42 U.S.C. § 1395nn(b)(2).
[65] HHS, *HHS Announces Physician Groups Selected for an Initiative Promoting Better Cancer Care* (Jun. 29, 2016), http://www.hhs.gov/about/news/2016/06/29/hhs-announces-physician-groups-selected-initiative-promoting-better-cancer-care.html.
[66] Va. Code Ann. § 54.1-3304.1. Note that Virginia considers all prescription drugs "controlled substances," not just those that are considered "controlled substances" by the DEA.
[67] *See* N.J. Stat. Ann. § 45:9-22.11, *et seq.*; *see also* N.Y. Educ. Law § 6807, *et seq*.

In all, there are 44 States[68] that either explicitly permit physician dispensing (e.g., through Board licensing), or that otherwise allow for the practice as part of the general, plenary authority granted to licensed physicians, and another two states that expressly allow it in the oncological context.[69] Thus, State prohibitions on physician dispensing is a distinct minority, and in general, physician dispensing is legal in almost all jurisdictions.

5.1.3 CMS Regulatory Framework Favors Physician Dispensing

Finally, the concept of physician dispensing finds further support directly in the Medicare regulations. Specifically, the language of the Medicare regulations state that "[a] Part D sponsor must ensure that Part D enrollees have adequate access to vaccines and other covered Part D drugs appropriately dispensed and administered by a physician in a physician's office."[70] This illustrates Medicare's view that physician dispensing is a permitted practice on the Federal level.

5.2 Physician-Owned Pharmacies Are Equally Permissible and Legal

Physician-owned pharmacies, defined as a pharmacy wholly-owned by, and integrated in, the physician practice (as distinguishable from dispensing physician practices) are equally permissible under applicable rules. Physician-owned pharmacies, to which physicians would refer Medicare patients to receive oncolytic drugs, are permissible when structured to fit within both applicable Safe Harbors and/or Exceptions to the Federal Anti-Kickback Statute and Stark Law, and are operated in accordance with State law.

5.2.1 Federal Law Permits Physicians to Own and Operate Licensed Pharmacies in Accordance with Certain Safe Harbors and Exceptions

Physician-owned pharmacies operate across the country in compliance with Federal law by falling into expressly enumerated Safe Harbors and Exceptions to certain Federal rules, that might otherwise be implicated based on the potential for self-referral. The two primary Federal statutes implicated when a physician owns a pharmacy and refers to it are the Stark Law (42 U.S.C. § 1395nn) and the Anti-Kickback Statute (42 U.S.C. § 1320a-7b). Both laws, as well the mechanisms for how physician-owned pharmacies fall within the respective Exceptions and Safe Harbors, are addressed briefly below.

Stark Law. As outlined above in 5.1.1, for a physician to refer a patient for DHS to an entity that he or she owns, the physician must fit within an exception to Stark Law. In this regard, a physician could legally own and operate a pharmacy pursuant to the parameters of the "In-Office Ancillary Services Exception" to the Stark Law. As discussed above (*see supra* 5.1.1), this Exception permits the furnishing of certain DHS that are ancillary to the referring physician's professional services where certain supervision, location and billing requirements are satisfied.[71]

In this instance, the services are provided "by an individual who is supervised by the referring physician or by another physician in the group practice;" "in a building in which the referring physician (or another physician who is a member of the same group practice) furnishes physicians' services unrelated to the furnishing of designated health services;" and "billed by an entity that is wholly owned by such physician or such group practice."[72] Because the pharmacy services will typically be furnished by non-physician

[68] *See* Munger et al., *supra* note 8.
[69] *See* N.J. Stat. Ann. § 45:9-22.11, *et seq.*; *see also* N.Y. Educ. Law § 6807, *et seq*.
[70] 42 C.F.R. § 423.124.
[71] 42 U.S.C. § 1395nn(b)(2).
[72] *Id*.

personnel, a physician need only provide "direct supervision" by being present in the office suite and immediately available to provide assistance and direction throughout the time services are being furnished.[73] For purposes of applying the Exception to prescription drugs, prescription drugs are deemed to be furnished when the drugs are dispensed by the pharmacy.[74] As such, this flexibility means that a physician-owned pharmacy is permitted under the Stark Law. Thus, properly structured physician-owned pharmacies across the country comport with Federal law.

Anti-Kickback Statute. Just as the Group Practice Safe Harbor (discussed in Section 5.1.1 *supra*) applies to physician dispensing, it also services to protect physician-owned pharmacies. The analysis is essentially identical to that for physician dispensing.

As such, Federal law clearly allows physician-owned pharmacies, provided certain conditions are met. Federal law would not contain these Exceptions and Safe Harbors if physician-owned pharmacies were not permissible, and Congress and CMS would certainly not have gone through the rigors of implementing these explicit Exceptions and Safe Harbors if these types of dispensers were not contemplated to participate in, and submit claims to, the Medicare Part D Program, and dispense outpatient drugs to Medicare beneficiaries. Thus, this further highlights the legitimacy of physician dispensing and physician ownership of pharmacies under the framework of Federal healthcare programs. As a result, CVS Caremark's recent expulsion of dispensing physicians as out-of-network providers is inconsistent with Federal law.

5.2.2 State Law

Just as with the Federal rules, many States have statutory analogues that would permit physician ownership of pharmacies. These laws act to expressly allow physicians to own and operate a separately licensed pharmacy. For example, Texas has a Patient Non-Solicitation law, which prohibits payment or acceptance of payment for referrals to or from a healthcare practitioner.[75] While a physician referring to a pharmacy in which he or she had an ownership interest would implicate this statute, the statute permits any practice permitted by the Federal Safe Harbors,[76] thereby allowing for physician-owned pharmacies in the State. Likewise, Florida prohibits referrals by physicians to an entity in which they have an ownership interest for healthcare services, but contains an exception similar to the Stark Law's In-Office Ancillary Services Exception, excluding supervised services provided to a provider or group's own patients from the definition of referral.[77] Therefore, if the physician-owned pharmacy dispensed to the owner-physician's own patients, under the direct supervision of the physician, it would be permitted under Florida law. Once again, these State laws serve as evidence of the permissibility of physician-owned pharmacies in the States that allow it, and support the conclusion that there is no legitimate reason to do away with the practice where otherwise permitted by law.

5.3 CVS Caremark's Interpretation of CMS Regulations Is Wrong and Unsupported

Turning back to the recent actions by CVS Caremark (as one example of broader PBM conduct), these actions must be weighed against applicable Medicare rules and regulations. When analyzed in this context, CVS Caremark's interpretation of CMS Regulations is simply wrong.

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[73] *See* Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, 66 Fed. Reg. 856, 881 (Jan. 4, 2001).
[74] *Id.*
[75] Tex. Occ. Code Ann. § 102.001.
[76] Tex. Occ. Code Ann. § 102.003.
[77] Fla. Stat. § 456.053.

5.3.1 CVS Caremark's Interpretation is Contrary to the History of Physician Dispensing Under the Medicare Framework and CMS Regulations

The Medicare program dates back to the passage of Title XVIII of the Social Security Act in 1965, which provided health insurance to people age 65 and older, regardless of income or medical history. At the time, Medicare was divided into two Parts: Part A (hospital insurance) and Part B (supplementary medical insurance). While at the outset, outpatient prescription drug coverage was not included within the Medicare program, Medicare *did* always cover those prescription drugs that were dispensed in the physician's office and not self-administered by the patient, in an effort to keep physicians from hospitalizing a patient just for a needed drug.[78] Thereafter, in the 1990s, Congress authorized coverage for orally-administered, outpatient drugs for cancer treatments.[79] By 2001, Medicare covered approximately 454 physician-dispensed prescription drugs under the Part B segment.[80] Thus, Medicare has a long history of permitting physician dispensing.

It was not until November 2003, and the passage of the Medicare Modernization Act of 2003, that Congress created the Medicare Part D program. Medicare Part D, also called the Medicare prescription drug benefit, became the Federal government program aimed at subsidizing the costs of prescription drugs and prescription drug insurance premiums for Medicare beneficiaries, providing third party coverage for outpatient drugs purchased by beneficiaries at a variety of practice sites, including retail pharmacies, mail order pharmacies and from other providers.

Nowhere in the Medicare Modernization Act of 2003 did Congress specifically differentiate between pharmacies and physicians, or otherwise exclude physicians from participating in dispensing networks. Nothing was interpreted or created at this time to detract from the longstanding practice of physician dispensing or physician ownership of pharmacies, or to suggest that these providers would not be able to participate equally in Medicare Part D plan networks.

Although Medicare Part D was created in 2003, the program did not go into effect until January 1, 2006. During that time, CMS undertook to begin writing rules and regulations to put the Medicare Part D program into place. It was during this process that CMS introduced the specific regulation that it is believed CVS Caremark now relies upon. Specifically, 42 C.F.R. § 423.124, the regulation addressing "special rules for out-of-network access to covered Part D drugs at out-of-network pharmacies," became effective March 22, 2005. The rule provided, *inter alia*, that "[a] Part D sponsor must ensure that Part D enrollees have adequate access to vaccines and other covered Part D drugs appropriately dispensed and administered by a physician in a physician's office."[81] Because this language appears in the rule addressing "out-of-network access" to covered Part D drugs, CVS Caremark has ostensibly taken the position that it should render dispensing physicians as "out-of-network" providers by default, and block any payments to them or participation by them in Part D networks.

However, as set forth in the rules' history, as evidenced by the Federal Register comment and response section, CMS clarified that Part D plans would be required to establish reasonable rules to ensure "access" to drugs dispensed out of physician offices.[82] The discussion in the Federal Register acknowledged

[78] *See generally* Thomas R. Oliver, Philip R. Lee, and Helene L. Lipton, *A Political History of Medicare and Prescription Drug Coverage*, 82 Milbank Q. 283 (2004), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2690175/pdf/milq0082-0283.pdf.

[79] *See* Medicare Payment Advisory Commission ["MedPac"], *Report to the Congress: Variation and Innovation in Medicare,* at 149–70 (Jun. 2003), *available at* http://www.medpac.gov/documents/reports/June03_Entire_Report.pdf?sfvrsn=0.

[80] U.S. Government Accountability Office ["GAO"], *Medicare Outpatient Drugs: Program Payments Should Better Reflect Market Prices*, at 4 (Mar. 14, 2002), *available at* http://www.gao.gov/assets/110/109174.pdf.

[81] 42 C.F.R. § 423.124(a)(2).

[82] Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194-01, 4268 (CMS Jan. 28, 2005) (final rule).

physician dispensing and administration of Part D drugs as a necessary practice, and called for a framework to ensure access.[83] Thus, CVS Caremark's recent "re-interpretation" of this regulation (which has been on the books for over a decade) belies the legislative and regulatory history of not only the Medicare program as a whole, but also the regulatory history of the very regulation they seek to interpret. Rather, it once again becomes clear that CVS Caremark's regulatory interpretation to exclude dispensing physicians is motivated by profits, rather than a true effort at compliance.

5.3.2 Custom and Practice Among CVS Caremark and Other PBMs Favors Physician Dispensing

Dispensing physicians being "in-network" becomes even clearer when considered against the backdrop of CVS Caremark's (and other PBMs and Part D Plan Sponsors') custom and practice of allowing dispensing physicians to participate as in-network providers for a variety of Part D networks. Specifically, CVS Caremark's exclusion of physician dispensing and possibly physician-owned pharmacies from the CVS Caremark retail network is a striking deviation not only from CVS Caremark's own practices, but is contrary to any other PBM interpretation of CMS regulation and guidance.

For over a decade (since the Medicare Part D Program took effect in 2006), CVS Caremark has continually allowed physician practices to participate as in-network providers, and to submit claims under Medicare Part D for reimbursement. Up until its most recent re-interpretation, CVS Caremark has credentialed dispensing physicians and physician-owned pharmacies, and has treated them – for all intents and purposes – as in-network "retail pharmacies." While CVS Caremark might have held them to certain standards more applicable to pharmacies for auditing purposes (i.e., record-keeping requirements), CVS Caremark had heretofore not taken issue with their general status as physicians rather than pharmacies, and consistently allowed them to participate in Medicare Part D networks.

This treatment is consistent with the actions of other PBMs and Part D Plan Sponsors. Specifically, PBMs routinely create avenues for dispensing physicians and physician-owned pharmacies to participate as in-network providers. For example, certain PBMs will create options in their credentialing forms for "dispensing physicians" as a business type to credential with the PBM, defining "dispensing physician" generally as a prescriber whose State license permits dispensing take-home medication from the physician's office.[84] Furthermore, in other network updates and Medicare Part D Addenda, PBMs have stated that a "dispensary" means a clinic where prescriptions are dispensed by a prescribing physician or other practitioner.

Likewise, while other PBMs may include certain differentiations between "General Retail Pharmacies" (i.e., "traditional pharmacy services provided by a licensed, non-wholesale pharmacy that maintains a reasonable stock of commonly dispensed medications in anticipation of walk-in customers, is open to the general public, and where patients can obtain medication while they wait"), and "Limited Retail Pharmacies" (i.e., "traditional pharmacy services provided by a licensed, non-wholesale pharmacy that maintains a reasonable stock of commonly dispensed medications in anticipation of walk-in customers, is *only open to a limited population* such as employees or patients of certain doctors, and where patients obtain medication while they wait"), they will still generally contract with dispensing physicians or physician-owned pharmacies, even in the Medicare Part D context. Thus, these PBMs clearly recognize the legitimate participation of a dispensing physician as an in-network provider.

[83] *Id.* at 4328.

[84] Due to confidentiality requirements within the various PBM contracts, direct quotation from and reference to the specific contractual documents cannot always be made.

More strikingly, none of the other PBMs have made a similar reinterpretation of CMS regulations in the way CVS Caremark has. Rather, this change in interpretation is made completely unilaterally by CVS Caremark, and is not based on any changes to the CMS regulations relating to physician dispensing or physician-owned pharmacies. A review of all major PBMs' Provider Manuals and survey of physician dispensing and physician-owned pharmacies found no similar action by Express Scripts, OptumRx, or Prime Therapeutics – the nation's other largest PBMs. Critically, CVS Caremark's changed policies are not based on any actual *changes* in rules or policy made by CMS. CVS Caremark has not sought approval from CMS or other Federal regulatory body for its unilateral decision to change its networks to exclude physician dispensing, which otherwise benefits the care and treatment of Medicare beneficiaries.

5.3.3 CVS Caremark's Recent Actions Are Blocked by the Federal Any Willing Provider Law

Federal law – enacted to protect providers' access to and participation in – government programs, acts a safeguard against large PBMs (like CVS Caremark) wielding unbridled power and excluding entire classes of providers. The Social Security Act established the Medicare program, and dictates both the scope of benefits and coverage, as well as provisions for provider enrollment and payment.[85] These Federal statutes governing the Medicare program control what powers are granted to CMS in the administration of the Medicare program, and supersede any regulation enacted by CMS that runs counter to the language of the statute. Importantly, the Federal statutes codifying the Medicare program include explicit "Any Willing Provider" laws, which relate directly to network access for Medicare providers, such as dispensing physicians and physician-owned pharmacies. These statutes apply to *all* Part D Sponsors, as Part D Sponsors are under the purview of CMS, pursuant to contracts between the Part D Plan Sponsors and CMS. Part D Sponsors, such as CVS Caremark, are *not permitted* to do that which CMS cannot do. Part D Sponsors are governed by CMS, and the regulations promulgated by CMS are subordinate to the enabling Medicare statutes, including the Medicare Any Willing Provider Law (42 U.S.C. § 1395w-104).

The Medicare Any Willing Provider Law explicitly requires that all Part D prescription drug plans permit "the participation of any pharmacy that meets the terms and conditions under the plan."[86] While this section references the participation of "any pharmacy," the Medicare statutes and regulations taken as a whole (as further described below), can be directly interpreted to clearly extend this requirement not only to physician-owned pharmacies, but also to dispensing physicians where permitted by State law.

This Medicare Any Willing Provider ("AWP") requirement applies directly to CVS Caremark. When a Part D Plan Sponsor, such as CVS Health, enters into a contract with CMS as a down-tier provider to provide drug coverage to Medicare beneficiaries, the Part D Plan Sponsor (and ultimately CVS Caremark as the down-tier PBM) must "agree to have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy."[87] Thus, CVS Caremark is expressly governed by Federal Law and is required to maintain a contract with CMS containing the AWP terms.

CMS takes the Medicare AWP requirements very seriously. As a testament to its resolve, CMS has recently issued Aetna a $1 million civil monetary penalty, and required it to submit a corrective action plan due to a determination that "Aetna's contracting process for CY 2015 did not comply with Part D program

[85] *See generally* 42 U.S.C. § 1395, *et seq.*
[86] 42 U.S.C. § 1395w-104(b)(1)(A).
[87] 42 C.F.R. § 423.505.

requirements because Aetna did not permit the participation of any pharmacy that met the terms and conditions under the plan, as required by section 1860D-4(b)(1)(A)."[88] Specifically, CMS states that:

> to comply with the AWP [any willing provider] requirement, a Part D plan sponsor must make standard terms and conditions available for all Part D plans it offers. For those terms to be reasonable and relevant, they must identify for the pharmacy the plan(s) to which they apply, and the offer must include language that obligates the Part D sponsor to include the pharmacy in the identified plan(s) upon the pharmacy's acceptance of the terms and conditions.[89]

Therefore, CMS clearly requires that Part D Sponsors comply with the Medicare AWP requirements, and CVS Caremark's refusal to contract with any provider that is willing to comply with their terms and conditions is a violation of these Federal statutes.

As noted above, these Federal statutory AWP requirements apply directly to physician-owned pharmacies and physician-dispensers. While the Medicare Any Willing Provider Law utilizes the term "pharmacy" in setting forth the AWP requirements, the term "pharmacy" is not defined in the related statutory sections and regulations. In the absence of a direct and specific definition,[90] rules of statutory interpretation would default to the commonly understood definition of a pharmacy, which historically has been determined at the State level.

In this vein, numerous States define a "pharmacy" or the "practice of pharmacy" in such a way that would extend to physician dispensing, and certainly to physician-owned pharmacies. For example, North Carolina defines "pharmacy" as "any place where prescription drugs are dispensed or compounded."[91] Delaware defines "pharmacy" in a similar manner – "a place where drugs are compounded or dispensed."[92] Likewise, a variety of States specifically require dispensing physicians to be directly licensed or permitted by the State Board of Pharmacy, including, among others, Virginia,[93] North Carolina,[94] and Florida.[95] Based on the fact that dispensing physicians often fall within the State law definition of "pharmacy" and at times are even directly licensed by the State Boards of Pharmacy, dispensing physicians may be validly considered "pharmacies" under the "any willing provider" requirements of Medicare Part D, thereby requiring Part D Plan Sponsors to contract with them as in-network providers. This is in line with the legislative intent of this statute.

Further, with respect to physician-owned pharmacies, these entities are specifically licensed pharmacies, inspected and regulated by their respective State Boards of Pharmacy. They hold pharmacy licenses no

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[88] CMS, *Letter to Aetna from Acting Director of Medicare Drug Benefit and C & D Data Group Amy K. Larrick Requesting Implementation of Corrective Action Plan* (Jan. 28, 2015) ["2015 CMS-Aetna Letter"], *available at* http://www.ncpa.co/pdf/aetna-awp-cap-jan-2015.pdf.

[89] CMS, *Letter to Medicare Part D Plan Sponsors Regarding Compliance with Any Willing Pharmacy (AWP) Requirements* (Aug. 13, 2015), *available at* http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=20065.

[90] In other parts of the CMS regulations, however, "retail pharmacy" is defined as "any licensed pharmacy that is not a mail order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy." 42 C.F.R. § 423.100. Even if it were argued that physician dispensers did not fall under the category of "retail pharmacies," access to non-retail pharmacies is included in the Medicare AWP provisions in the regulations for Part D plan sponsors, and Part D plan sponsors are permitted to supplement their contracted pharmacy network with non-retail pharmacies (i.e., mail order pharmacies, home infusion pharmacies, long-term care pharmacies, specialty pharmacies, etc.).

[91] N.C. Gen. Stat. § 90-85.3.

[92] Del. Code Ann. tit. 24, § 2502.

[93] Va. Code Ann. § 54.1-3304.1.

[94] N.C. Gen. Stat. § 90-85.21.

[95] Fla. Stat. § 465.0276.

different than any other retail pharmacy. As such, they are without question pulled within the purview of the Medicare Any Willing Provider Law.

Together, these facts eviscerate CVS Caremark's interpretation. The explicit nature and intent of these statutory directives not only supersede the regulations cited by CVS Caremark, but create clear and binding directives on the PBM to allow these providers into Part D networks.

Moreover, CVS Caremark cannot circumvent its statutory Medicare AWP obligations by creating unduly burdensome terms and conditions for participation – something it is ostensibly seeking to do by imposing an unnecessarily narrow definition of "retail pharmacy" in an effort to exclude dispensing physicians and physician-owned pharmacies. In this regard, the regulations implementing the Medicare Any Willing Provider Law go on to state that Part D Plan Sponsors "must contract with any pharmacy that meets the Part D Sponsor's standard terms and conditions,"[96] and do not specify that this is limited to "retail" pharmacies. CMS has recently interpreted these provisions to require that terms and conditions be reasonable, and has admonished Part D Sponsors when they have established terms and conditions that are unduly burdensome or onerous, and serve as artificial barriers of entry to limit network access.[97] Again, here, CVS Caremark's statements that a provider in the PBM's retail pharmacy networks must carry a full array of medications and drug therapies for patients, and must not be a "closed door" facility, only treating patients under their care, are both designed as arbitrary requirements to deny access to dispensing physicians and physician-owned pharmacies that otherwise comport with an applicable Federal Safe Harbor. These requirements are not comparable to the terms set forth by other PBMs in the industry, and prove once again, that CVS Caremark's current actions are motivated by profits, not compliance.

5.3.4 By Denying Network Access to Physicians, CVS Caremark's Actions Violate Medicare Patient Choice Laws

In addition to violating the Federal statutory requirement that willing and able providers be admitted into Medicare Part D networks, CVS Caremark's actions in blocking network access to dispensing physicians and physician-owned pharmacies run afoul of the Medicare Freedom of Choice Laws. Specifically, the Federal Medicare statute, 42 U.S.C. § 1395a, entitled "Free Choice By Patient Guaranteed," states that "[a]ny individual entitled to insurance benefits under [Medicare] may obtain health services from *any institution, agency, or person* qualified to participate under [Medicare] if such institution, agency, or person undertakes to provide him such services."[98] This law is designed to be consistent with the historical framework of the overall Medicare program, and to ensure access by patients to the provider of their choice. While the Any Willing Provider Law arguably inures to the benefit of the provider, the Freedom of Choice Law inures to the benefit of the patient.

In this context, the law is written to apply equally to *all providers*, so long as they are qualified to participate in the Medicare program. In this case, each of the dispensing physicians have and maintain valid Medicare provider numbers, and are credentialed with Medicare. Hence, they are clearly qualified to participate under Medicare, as they submit claims for medical services on the Part B side.

As such, Medicare beneficiaries are permitted to seek care from any entity participating in Medicare, including dispensing physicians. Denying a patient the right to see a provider of his or her choosing violates the Medicare Freedom of Choice Law, and when coupled with the Medicare Any Willing Provider Law (discussed above), strongly weighs in favor of dispensing physicians being "in-network" for Medicare

[96] 42 C.F.R. § 423.120(a)(8)(i).
[97] *See generally* 2015 CMS-Aetna Letter, *supra* note 88.
[98] 42 U.S.C. § 1395a (emphasis added).

patients. Again, this requirement finds authority in a Federal statute (42 U.S.C. § 1395a), governing CMS and the Medicare program as a whole. As a result, to the extent CMS's actions are curtailed by statute, so too are the various Medicare Parts and Plan Sponsors, and so too is CVS Caremark as a downstream-entity (notwithstanding a regulation it seeks to interpret to the contrary).

5.3.5 CVS Caremark's Actions Also Implicate Any Willing Provider Laws and Patient Freedom of Choice Laws Under Various States' Laws and Medicaid Regulations

The statutes governing the Medicare program are not the only statutory bases for any willing provider and patient freedom of choice laws. Any willing provider and freedom of patient choice principles are also found in a variety of other sources, including the Federal Medicaid statutes, individual State Medicaid regulations, and applicable State insurance codes.

With respect to the Medicaid program, Federal law establishing the program also guarantees beneficiaries free choice of providers, with the portion of the Social Security Act which addresses state plans for medical assistance stating that "any individual eligible for medical assistance (including drugs) may obtain such assistance from *any institution, agency, community pharmacy, or person, qualified to perform the service or services required* (including an organization which provides such services, or arranges for their availability, on a prepayment basis), who undertakes to provide him such services..."[99]

In addition to this Federal mandate, many States have enacted their own Medicaid any willing provider requirements. For example, Pennsylvania's Medicaid statutes provide that any managed care entity under contract with the Department of Public Welfare "must contract on an equal basis with any pharmacy qualified to participate in the Medical Assistance Program that is willing to comply with the managed care entity's pharmacy payment rates and terms and to adhere to quality standards established by the managed care entity."[100] These terms focus solely on willingness to accept payment terms and to comply with quality standards. In addition to the Federal requirement, laws and regulations like these serve to curtail CVS Caremark's action as it relates to the various State Medicaid Managed Care Plans administered by the PBM. Simply put, CVS Caremark cannot exclude dispensing physicians or physician-owned pharmacies from these Medicaid networks.

Finally, a majority of States additionally have their own patient freedom of choice and any willing provider laws that apply to all insurance policies issued in the particular State, or inure to the benefit of all patients residing in the State. For example, the North Carolina Insurance Code contains both any willing provider and freedom of choice requirements, stating in relevant part that a health benefit plan shall not:

> (1) Prohibit or limit a resident of this State, who is eligible for reimbursement for pharmacy services as a participant or beneficiary of a health benefit plan, from selecting a pharmacy of his or her choice when the pharmacy has agreed to participate in the health benefit plan according to the terms offered by the insurer;
>
> (2) Deny a pharmacy the opportunity to participate as a contract provider under a health benefit plan if the pharmacy agrees to provide pharmacy services that meet the terms and requirements, including terms of reimbursement, of the insurer under a health benefit plan, provided that if the pharmacy is offered the opportunity to participate, it must participate or no provisions of [this statute] shall apply...[101]

[99] 42 U.S.C. § 1396a.
[100] 62 Pa. Cons. Stat. § 449.
[101] N.C. Gen. Stat. § 58-51-37.

Likewise, the Delaware Insurance Code includes the "Pharmacy Access Act," which provides that "[a]ny person in the State may select the pharmacy of the person's choice as long as the pharmacy has agreed to participate in the plan according to the terms offered by the insurer," and "[a]ny pharmacy or pharmacist has the right to participate as a contract provider under a plan or policy if the pharmacy or pharmacist agrees to accept the terms and reimbursement set forth by the insurer."[102] These State laws are prime examples of the robust requirements that apply to all commercial insurance plans in each State.

The clear implication from the myriad State any willing provider laws is that in most jurisdictions, and on a national basis for Medicaid, insurers are required to accept into their pharmacy networks any pharmacy providers who are willing to accept their standard terms and conditions. While this White Paper is predominantly focused on the implications of CVS Caremark's actions on the Medicare program, it is important to note that CVS Caremark has extended the application of its policies to bar network access to dispensing physicians and physician-owned pharmacies in connection with *all plans*, including Medicaid and the commercial payors for which it provides pharmacy benefit management services. This is problematic for many reasons, most notably as CVS Caremark's actions are in clear contravention of the State laws requiring that an insurer accept into their network all pharmacy providers willing to meet their standard terms and conditions. CVS Caremark is therefore improperly excluding dispensing physicians and physician-owned pharmacies not just from Medicare, but from all networks, public and private, commercial and government, in violation of the laws of multiple jurisdictions.

5.3.6 Medicare's Patient Access Considerations and Geographic Limitations

CVS Caremark's recent action is also at odds with one of the consistent and overarching goals of the Medicare program, which is to ensure adequate access to care by Medicare beneficiaries. Congress and HHS have repeatedly expressed deep concern with enrollees' reasonable, adequate, and/or convenient access to participating Part D providers. To this end, Congress has provided statutory direction that Part D Plan Sponsors are required to "secure the participation in its network of a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access (consistent with rules established by the Secretary)."[103] These rules govern convenient or reasonable access to covered Part D drugs, including ensuring access to dispensing physicians. One such rule established for physician dispensing in particular is contained in 42 C.F.R. § 423.124, *et seq.*, which provides the following: "A Part D sponsor *must* ensure that Part D enrollees have adequate access to vaccines and other covered Part D drugs appropriately dispensed and administered by a physician in a physician's office . . . [and a] Part D sponsor *must* establish reasonable rules to appropriately limit out-of-network access to covered Part D drugs."[104] Taking all of these requirements together, it is clear that enrollees *must* have access to Part D drugs "appropriately dispensed and administered by a physician in a physician's office." As such, CVS Caremark's recent action diminishes mandatory patient access.

Commentary to these rules focuses on the question of what CMS would consider "appropriately dispensed." While CMS has suggested that "the application of this requirement will be limited to vaccines and a handful of drugs (for example, some injectable long-acting antipsychotics) that are appropriately dispensed and administered in a physician's office and are not covered under Part B, and that plans may establish utilization management policies and procedures to ensure that out-of-network coverage is

[102] Del. Code Ann. tit. 18, §7303. Although this is not an exhaustive list, other examples of State AWPLs include: Ala. Code § 27-45-3, Colo. Rev. Stat. § 25.5-5-504, 215 Ill. Comp. Stat. 134/72, Ind. Code § 27-8-11-3, N.H. Rev. Stat. Ann. § 420-B:12, N.J. Stat. Ann. § 26:2J-4.7, N.D. Cent. Code § 26.1-36-12.2, S.C. Code Ann. § 38-71-147, S.D. Codified Laws § 58-18-37, Tenn. Code Ann. § 56-7-2359, Tex. Ins. Code Ann. § 21.52B, Va. Code Ann. § 38.2-3407, Wis. Stat. § 628.36.
[103] 42 U.S.C. § 1395w-104(b)(1)(C)(i).
[104] 42 C.F.R. §§ 423.124(a)(2) and (c) (emphases added).

limited to such covered Part D drugs,"[105] this certainly is not all-inclusive. For example, in the oncology market, physician-dispensed oral oncolytics (along with ESRD drugs, and other highly customized therapies) can be differentiated from the majority of drugs that are covered under Part D – say, for example, drugs dispensed in areas such as dermatology or in the workers' compensation context – where there is a clear profit motive for the physician dispenser. Based upon improved patient outcomes and medication therapy management for oral oncolytics (as discussed in greater detail in Section 6 below), oral oncolytics properly should be included in the drugs that are appropriately dispensed in a physician's office.[106]

It is conceivable that CVS Caremark could seek to respond to these statutory "reasonable access" requirements, taking the position that CVS Caremark need only provide reasonable "out-of-network access" to the drugs dispensed by the physicians, and that it is justified in treating them as out-of-network providers. However, in light of the nature and circumstances surrounding many physician-dispensed medications, including specifically oncology medications, this position will accomplish nothing more than effectively denying all Medicare Part D beneficiaries any semblance of reasonable network access to physician-dispensed medication, out-of-network or otherwise. Under the regulatory framework, as contemplated when the regulation (42 C.F.R. § 423.124) was enacted, "[e]nrollees will be required to self-pay the physician for the cost of the vaccine (or other covered Part D drug appropriately dispensed and administered in a physician's office) and submit a paper claim for reimbursement by their Part D plan."[107] This would become a substantial and insurmountable hurdle for physician dispensing, as it would require the patient to pay up front for the drugs, which, in the case of oral oncolytics, are extremely expensive, in the range of $10,000 per month for the new oral medications.[108] Even if the PBM afforded reasonable out-of-network coverage, Medicare beneficiaries would be effectively foreclosed from ever actually obtaining medications from dispensing physicians, given the enormously rising costs of medications (especially oncology medication). The effect of this requirement would essentially block physician dispensing of oral oncolytics of all kinds, despite the advantages to patients and the recognition by CMS that physician dispensing of Part D drugs can be appropriate in some circumstances. Most importantly, this practical reality would result in a violation of Medicare's reasonable access requirements, which at a minimum, require reasonable access to physician dispensed medications even if on an out-of-network basis. By forcing dispensing physicians out-of-network altogether, CVS Caremark eliminates any access by its Medicare Part D beneficiaries to physician-dispensed medication. Therefore, the only option to ensure compliance with Medicare's reasonable access requirements is to continue with the longstanding practice by Medicare Part D Sponsors (including CVS Health) and allow dispensing physicians to remain in-network.

5.3.7 CVS Caremark's Recent Regulatory Interpretation Is Inconsistent with Recent and Ongoing HHS Initiatives Which Support Physician Dispensing for Medicare Patients

As noted in Section 5.1.1 above, as part of the CMS Innovation Center's development of new payment and delivery models designed to improve the effectiveness and efficiency of specialty care, CMS created multiple specialty models, including the Oncology Care Model (OCM). The OCM's chief aims are to provide higher quality, more highly coordinated oncology care at the same or lower cost to the Medicare program,

[105] Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194-01, 4268 (CMS Jan. 28, 2005) (final rule).
[106] *See id.* at 4233 (supporting the conclusion that CMS recognizes that oral oncolytics are a different class of drugs than many other Part D drugs, and that in many instances, the most appropriate use of these drugs is through dispensing directly by a physician).
[107] *Id.* at 4268.
[108] Egerton, *supra* note 11.

and will include government and commercial payors in the model. The Medicare arm of the OCM includes more than 3,200 oncologists and will cover approximately 155,000 Medicare beneficiaries nationwide. The Oncology Care Model began on July 1, 2016 and will run through June 30, 2021, and focuses on Medicare fee-for-service beneficiaries receiving chemotherapy treatment. The OCM focuses on physician-led care, and providing patients with timely, coordinated diagnostic and treatment services, focused on patient needs. OCM participants are Medicare-enrolled physician groups that furnish chemotherapy treatment, which includes chemotherapy drugs dispensed under Part D (and are thus considered "physician dispensing") as well as Part B. Dispensing physicians are participating in the OCM. This recent Medicare initiative is just one of many recent examples demonstrating that not only does Medicare permit physician dispensing, but in the oncology context, the practice is favored as promoting patient care. This further runs counter to CVS Caremark's recent and unsupported interpretation of the intended Medicare framework.

5.3.8 PBM Profit Motives and Federal Healthcare Laws

CVS Caremark's improper exclusion of dispensing physicians from Medicare Part D networks flouts the spirit and intent of the Medicare program and violates the PBM's obligations as a sponsor and administrator under the Part D program. All PBM actions (including CVS Caremark's) must also be considered against the backdrop of Federal healthcare laws. Any time patient directing or steering occurs based on financial considerations or profit motives, potential implications under the Federal Anti-Kickback Statute must be considered.

PBMs, as agents of Medicare, wield tremendous influence over patient access to drugs as well as arranging the providers from whom patients may receive service. When PBMs create restrictive "network access" rules, there is potential limitation on patient choice of provider and a concomitant decrease in competition. If a PBM is able to eliminate an entire class of trade from its networks (say, dispensing physicians), and exploits this policy change to drive patients to the PBM's wholly-owned retail and specialty pharmacies, patients will be denied the ability to receive their medication at the point of care. Restricted networks are harmful to patients who require specialty medications, including the vulnerable elderly and disabled who are a part of Medicare Part D PDPs, as they limit the patient's access and decrease the likelihood that the patient will actually fill the prescription and receive their medication.

More glaringly, if the PBM (as the agent for the Part D Plan Sponsor) can eliminate network access for physician providers and redirect specialty patients to its own specialty pharmacy (in which the PBM holds a financial interest), then the PBM will directly profit from the restricted network and the redirection of patients. Additionally, to the extent that the PBM then takes further steps to direct patients to its wholly-owned pharmacies after narrowing network access (namely, notifying beneficiaries that they can no longer use their existing provider but can utilize one of PBM's retail, specialty or mail order pharmacies)[109], said PBM's actions could directly implicate the Federal Anti-Kickback Statute.

The Federal Anti-Kickback Statute makes it unlawful and a criminal offense to knowingly and willfully solicit or receive any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal healthcare program.[110] The Anti-Kickback Statute clearly applies to the Medicare claims managed and adjudicated by PBMs, including CVS Caremark, as Federal healthcare payments are involved.

[109] *See, e.g.,* Barbara Martinez and David Armstrong, *CVS Appears to Steer Plan Patients to Its Stores*, Wall St. J. (*as updated* May 13, 2009, 12:01 AM), http://www.wsj.com/articles/SB124218519933814001.
[110] 42 U.S.C. § 1320a-7b(b)(1)(A).

To the extent a PBM (who owns its own retail, specialty and mail order pharmacies) steers business away from dispensing physicians, the natural, probable and foreseeable result is that said PBM will capture that business that is now "up for grabs." In this scenario, the PBM's network exclusion of the Medicare patient's treating physician, coupled with the PBM's efforts to then capture that business at its wholly-owned pharmacies, could be viewed as the referring, arranging for or recommending of service at a particular provider in such a way that is tied directly to financial remuneration. The remuneration that the PBM would receive in exchange for this referral is payment from Medicare for each patient that was previously serviced by a dispensing physician and is now serviced by the PBM's wholly-owned pharmacies. This remuneration is directly tied to the volume and value of the business that the PBM is ultimately able to redirect ultimately to its own pharmacies. Arrangements involving healthcare services under which payment is made based on the number of referrals that an entity provides are considered kickbacks, and these kickbacks are cause for concern, and violate the Anti-Kickback Statute. Furthermore, the Anti-Kickback Statute has been interpreted broadly by courts to cover any arrangement where one purpose of the remuneration is to induce or reward referrals. Accordingly, to the extent that this remuneration (i.e., the overall profit motivation) is *one purpose* of the action, then the Anti-Kickback Statute could be implicated.

Ultimately, without making any commentary specifically on CVS Caremark's actual actions or intentions, this section of the White Paper merely points out that there are Federal healthcare laws that seek to curb (both through civil and criminal penalties) actions by healthcare companies that put profits over patients. It is against this backdrop that the actions and motivations of PBMs must be considered, and these considerations further underscore the conclusion that dispensing physicians must not be excluded from Medicare Part D networks.

6 The Clinical and Economic Benefits of Physician Dispensing

Lastly, PBM efforts to remove dispensing physicians' participation in Medicare Part D networks overlooks the proven clinical and economic benefits of physician dispensing, as well as the important role they play in the healthcare system. It is unquestionable that the overarching trend in healthcare, and specifically for Medicare oncology patients, is towards integration and coordination of care that places tremendous emphasis on the physician as the primary clinician responsible for patient outcomes. CVS Caremark's exclusion of dispensing physicians from network access is in direct opposition to this evolving healthcare paradigm and negatively affects physicians' ability to properly manage their Medicare patients' care. As a result, patients lose, but CVS Caremark's economic motive is satisfied.

6.1 The Clinical Benefits of Physician Dispensing, Particularly in the Oncological Context

The management of patients with cancer is recognized as a unique challenge within the healthcare continuum. Traditional infusion chemotherapy is covered under Part B, and is administered in the physician's office. Chemotherapy under Part B is not paid or controlled by PBMs because it is not a pharmacy benefit. However, oral chemotherapy drugs are becoming increasingly available, with recent studies showing that of the over 800 anti-cancer drugs currently in clinical development, a quarter are oral oncolytics.[111] Providing pharmacy services to, and receipt of, patient medication directly at the physician's office, is an extension of the traditional chemotherapy model, and helps to ensure that

[111] Egerton, *supra* note 11.

patients receive their medication, understand the need for drug compliance, and optimizes the continuity of care. PBMs like CVS Caremark, using network access as a weapon, seek to change that paradigm.

Medication non-adherence (when patients fail to fill prescriptions) is a significant problem for healthcare in general. A 2010 study by Harvard Medical School found that almost 30% of prescriptions for new medications, and over 20% of all prescriptions were never filled.[112] Such medication non-adherence has been shown to be related to greater morbidity and mortality in chronic disease, and is estimated to increase healthcare costs in the United States by over $170 billion annually.[113] It should be noted that the abandonment rate for Medicare patients is higher than that for commercial patients.[114] According to the lead author of the Harvard study, significant factors contributing to non-adherence are likely to be affordability, physician-patient communication and the cumbersome process of filling out a prescription.[115] Furthermore, there were significant differences in the prescription fill rates between the Harvard study and those conducted in Europe, or in integrated care systems in the United States.[116] A study of non-adherence among patients at Kaiser Permanente of Northern California, where the patients could retrieve their medications almost immediately and at the same location as their doctor's office, found that only 5% of patients did not fill their initial prescriptions.[117] It is clear that centralizing patient care leads to increased medication adherence and thus, improved patient outcomes, which is also recognized by HHS with the Medicare-sponsored Oncology Care Model (*see*, Section 5.3.7, *supra*).

In-office dispensing streamlines the process of providing the patient with a drug, rather than using the typical specialty/mail order pharmacy route. A major advantage is the speed with which the patient receives their prescription at the physician's office compared to other dispensing sites. When a patient is prescribed an oral cancer prescription, it is typical for it to take one to two weeks for the drug to arrive when a PBM specialty/mail order pharmacy is used.[118] This is in contrast to physician dispensing which occurs at the physician office immediately. In some circumstances, physicians may dispense the "first fill" by delivering the medication to the patient's home after the patient has left the office. Although this practice may appear similar to the patient receiving their medication from a mail-order pharmacy, all the other benefits of physician dispensing are applicable, such as integrated medical records, patient counselling and monitoring of patient receipt of medication. The physician's office also has real-time access to the patient's insurance information, and can assist the patient in identifying financial assistance.[119] Since abandonment rates increase with greater out-of-pocket costs for the patient,[120] this easy access to financial assistance additionally increases adherence. The complexity of drug therapy is another significant factor in the abandonment of oral oncolytics,[121] but physician dispensing allows the physician to coordinate all aspects of the patient's medication management, and to provide counseling to the patient upon dispensing, which increases adherence to drug protocols. Further, the physician may schedule toxicity checks, to allow for early side-effect management and related dose adjustments, which, if needed, can be made quickly in order to optimize treatment.

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[112] Fischer et al., *supra* note 3.
[113] *Id.*
[114] Schwartzberg et al., *supra* note 2.
[115] Pauline W. Chen, *supra* note 1.
[116] *Id.*
[117] *Id.*
[118] Egerton, *supra* note 11.
[119] Barnes et al., *Oral Oncolytics: Addressing the Barriers to Access and Identifying Areas for Engagement*, Avalere Health (2004), http://www.avalerehealth.net/wm/show.php?c=&id=842.
[120] Schwartzberg et al., *supra* note 2.
[121] *Id.*

Separate pharmacies, including CVS Health's retail and specialty pharmacies, are not able to provide physician level services. While payors may think that pharmacies are in the best position to set up systems monitoring patient compliance, there is a lack of coordination between such pharmacies and physician offices.[122] For example, if a patient exhibits side effects, the patient is likely to speak to their physician's office, rather than the pharmacy, and the office may modify the dosing schedule.[123] The pharmacy would likely be unaware of this change, and, in the course of monitoring patient compliance, may provide conflicting instructions to the patient.[124] This could lead to treatment complications and potentially dangerous compliance issues for the patient.[125] In these situations, physician dispensing has a clear clinical advantage, as it eliminates the disconnect between the physician and pharmacy services.

Physician dispensing is additionally supported by the American Medical Association, which finds it appropriate for physicians to dispense drugs in their office practices when the dispensing primarily benefits the patient.[126] In the oncological context, the benefits to the patient are significant and apparent.

These vast clinical benefits are wholly overlooked by PBMs, including CVS Caremark, who has taken unilateral action to exclude the entire class of trade from continuing to service their Medicare patients. Ultimately, if not stopped, these actions run the risk of causing lowered adherence and patient harm.

6.2 Medicare Outcomes Based Reimbursement; Physician Control Over, and Financial Responsibility for, Patient Outcomes; and the Relationship Between Medication Therapy Management and Quality of Care

CMS, through a variety of rules, guidance, and agency statements, make it clear that physician involvement in drug management is crucial to quality patient care. Recent major revisions to Medicare serve to further support the proposition that physician dispensing is not merely contemplated by CMS, but is substantial element to the implementation, and success, of many new programs.

Congress and CMS have attempted, with varying degrees of success, to introduce programs aimed at increasing the quality of healthcare delivered to Medicare beneficiaries while concomitantly reducing the overall cost to the Medicare system. On April 22, 2016, The Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114-10) ("MACRA") was enacted. The intent of MACRA is to move to a significantly more integrated healthcare quality model, and to create a "Merit-Based Incentive Payment System" commonly referred to as "MIPS." MIPS becomes effective in 2019, and will initially affect physicians, nurse practitioners, CRNAs and CNSs. MIPS will utilize "performance categories" to determine the metrics for payments to these providers, and the categories will include: (i) quality; (ii) resource use; (iii) clinical practice improvement activities; and (iv) meaningful use of certified Electronic Health Records (EHR).

MACRA also created the concept of an alternative payment model ("APM"), which will serve as an alternative to the MIPS, and will allow providers to be compensated for certain quality and performance measures, and in some cases, will penalize providers that fall below certain benchmarks. The American Medical Association has identified angina, asthma, cancer, chronic kidney disease, diabetes, epilepsy, ovarian and endometrial cancer, pregnancy, and stroke as medical conditions that lend themselves to

[122] Barnes et al., *supra* note 119.
[123] *Id.*
[124] *Id.*
[125] *Id.*
[126] *See generally* AMA Code of Medical Ethics, *Opinion 9.6.6 Prescribing & Dispensing Drugs & Devices* (2016), *available at* http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics.page.

management with an APM model. MACRA also created the concept of "Advanced" APMs, which contemplate providers taking on more than nominal risk in connection with health outcomes. The OCM (as discussed in Section 5.3.7 above), is one APM on track to be an Advance APM in 2018.

The Oncology Care Model. As noted above, OCM is a payment model designed to test the effects of better care coordination, improved access to practitioners, and appropriate clinical care on health outcomes and costs of care for Medicare fee-for-service (FFS) beneficiaries with cancer who receive chemotherapy. OCM encourages participating practices to improve care and lower costs through episode-based payments that financially incentivize high-quality coordinated care. CMS expects that these changes made by the practices in response to OCM participation will result in better care, smarter spending, and healthier people.[127]

OCM employs a sophisticated system to collect information, including outcomes and claims data, that is then applied against a metric that evaluates the *quality and cost* of the care delivered during a particular episode of care. The episode of care is triggered by particular Medicare Part B claims or a Medicare Part D claim for an oral oncolytic or other chemotherapy drug. The actual episode of care expenditures are accounted for by combining the claims data for Medicare Parts A, B, and D, along with a monthly enhanced oncology service payment. This is then measured against a baseline model. The physician or physician group is compensated on the formula that takes into account the difference between the actual and baseline expenditure, ultimately, putting the physician in a degree of risk based on health outcomes.

This new payment model has the ability to dramatically impact the oncology physicians' practices in managing patient care and ensuring outcomes. Within the discipline of oncology, there has been an ever increasing shift from intravenous infusion chemotherapy agents to oral oncolytic drugs. This trend has a concomitant shift in reimbursement from health insurance (Medicare Part B, where no PBM is involved) to pharmacy benefit coverage (Medicare Part D, which is controlled by PBMs). This shift alters the policies that physicians, pharmacies and other providers must navigate to provide optimal, cost-effective care to their patients. In the traditional in-office infusion model, patients receive their chemotherapy treatment in the physician's office or hospital setting. The patient condition is monitored at each encounter and treatment can be modified accordingly. Moreover, the physician has first-hand, actual knowledge that the patient is receiving his or her appropriate medication.

When in-office chemotherapy is supplanted by oral oncolytic therapy, the patient has the option of making one trip to the pharmacy, or in the context of a mail order pharmacy, the medication is delivered right to the patient's home, both a seemingly more appealing experience for the patient. However, despite the fact that the use of oral oncolytic medication dispensed by a pharmacy seems on its face to be beneficial for the patient, in many circumstances it is not, and can have some troubling consequences. Recent studies have found that patients prescribed oral oncolytics fail to fill their initial prescriptions 10% of the time, and another quarter of patients had a delay in initiating another oncolytic.[128] This rate rose to 25% when the patient responsibility portion was over $500.[129] Moreover, the use of mandatory or preferred mail order networks by PBMs leads to increased waste of often-expensive and unwanted medication, thereby increasing overall healthcare spending.[130] CVS Caremark's exclusion of dispensing physicians from their Medicare network favors the less desirable mail-order paradigm.

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[127] See reference in website https://innovation.cms.gov/initiatives/Oncology-Care/.
[128] Sonya B. Streeter et al., *Patient and Plan Characteristics Affecting Abandonment of Oral Oncolytic Prescriptions*, 17 Am. J. Manag. Care, 5 Spec. No., SP38-SP44 (May 20, 2011), *available at* http://www.ncbi.nlm.nih.gov/pubmed/21711076.
[129] *Id.*
[130] National Community Pharmacists Association, *Waste Not, Want Not: Examples of Mail Order Pharmacy Waste* (Sept. 2011), https://www.ncpanet.org/pdf/leg/sep11/mail_order_waste.pdf.

Ultimately, the combination of CMS's focus on quality and the less than desirable fill-rates for oral oncolytics, make a compelling case for inclusion of dispensing physicians in PBMs' Part D networks. Physicians in all clinical disciplines are being held accountable by CMS for both the quality and cost of the care that they are providing, yet CVS Caremark is excising one of the most important tools available to the physician by precluding the physician from being able to manage the patient's drug regimen and monitor that compliance.

Chronic Care Management. CMS's policy position on physician monitoring of patients' drug compliance is also evidenced by the Chronic Care Management ("CCM") program introduced by CMS. CMS, in its guidance on CCM states "[t]he Centers for Medicare & Medicaid Services (CMS) recognizes care management as one of the critical components of primary care that contributes to better health and care for individuals, as well as reduced spending," and further states that part of the comprehensive care plan that CMS requires as part of CCM is "medication management."[131]

Together, Chronic Care Management and the Oncology Care Model are just two examples of CMS initiatives that clearly demonstrate the importance placed on proper drug management by CMS and that the quality of care and patient outcomes are directly related to optimal drug prescribing and patient compliance. Physicians, now more than ever, need the ability to order and dispense medication to their patients. Physicians are in the best position of any caregiver to prescribe, dispense, administer, and counsel patients on the applicable drug therapy. CVS Caremark, by removing the ability of physicians to dispense medications directly to their patients, is in opposition to virtually every program that CMS has recently introduced.

Moreover, physicians are now being held financially accountable for patient outcomes; outcomes that are often directly related to patient compliance with a particular drug regimen. Yet, under CVS Caremark's policy excluding dispensing physicians from network access, physicians will have to rely on retail and mail order pharmacies to fill prescriptions and counsel patients, despite the fact that many patients will fail to fill the prescriptions. Physicians that are excluded from the Medicare network will be blind to whether their patients are actually receiving their prescribed cancer treatment, yet the physician will be both professionally and financially at risk for the patients' outcome.

CVS Caremark is therefore placing physicians in an untenable position by enacting a policy that is diametrically opposed to the direction of CMS policies and the overarching trend in healthcare of outcomes-based reimbursement. This will have the effect of increasing costs to the overall system to the extent that dispensing physicians are stripped of their ability to coordinate all aspects of care for their patients in a clinically sound and financially responsible manner.

7 Conclusion

Physician dispensing is a vital part of the cancer care continuum, and must continue to be reimbursed by PBMs, in order to provide needed access to vulnerable patients. PBM action aimed at limiting patient access is immensely problematic, not just for patients, but for the overall healthcare system. Moreover, CVS Caremark's actions to shut out an entire class of trade from continuing to service the vulnerable Medicare Part D population, put profits over patients, and ignore vast clinical, economic and legal arguments to the contrary. If left unchecked, CVS Caremark's and other PBMs' actions threaten to unravel critical and longstanding components of the American healthcare system, and subvert public and

[131] *See generally* CMS, *Payment of Chronic Care Management Services Under CY 2015 Medicare PFS* (Feb. 18, 2015), *available at* https://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2015-02-18-Chronic-Care-Management-new.html (last visited July 12, 2016).

governmental efforts to improve financial accountability as well as the quality of patient care. Interested stakeholders, including patient and provider advocacy groups, lawmakers, regulators, CMS administrators, Plan Sponsors, Medicare Beneficiaries, and the general public at large must take action to safeguard these fundamental rights and core principles, in the interests of protecting patients.