Improving Patient Outcomes and Coordination of Care: Importance of Oncology Dispensing in the State of New York

FRIER LEVITT
ATTORNEYS AT LAW

Prepared by

Frier Levitt, LLC

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1 Executive Summary

The complexity and cost of healthcare in this country is ever increasing. With an aging population, States around the country – including New York – continue to face complicated challenges in containing costs, while providing more efficient care. Nowhere has that borne out more than in the context of cancer care. Costs of cancer care in the U.S. were estimated at over $124.5 billion in 2010, and are projected to reach as high as $173 billion by 2020. Medication therapies, including chemotherapies and oral oncolytic drugs, are making up an ever-increasing percentage of this spend.

Against this backdrop, physician dispensing in the oncology space is critical to improving patient outcomes and reducing costs. Complex chemotherapies have been soundly-administered by oncologists for some time, but with the advent of oral oncolytic therapies, the role of dispensing oncologists has never been more important. Pharmacies, especially PBM-owned pharmacies, are not able to provide patients with physician level services. Dispensing physicians help to close the gap in coordination that can often exist between pharmacies and physician offices. Dispensing physicians can monitor and react to patient side effects in real time, can avoid conflicting instructions to the patient, and can reduce time to care (as patients can pick up their medication at their physician's office). All this promotes patient outcomes and reduced overall costs.

These benefits specifically within the oncology space have long been recognized within the State of New York, which has a strong public policy in favor of oncology dispensing. While physician dispensing is generally restricted within the State of New York, an explicit statutory exception exists for dispensing oncologists. This same public policy is replicated in the Federal context as well, as Federal law permits, and the Medicare-Sponsored Oncology Care Model encourages, physician dispensing. In fact, explicit Safe Harbors exist to both the Stark Law and the Anti-Kickback Statute, which support physician dispensing. These Safe Harbors exist in the State law analogues found in New York as well.

With the overwhelming clinical and economic benefits of oncology physicians dispensing to their patients, it is important to open all pathways to allow oncologists to dispense to their patients. Among these pathways include the ability of oncologists to provide not just chemotherapy and oncology medications to patients, but critical ancillary and supplemental therapies to patients, that not only improve outcomes of patients, but serve to reduce costs through effective coordination of therapies.

Ultimately, if efforts are not made to protect and expand the scope of existing oncology dispensing, more and more of these complex (and costly) prescriptions will go to the PBM-owned mail order pharmacies. This is bad for patients and payors alike. The services and complex clinical integration that dispensing oncologists provide are critical to the healthcare system, and are simply unmatched by PBM-owned and operated pharmacies. In no other area of healthcare is it more important for patients to have a level of comfort and trust with respect to the medical care they are given, and the pharmacy services they receive. As such, all efforts must be made to preserve, prolong and expand this invaluable segment of the healthcare system in the State of New York.

2 Introduction

Oncology is a branch of medicine that deals with the prevention, diagnosis and treatment of cancer. The American Cancer Society estimates that in 2017 alone, there will be roughly 1,688,780 new cancer cases diagnosed and 600,920 cancer deaths in the United States.[1] Sadly, cancer diagnosis and treatment

[1] https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2017.html

affects many more people than just patients, with many more families and caregivers being directly impacted by the disease.[2] The practice of oncology encompasses three major components: (1) prevention, (2) early diagnosis, and (3) treatment. Treatment of cancer can vary greatly depending on the type and progression, but can often include surgery, radiation therapy, hormone therapy, immunotherapy/biological therapy, high-dose therapy with stem cell rescue, and chemotherapy.[3] Costs of cancer care in the U.S. were estimated at over $124.5 billion in 2010, and are projected to reach as high as $173 billion by 2020.[4] Chemotherapies and oral oncolytic drug costs make up an increasing percentage of this total spend. In this vein, cancer patients getting active treatment with chemotherapy account for only 22% of cancer patients, but incur almost 4 times the per-person cost of cancer patients not receiving chemotherapy.[5]

Within the State of New York, there are currently over 285 oncologists and over 135 separate oncology practices, not including hematology practices, OB/GYN practices, urology practices and dermatology practices, all who routinely treat patients for various types of cancer and related diseases. Of these practices, roughly 1,396 practitioners engage in some form of oncology prescribing to patients in the State of New York.[6] In 2016 alone, it is estimated that over 3 million prescriptions were filled and dispensed pursuant to an oncology protocol within the State of New York.

Generally speaking, 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 separate pharmacy.

Physician dispensing in the oncology space is widely viewed as a critical component of our healthcare delivery system from a legal perspective at both the State and Federal levels. As it stands in the State of New York, physicians are statutorily-permitted to dispense medication to patients pursuant to an oncological protocol.[7] Without the ability to in-office dispense, patients would be required to obtain oncology medications through a licensed pharmacy. In-office dispensing allows physicians greater flexibility with respect to their interactions with patients, which enhances a patient's overall care. Additionally, while New York physicians are generally limited to dispensing a 72-hour supply of medications to their patients, the State legislature has created an exception for physicians dispensing pursuant to an oncological protocol. This specific statutory exemption applies directly to oncology providers, recognizing the unique role they play in the healthcare system and the necessary medication management that comes with their practice.

Likewise, physician dispensing is completely legal under Federal law, and, in fact, is specifically permitted and even encouraged in many contexts. Both the Stark Law (42 U.S.C. § 1395nn) and the Anti-Kickback Statute (42 U.S.C. § 1320a-7b) provide specific Exceptions and Safe Harbors directly applicable in the physician dispensing context. Moreover, physician dispensing is a longstanding

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[2] See,
https://mcclellandinstitute.arizona.edu/sites/mcclellandinstitute.arizona.edu/files/ResearchLink_Cancer_2.4_0.pdf,
http://www.cancer.net/coping-with-cancer/talking-with-family-and-friends/family-life,
http://www.cancernetwork.com/review-article/crisis-cancer-psychological-impact-family-caregivers
[3] https://www.urmc.rochester.edu/encyclopedia/content.aspx?contenttypeid=85&contentid=P00591
[4] Mariotto AB, Yabroff KR, Shao Y, Feuer EJ, Brown ML. Projections of the cost of cancer care in the United States: 2010-2020. Journal of the National Cancer Institute. Jan 19, 2011;103(2):117-128;
http://www.milliman.com/uploadedFiles/insight/2016/trends-in-cancer-care.pdf
[5] http://www.milliman.com/uploadedFiles/insight/2016/trends-in-cancer-care.pdf
[6] Association of American Medical Colleges, *New York Physician Workforce Profile*, available at
https://www.aamc.org/download/447210/data/newyorkprofile.pdf
[7] N.Y. Educ. Law § 6807(2)(a)(8).

practice in the State of New York and is further permitted by the Medicare Any Willing Provider Law, which requires plan sponsors and insurance companies to permit the participation of any provider that is willing to meet the terms and conditions of the network.[8]

There are enormous benefits of in-office physician dispensing in the State of New York. These include increased patient medication adherence, enhanced patient monitoring and coordination, and a greater efficiency in receiving oncology medication which results in a cost reduction by eliminating unwanted or late – and therefore inaccurate – medications from mail order pharmacies. Many of these specific benefits are highlighted below.

Furthermore, the unique services available to cancer patients by dispensing physicians cannot always be obtained by patients at local, independent pharmacies. Dispensing oncology physicians can provide a superior paradigm to pharmacy dispensing. Indeed, dispensing oncology practices are often staffed with pharmacists, certified pharmacy technicians and nurses, all of whom remove barriers to patient access and educate patients on the prescribed medications. Further, dispensing oncology practices provide the perfect meld between medical and pharmacological care, routinely calling each patient at least once during the week after starting treatment to see how the patient is tolerating the treatment and to reinforce the importance of complying with the patient's treatment regimen. These heightened services, attentiveness and clinical integration are commonplace in dispensing oncology practices, but are unable to be reproduced by other pharmacy providers, especially mail order pharmacies. Physician dispensing in the oncology space must remain a core component of New York's healthcare delivery system, and all efforts must be made to expand patients' access to these lifesaving services.

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3 Physician Dispensing in the Oncology Space Is Critical to Improving Patient Outcomes and Reducing Costs

Physician dispensing can be attributed to enhanced patient outcomes including the speed with which a patient receives their medication, the patient's adherence to their medication, and the overall cost associated with treatment, both with respect to the patient's expense, as well as any associated insurers. Allowing physicians the ability to interact more completely with their patients benefits not only the patient, but the healthcare system as a whole.

3.1 Benefits of Physician Dispensing in All Forms

Cancer is a malignant disease in which abnormal cells grow uncontrollably in the body. Treatment is typically dependent upon the type of cancer and the stage at which it is discovered. Nevertheless, the most common treatments include radiation, surgery, and chemotherapy. Pharmacological intervention through intravenous chemotherapy has historically been performed by oncologists at infusion centers. However, oral oncolytics have been increasing in both popularity and effectiveness. While oral

[8] See 42 C.F.R. §423.120(8)(i)

chemotherapy has existed for decades, there has been a shift in the treatment of cancer patients from physician-administered (i.e. infused or injected) chemotherapy to oral oncolytics (which are self-administered by the patient) for a variety of 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 an oral pill form. Importantly, recently approved and available oral oncolytics are more targeted to disrupt precise 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 cells and rapidly growing healthy cells. However, even these advanced oral treatments can be very toxic and can have severe patient side effects if not monitored closely and dynamically. Providing medication directly at a physician's office helps to ensure that patients receive their medication and understand the need for drug compliance, which optimizes the continuity of care.

Pharmacies, including PBM-owned pharmacies, are not able to provide patients with physician level services. While payors may think that pharmacies are in the best position to set up systems monitoring patient compliance, there is an inherent gap in coordination between such pharmacies and physician offices.[9] 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.[10] The pharmacy would likely be unaware of this change, and, in the course of monitoring patient compliance, may provide conflicting instructions to the patient.[11] This could lead to treatment complications and potentially dangerous compliance issues for the patient.[12] In these situations, physician dispensing has a clear clinical advantage, as it eliminates the disconnect between the physician and pharmacy services.

Despite this, many Pharmacy Benefit Managers ("PBMs") require their insureds to obtain prescription medication, including oral oncolytics, from preferred mail order networks (often times controlled by the PBMs themselves). Mandating patients to participate in this requirement increases the opportunity for failure with respect to not only proper patient monitoring and coordination, but also with respect to cost. The use of mandatory or preferred mail order networks by PBMs leads to increased waste of inaccurate, often-expensive, and unwanted medication, thereby increasing overall healthcare spending.[13]

In-office physician dispensing streamlines the process of providing a patient with a drug when compared with the typical 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.[14] This is in contrast to physician dispensing which often occurs at the physician office immediately. These benefits of immediate delivery are equally available through physician owned pharmacies, as through direct, in-office dispensing.[15]

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[9] Barnes et al., *supra* note 119.
[10] *Id.*
[11] *Id.*
[12] *Id.*
[13] 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.
[14] Egerton, *supra* note 11.
[15] 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

Additionally, as the physician's practice can directly access the dispensing records, and in some cases actually consolidate the information into the electronic health record, the physician is in a better position not only to assure patient compliance with their drug regimen, but to provide complete coordination of care. Expansion of physician dispensing 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.[16]

Medication non-adherence 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.[17] Such medication non-adherence has been shown to increase morbidity and mortality rates in chronic disease, and is estimated to increase healthcare costs in the United States by over $170 billion annually.[18] Another recent study has 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.[19] This rate rose to 25% when the patient responsibility portion was over $500.[20] 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 a prescription.[21] 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.[22] 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.[23] 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.

The physician's office also has real-time access to the patient's insurance information, and can assist the patient in identifying financial assistance.[24] Since abandonment rates increase with greater out-of-pocket costs for the patient,[25] this easy and immediate access to financial assistance additionally increases adherence. The complexity of drug therapy is another significant factor in the abandonment of oral oncolytics,[26] but in-office dispensing allows the physician to coordinate all aspects of the patient's medication management, and to provide counseling to the patient upon dispensing. The physician's more direct interaction with the patient increases adherence to drug protocols as the patient experiences more coordinated and timely care. Further, the physician may schedule toxicity checks, to allow for early side-effect management and related dose adjustments, which, if needed, can

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mail-order pharmacy, all the other benefits of physician dispensing are applicable, such as integrated medical records, patient counseling and monitoring of patient receipt of medication.

[16] 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).

[17] Fischer et al., *supra* note 3.

[18] *Id.*

[19] 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.

[20] *Id.*

[21] Pauline W. Chen, *supra* note 1.

[22] *Id.*

[23] *Id.*

[24] 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.

[25] Schwartzberg et al., *supra* note 2.

[26] *Id.*

be made quickly in order to optimize treatment. 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.

Finally, physician dispensing finds a broad range of support, including from the American Medical Association ("AMA"), which finds it appropriate for physicians to dispense drugs in their office practices when the dispensing primarily benefits the patient.[27] In the oncological context, the benefits to the patient are significant and apparent.

3.2 Public Policy in New York Supports Oncology Dispensing

New York State has recognized the importance of physician dispensing in the oncology space and enacted law to specifically allow such dispensing. The intent of this law is clear from its history of amendments that oncologists provide unique services and benefits to their patients, which are enhanced by the ability to dispense medications directly to patients. Moreover, as discussed below, this law was enacted prior to the advent of oral oncolytics, and therefore it has only become more critical to ensure that the law is interpreted, applied, and amended broadly. Thus, this law evidences a strong public policy in favor of physician dispensing, particularly in the oncology context.

4 Oncology Dispensing Is Legal and Permitted by Federal Law and New York State Law

Healthcare is rife with instances of fraud, waste and abuse. In an effort to protect both patients and has the financial interests of payors, the government has enacted laws and regulations to limit instances where prescribers might be financially incentivized to authorize referrals, and to place restrictions practitioners' abilities to profit from selling ancillary services. The government views this as potentially improper not only because the patient is in a position to be influenced by a practitioner, which encourages over utilization, but also to ensure that practitioners are unable to abusively bill Federal and State health plans for unnecessary services.

However, with these concerns in mind, the government has enumerated exceptions and conditions under which it is considered appropriate for physicians to dispense medication in their offices (notwithstanding any concerns to the contrary). Therefore, in these cases, the government has found that the interests of patient care outweigh the limitations that would otherwise be applicable under the Federal and State law. In particular, physician dispensing is permissible under the Federal Anti-Kickback Statute and the Federal and New York State prohibition on self-referrals.

4.1 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

[27] *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.

located."[28] 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."[29] "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."[30] Thus, even the FTC has strongly supported the importance of dispensing physicians within a robust and competitive marketplace. In this section, we address the specific statutory and regulatory authorization for physician dispensing.

4.1.1 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 covered under Medicare Part D.[31] 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, these arrangements can be deemed compliant, and a physician may lawfully dispense to his or her own patients, provided the arrangement fits within one of the "Exceptions" to the Stark Law.

The In-Office Ancillary Services Exception to the Stark Law applies to direct physician dispensing. It contains certain supervision, building, and billing requirements, all of which have several options which may be satisfied.[32] 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.

To meet this Exception, DHS must be 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."[33] Because the pharmacy services will typically be furnished by non-physician personnel, a physician need only provide "direct supervision," pursuant to Federal

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[28] 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.

[29] 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).

[30] 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.

[31] *See* 42 C.F.R. § 411.351, *et seq.*

[32] *See generally* 42 U.S.C. § 1395nn, *et seq.*

[33] 42 C.F.R. § 411.355(b)

law, by being present in the office suite and immediately available to provide assistance and direction throughout the time services are being furnished.[34]

Generally, these statutory exceptions and safe harbors have been promulgated by the government based on a belief that protected conduct supports a beneficial public policy concern. Within in-office dispensing, the dispensing physician is personally furnishing the prescription drugs, 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.

4.1.2 Physician Dispensing Is Permitted by the Anti-Kickback Statute

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."[35] 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 "legitimate and beneficial activities,"[36] such as physician dispensing, 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 protects ancillary services provided by a "group practice,"[37] which excepts from violation any remuneration generated as a result of general investment interests in the physician's own practice or group practice (provided certain standards are met).[38] 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 must be a unified, centralized business as it relates to physician

[34] 42 C.F.R. § 411.355(b). It is also important to note that a physician owner of a licensed pharmacy referring prescription drug orders to that pharmacy may also comport with the Stark Law by fitting into this same Exception.
[35] 42 U.S.C. § 1320a–7b(b).
[36] H.R. Rep. No. 100-85, at 27 (1987).
[37] 42 U.S.C. § 1395nn(h)(4).
[38] 42 C.F.R. § 1001.952(p).

dispensing.[39] As such, physician dispensing is permitted under the Anti-Kickback Statute so long as it meets this exception.[40]

Thus, Federal law clearly allows physician dispensing, provided certain conditions are met. Federal law would not contain these Exceptions and Safe Harbors if physician dispensing were impermissible, 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 under the framework of Federal healthcare programs

4.2 New York State Law Equally Permits Physician Dispensing in the Oncology Setting

Physician dispensing is similarly permitted under New York State law, especially within the oncology context. Looking at the totality of applicable laws and regulations, it is clear that oncology dispensing is viewed as a critical component of the State's healthcare delivery system.

4.2.1 New York Has Created an Explicit Statutory Authorization for Physician Dispensing in the Oncology Setting

Pursuant to New York State law, only a person licensed as a pharmacist or otherwise authorized by law may engage in the practice of pharmacy.[41] The practice of pharmacy is defined to include, *inter alia*, the dispensing of drugs, medicines and therapeutic devices.[42] Thus, the pharmacy practice act within the State of New York creates strong limitations on the ability of any other healthcare provider to dispense medications, unless specifically licensed as a pharmacy.

However, as an exception to this limitation, New York permits a physician to supply his patients with such drugs as the physician deems proper in connection with his practice.[43] This exception to dispensing without licensure as a pharmacist is generally limited to a 72-hour supply of a particular drug.[44] However, in 1990,[45] one year after implementation of the 72-hour restriction,[46] the legislature enacted an additional exception to this limitation; physicians dispensing pursuant to an oncological protocol are not subject to the 72-hour limitation.[47] In recognition of the distinct needs of particular groups of patients, the State legislature provided that physicians are permitted to regularly dispense medications to their cancer patients.

Based on the history of amendments to the permissibility of physician dispensing, it is clear that the legislature not only sought to safeguard the dispensing of drugs outside of a pharmacy, but also recognized the unique circumstances of in-office dispensing for particular patients and medications. Thus, while the legislature increased the safeguards to dispensing by adding a 72-hour restriction to

[39] *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).
[40] It is also important to note that a physician owner of a licensed pharmacy referring prescription drug orders to that pharmacy may also comport with the Anti-Kickback Statute by fitting into this same Safe Harbor.
[41] N.Y. Educ. § 6803.
[42] N.Y. Educ. § 6801(1).
[43] N.Y. Educ. § 6807(1)(b).
[44] N.Y. Educ. § 6807(2)(a).
[45] 1990 N.Y. Sess. Law Serv. 18.
[46] 1989 N.Y. Sess. Law Serv. 777.
[47] N.Y. Educ. § 6807(2)(a)(9).

physician in-office dispensing,[48] it quickly enumerated exceptions, including for dispensing pursuant to an oncological protocol, one year later.[49] This makes clear the intent of the law, and acknowledgement of the legislature, with respect to the importance of permitting oncologists to have more discretion in treating their patients to improve medication adherence and enhance patient monitoring. The legislature's amendments to the permissibility of physician dispensing represents New York's broad public policy in favor of plenary physician dispensing in the context of oncology.

4.2.2 Oncology Dispensing Remains Consistent with Other Applicable State Laws

Physician dispensing is not only permissible pursuant to State laws governing pharmacy and medicine, but it also maintains compliance with New York law prohibiting self-referrals and fee splitting.

4.2.2.1 New York Prohibition on Self-Referrals

Similar to Federal Stark Law, New York prohibits physician "self-referrals." However, unlike the Stark Law, the New York prohibition applies irrespective of the source of payment.[50] In other words, a physician referring a patient for pharmacy services to an entity with which he has a financial relationship, including himself in the circumstance of in-office dispensing, will violate New York law whether the payor is Medicare, Medicaid, a private payor, or a cash paying patient. Thus, in many ways, New York's self-referral law is broader than its Federal counterpart.

Nevertheless, New York's prohibition has statutory exceptions to violations that are similar to those enumerated by Federal law. For instance, a physician in New York may dispense directly or maintain ownership in a properly structured pharmacy under New York's In-Office Ancillary Services Exception.[51] This exception requires the ancillary services, in this case pharmacy services, to be furnished (i) personally by the physician, a member of, or practitioner in, the physician's group practice, or an employee of the group practice who is supervised by the physician, (ii) in a building in which the physician (or member of the physician's group practice) typically furnishes physician services unrelated to pharmacy services, or another building which is used by the group for the centralized provision of services and (iii) billed by the physician, the physician's group practice, or an entity wholly owned by the physician or group practice.[52] Therefore, physicians may personally in-office dispense to their patients through this exception.

4.2.2.2 New York Fee Splitting

Pursuant to New York law, a physician's license may be revoked, suspended or annulled if the physician "has directly or indirectly requested, received or participated in the division, transference, assignment, rebate, splitting or refunding of a fee for…the furnishing of professional care, or service... or for or in connection with the sale, rental, supplying or furnishing of… medication"[53] Therefore, if a physician is deemed to have split his or her fees earned from the provision of professional care with another entity, the physician may be subject to license discipline.

However, a physician who in-office dispenses to his or her patient is not splitting a fee. Rather, the physician who dispenses directly to his patient is keeping both the fee for his professional medical service, as well as the reimbursement for the cost of the medication. The fee is not being divided among individuals. Therefore, fee splitting is not applicable to physician dispensing.

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[48] 1989 N.Y. Sess. Law Serv. 777
[49] 1990 N.Y. Sess. Law Serv. 18
[50] N.Y. Pub. Health § 238-a(1)(a).
[51] N.Y. Edu. §6807; N.Y. Pub. Health § 238-a(2)(b).
[52] N.Y. Pub. Health § 238-a(2)(b).
[53] N.Y. Educ. § 6509-a (McKinney 1993).

Physicians who in-office dispense to their patients may do so in compliance with New York laws, including but not limited to the prohibitions on self-referrals and fee splitting.[54]

5 Important to Open *All* Pathways to Allow Oncologists to Dispense to Their Patients

With these overwhelming clinical and economic benefits of oncology physicians dispensing to their patients, it is critical that oncology practices be afforded every opportunity to improve outcomes and the lives of the patients they serve. Unfortunately, however, barriers remain, not only from a regulatory perspective, but also from a payor and health insurance construct. Therefore, it is important that lawmakers, regulators and policy-makers work together to open all pathways to allow oncology providers to dispense crucial medications to their patients.

If oncology physicians are not able to dispense the complete array of their patients' medications necessary to manage their disease state, they may be left unable to impact performance based payment arrangements, and be left at a competitive disadvantage compared to other retail pharmacies. This is in addition to scenarios where the physician's medical benefit reimbursement is tied to overall patient outcomes (which are clearly impacted by the management of the patients' medication adherence and administration). Thus, it is critically important that physicians have the opportunity to provide not just necessary oncology medications to their patients, but the full range of supplemental and ancillary medications, crucial in enabling physicians to better control the results (and ultimately, their reimbursement).

As stated before, existing law in New York allows prescribers to dispense a greater than a 72-hour supply of drugs to a patient if such a dispensing is pursuant to an oncological protocol. For many reasons, including the potential for either cancer-related and/or antineoplastic-induced diseases, oncology providers must be able to continue dispensing a full range of medications to effectively treat and manage their patients' underlying condition.

For example, systemic therapy-induced emesis and nausea can significantly affect a patient's quality of life leading to poor compliance with further chemotherapy. In addition, emesis can result in metabolic imbalances, degeneration of self-care and functional ability, nutrient depletion, anorexia, wound dehiscence, decline in mental status, esophageal tears, and withdrawal from potentially useful or curative anticancer treatments. Given more than 90% of patients receiving highly emetogenic chemotherapy will have episodes of vomiting,[55] community oncologists must be able to treat and dispense the necessary medications to thwart such a detrimental condition. The ability to dispense the anti-emetic medications, examples of which are shown in Figure 1 below, enable community oncologists to immediately address this detrimental effect of anti-neoplastic treatment and ultimately improves patient care and the likelihood of treatment success. Further examples of the need for community oncologist to be able to dispense a wide array of therapeutic drug regimens are also seen

[54] It is important to note that physician owned pharmacies may exist in compliance with these laws as well.
[55] Hesketh PJ, Kris MG, Grunberg SM, et al. Proposal for classifying the acute emetogenicity of cancer chemotherapy. J Clin Oncol 1997; 15: 103-109.

with the treatment and prevention of cancer-associated venous thromboembolic (VTE) disease[56] and cancer-related infections.[57]

Figure 1.

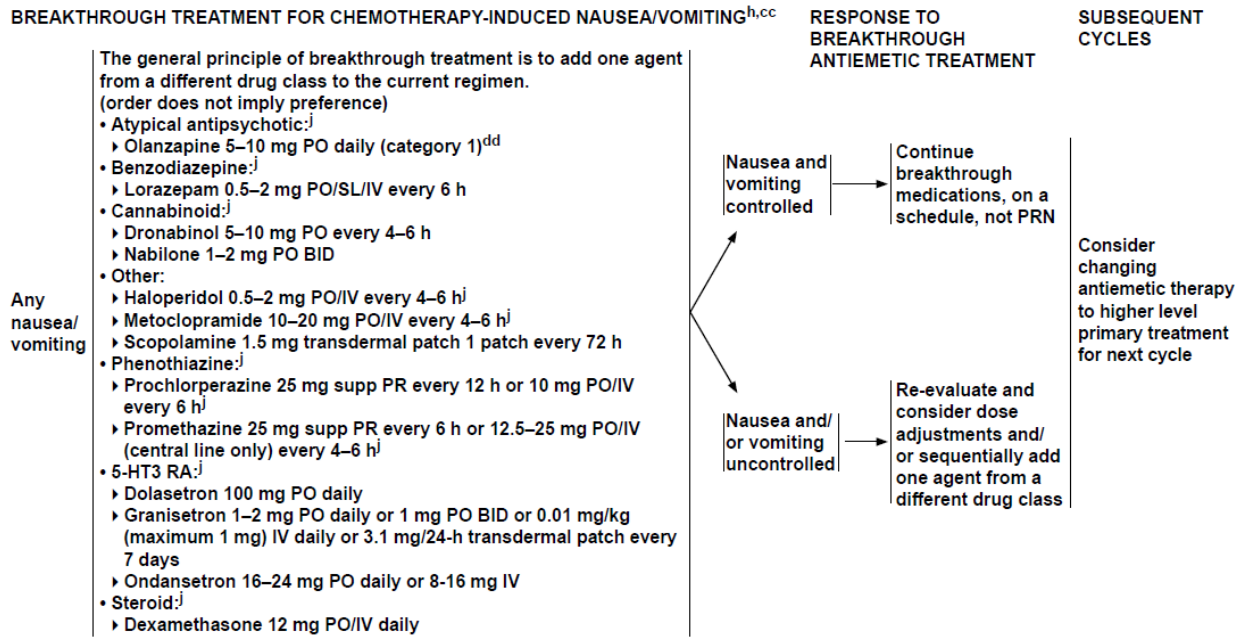

Figure 2.

INPATIENT/OUTPATIENT PROPHYLACTIC ANTICOAGULATION TREATMENT[1,2,3]

Agent	Standard Dosing	Obesity Dosing (BMI ≥40 kg/m^2)[4]
LMWH[5]		
• Dalteparin	5,000 units SC daily (category 1 for inpatient)	Consider 7500 units SC daily (limited data)
• Enoxaparin	40 mg SC daily (category 1 for inpatient)	Consider 40 mg SC every 12 hours
Fondaparinux[6]	2.5 mg SC daily (category 1 for inpatient)	Consider 5 mg SC daily (limited data)
UFH	5,000 units SC every 8–12 hours (category 1 for inpatient)	Consider 7500 units SC every 8 hours
Aspirin	81–325 mg daily (for low-risk multiple myeloma outpatients only)[7]	
Warfarin	Adjusted to INR 2–3[8]	

[56] VTE is a common and life threating condition in cancer patients. Results from a retrospective study of hospitalized adult cancer with neutropenia showed that approximately 3% to 12% of these patients, depending on the type of their malignancy, experienced VTE during their first hospitalizations. Prophylactically treating patients for VTE utilizing the medications listed in Figure 2 prevents this threating condition.

[57] There is an increased risk of infection in patients with cancer that results in higher morbidity and mortality. In certain instances, the malignancy itself can predispose patient to sever or recurrent infections. Nuetropenia has been recognized as a major risk factor for the development of infections in patients with cancer undergoing chemotherapy. Advances in antimicrobial therapy, see Figure 3, it is less common for patients to die from infections during the neutropenic period.

Figure 3.

ANTIBACTERIAL AGENTS: OTHER

OTHER ANTIBACTERIAL AGENTS	DOSE[b]	SPECTRUM	COMMENTS/CAUTIONS
Aminoglycosides • Amikacin • Gentamicin • Tobramycin	Consider single loading dose in critically ill patients with individualized monitoring of levels[c]	Activity primarily against Gram-negative organisms	Often used as empiric therapy in seriously ill or hemodynamically unstable patients
Ciprofloxacin[g] in combination with Amoxicillin/ clavulanate	500–750 mg PO every 12 hours or 400 mg IV every 8–12 h[c] 875 mg PO every 12 h[h]	• Good activity against Gram-negative and atypical organisms (eg, *Legionella* spp.) • Less active than "respiratory" fluoroquinolones against Gram-positive organisms • Ciprofloxacin alone has no activity against anaerobes	• Avoid for empiric therapy if patient recently treated with fluoroquinolone prophylaxis • Increasing Gram-negative resistance in many centers • Oral antibiotic combination therapy in low-risk patients • Data support fluoroquinolones for prophylaxis; however, in other clinical scenarios the risk:benefit analysis should be evaluated. Fluoroquinolone side effects should be taken into consideration (see the FDA warnings)
Levofloxacin	500–750 mg oral or IV daily[c]	• Good activity against Gram-negative and atypical organisms (eg, *Legionella* spp.) • Improved Gram-positive activity compared to ciprofloxacin • Levofloxacin has no activity against anaerobes • Moxifloxacin has limited activity against *Pseudomonas*	• Prophylaxis may increase bacterial resistance and superinfection[5] • Limited studies as empiric therapy in patients with fever and neutropenia • Prophylaxis in neutropenic patients[3,4] • Data support fluoroquinolones for prophylaxis; however, in other clinical scenarios the risk:benefit analysis should be evaluated. Fluoroquinolone side effects should be taken into consideration (see the FDA warnings)
Moxifloxacin	400 mg oral or IV daily		
Metronidazole	500 mg infused or oral every 6-8 h	Good activity against anaerobic organisms	
Trimethoprim/ sulfamethoxazole (TMP/SMX)	Prophylaxis: Single or double strength daily or Double strength 3 times per wk[c] Therapy: 15 mg/kg daily in divided doses based on the trimethoprim component	Activity against *P. jiroveccii*	• Highly effective as prophylaxis against *P. jiroveccii* in high-risk patients (See INF-6) • Monitor for myelosuppression, hepatotoxicity, and hyperkalemia

Recognizing the growing importance, volume and complexity of oncology dispensing, many physicians have taken proactive steps to employ clinical oncology pharmacists within their practices to provide additional oversight and management of oncological dispensing protocols. Within the bounds of existing New York law[58], clinical oncology pharmacists oversee the preparation, mixing, and dispensing of oncological medications. Oncology pharmacists educate patients about their prescribed medications, which helps to ensure the patient recognizes any potential side effects of the medication and remains adherent to their regimen. Thereafter, the oncology pharmacists will oftentimes follow up with the patients to see how the patient is tolerating the medication. These clinical oncology pharmacists are qualified, by training, by experience, and by licensure, to perform these delegated tasks, and in the case of dispensing physician practices, subject to the final dispensing oversight from the treating physician. Moreover, when practicing in a licensed, physician owned pharmacy setting, clinical oncology pharmacists can perform an even greater role in managing the patient's disease state and in coordinating the dispensing of medications. In both circumstances, these functions greatly benefit oncology patients.

Any proposed legislation that advances a physician's ability to in-office dispense or own a licensed pharmacy should be supported to ensure that the physician's scope of practice is plainly stated by the law. As currently written, the law that permits a physician to dispense directly to his or her patients is written in the negative, which may create confusion for both practitioners and regulatory bodies. The exception from licensure as a pharmacist that allows physicians to dispense directly to their patients should be blatant and, in the context of oncological dispensing, should be broad. Additionally, while there is no express prohibition on a physician's ownership in a pharmacy—only an implied permissibility—physicians would benefit from a modification to the law. Proposed legislation that

[58] NY Educ. § 6530(25).

enhances an oncologist's ability to treat his or her patients, or that clearly allows physician ownership of a pharmacy must be supported.

6 A World Without Dispensing Oncologists

As set forth above, dispensing oncologists provide high quality, patient-centric administration of life-saving medications. The services and complex clinical integration that dispensing oncologists provide are critical to the healthcare system, and are simply unmatched by chain retail and PBM-owned pharmacies. As such, New York State should expand the pathways for patients to avail themselves of these heightened services. On the other hand, if New York State restricts patient access to dispensing oncology practices, patients will continue to be funneled toward chain retail and mail order pharmacies owned by PBMs, which will result in many unintended negative consequences to patient care.

In this unique area of medicine, dispensing oncologists provide closer and more effective means of communication with patients and, most importantly, provide an atmosphere where patients are comfortable talking about their disease and treatment thereof. Open communication with treating physicians is essential for the successful treatment of various forms of cancer, and cannot be duplicated in a pharmacy environment. Indeed, in-person exchanges between physician and patient allows the dispensing physician to remain cognizant of any changes in the patient's condition and immediately modify the patient's treatment accordingly, and also ensures that the patient remains adherent to his/her treatment regimen. Allowing and encouraging physician dispensing of oncology medications will serve to remove this disconnect and allow for the most effective, and efficient, treatment of patients.