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January 16, 2018

The Honorable Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4182-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: *Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (CMS-4182-P, Federal Register, Vol. 82, No. 227, at 56336-56527)*

Dear Administrator Verma:

On behalf of the Board of Directors of the Community Oncology Alliance (“COA”), I am submitting this comment letter regarding the Center for Medicare & Medicaid Services’ (“CMS”) proposed *Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program* as set forth in CMS-4182-P, Federal Register, Vol. 82, No. 227, at 56336-56527 (the “Proposed Rule”).

Background on COA and the Community Oncology Pharmacy Association (“COPA”)

COA is a non-profit organization dedicated to advocating for community oncology practices and, most importantly, the patients they serve. COA is the only organization dedicated solely to independent community oncology where the majority of Americans with cancer are treated. The mission of COA is to ensure that patients with cancer receive quality, affordable, and accessible cancer care in their own communities. For more than fifteen (15) years, COA has built a national grassroots network of community oncology practices to enhance the effectiveness and efficiency of cancer care, as well as to advocate for public policies that benefit patients with cancer. Individuals from all perspectives of the cancer care delivery team – oncologists, administrators, pharmacists, mid-level providers, oncology nurses, patients, and survivors – volunteer their time on a regular basis to lead COA and serve on its committees.

Several years ago, COA formed COPA in response to the increasing number of community cancer practices providing oral cancer drugs and ancillary therapies at the site-of-care. Given the increased availability of cancer drugs in oral formulations, which in many cases provide meaningful therapeutic benefits versus injectable formulations, it is critical that practices provide these oral drugs at the site-of-care, closely integrated with their treatment. This is especially important given the non-compliance problems cited extensively in the literature with oral cancer medications versus the certainty of injectable drugs administered at the site-of-care. Teams of oncologists, mid-level providers, oncology nurses, pharmacists, and ancillary staff have to be diligent in educating patients about oral medications, potential drug side effects, and the importance of compliance, as well as helping to overcome patient financial and insurance issues that often are barriers to oral cancer drug compliance.

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As a non-profit focused on enhancing care for patients receiving oral cancer drugs and ancillary therapies at the site-of-care, COPA is in the unique position of serving as a non-commercial organization dedicated to addressing a variety of pharmacy issues, all in the sole interest of patient care. In this vein, the mission of COPA is to foster oral cancer therapy that is tightly integrated into cancer patient treatment at the site-of-care. Specifically, COPA:

1. Helps community cancer clinics enhance outcomes of patients with cancer treated with oral medications by improving the quality, efficiency, and financial viability of dispensing oral cancer drugs and ancillary oral therapies in community cancer clinics;
2. Establishes quality standards, best practice benchmarks, operating procedures, and other clinical/operating processes to enhance patient care;
3. Provides a forum for community cancer clinics dispensing oral cancer drugs or operating on-site retail pharmacies to share best practices and information, especially relating to current and proposed regulations from state pharmacy boards;
4. Develops the quality/value proposition of “integrated oral cancer treatment” for private payers, Medicare, and primary payers, such as employers and unions, and how site-of-care integration improves patient care; and
5. Educates pharmaceutical companies on the clinical/value proposition of “integrated oral cancer treatment” and develops processes/standards for limited or special distribution drugs.

Unfortunately, due to the increasing availability and cost of oral cancer drugs, there are commercial interests – most notable those of the pharmacy benefit managers (PBMs) – that are attempting to separate oral cancer therapy from the site-of-care and oncologist control. The PBMs’ motivation for doing this is the substantial profit potential that can be derived by effectively controlling – *and even influencing* – the distribution and prescribing of these expensive specialty drugs by their wholly-owned or affiliated specialty pharmacies. This control of specialty drug distribution not only interferes with the physician-patient relationship, which is especially critical in a disease state such as cancer, but also threatens effective treatment and, literally, the lives and well-being of patients with cancer.

Comments on the Proposed Rule

Our comments on the Proposed Rule, referencing specific sections as published in the Federal Register, follow.

I. Comments to Proposed Rulemaking Regarding “Pharmacy Payment Adjustments”

Issue: CMS proposes to eliminate the newly-created “reasonably determined exception” language within the definition of “negotiated price” contained in 42 C.F.R. § 423.100 and instead require that all provider price concessions be reflected in the negotiated price at the point-of-sale and reported to CMS on a Prescription Drug Event (“PDE”) record as opposed to a DIR record, even where such concessions are contingent upon performance by the pharmacy.

Recommendations: COA strongly agrees with CMS’ proposal to require that all price concessions be reported and reflected in the negotiated price at the point-of-sale. COA agrees with CMS that this will allow for greater transparency and consistency in the reporting of pharmacy price concessions, and will provide greater clarity on what a provider can expect to be paid when dispensing a medication. Additionally, COA agrees that this will help to discourage the shifting of costs from sponsors and administrators to beneficiaries and taxpayers.

However, as is the case with prior proposed rulemaking surrounding the implementation of the “reasonably determined exception,” there will likely be concerns expressed by PBMs, their trade association, and plan sponsors – which, we note, are increasingly part of and controlled by the PBMs themselves due to corporate mergers and acquisitions – that the Proposed Rule will entirely eliminate the regulatory exemption from negotiated price reporting for any pharmacy concessions. Previously, Acting Director Cheri Rice of CMS’ Part C and D Programs communicated on November 5, 2014 to Prescription Drug Plan (“PDP”) sponsors and interested

parties that CMS “*did not intend to eliminate the regulatory exemption from negotiated price reporting.*” Clearly, by requiring that all price concessions now be reported and reflected in the negotiated price, CMS has since changed its position to what is now in the Proposed Rule.

COA is concerned that PBMs, their trade organization, and/or other parties against drug channel price transparency will argue, as they have done repeatedly in the past, that this position by CMS violates the federal “non-interference” clause contained in the Medicare Modernization Act (“MMA”). In particular, Section 1860D-11(i) of the MMA states, in pertinent part that, “*in order to promote competition under this part and in carrying out this part, the Secretary [of HHS] ... may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors...*” For example, on October 24, 2014, Thomas Schatz of the Council for Citizens Against Government Waste expressed concern to CMS that “*negotiated price concessions and incentives, whether they can be reasonably determined at the point-of-sale or not, are all part of the contract deliberations between PDP sponsors and pharmacies. CMS has repeatedly attempted to insert itself into and interfere with sensitive and fluid negotiations between the drug plan’s sponsors and pharmacies. Should CMS succeed in this misguided campaign, price concessions and incentives will cease, killing what has helped PDP sponsors and pharmacies respond quickly to what beneficiaries and taxpayers want: low prices and good service.*”

The reality, however, is that retroactive price concessions in the form of *post* point-of-sale rebates as implemented by plan sponsors and PBMs actually **increase drug prices and out-of-pocket costs** for beneficiaries and Medicare. Post point-of-sale rebates have become the “price of doing business” by pharmaceutical manufacturers and are factored into their product pricing. As the scope and magnitude of rebates continue to increase, they fuel initial and subsequent drug price increases. Yet, because these are post point-of-sale rebates by drug manufacturers, beneficiaries do not receive the benefit of the rebate price concession at the actual point-of-sale. Instead, beneficiaries pay for drugs – either in whole or in part in the form of insurance copayments – based on artificially high “list” price of drugs, not true lower “net” prices after rebates. So, beneficiaries are not only forced to pay artificially high drug “list” prices but are also subject to higher prices fueled by rebates that manufacturers account for in setting “list” drug prices. Furthermore, higher list prices “push” Medicare beneficiaries into the coverage gap – the so called “donut hole” – faster, thereby exposing beneficiaries to higher cost sharing payments until they exit the donut hole and Medicare assumes the majority of the payment obligation.

As a result of this worsening situation, COA urges CMS to disregard any “red herring” arguments that the Proposed Rule could be tantamount to interfering with negotiations between drug providers and plan sponsors or PBMs in contravention of the MMA. CMS is authorized to take steps, including implementing measures to promote meaningful price transparency, to ensure that the “Triple Aim” is realized with respect to Medicare in improving beneficiaries’ experience of care, improving the health of Americans, and reducing costs for both Medicare and its beneficiaries.

COA generally agrees with requiring that all rebates and similar after-sale price concessions be reported and factored into the “negotiated” prices at the point-of-sale, such that point-of-sale prices more accurately reflect true “net” drug prices. However, we are **very concerned** that this does not go far enough in addressing price concessions in the form of direct and indirect remuneration fees (“DIR Fees”) that are now being recouped by PBMs on a far larger scale. CMS even opined in the Proposed Rule that “*based on the aggregate pharmacy payment adjustment data submitted to CMS by Part D sponsors[,] performance-based pharmacy price concessions, net of all pharmacy incentive payments, increased most dramatically after 2012.*” Moreover, there is concern that by requiring the negotiated price starting in 2019 to reflect the lowest possible reimbursement that a participating network pharmacy could receive from a particular Part D sponsor for a covered Part D drug, it will place serious downward reimbursement pressures on providers in such a manner that reimbursements may fall below the acquisition costs of covered Part D drugs.

In this vein, there is also concern that if plan sponsors and PBMs are able to pay providers the lowest possible reimbursement up front, with the possibility of the provider receiving a bonus at some later point in time, there is the risk that a plan sponsor or PBM could seek to pay the provider less than the cost of acquisition of the drug. This would require providers to “float” the cost of the medication, hoping to later receive a bonus that would ultimately cover the actual costs. This type of framework cannot be economically sustained and runs the risk of leading to poorer patient care.

Rather than take up excessive space in the body of this comment letter, attached is a whitepaper we commissioned on DIR Fees. PBMs are “gaming” the system by charging pharmacy providers – retail pharmacy stores, specialty pharmacies, physician practices with an associated pharmacy or dispensing facility, etc. – a variety of DIR Fees under the guise of network participation fees, quality performance fees, and similar types of post point-of-sale charges to pharmacy providers. PBMs are charging these retroactive DIR Fees as agents of plan sponsors and, in the process, extracting at least a percentage of the retroactive rebates as payment for their administrative “services.” Furthermore, by masking these DIR Fees as different types of administrative, network, or program fees, instead of true remuneration (direct or indirect), PBMs profit in two significant ways: one, by pocketing DIR Fee profits, but not reporting those fees to CMS as direct or indirect remuneration, thus not lowering PBM adjusted reimbursement; and, two, charging these DIR Fees off of inflated “list” drug prices. This latter point is very significant in that PBMs have a vested financial interest in increasing the scope and magnitude of retroactive rebates, regardless of where or how they are shared in any part with plan sponsors, because DIR Fees are computed as a percentage of “list” drug prices. The higher the list prices the more PBMs profit.

In relation to DIR Fees that are charged under the guise of quality performance, COA has routinely witnessed plan sponsors and PBMs utilizing “quality metrics” to determine levels of price concessions based on factors that have nothing to do with the particular provider’s provider type. For example, PBMs measure the quality of cancer care drug delivery based on metrics relating to hypertension or diabetes drug management. This is the proverbial “apples to oranges” measurement, leaving certain types of providers, including community cancer clinics providing oral medications, at a distinct disadvantage when they are judged on irrelevant quality metrics they cannot impact. Additionally, this practice can result in poorer patient care, as certain types of providers may be forced to scale-back their enhanced patient services that go along with dispensing and managing complex therapies, and particularly so with specialty medications.

As such, COA recommends the following:

1. CMS promulgate rules, or seek legislation, eliminating *retroactive* DIR Fees;
2. CMS promulgate rules which correspond with its proposed rule on the Any Willing Pharmacy law by requiring that any price concessions be “reasonable and relevant” as reimbursement terms for their network pharmacy providers;
3. CMS clarify that pharmacy price adjustments may not be used to shift insurance risk disguised as financial risk to providers;
4. CMS promulgate rules which require beneficiary (and representative) access to negotiated prices so that they know the net prices and can make informed purchasing decisions, e.g., the cost differentials between generics and different brands of the same drug product;
5. CMS promulgate rules requiring plan sponsors and PBMs to utilize quality measurement criteria that are consistent with the various specific provider types, such as specialty pharmacies, retail pharmacies, physician in-office dispensing, and other providers, to ensure that providers’ performance is measured against similarly situated providers and is relevant to the type of medical care provided; and
6. CMS allow and require a one-year demonstration period in 2019, the data from which will be used to measure the negotiated prices in 2020 (as opposed to assuming the lowest possible reimbursement from the start).

II. Comments to Proposed Rulemaking Regarding “Any Willing Pharmacy” Requirements

Issue: CMS proposes to clarify the definitions of “mail-order” pharmacy and to clarify the application of the Any Willing Pharmacy law to providers with unique business models or services.

COA understands CMS’ effort to define “mail-order pharmacy” in such a way to prohibit Part D plan sponsors from wrongfully classifying pharmacies that simply provide home delivery services by mail as “mail-order pharmacies.” In today’s pharmaceutical marketplace, patients increasingly expect to receive their medications delivered, even by their community retail pharmacies. Moreover, particularly among specialty medications, there are often specific handling requirements, such as temperature control management, that are best achieved through direct home delivery. COA has seen plan sponsors and PBMs routinely deny providers, or put up other obstacles to network admission, when such providers are otherwise willing and capable of meeting the network’s terms and conditions, but happen to deliver (through a delivery service or the mail) certain medications to their patients.

Recommendations: In this vein, COA specifically commends CMS’ effort to clarify the definition of “mail-order” to be tied to the dispensing of 90-day supplies of maintenance medication, and recommend that additional rules be made to clarify and solidify this definition and distinction.

Additionally, COA recommends that CMS modify the definition of “network pharmacy.” Currently, a “network pharmacy” is defined as a “licensed pharmacy that is under contract with a Part D sponsor to provide covered Part D drugs at negotiated prices to its Part D plan enrollees.” Pursuant to 42 C.F.R. 423.124(a)(2), Part D beneficiaries are entitled to not only obtain prescription medication from a licensed pharmacy but also must be afforded adequate access to covered Part D drugs appropriately dispensed and administered by a physician in a physician’s office as allowed by state pharmacy law and regulation. In order to clarify this concept and prevent plan sponsors and PBMs from circumventing the Any Willing Pharmacy law based on this distinction, we request that CMS adjust the definition of a “network pharmacy,” or alternatively modify its reference to a “network provider,” and to define such term as “a provider licensed and authorized to dispense medications that is under contract with a Part D sponsor to provide covered Part D drugs at negotiated prices to its Part D plan enrollees.”

Issue: CMS has proposed to require plan sponsors and PBMs to admit any pharmacy willing and capable of meeting the “floor” of reasonable and relevant terms and conditions, and that such terms and conditions must take into account providers with unique or alternative pharmacy and/or drug dispensing operations, as allowed and dictated by state pharmacy law, but that do not necessarily fit squarely into one provider type.

Recommendations: COA supports CMS’ position on requiring Part D plan sponsors to have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing provider may access the standard contract and participate as a network pharmacy, in accordance with 42 C.F.R. § 423.505(b)(18). However, we respectfully submit that the language contained in the Proposed Rule should be broadened and reinforced. We regularly see heightened barriers to a provider’s ability to participate in the network at all, thereby raising the question of whether the terms are actually reasonable and relevant. For example, plan sponsors’ imposition of the requirement that pharmacies obtain multiple accreditations limits willing and able providers from participating in networks.

In addition, language consistent with the Medicare Part D Manual related to the reasonable and relevant terms and conditions of plan sponsors’ network participation must be more specific, particularly with respect to financial terms, including reimbursement rates. The extended definition of “reasonable and relevant” should prevent financial terms that result in a negotiated reimbursement rate that, inclusive of payment adjustment, results in a loss to the provider, as such a term would not be “reasonable.” Defining the “reasonable and relevant terms” more specifically will prevent plan sponsors from excluding competent providers and ensure that patients are afforded greater access to providers participating within networks. Requiring reasonable and relevant terms and conditions is an excellent measure with respect to ensuring providers’ ability to participate and will increase network access for patients. That said, the reasonable and relevant terms should be precisely defined by law. As noted above, this should be tied in with CMS’ treatment of price concessions, and that any contract calling for

performance adjustments must be reasonable and relevant, both in terms of the quality metrics used to measure performance, and in terms of the net reimbursement rates provided to pharmacies.

Furthermore, while there may be instances where Part D plan sponsors' use of accreditation as a participation requirement is appropriate, we note that there are many instances where such an accreditation requirement would not be proper as an across-the-board requirement, particularly among different provider types. For example, while it may be appropriate to require a pharmacy to maintain a certain type of accreditation to dispense specific specialty medications that require close coordination with the patient's prescribing physician, the same might not be true or applicable for in-office dispensing physicians. Therefore, COA suggests that CMS permit Part D plan sponsors to use accreditation "as appropriate" based on the provider type, such that different categories of providers dispensing do not necessarily need to be held to the same standards (particularly when the required accreditation is not applicable to the provider type).

Finally, COA agrees with CMS' position of not supporting the use of a Part D plan sponsor, or PBM, specific credentialing criteria in lieu of, or in addition to, accreditation by recognized accrediting organizations. Moreover, based on provider experience, we know that PBM-specific credentialing is a convenient way of giving PBMs the ability to deny providers access to networks on a pre-textual or bad faith basis, particularly in light of PBMs' common ownership of pharmacies competing with independent providers vying for participation in PBM networks. If a PBM mandates credentialing, such credentialing should not be duplicative, PBM-specific, and not excessively burdensome to providers seeking network access. This concept should be reinforced in the final Proposed Rule.

Issue: CMS proposes to prohibit plan sponsors and PBMs from limiting providers' ability to dispense specialty medications when they have access to such medications and are capable of dispensing such medications, or otherwise requiring access to a lengthy list of specialty medications as a prerequisite to dispense any specialty medications.

Recommendations: COA strongly supports CMS' requirement that PBMs admit providers based on standard terms and conditions, and provide access to dispensing all qualified medications (including specialty medications) under their participation agreements. We agree with CMS' concern that Part D plan sponsors might use their standard pharmacy network contracts in a way that inappropriately limits dispensing of specialty drugs to certain pharmacies. For example, we have seen one PBM seek to prevent community cancer clinics from dispensing Imbruvica and Venclexta, when such clinics otherwise have access to these limited distribution drugs and are qualified to dispense and manage these medications. As another example, we have seen another PBM require providers to maintain access to a laundry list of limited distribution drugs in order to participate in the PBM's "specialty network" and thereby dispense the limited distribution drugs to which they already have access.

We agree with CMS' finding that because a provider's ability to dispense certain medications is not dependent on the provider having the ability to dispense other medications, it is not relevant for sponsors to require providers to dispense a particular roster of certain drugs or drugs for certain disease states in order to receive standard terms and conditions for network participation as a contracted network pharmacy for that Part D plan sponsor. Consistent with CMS' longstanding policy, we would not expect Part D plan sponsors to limit dispensing of certain drugs, or drugs for certain disease states, to a subset of network providers if other contracted network providers are capable of, and appropriately licensed under applicable state law(s), to do so.

Ultimately, COA requests that CMS clarify the concept of the "floor" of minimum requirements by which all "similarly situated pharmacies" must abide. For example, can a Part D plan sponsor create separate terms and conditions for participation in a "specialty pharmacy network," or must all providers be offered a "floor" of minimum requirements to be able to perform the entry-level contract? COA urges CMS to clarify the "floor" of minimum requirements be offered as an entry-level to all qualified providers. Additionally, COA recommends that CMS require PBMs and plan sponsors alike to offer standard terms and conditions on an equal basis, subject

to the “floor” of minimum requirements, to all participating providers, specifically including PBM or plan sponsors’ wholly or commonly owned pharmacies.

Finally, COA requests that CMS differentiate, by definition, a “specialty network” and a “preferred network,” as these terms should not be interchangeable. All providers should be afforded the opportunity, if qualified, to enter a “specialty network” based on the “floor” of minimum requirements and on an equal basis with other participating providers. Moreover, providers should not be forced to forgo retail business by joining a specialty network.

Issue: CMS proposes rules requiring plan sponsors and PBMs to disseminate contract terms when requested by providers, and within a set time period.

Recommendations: COA acknowledges CMS’ recitations of evidence of complaints that Part D plan sponsors and PBMs delay sending requested terms and conditions for weeks or months, or require pharmacies to complete extensive paperwork demonstrating their eligibility to participate in the sponsor’s network before the sponsor will provide a document containing the standard terms and conditions. By way of recent example, CVS Caremark subjected in-office dispensing physician practices to months of delays in simply being provided with the ability to apply for network participation. Unreasonable delays then continued through the actual credentialing process.

COA agrees with CMS that such delay tactics have the effect of frustrating the intent of the Any Willing Pharmacy requirement, and as a result, we believe it is necessary to codify specific procedural requirements for the delivery of pharmacy network standard terms and conditions. COA agrees with CMS’ establishment of response deadlines for when Part D plan sponsors must furnish their standard terms and conditions to requesting providers, including having their next contract year’s standard terms and conditions available for providers upon request no later than September 15th of each preceding year, and requiring Part D plan sponsors to provide the applicable standard terms and conditions to a requesting provider within two (2) business days of the provider’s request. Language requiring the dissemination of contract terms in a prescribed manner will benefit providers such that entry into a network is less burdensome, thereby increasing the accessibility of such providers to beneficiaries. COA supports the adoption of this requirement, but requests that CMS specifically enumerate that this requirement applies directly to any downstream or first-tier contractor of the plan sponsor that performs functions on behalf of the plan sponsor, specifically including PBMs.

Conclusion

COA lauds CMS’ efforts to provide clarity regarding Part D networks, and to increase transparency and access for beneficiaries to utilize the provider of their choice. We urge CMS to look past the self-serving and financially-motivated interests sure to be raised by PBMs and supporting trade organizations that seek to compete with network providers, in addition to managing Part D plans. COA urges CMS to act in line with the extensive recent findings and analyses demonstrating the increased costs imposed by retrospective pharmacy price adjustments and DIR Fees have on beneficiaries and taxpayers alike, and to take additional steps to help reduce the overall cost of care for patients.

We appreciate the opportunity to provide insight and comments to CMS and, as always, welcome the opportunity to discuss any of our comments with CMS.

Sincerely,



Jeff Vacirca, MD
President

PBM DIR Fees Costing Medicare and Beneficiaries: Investigative White Paper on Background, Cost Impact, and Legal Issues

Prepared by

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Commissioned by the Community Oncology Alliance

January 2017

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1 Executive Summary

2016 was a year of intense focus, debate, and even epiphany as to the reasoning behind our nation’s escalating drug costs and their impact on both the Medicare program and beneficiaries. The media, public, and legislators began to recognize that pharmacy benefit managers (“PBMs”)—once seen as the key to controlling drug costs—may actually be causing higher drug prices as they become an increasingly large part of the national health care system.

One way in which PBMs have driven up drug costs are with murky “direct and indirect remuneration” fees (DIR Fees) charged to providers who dispense drugs, such as retail and specialty pharmacies and physician-run medical practices that operate retail pharmacies or dispensing facilities (collectively, “Pharmacy Providers”). DIR Fees charged by PBMs to Pharmacy Providers lack any reasonable transparency, threaten the viability of Pharmacy Providers, and, most importantly, increase the cost of drugs to Medicare and beneficiaries.

The concept of legitimate “direct and indirect reimbursement” or “DIR” is not new to the Medicare Part D program. However, the relatively-recent business tactic of PBMs recouping from Pharmacy Providers up to 9% of gross drug dispensing revenue under the guise of the overly-broad term “DIR Fees” is new. This practice has even drawn the attention of CMS and Congress because of the drastic financial impact DIR Fees are having on Pharmacy Providers and the Medicare Part D program. The purpose of this White Paper is to explore the history and background of legitimate DIR, as originally intended; explain how performance-based DIR Fees are different, mislabeled and misapplied; review the related legal and regulatory issues surrounding DIR Fees; and show how DIR Fees are increasing costs to both the Medicare program and its beneficiaries, who are often seniors on fixed incomes.

Original, and Legitimate, Concept of DIR

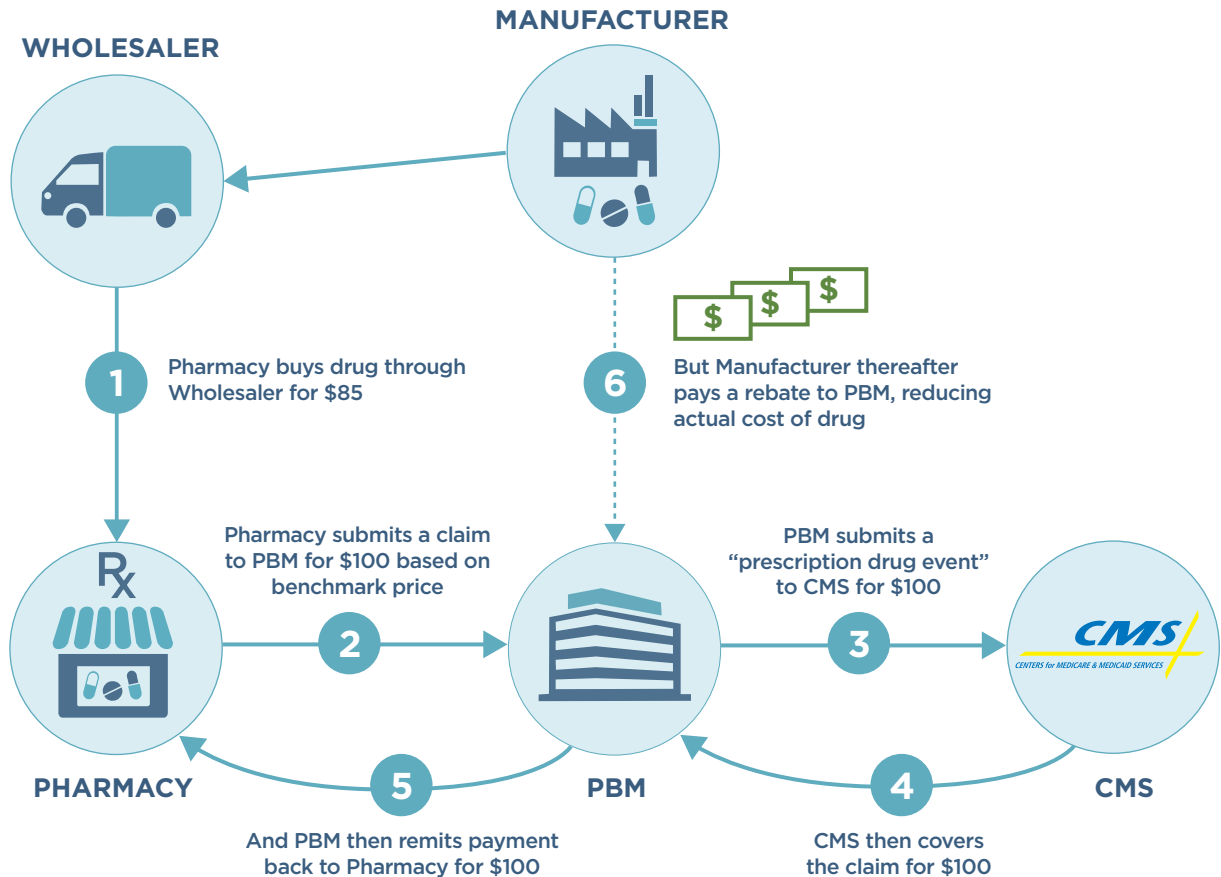
The concept of DIR arose out of Medicare Part D, the Federal program created by the Medicare Modernization Act of 2003 (“MMA”) to provide pharmacy benefits to Medicare beneficiaries. Under Medicare Part D, the Centers for Medicare & Medicaid Services (“CMS”) contracts with various Part D plan sponsors to administer Medicare Part D plans. In turn, Medicare Part D plan sponsors contract with PBMs to administer the drug benefits of such plans.

PBMs are third-party corporations that are primarily responsible for contracting with Pharmacy Providers, negotiating reimbursement rates, and processing drug claims. Since 2011, the PBM marketplace has transformed considerably, consolidating into only four national PBMs that control prescription drugs for 266 million Americans, or 80% of the market. Recognizing the profit that can be made from controlling specialty drugs such as oral oncolytics, all the major PBMs have acquired or launched their own specialty pharmacies.

PBMs contract with a network of providers—such as freestanding retail pharmacies and physician-run medical practices, including community oncology practices that have integrated on-site pharmacies or dispensing facilities—and reimburse claims submitted by these participating Pharmacy Providers. Within the Medicare Part D program, CMS reimburses Part D sponsors—and, in turn, their PBMs—based on the actual costs to the plan for the prescription drug claim or the negotiated prices paid out to the Pharmacy Provider at the point-of-sale.

The history of pharmaceutical rebates to PBMs helps explain the origin and necessity of legitimate DIR. In exchange for placing their products on a plan’s formulary, pharmaceutical manufacturers began paying rebates, and similar fees, to PBMs. These manufacturer rebates lowered the overall cost for drug claims to the plan. To arrive at the actual “net” cost of all drugs under Part D, so that it can appropriately and legally base reimbursement on the lowest price, CMS implemented the concept of DIR. Through this concept, plan sponsors and PBMs are required to report all “direct” and “indirect” remuneration received from third-parties,

such as manufacturers. Because manufacturer rebates were not “known or knowable” until a prescription had been dispensed to the patient and claim processed at the point-of-sale (a part of the claims process known as “adjudication”), such remuneration was accounted for and reconciled afterwards, when Medicare did a “true up” of DIR received, or paid out, by a PBM. This concept is illustrated below.



New Performance-Based DIR Fees for PBM Profits

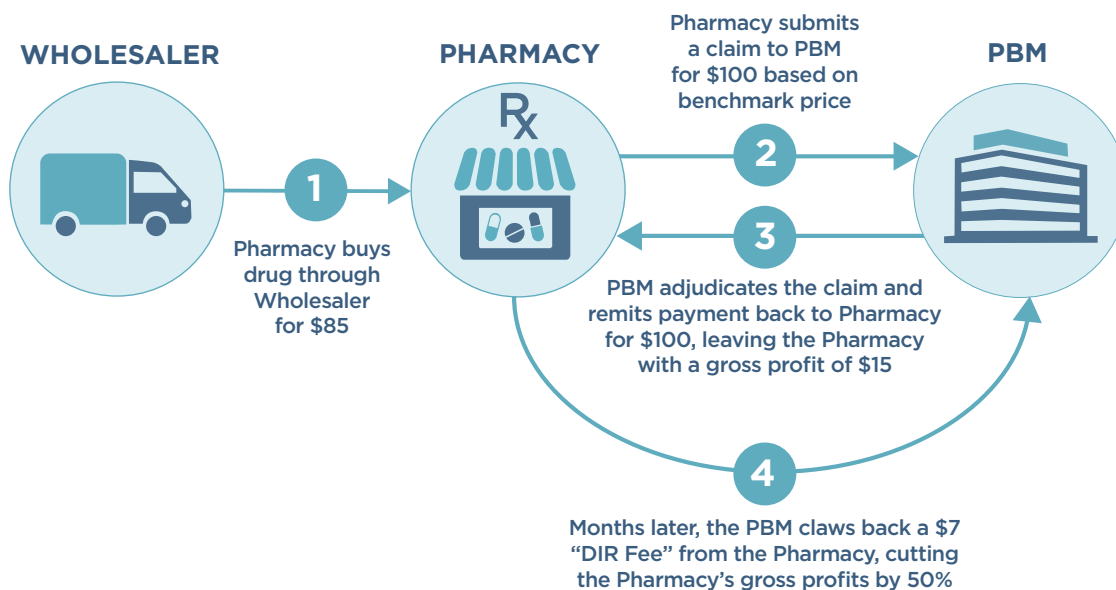
Over time, Part D plan sponsors and PBMs began to incorporate different payment and network structures with their participating Pharmacy Providers. Among those strategies included the introduction of what have become known and referred to as DIR Fees charged to Pharmacy Providers, and which are distinct from the original and legitimate DIR reported to Medicare.

In theory—and as originally contemplated by CMS—these DIR Fees would provide Pharmacy Providers with additional reimbursement based on certain quality performance metrics. However, over the last year or so, DIR Fees have been twisted by PBMs into an abusive and overly-broad “backdoor” vehicle for clawing back additional monies and increasing their own profits—at the expense of Medicare and beneficiaries.

<i>Original DIR</i>		<i>New DIR Fees</i>
<i>Payments or other reimbursement received by PBMs from a variety of other sources that lowered the ultimate “true cost” of the medication, such as including manufacturer rebates.</i>	vs.	<i>“Backdoor” fees, chargebacks or other recoupments imposed by PBMs on Pharmacy Providers after a drug claim is submitted, adjudicated, and even paid out to a Pharmacy Provider.</i>

While DIR Fees can encompass a variety of charges to Pharmacy Providers—such as “pay-to-play” fees for preferred networks, network access fees, or administrative fees—one increasing area of concern is that PBMs have begun to tie them to various measures of pharmacy “performance.” These “performance-based” DIR Fees may be a flat rate—\$2.00 to \$7.00 per claim is a typical range of flat fees—or may be percentage-based, with 3% to 9% of the gross drug reimbursement per claim being a typical range of a percentage-based fee.

PBMs and Part D plan sponsors have used their requirement to meet certain overall quality measures as justification for imposing such performance-based DIR Fees. However, plan-specific quality metrics are inappropriate because they are not actually measured at the Pharmacy Provider level. The concept of PBM-imposed DIR Fees assessed against Pharmacy Providers is illustrated below.



Fundamentally, performance-based DIR Fees imposed by PBMs have no basis in law. Nowhere in the MMA, CMS regulations, or any CMS guidance are PBMs authorized to charge Pharmacy Providers with percentage-based DIR Fees under the guise of “performance” or “quality.”

While PBMs contend such DIR Fees are based on Pharmacy Provider performance, the metrics used by PBMs in assessing performance offer Pharmacy Providers little, if any, opportunity to actually influence their quality scores. Moreover, the logic of the performance criteria is questionable, at best. PBMs assess performance based primarily on certain types of maintenance medications—such as diabetic products or statins—but assess DIR Fees against the gross reimbursement **for all prescriptions received by Pharmacy Providers, not just maintenance medications.** This results in an inappropriate quality metric for specialty Pharmacy Providers, such as community oncology clinics with integrated on-site pharmacies or dispensing facilities, that dispense few, if any, maintenance medications. However, specialty drugs, such as oral oncology medications, provide a virtual bonanza for PBMs. For example, a 5% DIR Fee on a \$2,000 oral cancer drug provides a \$100 profit to the PBM each time the drug is dispensed.

In addition, there are a number of problems with PBMs' imposition of performance DIR Fees. Arguably, the biggest problem stems from the fact that DIR Fees are typically assessed months after the drugs are dispensed and claims are submitted by Pharmacy Providers. Thus, Pharmacy Providers have no way of understanding and accounting for what the final “net” payment amount for specific drug claims will be until **after** the DIR Fee is applied and clawed back. Retroactive DIR Fees create a lack of transparency and accounting for Pharmacy Providers.

Likewise, while PBMs are supposed to report retroactive DIR Fees received from Pharmacy Providers in an accounting of DIR to Medicare, very few PBMs actually call such fees “DIR Fees,” obscuring them in other terms such as “network variable rates” or “pharmacy performance payments.” Failure to designate these charges as DIR Fees is more than just semantics as they have a very real cost to beneficiaries and Medicare and should be known.

DIR Fees cost Medicare, beneficiaries, and ultimately taxpayers more by obscuring the true net cost of drugs. The inflated upfront (point-of-sale) drug cost will result in higher cost sharing obligations, which in turn push beneficiaries into, and then out of, the Medicare Part D “donut hole” coverage gap faster. Stated differently, an enrollee will hit the coverage gap sooner if the full amount of the claim reported at the point-of-sale is applied towards the coverage limits, as opposed to the ultimate **actual cost** to the Part D plan sponsor after the PBM claws back any DIR Fees. There is no evidence that beneficiaries' out-of-pocket costs are lowered or reimbursed by PBMs after these inflated costs are adjusted by DIR Fees. Thus, PBM-imposed DIR Fees accelerate the triggering of the “donut hole” compared with a scenario where such fees are taken into account at the point-of-sale.

This very concept was borne out of a critical report released by CMS on January 19, 2017. In the CMS Fact Sheet, CMS issued a rare public criticism of the PBMs' activities in contributing to the rise in DIR as a percentage of overall Medicare Part D spending. While passing no judgment on the legality (or lack thereof) of the concept, the report specifically cited DIR as contributing to increased drug costs, and in turn, increased beneficiary out-of-pocket amounts and Medicare spending. However, the report only took into account DIR that was actually reported and returned to Medicare. Thus, CMS's findings would only be further pronounced if they included all such chargebacks—including DIR Fees—from the Pharmacy Providers that are not fully reported and returned to Medicare by the PBMs.

It is clear that PBMs have rigged the system to reap tremendous profits from drugs off the back of Medicare and beneficiaries—that is, seniors often on fixed incomes—and the taxpayers who fund the Medicare program. Additionally, **exploding DIR and DIR Fees also are fueling prices of specialty drugs, such as oral cancer therapies.**

From a legal perspective, performance-based DIR Fees being implemented by PBMs have no basis in law or regulation and may, in fact, violate certain laws. PBMs' actions in imposing DIR Fees appear to violate the Administrative Procedure Act as new Federal legislation or formal rulemaking would be required in order for such PBM-imposed DIR Fees to comply with existing law relating to provider reimbursement under

Medicare. Additionally, DIR Fees effectively alter the net reimbursement to Pharmacy Providers sufficient enough to trigger other provisions under Federal law, including the Federal Any Willing Provider Law (requiring terms and conditions—including reimbursement—to be reasonable and relevant) and the Federal Prompt Payment Law (limiting the *ex post facto* recoupment of previously adjudicated amounts for clean claims).

At their core, PBM-imposed retroactive DIR Fees are “unclear” as to logic, process, and legal basis. PBMs have developed these DIR Fees as an attempt to facially conform to the letter of the law by keeping contracts with Pharmacy Providers “reasonable,” while recouping uncounted-for DIR Fees after the point of sale that effectively circumvent the law and often result in below-cost reimbursement to Pharmacy Providers. DIR Fees are for the benefit of PBMs, not Medicare and beneficiaries, and artificially inflate out-of-pocket costs to Medicare beneficiaries and to the Medicare program as a whole, all while severely burdening Pharmacy Providers.

A Legislative Fix in the 115th Congress

CMS, under the Obama Administration, has proposed that PBMs include DIR Fees in the point-of-sale price, and has set forth other DIR reporting requirements incumbent on PBMs. However, under pressure from the PBM lobby, CMS rescinded such proposed guidance and has failed to specifically address the issue of DIR Fees. There were two bills in the 114th Congress (companion bills in the House and Senate) that would effectively eliminate retroactive DIR Fees in most circumstances. It is expected that both bills will be reintroduced in the 115th Congress.

Because of the significant, negative impact caused by such DIR Fees, further action is needed, both by CMS, under the Trump Administration, and Congress. CMS has already noted the negative impact of reported DIR on Medicare and beneficiary spending, and needs to address this growing problem through specific, tailored guidance that clearly sets forth the Pharmacy Providers’ rights and PBMs’ responsibilities. ***Congress must work diligently on passing legislation that would put a stop to the opaque and costly practice of PBM-imposed DIR Fees***

2 Introduction

In the American health care system, plan sponsors (such as health insurers, self-funded employers, and government programs) often outsource the administration of prescription drug benefits to companies known as pharmacy benefit managers or “PBMs.” PBMs are third-party corporations that are primarily responsible for contracting with pharmacies, negotiating reimbursement rates, and processing drug claims. Since 2011, the PBM marketplace has transformed considerably, consolidating into only 4 national PBMs that control prescription drugs for 266 million Americans, or 80% of the market. Recognizing the profit that can be made from controlling specialty drugs, such as oral oncolytics, all the major PBMs have acquired or launched their own specialty pharmacies.

In an increasingly consolidated pharmacy benefits industry, PBMs have used their immense market share to design a variety of business tactics aimed at gaining additional profits, reducing amounts paid to providers, and driving prescription volume to the PBMs’ wholly-owned pharmacies. However, no PBM policy has had more impact on Medicare beneficiaries and providers who dispense drugs, such as retail and specialty pharmacies and physician-run medical practices with retail pharmacies or dispensing facilities (collectively, “Pharmacy Providers”), than that of “direct and indirect remuneration” fees (DIR Fees).

The concept of DIR was originally intended by the Centers for Medicare & Medicaid Services (“CMS”) as a mechanism to “preserve the competitive nature of the Part D program by ensuring a level playing field for Part D sponsors, regardless of their contractual arrangements with PBMs.”¹ The term “direct and indirect remuneration” (“DIR”) relates to a drug price reporting requirement instituted by CMS for all Part D sponsors. Its intended purpose is to accurately report to CMS the rebates and other “price concessions” received from manufacturers or Part D providers, that could not be reasonably determined at the point-of-sale. In essence, DIR is a broad term that is intended to fully account for the *net* amounts actually paid by a Part D sponsor for a given drug.²

However, in recent years PBMs have warped the original concept of DIR and have begun to implement so-called DIR Fees in a completely unintended way, drastically reducing transparency, and muddling the accuracy of reported drug reimbursement rates. The results are increased prescription drug costs to both the Medicare program and its beneficiaries, often seniors on fixed incomes, as well as Pharmacy Providers actually losing money by filling prescriptions that are reimbursed by the PBMs substantially below costs.

In this White Paper we will explore the true, originally-contemplated nature of DIR and the exact statutory and regulatory basis for the concept. With this backdrop, we will explore how newfangled DIR Fees are being misused by PBMs and vertically-integrated Medicare Part D plan sponsors to generate significant profit, rather than benefit Medicare and its beneficiaries. From there, we will explore the pervasive impact of DIR Fees on Medicare beneficiaries, the system as a whole, and on Pharmacy Providers. We will then look at what is being done by the Federal government to address the serious and important issues posed by DIR Fees. Finally, we will explore how PBM-imposed DIR Fees violate several laws and regulations, and what must be done to address them.

Ultimately, if the imposition of DIR Fees on Part D Pharmacy Providers by Part D plan sponsors is allowed to continue as a practice in its current fashion, it will fundamentally and unfairly shift the costs necessarily attendant with administering prescription drug benefits from Part D plan sponsors to Part D Pharmacy Providers, taxpayers, and patients, and the overall health care system will suffer as a result.

¹ Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions, 74 Fed. Reg. 1494-01, 1512.

² Adam Fein, *Behind Diplomat Pharmacy’s Plunge: A Primer on DIR Fees in Medicare Part D*, Drug Channels (November 8, 2016), available at <http://www.drugchannels.net/2016/11/behind-diplomat-pharmacys-plunge-primer.html> (last visited on Dec. 2, 2016).

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3 The Origins of DIR and DIR Fees

The broader concept of DIR does have legitimate underpinnings within the Medicare regulatory framework. In the Social Security Act (42 U.S.C. § 1395w-102), “direct or indirect reimbursement”—or DIR—was initially a method for CMS to increase transparency regarding the real cost of drug transactions in the Medicare prescription drug benefit program. However, despite CMS’s good intentions, the PBM industry has taken the concept of DIR and warped it into what amounts to be an *ex post facto* “clawback” from Medicare Pharmacy Providers. To better understand how the PBM industry has distorted CMS’s usage of DIR, a brief overview of the history of Medicare and DIR is necessary.

3.1 Background of Medicare Part D

Drug benefits under Medicare are a fairly recent addition to the program. Indeed, although Medicare was established in 1965³, it did not feature a prescription drug benefit until President George W. Bush signed the Medicare Prescription Drug, Improvement, and Modernization Act (“MMA”) into law in 2003. With the passage of the MMA, both the Medicare+Choice program—now commonly referred to as Medicare Advantage (“MA” or “Part C”)—and the Voluntary Prescription Drug Benefit Program (“Part D”)⁴ were established. However, although the MMA was originally enacted in 2003, the prescription drug benefit program did not go into effect until 2006.⁵ Thus, Medicare’s prescription drug benefits program has been in operation for just over a decade.

To help alleviate the enormous obligations attendant with the administration of the Medicare and Medicaid programs, CMS contracts with Part D “plan sponsors” to administer enrollees’ prescription drug benefits under Medicare Part D.⁷ Part D plan sponsors, likewise, delegate these administrative obligations through contracting with “first tier entities”—i.e. PBMs such as CVS/Caremark Corp., Humana, Inc., OptumRx, Inc., Express Scripts, Inc. and others.⁸ To receive prescription drug coverage under Medicare, eligible enrollees then must join one of the Medicare Advantage or Part D plans approved by CMS.⁹ In 2016, approximately 72% of all 57 million Medicare-eligible individuals, were enrolled in a Part D prescription drug benefit plan (“PDP”).¹⁰

PDPs are administered by private companies—known as “plan sponsors”—that contract with CMS to offer prescription drug coverage. Plan sponsors include insurance companies (such as Aetna or Blue Cross

³ See generally Title XVIII of the Social Security Act, as codified Title 42, Chapter 7, Subchapter XVIII of the United States Code, 42 U.S.C. §§ 1395 through 1395lll, *et seq.*

⁴ See generally 42 U.S.C. §§ 1395w-21 through 1395w-28, *et seq.*

⁵ See generally 42 U.S.C. §§ 1395w-101 through 1395w-154, *et seq.*

⁶ See 42 U.S.C. § 1395w-101(a)(2).

⁷ See 42 U.S.C. § 1395w-112, *et seq.* (providing the statutory requirements governing CMS’ contracts with prescription drug plan [“PDP”] sponsors).

⁸ See 42 C.F.R. § 423.4 (“First tier entity means any party that enters into a written arrangement, **acceptable to CMS**, with a Part D plan sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D.”) (emphasis added).

⁹ See 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>.

¹⁰ See The Henry J. Kaiser Family Foundation, *The Medicare Part D Prescription Drug Benefit*, <http://kff.org/medicare/fact-sheet/the-medicare-prescription-drug-benefit-fact-sheet/> (last visited Oct. 28, 2016).

Blue Shield) who sponsor PDPs and delegate management of the benefit to separate PBMs and affiliates or wholly-owned subsidiaries of PBMs (such as SilverScript, which is owned by CVS Health, and Humana) that integrate the PDP with the administration of the pharmacy benefit. Enormous latitude and autonomy has been given to the Part D plan sponsors and PBMs. Because of the often interrelated nature and aligned financial interests of PBMs and Part D plan sponsors (including through unity of ownership), the two are often referred to as acting together in this White Paper.

As noted, plan sponsors hire PBMs to manage the pharmacy benefit, and to exercise discretion and control over administrative decisions, such as which Pharmacy Providers will be “in-network,” the reimbursements that Pharmacy Providers receive, and the expenses, such as DIR Fees that are imposed on Pharmacy Providers.

Finally, PBMs then contract with Pharmacy Providers, or “downstream entities,” to create a network of participating Pharmacy Providers. Enrollees may then obtain Part D prescription drug products from those Pharmacy Providers that are “in-network” for their particular PDP. As defined earlier in this document, these Pharmacy Providers typically include free-standing retail or specialty pharmacies, as well as retail and community pharmacies connected to medical practices and/or physician practices with dispensing facilities.

The power of plan sponsors and PBMs under the Part D program is strictly limited by Medicare laws as enacted by Congress and by Medicare regulations, rules, requirements, and guidance properly promulgated by U.S. Department of Health and Human Services (“HHS”) or its “sub-agency” CMS.¹¹

In enacting the MMA, congressional intent is clear that payment of benefits administered under Part D is entrusted to HHS, which delegates its payment authority through written contracts with Part D plan sponsors.¹² In the pharmacy benefits context, Part D plan sponsors delegate this payment authority through contracts with PBMs as “first tier entities,” and altogether work in concert with Pharmacy Providers as “downstream entities” to provide benefits to Medicare beneficiaries, subject to regulatory oversight.¹³ The rule of law controls such relationships and the power of each entity within this stream.

3.2 CMS Utilizes DIR to Increase Transparency of Medicare Part D Costs

Under the Medicare Part D program, CMS reimburses Part D plan sponsors and in turn, their PBMs, for the costs of prescription drugs actually paid by the Part D plan sponsor, based on claims submitted by Pharmacy Providers. Thus, for example, if a participating Pharmacy Provider submitted a claim for \$100 and the PBM paid out \$100 to the Pharmacy Provider based on the negotiated price, CMS would cover the \$100 cost of that claim since that was the PBM’s actual cost.

However, in many instances the Part D plan sponsor or its PBM’s actual cost may differ from the exact figure adjudicated and paid out at the point-of-sale. This scenario arises most commonly following the receipt of manufacturer rebates. Such rebates received by PBMs and Part D plan sponsors after the point-of-sale from pharmaceutical companies, obviously lower the net cost of the drug claim as borne by the plan. Consider the example above, only this time, while the PBM may have initially paid out \$100 to the Pharmacy Provider at the point-of-sale, it later received a rebate of \$15 from the manufacturer many months after the claim had been processed. This would reduce the net cost to the Part D plan sponsor for that prescription drug claim to \$85. See, *Illustration 1* (below). CMS wants to ensure that it shares in those savings, and has implemented guidance and regulations seeking to provide increased drug pricing transparency.

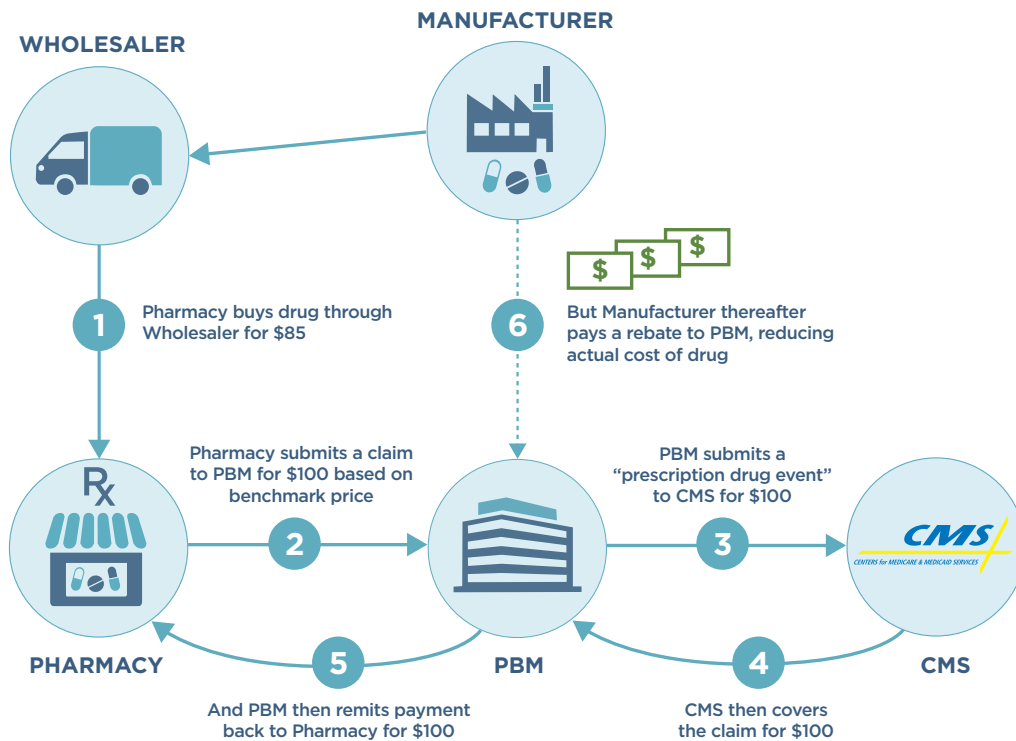
¹¹ See generally Discussion, *infra*, at Section 6.A.

¹² See, e.g., 42 U.S.C. §§ 1395w-102, *et seq.*

¹³ See generally 42 C.F.R. §§ 423.505, *et seq.*

Illustration 1

Impact of Manufacturer Rebate on Prescription Drug Event



In seeking to ensure that such manufacturer rebates were properly accounted for and passed on, CMS sharpened its definition of “actually paid” to account for such funds received by Part D Sponsors as “direct or indirect remuneration,” otherwise known as DIR:

Actually paid means that the costs must be actually incurred by the Part D sponsor and must be net of any **direct or indirect remuneration** (including discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers) from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred under the Part D plan. **Direct and indirect remuneration** includes discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits from manufacturers, pharmacies or similar entities obtained by an intermediary contracting organization with which the Part D plan sponsor has contracted, regardless of whether the intermediary contracting organization retains all or a portion of the direct and indirect remuneration or passes the entire direct and indirect remuneration to the Part D plan sponsor and regardless of the terms of the contract between the plan sponsor and the intermediary contracting organization.¹⁴

¹⁴ 42 C.F.R. § 423.308 (emphasis added).

Thus, CMS ensured that the definition of “actually paid” would encompass all “direct and indirect remuneration”—DIR—that is received by a Part D plan sponsor or its PBM, including, but not limited to, manufacturer rebates and pharmacy price concessions.¹⁵

To ensure that DIR data is made known to CMS, Part D plan sponsors are required, as a condition of payment, to fully disclose all information necessary for carrying out the payment provisions of Medicare Part D.¹⁶ As such, Part D plan sponsors are required to report drug costs and DIR to CMS.¹⁷ For instance, on or before June 2016 (the reconciliation deadline), Part D plan sponsors were required to submit to CMS their DIR data for 2015.¹⁸ After gathering and reconciling the DIR data, the Part D plan sponsor must identify and notify CMS of any overpayment.¹⁹ Notably, if the Part D plan sponsor fails to notify CMS of an overpayment within sixty days of its annual reconciliation, the Part D plan sponsor may be found to have violated the federal False Claims Act.²⁰

It would be an understatement to say that the concept of DIR is incredibly complex. The goal of DIR, as contemplated by CMS, is to account for after-the-fact, direct or indirect remuneration, paid out or received by PBMs and Part D plan sponsors from a variety of sources. However, with this regulatory backdrop, certain PBMs and Part D plan sponsors twisted and abused the concept of DIR to justify after-the-fact “fees” imposed on Pharmacy Providers, which ultimately obscure drug pricing and the reconciliation process.

4 PBMs’ Use of DIR Fees to Clawback Fees from Pharmacy Providers After the Point-of-Sale

As previously noted, prescription drug benefits—including those within the Medicare Part D program—are managed by PBMs who serve as the middlemen in an increasingly complex prescription drug reimbursement paradigm. The PBMs’ stated function is to develop and maintain drug formularies, contract with a network of Pharmacy Providers, negotiate discounts and rebates with drug manufacturers, and process and pay prescription drug claims.²¹

However, the PBM industry has become exceedingly consolidated. Only four PBMs (Express Scripts, Inc., CVS/Caremark Corp., OptumRx, and Prime Therapeutics) now control more than 80% of the market share in the United States.²² See, *Figure 1* (below). As consolidation and integration has increased, these companies have used their immense market share to design a variety of business tactics aimed at gaining additional profits, reducing amounts paid to Pharmacy Providers, and driving prescription volume to the PBMs’ wholly-owned pharmacies. These include mandatory mail order for maintenance medications (in which patients are denied a choice of pharmacy and forced to receive drugs from the PBM’s wholly-owned mail order pharmacy), arbitrary exclusion of specialty pharmacies from PBM networks, and below-acquisition cost reimbursement. Altogether, PBM business tactics make it nearly impossible for Pharmacy Providers to stay viable. However, no PBM policy has been more impactful to Pharmacy Providers than that of DIR Fees.

¹⁵ See CMS, “Final Medicare Part D DIR Reporting Requirements for 2015” (May 31, 2016).

¹⁶ 42 U.S.C. §1395w-115(f)(1)(A)

¹⁷ See “Final Medicare Part D DIR Reporting Requirements for 2015,” CMS, May 31, 2016

¹⁸ See “Final Medicare Part D DIR Reporting Requirements for 2015,” CMS, May 31, 2016

¹⁹ 42 C.F.R. § 423.360

²⁰ 42 C.F.R. § 423.360(c)

²¹ American Pharmacists Association, *Pharmacy Benefit Management* (2013),

https://www.pharmacist.com/sites/default/files/files/Profile_26%20PBM%20Final%20071213.pdf (last visited Jan. 26, 2017).

²² 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>.

Figure 1

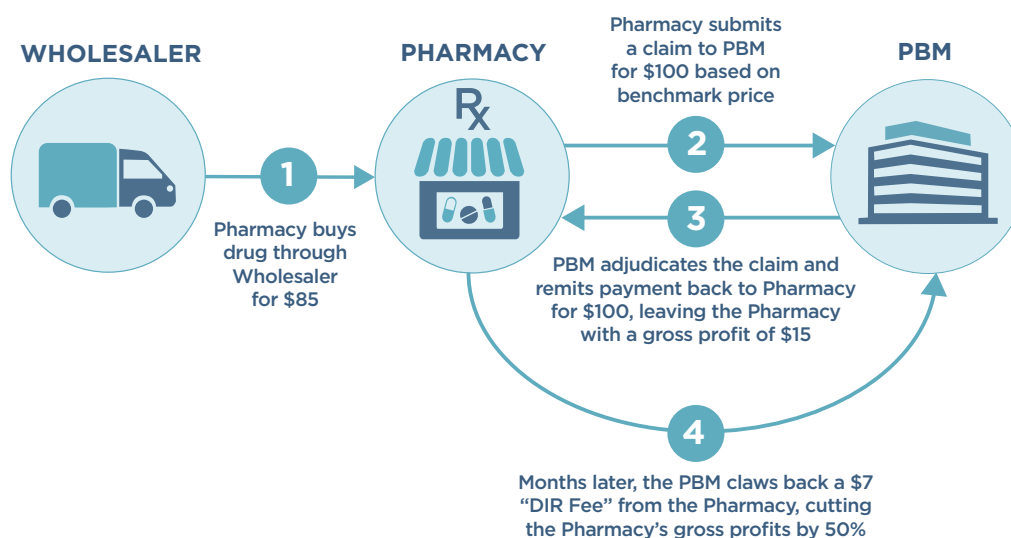
PBM Mergers and Consolidations in Last Five Years

2011							
2013							
2015							

The PBM industry has wholly warped the meaning of DIR. While different iterations of DIR have existed in PBM contracts for some time, it was not until late-2015, early-2016, that PBMs began unilaterally modifying existing provider agreements with Pharmacy Providers to include their own version of DIR Fees. Medicare Part D provider agreements are often “contracts of adhesion,” where Pharmacy Providers are either forced to accept the PBM’s terms and conditions—which PBMs are free to modify at any time—or to discontinue participation in the PBM’s network. This is even truer in the context of “preferred pharmacy networks,” which PBMs and Part D plan sponsors use as a way of lowering contract reimbursement in exchange for (in theory) greater patient volume.

It is against this backdrop of consolidation and contract leverage that PBMs have begun retracting or “clawing back” millions of dollars from Pharmacy Providers in a variety of fashions, all under the umbrella of DIR Fees. These PBM-imposed DIR Fees on Pharmacy Providers can include “pay-to-play” preferred pharmacy networks under Medicare Part D; payment reconciliations or “true ups” based on guaranteed contracted rates; payment adjustments based on fulfillment of performance or quality metrics; or a combination of the above. See *Illustration 2* for an example of how these might work (below).

Illustration 2



In this White Paper, we focus primarily on the after-the-fact fees imposed by PBMs on Pharmacy Providers, particularly in the Medicare Part D context. While DIR Fees impact all Pharmacy Providers, this White Paper pays particular attention to the unique impact on community oncology practices with integrated retail pharmacies or dispensing facilities.

4.1 Performance-Based DIR Fees

Performance-based DIR Fees are perhaps one of the most important issues facing Pharmacy Providers today. Performance metric fees entail a PBM's review of a Pharmacy Provider's performance in a number of "quality metric" categories. The therapeutic categories can include, but are not limited to, diabetes, congestive heart failure, hypertension, respiratory, coronary artery disease, breast cancer, depression and cholesterol. The categories reviewed by the PBM may be, but are not always, based off of the categories reviewed by CMS under the Star Rating System (*see* Section 4.2, below).

Based on the Pharmacy Provider's performance in these "quality metric categories," they are typically assessed a corresponding DIR Fee by the PBM, with lower performing Pharmacy Providers being assessed higher DIR Fees and better performing Pharmacy Providers being assessed lower DIR Fees. Critically, a Pharmacy Provider that does not submit claims that fall within the purview of a PBM's quality metric categories, often will, nevertheless, be assessed a DIR Fee. In these cases, the DIR Fee charged back from the Pharmacy Provider **will be based upon the Part D plan sponsor's average performance scores, rather than the provider's actual performance**. In essence, a provider that does not provide services for patients within the PBM's listed quality metric categories will be assessed DIR Fees based on the performance of their competitors in each quality metric category for all drugs dispensed. This system lacks logic and can economically punish Pharmacy Providers.

Performance metric DIR Fees can be based on a flat fee or percentage basis. For example, a flat fee performance metric DIR Fee would have the PBM withhold \$5.00 from each claim submitted by the Pharmacy Provider to the PBM. The PBM will review the Pharmacy Provider's performance in three categories and will refund to the Pharmacy Provider \$0.50 for each category in which the Pharmacy Provider performs in at least the 50th percentile, but below the 80th percentile. For each category that the Pharmacy Provider performs above the 80th percentile, \$2.25 will be refunded. Thus, if a Pharmacy Provider performs between the 50th to 79th percentile for all three categories, the Pharmacy Provider will receive a \$1.50 refund and will forego the balance—\$3.50—to the PBM. Effectively, therefore, the Pharmacy Provider has paid a \$3.50 DIR Fee. This is illustrated in *Table 1* (below).

Table 1

	Below the 50 th Percentile	Between the 50 th and 79 th Percentile	Above the 80 th Percentile
Adjudicated Price	\$100.00	\$100.00	\$100.00
Per Claim Withhold	-\$5.00	-\$5.00	-\$5.00
Category 1 Refund	\$0.00	\$0.50	\$2.25
Category 2 Refund	\$0.00	\$0.50	\$2.25
Category 3 Refund	\$0.00	\$0.50	\$2.25
Net Reimbursement to Pharmacy	\$95.00	\$96.50	\$101.25

Flat fee DIR Fees can be particularly problematic for community retail pharmacies and in the context of lower cost brand or generic medications. In this scenario, a \$5.00 per claim fee could encompass all of the pharmacy's modest profit on the claim, and often results in the pharmacy losing money when dispensing the prescription.²³

²³ Adam Fein, *Behind Diplomat Pharmacy's Plunge: A Primer on DIR Fees in Medicare Part D*, Drug Channels (November 8, 2016), available at <http://www.drugchannels.net/2016/11/behind-diplomat-pharmacys-plunge-primer.html> (last visited on Dec. 2, 2016).

Performance metric DIR Fees may also be percentage-based. Using this model, a percent of the total claim submitted by the Pharmacy Provider will be assessed a DIR Fee, with the percentage being dictated by the Pharmacy Provider's performance in a number of categories. An example of percentage-based performance metric DIR Fees is illustrated in *Table 2* (below), where the Pharmacy Provider with the highest performance score pays a somewhat lower DIR Fee than one with the lowest performance score.

*Table 2*²⁴

Performance Score	DIR Fee %	Impact with <i>Drug X</i>	Pharmacy with Performance Score of 5	Pharmacy with Performance Score of 1
5	3.5%	<i>Ingredient Cost Paid</i>	\$229.98	\$229.98
4	4.0%	<i>Dispensing Fee Paid</i>	\$1.00	\$1.00
3	4.5%	<i>Patient Copay</i>	\$10.00	\$10.00
2	5.0%	<i>Total Amount Paid</i>	\$220.98	\$220.98
1	5.5%	<i>DIR Fee</i>	\$8.05	\$12.65
		<i>Total Net Reimbursement</i>	\$212.93	\$208.33

In either case, while such DIR Fees are couched in incentivizing better “performance,” both types of fees do not actually provide additional payment incentives over the contracted and adjudicated price of the drug. Rather, with both types of DIR Fees a strongly performing Pharmacy Provider can only hope to minimize the amount clawed back by the PBM. In either case does the Pharmacy Provider stand to gain additional payment over the point-of-sale price.

Perhaps most critically, DIR Fees are calculated retrospectively, and are assessed against the Pharmacy Provider many months after they have been reimbursed on claims submitted to the PBM. Indeed, many PBMs utilize a four-month window to measure performance and thereafter assess DIR Fees against the Pharmacy Provider. For instance, a PBM will measure a Pharmacy Provider's performance from January through April. In May, the PBM will calculate the Pharmacy Provider's performance in each category and determine the applicable DIR Fee to be imposed. Once the PBM is finished calculating the Pharmacy Provider's performance during the four-month window, it will begin assessing DIR Fees on claims submitted by the Pharmacy Provider to the PBM from June through August. Thus, PBMs are clawing back the Pharmacy Provider's reimbursement *months* after the point-of-sale and the Pharmacy Provider has no way of knowing how much it should expect to have taken back until the clawback actually occurs.

Depending on the type of provider, the impact of flat fee or percentage-based DIR Fees can be further exacerbated. Indeed, as noted above, flat fee DIR Fees are especially dangerous to community retail pharmacies, as the \$5.00 clawback can actually cause pharmacies to lose money by filling the prescription. Likewise, percentage-based DIR Fees can have an extreme impact on higher cost specialty medications, such as cancer drugs, resulting in PBMs clawing back several thousands of dollars per claim. For example, in the case of a high-cost \$40,000 Hepatitis C medication, a 5.5% DIR Fee would result in the PBM clawing back over \$2,000 on just that one claim alone (even though that medication might not fall within any of the measured quality metrics).

This is extremely problematic, as these higher-cost specialty medications have even slimmer gross percentage margins, and the 3% to 9% DIR Fees may eat up all of the Pharmacy Provider's modest margins or

²⁴ Melanie Maxwell, *Understanding Pay for Performance and DIR Impact to Pharmacy Reimbursement RxSelect Pharmacy Services*, 20, 22 (Sept. 12, 2015), <http://www.morx.com/assets/docs/2015AC/9-12-15%20%20415%20pm%20%20%20%20mapc%202015%20third%20party%20landscape%20maxwell.pdf> (last visited Jan. 26, 2017).

cause them to actually lose money, particularly when considering the additional, unreimbursed costs that go along with the high-touch services required of such Pharmacy Providers as community cancer practices.

For providers providing a large percentage of higher cost specialty medications, the aggregate impact of DIR Fee clawbacks can be staggering. Some Pharmacy Providers have reported being charged over \$200,000 in DIR Fees per PBM, per quarter. This is certainly a widespread issue as evidenced by a publicly traded specialty pharmacy announcing recoupment of over \$10 million in DIR Fees from PBMs in 2016.²⁵

4.2 Misapplication of CMS's Star Rating System

PBMs attempt to justify the imposition of performance metric DIR Fees by referencing CMS's Star Rating System. Medicare uses a Star Rating System to measure how well Medicare Advantage and Part D prescription drug plans perform. For Part D plans and Medicare Advantage plans covering drug services, there are four (4) overall rating categories: (1) drug plan customer service, (2) member complaints and changes in the drug plan's performance, (3) member experience with plan's drug services, and (4) drug safety and accuracy of drug pricing.²⁶ Within each category are a number of "measures," which act as sub-categories. The measures are comprised of numerous different areas of review, including (1) medication adherence for diabetes medications, (2) medication adherence for hypertension, (3) medication adherence for cholesterol, and (4) medication therapy management program completion rate for comprehensive medication reviews.²⁷ Each measure is assigned a star, the category scores are aggregated and each plan is assigned a rating from 1 to 5 stars, with five being the highest and one being the lowest score.²⁸

However, it is important to note that the Star Rating System was designed by CMS to apply to Part D plan sponsors, not to Pharmacy Providers. In fact, there are numerous benefits ***for plans*** that receive a 5-star rating by CMS's Star Rating System. First and foremost, a plan's rating is publicly displayed on Medicare's website. Additionally, Medicare beneficiaries are permitted to enroll in 5-star rated plans at any time throughout the year through a "special enrollment period," as opposed to non-5-star plans, which only have open enrollment for about two months out of the year.²⁹

Most significantly, highly performing plans are entitled to quality bonus payments based on the Star Rating system. The Patient Protection and Affordable Care Act allows for quality bonus payments to "qualifying plans" that have a Star Rating of four (4) stars or higher.³⁰ Quality bonus payments have become a substantial source of revenue for Medicare Advantage plan sponsors. For example, UnitedHealthcare is due for an approximate \$1.4 billion bonus, while Humana expects to receive a bonus upwards of \$1.5 billion in 2017.³¹

Because PBMs and Part D plan sponsors are directly impacted financially by the CMS Star Rating System, PBMs have in turn sought to artificially pass along performance requirements to Pharmacy Providers, assessing them on these same criteria and justifying imposition of performance-based DIR Fees as "incentives"

²⁵ Diplomat Pharmacy, Inc., Quarterly Report for the Period Ending September 30, 2016 2 (Form 10-Q) (Nov. 2, 2016), *available at* https://www.sec.gov/Archives/edgar/data/1610092/000110465916154225/a16-17170_110q.htm.

²⁶ CMS, *Star Ratings*, [https://www.medicare.gov/find-a-plan/\(S\(4emd5e55lrt5j22pu5kbpv55\)\)/staticpages/rating/planrating-help.aspx?AspxAutoDetectCookieSupport=1](https://www.medicare.gov/find-a-plan/(S(4emd5e55lrt5j22pu5kbpv55))/staticpages/rating/planrating-help.aspx?AspxAutoDetectCookieSupport=1) (last visited Jan. 26, 2017).

²⁷ CMS, *2016 Part C & D Star Ratings Measures*, https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2016_Star_Ratings_Measure_List.pdf (last visited Jan. 26, 2017).

²⁸ David Nau, *The Growing Importance of Medicare Star Ratings* (Feb. 29, 2016), <https://imedicare.com/articles/the-growing-importance-of-medicare-star-ratings/> (last visited Jan. 26, 2017).

²⁹ See Memorandum from Michael Crochunis to Medicare Advantage Organizations, *Establishing a Special Election Period (SEP) to Enroll in 5-Star Medicare Advantage Plans in Plan Year 2012*, Nov. 19, 2010.

³⁰ 42 U.S.C. § 1395w-23(o)

³¹ Phil Galewitz, *Medicare Plans Score Higher Ratings And Millions In Bonuses* (Mar. 7, 2016), *available at* <http://khn.org/news/medicare-plans-score-higher-ratings-and-millions-in-bonuses/>.

based on these criteria. Plan sponsors and PBMs argue that DIR Fees are a mechanism to heighten the quality of a plan's participating Pharmacy Providers.

While ensuring quality in the delivery of health care is universally accepted, there are serious problems with tying DIR Fees to Pharmacy Provider performance, especially when they are assessed based on the CMS Star Rating System. Aside from the fact that these performance-based DIR Fees obfuscate the reimbursement initially agreed to by Pharmacy Providers, and that they often effectively reduce drug reimbursement rates to below acquisition cost, many of the quality metrics that are used by PBMs to review and rate Pharmacy Providers are simply inapplicable to many Pharmacy Providers. For example, based on the CMS Star Rating System, typical quality metric categories include statin adherence, diabetes adherence, adherence for cholesterol medication, and formulary compliance. For many Pharmacy Providers, especially those dealing with the dispensing of specialty medications, such as community oncology practices providing oral oncolytics to their cancer patients, these categories may represent only a nominal, if any, portion of practices' overall clinical operations. See *Illustration 3* (below).

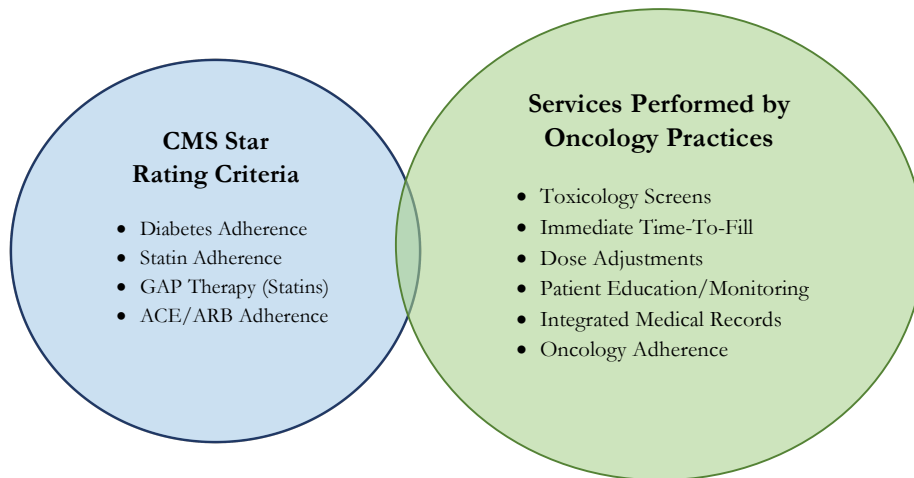
Illustration 3



Consider the typical community oncology practice that maintains an on-site retail pharmacy or in-office dispensing facility as a service to its patients. The reason for providing drugs at the point-of-care is for patient convenience and to ensure better medication compliance and adherence. As such, these on-site pharmacies and dispensing facilities are focused on servicing the practice's cancer patients with oral cancer drugs and ancillary therapies. Thus, not only would the patients receiving medication be limited to a small subset of the overall patient population, but the medications dispensed would be limited primarily to oncology medications to treat patients' cancer conditions. The practice would dispense hardly any, if any at all, diabetes drugs, statins, cholesterol medications, or any other product that would fall within the criteria for the CMS Star Rating System. To apply compliance with the CMS Star Rating System as a performance metric of the practice's overall performance is inappropriate and not a true indication of quality.

Illustration 4 (below) delineates the differences in the lifesaving services provided on a daily basis by community oncology practices with retail pharmacies or dispensing facilities versus the applicable areas of "quality measures" as captured by the CMS Star Rating System.

Illustration 4



Finally, as noted above, there are significant problems with the methodologies used by PBMs to collect and measure this “performance” data. PBM contracts are basically nonexistent with respect to clear explanations as to how “performance” is achieved, beyond simply referring to third party companies who track and measure performance on behalf of pharmacies, using each vendor’s proprietary methodology. Beyond that, the contract documents generally state that the Pharmacy Provider’s performance in the various categories will be given a relative weighting, then ranked among all participating Pharmacy Providers within the network. Thus, Pharmacy Providers are given *virtually no guidance* on how they could impact their overall performance scores.

Notwithstanding these practical problems, CMS has not made any express connection between the Star Rating system and DIR Fees because this would have required formal rule-making under the Administrative Procedure Act. Instead, and as explored in greater detail below, the tying of the CMS Star Rating System to DIR Fees clawed back from Pharmacy Providers is purely a PBM creation. As such, the PBM industry’s reliance on the CMS Star Rating System to impose DIR Fees is wholly improper and unjustifiable.

4.3 PBMs Shifting Characterization of DIR Fees to Avoid Accurate DIR Fee Reporting and Repayment Requirements

Importantly, not every PBM imposing a *post hoc* “fee” on providers refers to these charges as DIR Fees. In fact, many PBMs have different terminologies for these charges, such as “network rebates,” “pharmacy performance payments,” or “network variable rates.” For example, in CVS/Caremark’s most recent contracts, these fees have been referred to as “Network Variable Rates.” Operatively, however, these charges work very similarly from the Pharmacy Provider’s perspective, regardless of what they are called—they result in the Pharmacy Provider having funds clawed back by the PBM after the point-of-sale and after the Pharmacy Provider has accepted an adjudicated negotiated price and dispensed the medication to the patient.

This unwillingness to designate these charges as DIR Fees however, may be more than semantics used by PBMs. Rather, PBMs may use these distinctions in terminology to avoid the various statutory and regulatory reporting and repayment requirements under Medicare that would otherwise apply to DIR Fees. ***Because of the shifting characterization of DIR Fees employed by PBMs, the amounts collected by PBMs under this guise may, or may not, be reported back to CMS, and worse yet, may or may not, ultimately be returned to Medicare.*** Rather, by not characterizing these charges as DIR Fees PBMs and PBM wholly-owned Part D plan sponsors may ultimately retain them as additional profits, a kind of “tax” on participating Pharmacy Providers.

There is little, if any, evidence that DIR Fees, however characterized, that are clawed back from the participating Pharmacy Providers, are **actually paid** back to Medicare through any formal reconciliation. Moreover, the vertical integration between Part D plan sponsors, PBMs, and wholly-owned pharmacies present the potential for abuse. Without these DIR Fees being fully and transparently reported back and reconciled to Medicare, current data on the immense negative financial impact of traditional, known DIR (which CMS has noted is increasing at an alarming rate) would actually be understated, as it is impossible to quantify such unreported and non-transparent DIR.³² In essence, such DIR Fees are a hidden, profit-driven PBM tax, that are likely making a bad situation worse.

Thus, it is important for participants in the Medicare framework, including HHS, CMS, and integrated plan sponsors/PBMs—such as CVS/Caremark—to fully reveal the flow of money and reconciliation of these fees from the provider, to the PBM, to the plan sponsor, and ultimately, to the Medicare program.

5 The Cost and Impact of DIR Fees

PBM-imposed DIR Fees have had, and will continue to have, an immeasurable impact on providers, patients, and the Medicare Part D program as a whole. As outlined below, DIR Fees impact Medicare Part D beneficiaries by raising out-of-pocket costs and accelerating the triggering of Medicare’s coverage gap, commonly referred to as Medicare’s “donut hole.” Likewise, as noted in a recent CMS Report, DIR Fees increase the costs to Medicare in the form of catastrophic coverage, ultimately shifting costs from PBMs and Part D plan sponsors to CMS. Additionally, imposing after-the-fact reductions off of negotiated prices in the form of DIR Fees—many of which are not returned or even reported to the government until months after the initial claim is paid—allow PBMs to gain additional profits at the expense of the Federal Government and ultimately the taxpayer. Finally, PBMs’ use of DIR Fees often results in a substantial and unreasonable reduction in Pharmacy Providers’ reimbursements and enables PBMs to avoid certain reporting requirements contained in state and Federal maximum allowable cost (“MAC”) transparency laws.

5.1 The Medicare Part D “Bidding Process” and Manipulation by DIR Fees

The advent of DIR Fees has provided PBMs and Part D plan sponsors with a new opportunity to manipulate the Medicare Part D sponsor bidding process and capture more patients and more profits, all while burdening Pharmacy Providers. This is particularly so in a time where PBMs and Medicare Part D plan sponsors have become one-in-the-same through mergers and consolidations. By way of example, Express Scripts, Inc., CVS/Caremark Corp., and OptumRx, Inc., three of the largest PBMs, all own, or are directly affiliated with, one or more Medicare Part D plan sponsors.³³ This, combined with the fact that these PBMs own their own mail order and specialty pharmacies, create unique incentives for the PBMs to utilize DIR Fees to manipulate every aspect of the Medicare Part D process, including the bidding process.

This level of integration begs the question of who is most responsible for the growth in DIR Fees—PBMs, Part D plan sponsors, or both? Importantly, while Part D plan sponsors are responsible for submitting bids for providing Part D plan administration, it has been PBMs who are designing the plans containing DIR Fees. Conceivably, Part D plan sponsors would then submit plans for approval by CMS potentially including reference to DIR Fees, as explained below. In either event, this distinction is often blurred, as many times the PBM and Part D plan sponsor are both part of the same company.

³² See, CMS, *Medicare Part D – Direct and Indirect Remuneration (DIR)* (Jan. 19, 2017), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html> (last visited Jan. 26, 2017).

³³ Express Scripts Medicare Prescription Drug Plan, SilverScript, and UnitedHealthcare’s AARP MedicareRx Prescription Drug Plans, respectively.

That being said, this analysis starts with the extent to which DIR (whether in the form of rebates received from manufacturers or fees paid out or received from providers) must be reported to CMS. It is clear that certain forms of DIR are fully contemplated within the Medicare Part D framework (i.e., manufacturer rebates received by PBMs and plans after the point-of-sale). Putting aside for a moment the problems with the manner in which PBMs and Part D plan sponsors have assessed DIR Fees against Pharmacy Providers, Medicare regulations set forth certain requirements that any “direct and indirect remuneration” received by PBMs and Part D plan sponsors (regardless of its form) be reported back and even refunded to CMS. This section discusses not only the requirements for how such DIR is to be reported and returned to the Federal government (and how PBMs and Part D plan sponsors are manipulating this process of their own benefit), but also the steps PBMs and Part D plan sponsors may take in an attempt to avoid even these reporting requirements.

CMS allows any potential Medicare Part D plan sponsor to submit a bid for prospective services.³⁴ A plan sponsor’s bid must reflect the sponsor’s proposed benefit package, premium, applicable anticipated cost sharing, and estimated average monthly revenue requirements to provide the benefit, and include the administrative costs and estimated return on investment.³⁵ Each bid is submitted to CMS, no later than the first Monday of June of the calendar year preceding the year the sponsor intends to offer the coverage.³⁶ The Part D plan sponsor’s bid must also account for its anticipated DIR. As noted in Section 423.308 of the Code of Federal Regulations “direct and indirect remuneration” includes such things as discounts, chargebacks, rebates, cash discounts, upfront payments, coupons, or other price concessions or similar benefits from manufacturers, pharmacies, or similar entities obtained by, or paid out from, a Part D plan sponsor or its PBM that cannot be reasonably estimated at the point-of-sale. By law, the Part D plan sponsor’s anticipated DIR would include an estimation of DIR Fees, whether they are incentive payments to later be paid out to Pharmacy Providers, or whether they are performance-based clawbacks under the aegis of DIR Fees. Either way, such DIR Fees are (by design) incapable of being calculated at the outset of the bid or during the course of administering the plan, such as at point-of-sale. Therefore, their impact is reconciled only after the plan has been administered.

CMS acknowledges that a sponsor’s bid can be affected by uncertainties and result in discrepancies between the actual spending and the proposed bid amount. Therefore, six months after the end of each calendar year, CMS is supposed to perform a reconciliation of prospective payment with actual costs that sponsors paid to administer their plans.³⁷ During reconciliation, CMS may determine that a bid exceeded the actual spending of the plan and therefore request the sponsor to reimburse CMS a percentage of the overpayment.³⁸ Within the reconciliation process, CMS accounts for the net rebates and discounts, including DIR Fees imposed on Pharmacy Providers, that the Part D plan sponsor received and may have impacted its overall annual spending. While the estimate of these fees is intended to be removed from the bid upon its initial submission, the actual annual amount is difficult to predict and is only accurately reflected during reconciliation.³⁹

A Part D plan sponsor owned by a PBM could utilize DIR Fees in the bidding process to overestimate anticipated spending by conservatively estimating the fees it will collect. Used in this way, DIR Fees may result

³⁴ 42 C.F.R. § 423.265(b).

³⁵ 42 C.F.R. § 423.265(c); 42 C.F.R. § 423.265(d) (Specific requirements for bids include: (1) a description of the coverage to be provided under the plan, including any supplemental coverage, deductible and cost sharing, (2) actuarial certification that the values are calculated according to CMS guidelines on actuarial valuation, (3) the service area of the proposed plan, (4) the level of risk assumed in the bid, (5) an estimate of the plan’s average prescription drug risk score for purposes of risk adjusting any supplemental premium, and (6) additional information CMS requests to support bid amounts and facilitate negotiation); 42 C.F.R. § 423.265(b) (Upon receiving a bid proposal, CMS “may decline to accept any or every bid submitted by a Part D sponsor or potential Part D Sponsor.” Additionally, CMS will not approve bids that it finds are likely to “substantially discourage enrollment” of eligible individuals).

³⁶ 42 C.F.R. § 423.265(b)(1).

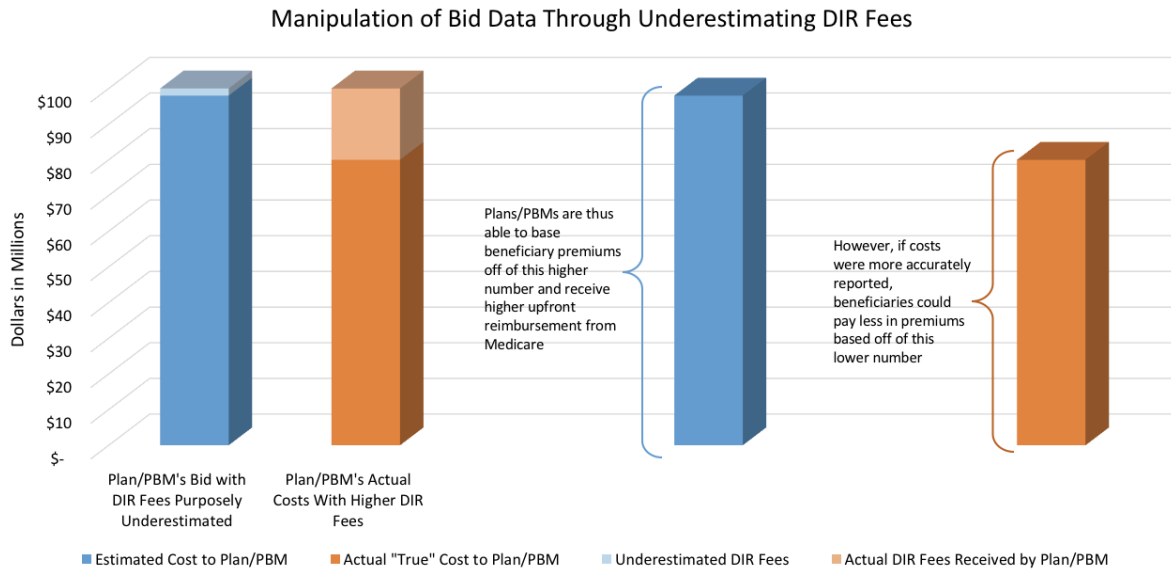
³⁷ MedPac, *Report to the Congress: Medicare and the Health Care Delivery System*, Ch. 6, 141 (Jun. 2015), available at <http://www.medpac.gov/docs/default-source/reports/chapter-6-sharing-risk-in-medicare-part-d-june-2015-report.pdf?sfvrsn=0>.

³⁸ *Id.* at 141.

³⁹ *Id.* at 158.

in a bid with a prospective cost exceeding actual cost, allowing additional profits not contemplated by CMS in accepting the bid. While CMS is supposed to recoup a portion of the excess it has paid to the Part D plan sponsor based on the inaccuracy in estimated DIR Fees, the inflated bid is a determinant factor in beneficiary premiums, which are not recovered from beneficiaries.⁴⁰ This means that by underestimating the value of anticipated DIR Fees Part D Sponsors can exact higher premiums from beneficiaries, which do not need to be refunded once annual reconciliation occurs. This is shown in *Illustration 5* (below).

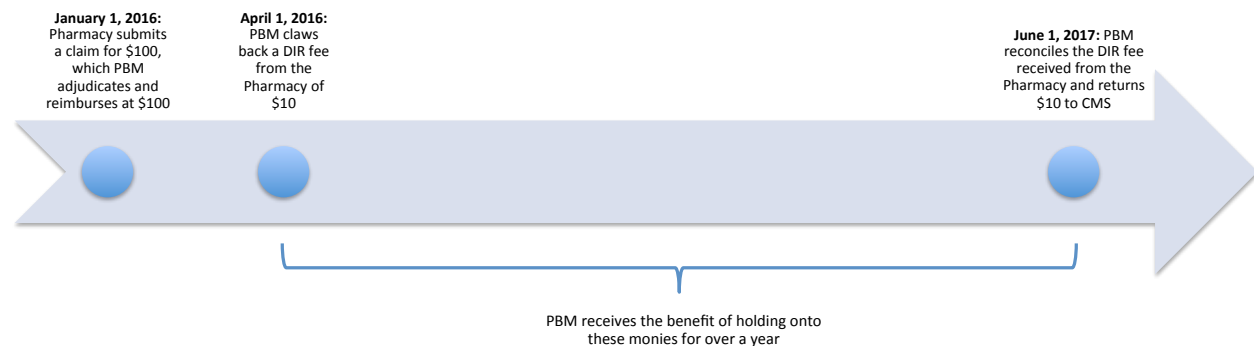
Illustration 5



By underreporting or underestimating expected DIR Fees that a Part D plan sponsor/PBM expects to take back from Pharmacy Providers, a Plan can submit a bid to CMS with inflated costs, resulting in not only higher beneficiary premiums, but also higher upfront reimbursement from CMS.

Furthermore, in this vein, the Part D plan sponsor's recovery of DIR Fees from Pharmacy Providers allows the Part D plan sponsor to hold fees otherwise due and owing to CMS and to retain the benefit of "floating" that money until reconciliation and the "true up" occurs. The excess fees are considered overpayments, which CMS requires to be paid back; however, this is not before PBMs and/or Part D plan sponsors are ultimately able to collect interest on the excess funds. This is shown in *Illustration 6* (below).

Illustration 6



⁴⁰ 42 C.F.R. § 423.279(a) (CMS uses approved bids to calculate a national average monthly bid which determines CMS's subsidy to the plan and a national base beneficiary premium); 42 C.F.R. § 423.286 (The base premium is then used to determine the actual beneficiary premium for each plan. For example, if a plan exceeds the national average bid, its beneficiaries are then responsible for the excess through a higher monthly premium.).

Moreover, these reporting and repayment concepts are subject to the considerations noted above, to the extent PBMs seek to characterize these fees outside the DIR context. While PBMs and Part D plan sponsors are required to report and return all forms of DIR, ***when PBMs and Part D plan sponsors characterize these chargebacks as something other than DIR (i.e., “network rebates,” “pharmacy performance payments,” or “network variable rates”), there is little evidence that the funds are reported and returned to Medicare.*** Thus, in this scenario, it would not just be a case of PBMs and Part D plan sponsors gaming the system to hold onto funds and collect additional interest and profits before returning the funds to CMS; rather, this would be a situation of PBMs and Part D plan sponsors not complying with the overarching reporting and reconciliation requirements incumbent in the Medicare Part D program.

In either event, this model enables PBMs and plan sponsors to create an artificial surplus in order to cushion themselves against uncertain administrative costs, and to derive benefit from that surplus. This costs the overall system more money as a result of these opaque fees, by affording PBMs and plans the benefit of this float at the expense of CMS.

5.2 DIR Fees Unfairly Accelerate the Triggering of Medicare Part D’s “Donut Hole”

Under Medicare Part D, most plans have what is called the “coverage gap.” This coverage gap is essentially a threshold limit on the coverage of prescription drug products by Part D plans. In 2016, this limit was \$3,310.00.⁴¹ When a Medicare enrollee and their Part D plan collectively spend up to the limit on covered prescription drug products in a given year, the enrollee will have entered the coverage gap and will have a higher out-of-pocket or “cost-sharing” amount when paying for prescription drugs. This will continue until another out-of-pocket threshold for catastrophic care is reached, at which point the Medicare program covers 80% of drug costs. In 2016, the threshold for catastrophic care was \$4,850.00.⁴²

When enrollees are in the coverage gap between these two thresholds—referred to as the “donut hole”—they will be charged much higher out-of-pocket costs. In particular, Medicare Part D enrollees in 2016 paid up to 45% of the total cost of brand-name prescription drug products and up to 58% for generic drugs while in the “donut hole.”⁴³ While the Federal government has sought to close this “donut hole” by 2020 with the passage of the Affordable Care Act,⁴⁴ seniors continue to find themselves in the “donut hole” and HHS estimates that more than 25% of all Part D participants who trigger the coverage gap, will discontinue adherence to their prescription drug regimens.⁴⁵ Bad drug adherence translates into poor outcomes, which ultimately costs Medicare money in the form of more enrollee doctor visits and costly, avoidable hospital admissions.

The use of DIR Fees by PBMs (and ultimately by Part D plan sponsors) accelerates the triggering of the Part D “donut hole” by enrollees. This is because the price ***actually paid*** by the Part D plan sponsor after the application of the later-in-time DIR Fee is lower than the amount initially paid out by the Part D plan sponsor (or its PBM) at the point-of-sale and applied to the enrollees’ coverage limits. Consider that a Part D plan sponsor pays the full, negotiated price for a prescription drug to a Part D provider at the point-of-sale for an enrollee, who is in the “initial coverage” stage. However, months later, a DIR Fee is charged

⁴¹ See CMS, *Costs in the Coverage Gap*, <https://www.medicare.gov/part-d/costs/coverage-gap/part-d-coverage-gap.html> (last visited Nov. 2, 2016).

⁴² *Id.*; see also CMS, *Catastrophic Coverage*, <https://www.medicare.gov/part-d/costs/catastrophic-coverage/drug-plan-catastrophic-coverage.html> (last visited Nov. 2, 2016).

⁴³ *Id.*

⁴⁴ See generally CMS, *Closing the Coverage Gap—Medicare Prescription Drugs Are Becoming More Affordable* (January 2015), available at <https://www.medicare.gov/pubs/pdf/11493.pdf> (last visited Nov. 2, 2016).

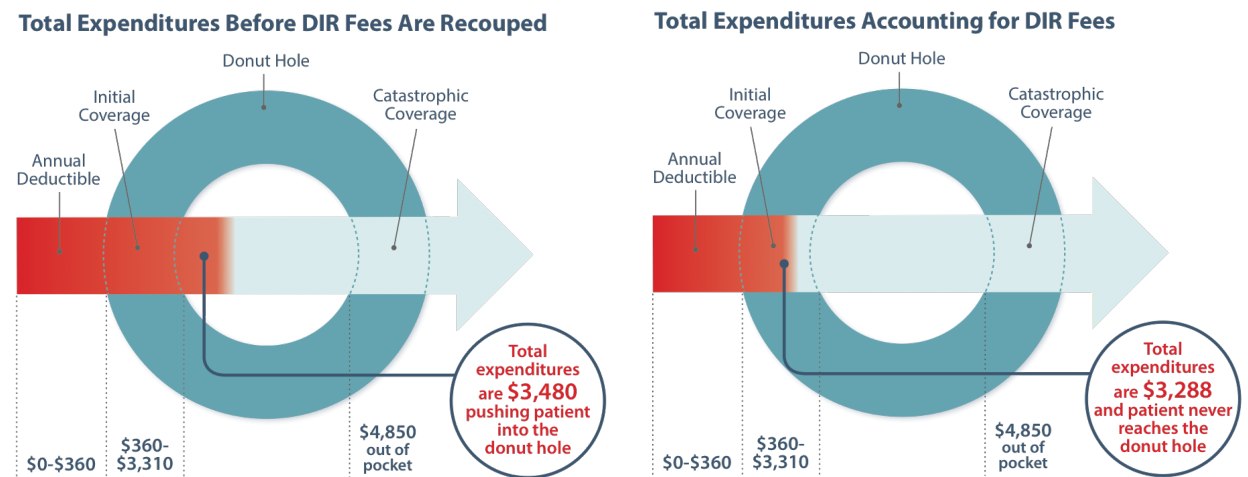
⁴⁵ See Jason Claffey, *Medicare ‘Donut Hole’ Checks in the Mail*, *Foster’s Daily Democrat* (Aug. 14, 2010), <http://archive.is/RKP2u> (last visited Nov. 2, 2016) (“DHHS estimates more than a quarter of Part D participants who hit the donut hole stop following their drug regimen.”)

to and clawed back from the Part D provider such that the **actual cost** to the Part D plan sponsor is reduced by 3% to 9%. Thus, the enrollee may often enter the “donut hole” prematurely because of these inflated, original point-of-sale prices which count towards the enrollee’s total expenditures for the year.

Stated differently, an enrollee will hit the coverage gap sooner if the full amount of the claim reported at the point-of-sale is applied towards the coverage limits, as opposed to the ultimate **actual cost** to the Part D plan sponsor after the PBM claws back any DIR Fees. There is no evidence that the Part D plan sponsors, or their PBMs, account for these post-adjudication DIR Fees to correspondingly reduce the amounts that goes toward the coverage gap. Thus, retroactive PBM-imposed DIR Fees accelerate the triggering of the “donut hole” compared with a scenario where the DIR Fees are accounted for at the point-of-sale.

Consider this scenario: assume a Medicare patient receives a drug with a negotiated price of \$290 per month, as determined at the point-of-sale. After twelve fills at \$290 per fill, the patient will be in the “donut hole” and will be responsible for a higher cost sharing amount for all prescriptions until the patient hits the catastrophic coverage limits. However, if the point-of-sale price had reflected the 5.5% DIR Fee that is subsequently clawed back by the PBM, the patient would have never reached the “donut hole” to begin with. This is shown in *Illustration 7* (below).

Illustration 7



Notably, this acceleration to the “donut hole” is likely not known to the enrollee because PBMs do not tell enrollees about the fees recouped from Pharmacy Providers and given back to the Part D plan sponsor, nor is there any evidence that copayment amounts, previously paid by enrollees, are revised after the later-in-time DIR Fees are taken into account.

This concept was specifically noted in a Fact Sheet issued by CMS on January 19, 2017.⁴⁶ The report analyzed DIR of all kinds that were reported and reconciled back to CMS, including DIR in the form of manufacturer rebates. Even when looking just at these reported DIR (not even including any DIR Fees that may not be reported or returned to CMS by PBMs and Part D plan sponsors), CMS found striking evidence that the imposition of such high DIR “does not reduce the cost of drugs for beneficiaries at the point-of-sale.”⁴⁷

⁴⁶ See CMS, *Medicare Part D – Direct and Indirect Remuneration (DIR)*, (Jan. 19, 2017), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html>.

⁴⁷ *Id.*

DIR Fees could have a significant negative impact on Medicare enrollees' premiums and out-of-pocket costs, which studies have shown can lead to dangerous decreases in patient adherence rates.⁴⁸ Additionally, since many of the metrics for DIR Fees assessed by PBMs and/or Part D plan sponsors are also based on patient adherence rates, the acceleration of the coverage gap unfairly works to frustrate the Pharmacy Provider's ability to better satisfy compliance with such performance metrics.

5.3 PBM-Imposed DIR Fees Shift Costs from Part D Sponsors at the Expense of Increasing the Costs to Medicare for Catastrophic Coverage and Subsidy Payments

Just as DIR Fees contribute to higher out-of-pocket spending by beneficiaries, in the form of higher copayments after being pushed into the “donut hole,” they also increase ultimate costs to Medicare in terms of its catastrophic coverage. Medicare pays the Part D cost-sharing obligations on behalf of millions of low income Medicare beneficiaries, many of whom are dually eligible for Medicare and Medicaid. In addition, Medicare provides catastrophic coverage for individuals who have passed through the “donut hole,” meaning they have had total out-of-pocket expenditures exceeding the catastrophic limit (\$4,850 in 2016).

CMS recently noted the steady but substantial growth of point-of-sale drug costs, combined with rapid increases in DIR, in a Fact Sheet issued by CMS on January 19, 2017.⁴⁹ Noting that such higher upfront drug costs places more of the burden on beneficiary cost-sharing, CMS also explicitly noted that “Medicare’s costs for these beneficiaries also grow. Higher beneficiary cost-sharing also results in the quicker progression of Part D enrollees through the Part D drug benefit phases and potentially leads to higher costs in the catastrophic phase, where Medicare liability is generally around 80 percent.”⁵⁰ Thus, DIR Fees not only increase upfront drug costs and, in turn, beneficiary copayment responsibility, but also result in increased Federal government spending on catastrophic coverage, once initial coverage and the “donut hole” have been satisfied.

More critically, however, the CMS report identified an important phenomenon relating to how such DIR is reported and reconciled to the Part D plans and to Medicare. Importantly, the report asserted that the growing use of DIR has contributed to an important shift in Part D spending distribution from Part D plan sponsors to Medicare itself (and ultimately, the taxpayer). Once patients reach the catastrophic phase, Part D plans are responsible for only 15% of costs (as opposed to 75% in the initial coverage phase and between 35% and 55% in the “donut hole”).⁵¹

Moreover, CMS noted that the largest share of DIR (including rebates and other price concessions) is allocated to reduce Part D plan liability, and not returned to Medicare.⁵² See, *Figure 2* (below). Therefore, the high price-high DIR trend noted by CMS has a disproportionate impact on plan liability. “In other words, Part D sponsors, who control drug spending for Medicare, are, in fact, responsible for only a share of Part D drug spending, and, as a result of the increasing preference for high price-high DIR arrangements, that proportion is shrinking each year.”

Thus, PBMs and Part D plan sponsors ***actually have a financial incentive to increase the upfront costs of drugs***—and higher priced drugs at that—while also increasing the amounts received after the point-

⁴⁸ See Jason Claffey, *Medicare ‘Donut Hole’ Checks in the Mail*, Foster’s Daily Democrat (Aug. 14, 2010) <http://archive.is/RKP2u> (last visited Nov. 2, 2016) (“DHHS estimates more than a quarter of Part D participants who hit the donut hole stop following their drug regimen.”)

⁴⁹ See, CMS, *Medicare Part D – Direct and Indirect Remuneration (DIR)* (Jan. 19, 2017), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html> (last visited Jan. 26, 2017).

⁵⁰ *Id.*

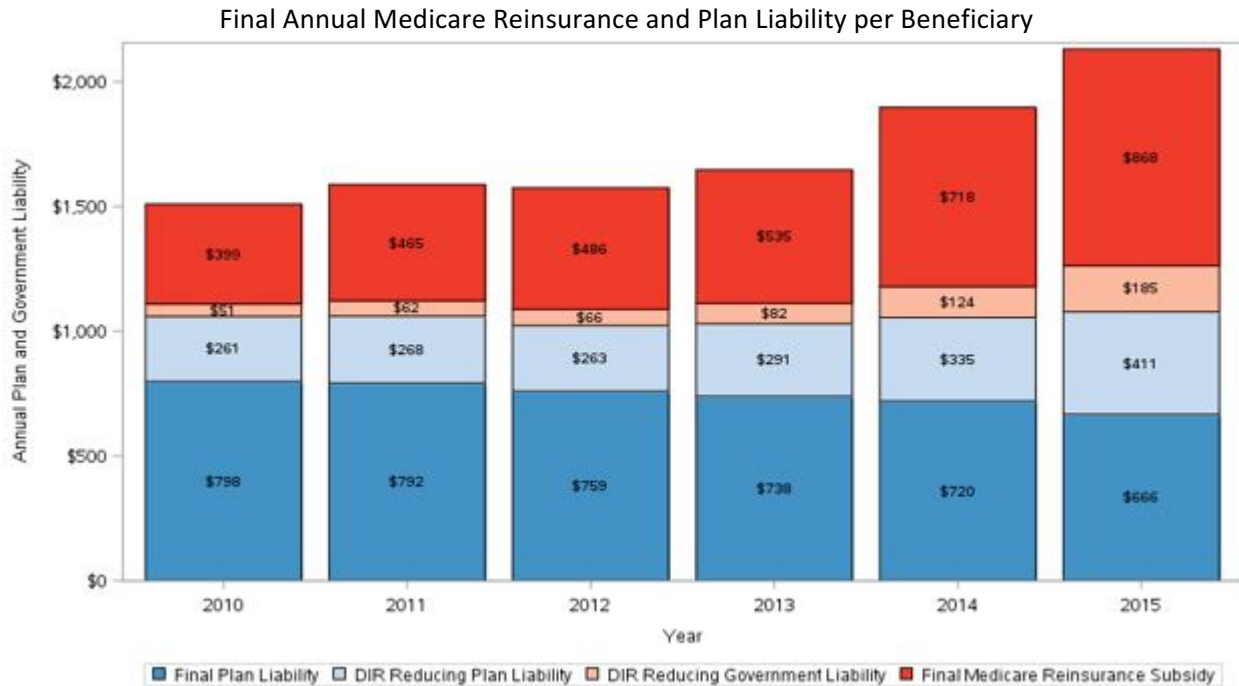
⁵¹ *Id.*

⁵² *Id.*

of-sale through DIR and DIR Fees. This in turn causes a shift of financial liability from PBMs and Part D plan sponsors directly to Medicare and the beneficiaries.

As illustrated by *Figure 2* (below), higher levels of DIR also have resulted in continually higher net costs to the Medicare program, and “ease the financial burden borne by Part D plans essentially by shifting costs to the catastrophic phase of the benefit, where plan liability is limited.”⁵³

*Figure 2*⁵⁴



Perhaps most striking, is the fact that these findings may only be amplified based on the fact that many of the PBM-imposed DIR Fees explored in this White Paper are *in addition to* true DIR. These unreported additional DIR Fees charged back from Pharmacy Providers and not reported or refunded to Medicare only exacerbate the problem. ***Furthermore, because they are not reported to CMS, it is impossible to even estimate the explosion in DIR Fees.***

5.4 PBMs’ Use of DIR Fees Circumvents the Negotiated Price and Results in Unsustainable Reimbursements to Providers

By imposing DIR Fees on Pharmacy Providers retroactively, PBMs are able to reduce the ultimate “negotiated price” between Pharmacy Providers and PBMs through “backdoor,” *post hoc* withholdings. PBMs design these withholdings to provide little quality incentives for Pharmacy Providers, while at the same time, capturing the ever-increasing “spread” differential between the reported “negotiated price” and the “reconciled

⁵³ *Id.*

⁵⁴ See CMS, *Medicare Part D – Direct and Indirect Remuneration (DIR)* (Jan. 19, 2017), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html> (last visited Jan. 26, 2017).

negotiated price.” This phenomenon creates a gap in the plan sponsor’s reporting of costs to Medicare, as DIR Fees are necessarily imposed on Part D providers after the point-of-sale.

In circumventing the adjudicated “negotiated price” through backend recoupments from providers, DIR Fees often allow PBMs to pay Pharmacy Providers well *below* acquisition cost of the drug products even though it appears to CMS and to the Pharmacy Providers themselves at the point-of-sale that negotiated reimbursement rates are otherwise reasonable.

Flat fee DIR Fees can range from \$2.00 to \$7.00 per prescription claim, and percentage-based DIR Fees range from 3% to over 9% of the prescription cost. Because average per-prescription gross profits at retail pharmacies are less than \$15, even seemingly modest flat fee DIR Fees will significantly reduce a Pharmacy Provider’s operating margins, or may even put them under water.⁵⁵ Similarly, in the context of brand name and specialty medications, a pharmacy’s gross margins average 4% to 7%.⁵⁶ Thus, a percentage based DIR Fee of 3% to 9% erodes nearly all of the pharmacy’s operating margin, even putting the Pharmacy Provider significantly underwater. An across the board clawback of 3% to 9% on every claim cannot be sustained.

5.5 DIR Fees Create a Financial Incentive for PBMs to Increase Drug Prices

Percentage-based DIR Fees create a perverse financial incentive for PBMs to drive up the overall cost of medications. The higher the overall drug cost, the higher the percentage-based DIR Fee. This is a concept that has been borne out recently in other recent high-profile cases involving PBM rebates. In those cases—as in the case with DIR Fees—because PBMs receive revenue based on a percentage of overall drug cost, PBMs have a vested financial interest in having the highest list-priced drug dispensed, because their revenue is larger. This practice has been recently exposed with testimony and evidence from various manufacturers—including Mylan⁵⁷, Novo Nordisk⁵⁸ and Amgen⁵⁹—where pharmaceutical manufacturers were compelled to increase the costs of their drugs to keep up with PBMs’ demands for greater rebates and fees, of which it should be noted, PBMs retain a portion for themselves.

Unfortunately, the same phenomenon can occur with percentage-based DIR Fees. That may help explain why PBMs have sought to apply DIR Fees not just to the claims subject to the performance criteria delineated above, but have expanded DIR Fees to high cost specialty medications, which in turn, yield a higher overall fee.

These higher overall drug costs affect beneficiaries and taxpayers alike. Beneficiaries are forced to pay more for drugs than might otherwise be the case because of a higher initial list price. In addition, by spending more money on drugs, beneficiaries may be burdened with additional out-of-pocket expenses, as they are pushed into the “donut hole” faster. This also costs the Medicare program (and ultimately taxpayers) more, as CMS is the ultimate payor for the vast majority of the drug costs for beneficiaries.

⁵⁵ Adam Fein, *Behind Diplomat Pharmacy’s Plunge: A Primer on DIR Fees in Medicare Part D*, Drug Channels (November 8, 2016), available at <http://www.drugchannels.net/2016/11/behind-diplomat-pharmacys-plunge-primer.html> (last visited on Dec. 2, 2016).

⁵⁶ *Id.*

⁵⁷ Linette Lopez, *These companies you’ve never heard of are about to incite another massive drug price outrage*, Business Insider (September 12, 2016), available at <http://www.businessinsider.com/scrutiny-express-scripts-pbms-drug-price-fury-2016-9> (last accessed January 26, 2017).

⁵⁸ Denise Roland and Peter Loftus, *Insulin Prices Soar While Drugmakers’ Share Stays Flat*, Wall Street Journal (October 7, 2016), available at <http://www.wsj.com/articles/insulin-prices-soar-while-drugmakers-share-stays-flat-1475876764> (last accessed January 26, 2017).

⁵⁹ Joseph Walker, *Drugmakers Point Finger at Middlemen for Rising Drug Prices*, Wall Street Journal (October 3, 2016), available at <http://www.wsj.com/articles/drugmakers-point-finger-at-middlemen-for-rising-drug-prices-1475443336> (last accessed January 26, 2017).

Exploding DIR and DIR Fees also are fueling prices of specialty drugs, such as oral cancer therapies. Increasing rebates flowing to PBMs and plan sponsors force pharmaceutical manufacturers to increase prices for their drugs to compensate for a large percentage extracted by PBMs and plan sponsors. A study by the Berkeley Research Group reported, “that brand manufacturers realize 39 percent of initial gross drug expenditures. Of the remainder, 42 percent is realized by non-manufacturer entities, including amounts realized by participants in the supply chain (22 percent) and transferred by manufacturers to other stakeholders through retrospective rebates, discounts, and fees (20 percent).”⁶⁰ Both DIR and DIR Fees have become an accelerant that are fueling higher drug prices.

5.6 PBMs Utilize DIR Fees to Undermine “Maximum Allowable Cost” Transparency Laws

DIR Fees also work to afford PBMs a great degree of latitude in manipulating the reimbursement amounts paid to participating Pharmacy Providers and to circumvent certain legal and regulatory safeguards aimed at increasing transparency and fairness in pricing. Over the past several years, PBMs have begun to develop the concept of “Maximum Allowable Cost” (“MAC”) as an alternative drug reimbursement benchmark. Virtually all PBMs have created some form of “MAC lists,” which in essence is a “payer or PBM-generated list of products that includes the upper limit or maximum amount that a plan will pay for generic drugs and brand name drugs that have generic versions available.”⁶¹ The stated intention of MAC pricing was to encourage pharmacies to actively seek out lower cost sources for multisource drug products, with the aim of lowering overall prescription drug spending.⁶²

However, PBMs have utilized MAC pricing lists in opaque and abusive ways, which inure only to their benefit and serve to increase the “spread” between amounts PBMs receive from plan sponsors and amounts PBMs reimburse to Pharmacy Providers.⁶³ By way of example, PBMs set purposefully low MAC pharmacy reimbursement rates that do not reflect the contemporaneous fluctuations in the industry benchmark “average wholesale price” or “wholesale acquisition cost” for each drug product.⁶⁴ At the same time, PBMs will circulate separate MAC pricing lists for the same drug transactions which actually have higher MAC rates charged to their plan sponsor clients who ultimately pay for prescription drugs based on an entirely different MAC list than the ones given to Pharmacy Providers.⁶⁵ This practice results in a larger “spread” for PBMs as they utilize MAC lists to widen the gap of payments made to the Pharmacy Provider and received by the ultimate payor.⁶⁶ Because PBMs closely guard their MAC pricing list data and methodologies as “proprietary” business information, the nature and extent to which PBMs are deriving profits due to the lack of price transparency cannot be reasonably monitored and remains generally unknown to taxpayers in connection with the Medicare program.

Nevertheless, state legislatures have caught on to these schemes and have recognized that PBMs’ conduct needs to be better understood and more heavily regulated by state and Federal governments to ensure pricing transparency. To that end, several states have enacted various laws seeking to regulate MAC pricing

⁶⁰ Aaron Vandervelde and Eleanor Blalock, *The Pharmaceutical Supply Chain: Gross Drug Expenditures Realized by Stakeholders*, Berkeley Research Group 1 (Jan. 2017), available at http://www.thinkbrg.com/media/publication/863_Vandervelde_PhRMA-January-2017_WEB-FINAL.pdf.

⁶¹ National Community Pharmacists Association, *The Need for Model Language Regarding PBM “Maximum Allowable Cost” (MAC) Reimbursement*, http://www.ncpanet.org/pdf/leg/feb12/mac_onepagerfinal.pdf (last visited Oct. 26, 2016).

⁶² See, e.g., Express Scripts, *MAC Pricing Incent More Affordable RX* (Feb. 24, 2016), <https://lab.express-scripts.com/lab/insights/drug-options/mac-pricing-incent-more-affordable-rx> (last visited Jan. 26, 2017).

⁶³ See, e.g., Linda Cahn, *Don’t Get Caught by PBMs’ MAC Mousetraps*, Managed Care Magazine (Sept. 2008), available at <http://www.managedcaremag.com/archives/2008/9/don%E2%80%99t-get-caught-pbms%E2%80%99-mac-mousetraps>.

⁶⁴ National Community Pharmacists Association, *The Need for Model Language Regarding PBM “Maximum Allowable Cost” (MAC) Reimbursement*, http://www.ncpanet.org/pdf/leg/feb12/mac_onepagerfinal.pdf (last visited Oct. 26, 2016).

⁶⁵ *Id.*

⁶⁶ *Id.*

and to control PBMs' conduct in maintaining accurate and transparent MAC pricing lists. For example, Arkansas recently passed MAC transparency laws as contained in Ark. Code Ann. §§ 17-92-507, *et seq.*, which generally provides that a PBM must: (1) provide access to its MAC list upon request; (2) update its MAC list on a weekly basis to reflect significant increases in acquisition costs; (3) provide a reasonable administrative process, including an appeals procedure for providers to challenge unreasonable reimbursements such as those below acquisition cost; and (4) provide no less reimbursement to providers than it provides to its own "affiliated" pharmacies, among other things.⁶⁷ In California and Ohio, MAC pricing laws were also enacted within the past year which prohibit pricing below acquisition cost and grant rights to providers to appeal unreasonable MAC pricing rates, among other things.⁶⁸

Although states are enacting laws to protect the rights of Pharmacy Providers to challenge unreasonable reimbursement rates under the MAC pricing regime in place for prescription drug benefits, PBMs continually circumvent and refuse to adhere to these laws.⁶⁹ For example, the validity and applicability of Arkansas' MAC pricing statute contained Ark. Code Ann. §§ 17-92-507 is currently being challenged in Federal court by the largest PBM trade organization, the Pharmaceutical Care Management Association ("PCMA"), arguing, among other things, that the legislation is inconsistent with the MMA.⁷⁰

Despite the relentless challenge from the PBM industry, Medicare Part D also contains a more general, but similar, requirement to MAC transparency laws, providing that "[i]f the PDP sponsor of a prescription drug plan uses a standard for reimbursement of pharmacies based on the cost of a drug, each contract entered into with such sponsor under [Part D] with respect to the plan shall provide that the sponsor shall update such standard not less frequently than once every 7 days, beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug."⁷¹ Despite this requirement, it is proving difficult for CMS to enforce without defining or providing guidance as to what constitutes the accurate reflection of "the market price of acquiring" prescription drug products.⁷² DIR Fees ostensibly allow PBMs to skirt MAC transparency laws because the amounts PBMs recover from Pharmacy Providers are arguably not characterized as a drug cost, but rather as a performance metric.

As DIR Fees become more prevalent in both Medicare and commercial networks, the threats to MAC transparency laws become more pronounced. Ultimately, these trends highlight the need for national reform on the Federal level to ensure not only MAC transparency, but also a more accurate and equitable system of reimbursement, creating clarity and fairness for all stakeholders in the Medicare framework.

6 Washington's Response to Limit or Otherwise Prohibit DIR Fees

The significant impact of both DIR and DIR Fees on Pharmacy Providers across the United States is beginning to be understood by the Federal government. Indeed, both CMS and Congress have made forays

⁶⁷ See generally Ark. Code Ann. §§ 17-92-507, *et seq.*

⁶⁸ See generally Cal. Bus. & Prof. Code §§ 4440 and Ohio Rev. Code Ann. §§ 3959.111, *et seq.*

⁶⁹ States have recently found significant difficulty in crafting MAC pricing laws and regulations which do not trigger various pre-emption clauses contained in the Social Security Act and the Employee Retirement Income Security Act of 1974 ("ERISA"). Vermont, who had enacted some of the broadest and robust health care laws (along with approximately 20 other States) requiring the reporting of reimbursement data by all payers to be compiled into an "all-inclusive health care database", recently had such laws severely limited by the United States Supreme Court in *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936 (2016). In *Gobeille*, the Court held that Vermont's reporting laws contained in Vt. Stat. Ann. tit. 18, §§ 9410, *et seq.*, were pre-empted by ERISA as applied to employee benefit plans.

⁷⁰ See *Pharm. Care Mgmt. Ass'n v. Rutledge*, Case No. 4:15-CV-00510 (BSM), 2015 WL 11108983 (E.D. Ark. Nov. 25, 2015).

⁷¹ 42 U.S.C. § 1395w-112(b)(6).

⁷² See generally National Community Pharmacists Association, *Letter to CMS regarding PBM Non-Compliance of Part D Plans/PBMs with Federal Statutory Requirement Regarding Use of Drug Pricing Standards* (April 1, 2016), available at <http://www.ncpa.co/pdf/mac-letter-cms-2016.pdf>.

into the space, each issuing commentary and/or proposed measures to specifically address or limit DIR Fees, and such measures are in their nascent stages.

6.1 CMS Introduces Proposed Guidance to Limit the Applicability of DIR

One of the major problems with the concept of DIR, including particularly the PBM-imposed DIR Fees charged back against providers, is that they create immense confusion in what constitutes the actual “negotiated price” between PBMs and Pharmacy Providers. In 2014, CMS responded to criticism that pricing terms for prescription drugs in the Medicare Part D arena were convoluted and misleading, and proposed guidance to further define a Part D plan sponsor’s “negotiated price.”

Under applicable CMS regulations, a Part D plan sponsor’s “negotiated price” is the amount that a Pharmacy Provider actually receives and retains as payment in connection with a Part D claim.⁷³ Price concessions, which are generally concessions made by participating Pharmacy Providers back to Part D plan sponsors or their PBMs, are often used in determining a Part D plan sponsor’s “negotiated price.”⁷⁴ Negotiated prices are reported to CMS by Part D plan sponsors (or their PBM agents) by way of Prescription Drug Event (“PDE”) submissions. Over the past few years, CMS has had concerns that Part D plan sponsors were reporting certain price concessions as DIR Fees (which are excluded from the Part D plan sponsor’s “negotiated price”), rather than as price concessions (which are included in the Part D plan sponsor’s “negotiated price”).⁷⁵ This is critical because the negotiated price identifies to the Pharmacy Provider what they will ultimately receive for the prescription drug claim. Moreover, with some Part D plan sponsors including price concessions as DIR and others reporting price concessions as part of their “negotiated price,” CMS was concerned that PDE data was inconsistent across the Part D program and could lead to unlevelled playing fields in bidding and cost reporting.⁷⁶

As a result, in May 2014, CMS revised the definition of “negotiated price.” Effective in 2016, “negotiated price” was defined as “the amount a Pharmacy Provider would receive, in total, for a particular drug from a Part D sponsor or other intermediary contracting organization, which was:

- (1) inclusive of all price concessions from network pharmacies, except those contingent price concessions that cannot be reasonably determined at the point-of-sale;
- (2) Inclusive of any dispensing fees; but
- (3) excluded additional contingent amounts, such as incentive fees, if these amounts increase prices and cannot be reasonably determined at the point-of-sale; and
- (4) not rebated back to the Part D plan sponsor (or its agent) in full or in part⁷⁷

Therefore, Part D plan sponsors would only be able to utilize DIR for price concessions that could not reasonably be determined at the point-of-sale. In CMS’s Final Rule, CMS stated that it would provide guidance as to which types of pharmacy price concessions could be reasonably determined at the point-of-sale.

Thereafter, on September 29, 2014, CMS released draft guidance which sought to clarify the types of pharmacy price concessions that could be reasonably determined at the point-of-sale—again, the goal being to increase clarity and predictability for Pharmacy Providers to know what they would be paid when submitting a

⁷³ 42 C.F.R. § 100

⁷⁴ *Id.*

⁷⁵ Cheri Rice, Direct and Indirect Remuneration (DIR) and Pharmacy Price Concessions, Centers for Medicare and Medicaid Services, September 29, 2014.

⁷⁶ *Id.*

⁷⁷ 42 C.F.R. § 423.100.

claim and accepting the adjudicated price.⁷⁸ In its guidance, CMS sought to apply an inclusive, expansive standard to the “reasonably determined at point-of-sale” standard.⁷⁹ More specifically, CMS sought to establish that any price concession that could be ***reasonably approximated*** at the point-of-sale should not be included as DIR, but instead, as part of the negotiated price.⁸⁰ Again, the goal being to address the growing problem of Pharmacy Providers having no idea what they would ultimately be paid for certain prescription drug claims, in addition to the impact on Medicare and beneficiary spending.

CMS provided examples of fees that should be considered part of the negotiated price, and noted that a basic rate to the Pharmacy Provider at the point-of-sale, with subsequent enhanced payment rates based on different factors, such as generic utilization, pharmacy market share, pharmacy network size, or other metric is considered a price concession that ***could*** be reasonably determined at the point-of-sale, and thus, should be disclosed to the provider at the point-of-sale.⁸¹ This would mean that such flat fee and many of the percentage-based DIR Fees would need to be included in the negotiated price, not treated as separate. This would ensure that the Pharmacy Providers knew exactly what they would be paid and would enable them to determine ***at the point-of-sale***, whether such amounts were below acquisition cost. This would also pass along the benefits to the patient and the Medicare Part D program, avoiding the premature entry into the “donut hole.”

Making a clear effort to increase transparency in prescription drug pricing and to close loopholes in the definition of “negotiated price” that had been exploited by the industry, CMS explained that “if the contingent pricing can be ***reasonably approximated using recent experience***, then we believe the total price, inclusive of the enhancements, should be reported in the negotiated price of the Part D drug.”⁸² Further, CMS stated that if a Part D sponsor reported a particular price concession as DIR to CMS, the Part D sponsor would be required to provide an explanation as to why the price concession could not be reasonably determined at the point-of-sale.⁸³ Again, the result of this clarification would be that PBMs and Part D plan sponsors would be pressured to more accurately state the true negotiated price at the point-of-sale, and would be pushed away from utilizing murky and opaque after-the-fact DIR Fees (such as those described above). This process would also ensure a more accurate bidding process.

In its memorandum, CMS indicated that the revision to the definition of “negotiated price” would be effective January 1, 2016, and welcomed members of the industry to submit comments addressing the draft guidance.⁸⁴

6.2 CMS Fails to Implement its Proposed Guidance

After issuing its proposed guidance on DIR Fees CMS permitted interested parties to provide comments. PBMs, Part D plan sponsors, and associated lobbyists aggressively challenged CMS’s proposed guidance. For instance, the Council for Citizens Against Government Waste (an alter ego for the PBM lobby⁸⁵) issued an aggressive letter to CMS Administrator Marilyn Tavenner dated October 24, 2014, which alleged that CMS’s proposed guidance violated numerous Federal laws, including the “non-interference” clause contained

⁷⁸ Cheri Rice, Direct and Indirect Remuneration (DIR) and Pharmacy Price Concessions, Centers for Medicare and Medicaid Services, September 29, 2014.

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² *Id.*

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ See, Bill Adair, *For Price, Watchdog Will Be an Advocate*, Tampa Bay Times (April 2, 2006), available at http://www.sptimes.com/2006/04/02/Worldandnation/For_price_watchdog_w.shtml (last visited Dec. 2, 2016); see also, B. Douglas Hoey, *Medicare’s Right to Tackle Part D Slush Fund for PBMs*, Morning Consult (November 4, 2014), available at <https://morningconsult.com/opinions/medicares-right-tackle-part-d-slush-fund-pbms/> (last visited Dec. 2, 2016).

in the MMA and the Federal Administrative Procedure Act.⁸⁶ After reviewing comments submitted by industry, CMS, by way of a memorandum dated November 5, 2014, backed off of its earlier proposal to revise the definition of “negotiated price” and ultimately determined that it would not, at that time, adopt any guidance proposed in its September 29, 2014, memorandum.⁸⁷

In response, a number of U.S. Senators and Representatives have urged CMS to adopt its proposed guidance. By way of letter dated October 12, 2015, several Representatives submitted a letter to CMS urging it to finalize the proposed guidance, stating that “Some Part D plan sponsors have manipulated how and when to report certain price concessions” and that “such manipulation has resulted in an unfair playing field...”⁸⁸ The letter particularly focused on the effect DIR Fees had on data provided in the Medicare Plan Finder and noted that DIR Fees may result in “Medicare beneficiaries ... relying on inaccurate data when using the Medicare Plan Finder website to compare the cost of filling a prescription among competing pharmacies and drug plans.”

Likewise, by way of letter dated June 15, 2016, several Senators submitted a similar letter to CMS urging the adoption of the proposed guidance, arguing that “DIR fees prevent the pharmacy from knowing the true reimbursement amount of drugs being dispensed at the point of sale, and in some cases DIR fees have resulted in preferred pharmacy prices appearing lower than they actually are.”⁸⁹

Despite these requests and clear concern by Congress, CMS has not issued any further guidance relating to the interplay between DIR Fees and the definition of “negotiated price.” In the meantime, Pharmacy Providers continue to face mounting DIR Fees assessed long after the point-of-sale.

6.3 Proposed Legislation Addressing DIR Fees

Based on the increasing impact of DIR Fees on consumers and providers, on September 8, 2016, the United States House of Representatives introduced the “Improving Transparency and Accuracy in Medicare Part D Spending Act” (H.R. 5951) and a companion bill in the Senate (S. 3308), which aim to prohibit the use of retroactive DIR Fees by Medicare Part D plan sponsors and PBMs. Together, the proposed legislation would amend the Social Security Act by adding a section entitled “Prohibiting Retroactive Reductions in Payments on Clean Claims.” The proposed legislation would effectively prohibit Part D plan sponsors and their agents (such as PBMs) from retroactively reducing payment on clean claims altogether—essentially seeking to do away with after-the-fact PBM clawbacks under the guise of DIR Fees. Critically, the proposed legislation further serves to clarify longstanding congressional intent that DIR was never meant to encompass after-the-fact payments from providers to PBMs under the aegis of performance metrics, but instead, fully contemplated retroactive payment **increases** to providers, leaving such contractual incentive payments intact.

It is evident that H.R. 5951 and S. 3308 would have a significant effect on PBM-imposed DIR Fees; however, both bills expired with the end of the 114th Congress in 2016. As of the date of this publication, there are indications that similar bills will be re-introduced in the 115th Congress.

Despite the uncertainty with the measures pending from CMS and Congress, various ancillary laws and regulations exist casting doubt on retroactive PBM-imposed DIR Fees and standing for the conclusion that these fees remain a violation of the core intent of Federal law.

⁸⁶ CCAGW, *Letter to CMS Admin. Marilyn Tavenner Regarding Part D Draft Guidance*, (October 24, 2014), available at <http://www.ccagw.org/legislative-affairs/agency-comments/ccagw-sends-letter-cms-admin-marilyn-tavenner-regarding-part-d>.

⁸⁷ Cheri Rice, *Direct and Indirect Remuneration and Pharmacy Price Concessions*, Centers for Medicare and Medicaid Services, November 5, 2014.

⁸⁸ Rep. Scott, A., et al., *Letter from 30 U.S. Representatives to Acting Administrator of the Department of Health and Human Services, Andy Slavitt*, NCPA (June 14, 2016), available at <http://www.ncpa.co/pdf/cms-dir-fees-loeb-sack-carter-welch.pdf> (last accessed January 26, 2017).

⁸⁹ Sen. Moore Capito, S., et al., *Letter from 16 U.S. Senators to Acting Administrator of the Department of Health and Human Services, Andy Slavitt*, NCPA (June 15, 2016), available at <http://www.ncpa.co/pdf/senate-dir-letter-061516.pdf> (last accessed January 26, 2017).

6.4 CMS Issues Report on Impact of Legitimate DIR on Medicare and Beneficiary Spending

With the national debate continuing regarding not just DIR Fees clawed back from Pharmacy Providers, but also the sharply rising costs of prescription drugs, on January 19, 2017, CMS released a Fact Sheet entitled “Medicare Part D – Direct and Indirect Remuneration (DIR).” The report examined the growing trends in after-the-fact compensation that is paid out or received by a PBM or Part D plan sponsor outside of the point-of-sale, which serves to change the final cost of the drug for the payer or the price paid to the pharmacy for the drug. As noted in Sections 5.2 and 5.3 above, the report issued stark findings relating to the effects these DIR arrangements are having on increasing beneficiary out-of-pocket spending, as well as, overall Medicare financial liability. However, nowhere in the report did CMS take any position on the legality or propriety of this phenomenon. Rather, the report simply elucidated the impact of this murky and questionable practice being perpetrated by the industry.

What’s more, CMS’s report focused primarily on true, traditional DIR that is reported and reconciled to Medicare (i.e., manufacturer rebates), and did not connote an overall understanding of what many PBMs are doing in terms of charging 3% to 9% “performance” based DIR Fees on all claims dispensed by a Pharmacy Provider. While the Report suggests, in but one sentence, that DIR could encompass “concessions paid by pharmacies,” it is contained in the opening summary paragraph with no supporting graphs or citations, and contains no reference to the murky and ambiguous terms (such as, “network variable rates”) used by PBMs to shroud their DIR Fee chargebacks against Pharmacy Providers.

7 DIR Fees Violate Federal Law

The PBM industry’s use of DIR Fees to retroactively clawback monies from providers is wholly impermissible under Federal law, both in terms of establishing an accurate negotiated price and in terms of the methodology employed by PBMs in calculating such fees (particularly as related to performance based fees). Indeed, not only are PBMs and Part D plan sponsors exceeding the authority provided to them by Congress, HHS, and CMS, but such PBM-imposed DIR Fees are blatant violations of a variety of Federal laws, including the Any Willing Provider law as well as the Federal Prompt Pay law.

7.1 There Is No Statute, Regulation, or Guidance that Expressly Permits PBMs to Clawback DIR Fees from Pharmacy Providers Based on Performance

As noted above, statutory and regulatory reference to DIR and/or DIR Fees is exceedingly scant. In fact, there is absolutely no reference to “direct and indirect remuneration” or “DIR” in the MMA except for 42 U.S.C. § 1395w-102(d) in its definition of “negotiated prices.” In that section, the statute states only that “negotiated prices shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered Part D drugs, and include any dispensing fees for such drugs.” While “direct or indirect remuneration” is not specifically defined in the statute, the overarching legislative interpretation of DIR suggests that it is intended to encompass payments received from manufacturers, suggesting that such DIR be made available to the Part D plan sponsor or organization “by a manufacturer.”⁹⁰

⁹⁰ 42 U.S.C. § 1395w-102(d)(2). It should also be noted that even outside the Medicare Part D context, to the extent DIR is addressed in Federal law, it connotes primarily remuneration received from pharmaceutical manufacturers. *See, e.g.*, 42 U.S.C. § 1395w-141 and 42 U.S.C. § 18002.

Importantly, nowhere in this section, or the whole of the MMA, does the law contemplate DIR Fees to be retracted from a Pharmacy Provider and certainly nowhere do the statutes expressly permit Part D plan sponsors or PBMs to impose a 3% to 9% per claim DIR Fee based on “performance.” Rather, the overwhelming context of the MMA militates against after-the-fact recoupments from Pharmacy Providers.

Likewise, Federal regulations are equally devoid of any suggestion that PBMs should be entitled to impose retroactive “fees” on Pharmacy Providers, especially after the point-of-sale. In defining “actually paid,” 42 C.F.R. § 423.308 provides clarification on DIR, stating that they include “discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers” from any source, including manufacturers, pharmacies, enrollees, or any other person. Here, the retroactive performance-based DIR Fees assessed by PBMs do not fall into those enumerated categories of contemplated remuneration. Nowhere in the regulations does it suggest that a PBM may assess after-the-fact fees against a provider, and nowhere in the regulation does it give authority for PBMs to measure DIR Fees based on “performance.”

Finally, there is nothing in any existing guidance from CMS that would permit PBMs to impose DIR Fees in the manner currently being carried out. As noted above, CMS has proposed guidance aimed at clarifying the definition of terms such as “negotiated price” or “actually paid” in such a way that would require any such after-the-fact fees to be included in the price adjudicated at the point-of-sale. What CMS wanted was to ensure transparency and clarity on the part of the provider and also to avoid Medicare paying more up front based on a negotiated price at the point-of-sale that does not contemplate applicable DIR Fees.

While CMS’s proposed guidance has not been finalized, CMS has put out a *Final Medicare Part D DIR Reporting Requirements for 2015* memorandum dated May 31, 2016.⁹¹ This memorandum aimed to provide guidance to Part D plan sponsors regarding DIR reporting requirements for the contract year 2015 (2015 DIR Fees were reported in 2016).⁹² The memorandum listed 11 different categories of DIR that Part D plan sponsors were required to be used when reporting DIR to CMS. Many of the categories addressed different types of rebates received from manufacturers or other risk-sharing arrangements.

Only 2 categories were directly applicable to DIR Fees charged back or paid out to Pharmacy Providers by PBMs. Specifically, DIR #8 (“Generic Dispensing Incentive Payments and Adjustments”) and DIR #9 (“Other Pharmacy Incentive Payments and Adjustments”) are the only categories that could remotely cover performance-based DIR Fees. Importantly, neither of these categories give PBMs the ability to extract performance-based DIR Fees amounting to 3% to 9% of the pharmacy’s gross reimbursement. With respect to DIR #8, this category is intended to account for “any sum received from or paid to a pharmacy after the point-of-sale based on the pharmacy’s performance in encouraging the dispensing of generic drugs.” While this could theoretically give rise to PBMs recouping DIR Fees from pharmacies based on generic dispensing rates, importantly, this type of fee is contemplated as being limited to a portion of the “prospective dispensing fee” the PBM pays out to the pharmacy per claim. Medicare dispensing fees are usually between \$0.00 and \$0.50. Thus, CMS contemplated that DIR Fees would be a portion of less than \$0.50. This guidance does *not* contemplate a PBM recouping potentially hundreds of dollars per claim based on a percentage of the overall reimbursement amount.

Likewise, with respect to DIR #9 contained in the CMS guidance, this category addresses other pharmacy incentive payments and adjustments. While this category discusses certain qualitative measures, it contemplates such after-the-fact *incentive payments* to be awarded *to pharmacies* based on “achieving”

⁹¹ CMS, *Final Medicare Part D DIR Reporting Requirements for 2015*, 4 (May 31, 2016), available at http://www.npaonline.org/sites/default/files/PDFs/Final%20Medicare%20Part%20D%20DIR%20Reporting%20Requirements%20for%202015_1.pdf.

⁹² *Id.*

certain performance measures. Nowhere does it contemplate a PBM **taking back** 3% to 9% of gross reimbursement from pharmacies based on performance. In fact, the only reference to DIR Fees going from the pharmacy to the PBM, refer to “per-claim administrative fees collected or paid by a Part D sponsor or PBM from or to pharmacies after the point-of- sale,” such as preferred pharmacy fees, fees related to extended supply rates, etc. Again, none of these fees contemplate percentage-based DIR Fees assessed against all of the providers’ claims. Moreover, in releasing its January 19th Fact Sheet on DIR, nowhere did CMS sanction 3% to 9% recoupments against Pharmacy Providers under the aegis of DIR Fees. Other than a four-word passing reference to “concessions paid by pharmacies,” it is almost as if CMS is not aware that certain PBMs are charging up to a 9% DIR Fee against the gross revenues of all claims dispensed by Pharmacy Providers.

Thus, there is simply no support in any statute, regulation, rule, or guidance giving PBMs the right to assess a 3% to 9% per claim clawback under the aegis of DIR Fees. PBMs and Part D plan sponsors are completely without legal or regulatory basis to act in this fashion. This is important when assessed against the backdrop of the Administrative Procedure Act and the authority for regulatory agencies and their agents to take action.

7.2 PBMs Are Exceeding Their Administrative Authority Under Part D in Imposing DIR Fees

As noted above, the primary justification many plan administrators give to impose DIR Fees on Medicare Part D providers is that Part D plan sponsors are held responsible for their Quality Star Ratings by the government and consumers, and therefore, their respective participating providers should also share in such responsibilities. While payments for physicians’ medical services under Medicare are just now starting to be tied to various “value based” models, such as the Merit-based Incentive Payment System (“MIPS”) and Alternative Payment Models (“APMs”), to adopt a new standard for reimbursement of physicians under the Medicare Access and CHIP Reauthorization Act (“MACRA”), there is simply no legislative corollary to MACRA within the prescription drug benefit space under Part D. Nor has HHS promulgated any regulations or guidance which would require Part D providers to be reimbursed on a “value based” model in the prescription drug context pursuant to express statutory mandate. Without such legislation, congressional intent is clear that the existing provider reimbursement model in place for coverage by governmental prescription drug programs is to remain wholly intact as the standard for reimbursement of Part D providers.

Imposition of DIR Fees on providers is beyond the power of PBMs. Congress created HHS and imbued it with certain, but limited, regulatory authority.⁹³ CMS is the agency within HHS charged with administering the Medicare program, including Medicare Part D.⁹⁴ In the absence of direct legislation from Congress, rules, requirements, and regulations pertaining to Medicare, must be promulgated pursuant to the Secretary of HHS’s rulemaking authority under 42 U.S.C. §§ 1395hh, *et seq.* Without appropriate rule making, PBM-imposed DIR Fees do not have a proper basis in law.⁹⁵ Federal law provides that “[n]o rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard governing . . . the payment for services . . . under this subchapter shall take effect unless it is promulgated by the Secretary by regulation . . .”⁹⁶ While HHS’s rulemaking authority is construed by some courts as being generally broad, it is nevertheless limited by statutes contained in Title 42, Chapter 7, Subchapter XVIII—which encompasses the body of laws enacted by Congress governing the Medicare and Medicaid programs, including the MMA. Additionally, HHS may not violate the Administrative Procedure Act in taking an “agency action” with respect

⁹³ See generally 5 U.S.C. App., *et seq.*; see also 42 U.S.C. §§ 1395hh, *et seq.*

⁹⁴ See generally Medicare Part D, as codified 42 U.S.C. §§ 1395w-101-154, *et seq.*

⁹⁵ See generally 42 U.S.C. § 1395hh(a), *et seq.* (providing, in pertinent part, the “Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter . . .”).

⁹⁶ 42 U.S.C. § 1395hh(a)(2).

to the promulgation of such rules, requirements, and regulations.⁹⁷ DIR Fees, as implemented by the PBMs, violate the Administrative Procedure Act.

As noted above, CMS contracts with Part D plan sponsors to administer enrollees' prescription drug benefits under Medicare Part D.⁹⁸ Part D plan sponsors, likewise, delegate these administrative obligations through contracting with PBMs or "first tier entities."⁹⁹ In turn, PBMs contract with Pharmacy Providers, or "downstream entities," to create the Medicare Part D infrastructure necessary to fulfill the legislative intent of Congress to provide prescription drug coverage to Medicare enrollees.¹⁰⁰ With each successive entity's involvement in the Medicare Part D program, the legal rights and duties are constrained through contractual agreements, all of which must be "acceptable to CMS."¹⁰¹ By law, Part D plan sponsors and their administrators, such as PBMs, must establish reasonable contract terms as between Part D plan sponsors, first tier, downstream, and related entities which "comply with all applicable Federal laws, regulations, and CMS instructions."¹⁰² PBMs are contracted administrators of Medicare Part D and virtual agents clothed in the regulatory authority of the government. ***By unilaterally imposing performance-based DIR Fees on Pharmacy Providers, PBMs have created an unreasonable, non-negotiable contract term which is necessarily "a rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard governing . . . the payment for services" for Part D providers.***¹⁰³ ***This is the very type of administrative action that requires appropriate rule making and, if not, may properly be challenged in court.***¹⁰⁴

Put simply, Medicare Part D pharmacy benefit management is ***limited*** by legislative and regulatory oversight as PBMs administering pharmacy benefits for Medicare Part D enrollees can do only that which has been duly authorized by Congress and HHS. Although HHS may delegate its regulatory authority to promulgate such rules and standards for providers under Part D to CMS, CMS may in turn delegate some of its limited regulatory authority to private administrators. However, this does not absolve HHS of accountability for the promulgation of such rules, particularly where—as is certainly the case with Part D plan sponsors and PBMs who own and operate their own competing network pharmacies—such administrators are also "active market participants."¹⁰⁵ Therefore, various laws work to check HHS's ability to "abandon markets to the unsupervised control of active market participants," and to the extent that such laws are violated by such participants exercising regulatory authority on HHS's behalf, HHS may nevertheless be held accountable for the actions of such participants.¹⁰⁶

⁹⁷ See generally 5 U.S.C. §§ 551 through 559, *et seq.*

⁹⁸ See 42 U.S.C. § 1395w-112, *et seq.* (providing the statutory requirements governing CMS' contracts with prescription drug plan ["PDP"] sponsors).

⁹⁹ See 42 C.F.R. § 423.4 ("First tier entity means any party that enters into a written arrangement, ***acceptable to CMS***, with a Part D plan sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D.") (emphasis added).

¹⁰⁰ See *id.* ("Downstream entity means any party that enters into a written arrangement, ***acceptable to CMS***, with persons or entities involved with the Part D benefit, below the level of the arrangement between a Part D plan sponsor (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.") (emphasis added).

¹⁰¹ See, e.g., 42 C.F.R. §§ 423.505, *et seq.* (providing regulatory requirements for Part D contract provisions).

¹⁰² See 42 C.F.R. 423.505(i)(3)(iv)

¹⁰³ See, e.g., 42 C.F.R. §§ 423.1976, 423.1990, and 423.2136 (providing judicial review of agency action under Medicare Part D); see also 5 U.S.C. §§ 701 through 706, *et seq.* (providing for judicial review of agency action and setting forth remedies under the Administrative Procedure Act).

¹⁰⁴ See, e.g., 42 C.F.R. §§ 423.1976, 423.1990, and 423.2136 (providing judicial review of agency action under Medicare Part D); see also 5 U.S.C. §§ 701 through 706, *et seq.* (providing for judicial review of agency action and setting forth remedies under the Administrative Procedure Act).

¹⁰⁵ See, e.g., *N. Carolina State Bd. of Dental Examiners v. F.T.C.*, 135 S. Ct. 1101, 1117 (2015) (holding that if the government "wants to rely on active market participants as regulators, it must provide active supervision" in order to be immune from liability).

¹⁰⁶ *Id.*; see also generally 5 U.S.C. §§ 701 through 706, *et seq.* (providing for judicial review of agency action and setting forth remedies under the Administrative Procedure Act).

Critically, there is no current law nor regulation which permits DIR Fees in the manner PBMs have sought to impose. In order for such DIR Fees to be effective as a legal standard for provider reimbursement under Medicare, either new Federal legislation would have to be enacted or formal rulemaking would need to occur. The government cannot circumvent this reality by abandoning its legal obligations to create such a “rule, requirement, or other statement of policy” to PBMs or Part D plan sponsors. Fortunately, as noted above, it appears that the government is responding in kind to DIR Fees, and has proposed legislation to completely ban the practice.

7.3 DIR Fees Violate the Federal Any Willing Provider Law

Other Federal laws also act as safeguards to a Pharmacy Provider’s access to, and participation in, Federal health care programs. These laws help curtail PBMs from wielding limitless power. The Social Security Act, which established the Medicare program, dictates the scope of Medicare benefits and coverage, as well as, provisions for Pharmacy Provider enrollment and payment.¹⁰⁷ Further, the Social Security Act controls what powers are granted to CMS in administering the Medicare program and effectively supersedes any CMS regulations that act contrary to the language of the statute. Critically, the Social Security Act includes the “Any Willing Provider” law (“AWPL”), which relates directly to provider access and reimbursement in the Medicare program. The AWPL applies to all Part D plan sponsors and their downstream entities, such as PBMs.¹⁰⁸

The Federal AWPL and accompanying regulations require that a Part D plan sponsor admit any “pharmacy”¹⁰⁹ into its network that is willing to meet the terms and conditions of the network.¹¹⁰ Indeed, when a Part D plan sponsor enters into a contract with a PBM as a down-tier provider to provide drug coverage to Medicare beneficiaries, the Part D plan sponsor and the 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.”¹¹¹ ***As articulated below, DIR Fees charged by PBMs on their networks result in unreasonable terms and conditions.***

CMS acknowledges the importance of the AWPL in ensuring Medicare Part D beneficiaries with convenient access to life-saving medications. As a result, CMS has vigorously enforced the requirements set forth in the AWPL and has harshly punished Part D plan sponsors who have enacted policies and procedures in violation of its requirements. For example, CMS previously issued a \$1 million civil monetary penalty against Aetna, a plan sponsor, and required it to submit a corrective action plan after determining that “Aetna’s contracting process for CY 2015 did not comply with Part D program requirements because Aetna did not permit the participation of any pharmacy that met the terms and conditions under the plan...”¹¹² In its letter reprimanding Aetna, CMS stated:

¹⁰⁷ See generally 42 U.S.C. §§ 1395, *et seq.*

¹⁰⁸ 42 C.F.R. § 423.505(i)(3)(iv).

¹⁰⁹ Notably, while the word “pharmacy” is used in the above-referenced AWPL, the definition of “pharmacy” is not currently defined within Medicare statutes and regulations. Instead, the definition of “pharmacy” defers to each States’ own definition contained in its licensing laws. *See* 42 U.S.C. § 1395w-112(g). Many states define pharmacy in such a way that would include physician dispensing and physician owned pharmacies. For example, physicians are authorized as “licensed health care provider[s]” under New York State law governing the practice of pharmacy to dispense prescription drug products, *see generally* N.Y. Educ. Law § 6807, *et seq.*, and especially the “dispensing of drugs pursuant to an oncological . . . protocol.” Additionally, North Carolina defines “pharmacy” as “any place where prescription drugs are dispensed or compounded.” *See* N.C. Gen. Stat. 90-85-3. Likewise, Delaware defines “pharmacy” as “a place where drugs are compounded or dispensed.” *See* Del. Code. Ann. Tit. 24-2502. Moreover, a number of States, including Virginia, North Carolina, and Florida require dispensing physicians to be directly licensed or permitted by their respective State Boards of Pharmacy. *See* Va. Code Ann. 54.1-3304.1, N.C. Gen. Stat. 90-85-21, and Fla. Stat. 465.0276 respectively.

¹¹⁰ 42 U.S.C. § 1395w-104(b)(1)(A); 42 C.F.R. 423.120(a)(8)(i).

¹¹¹ 42 C.F.R. § 423.505

¹¹² 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, 2016), available at <http://www.ncpa.co/pfd/aetna-awp-cap-jan-2015.pdf>.

*“To comply with the AWP 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 language 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.”¹¹³ (emphasis added)*

Thus, it is not enough for Part D plan sponsors and PBMs to allow any willing pharmacy access to their networks, but the terms and conditions of the network must be reasonable and relevant.

While CMS has provided little guidance on what constitutes “reasonable” and “relevant” terms and conditions, importantly, CMS has expressly noted that pharmacy reimbursement rates are part of the terms and conditions that must also be “reasonable and relevant” in accordance with the Federal AWPL. CMS acknowledges that if reimbursement terms are unreasonably low in Medicare Part D networks, pharmacies throughout the country may not be able to afford participating in the networks, which would result in Medicare beneficiaries having a harder time accessing Medicare Part D services. Therefore, by way of example, CMS has stated that “offering pharmacies unreasonably low reimbursement rates for certain ‘specialty’ drugs may not be used to subvert the convenient access standards. In other words, Part D sponsors must offer reasonable and relevant reimbursement terms for all Part D drugs as required by [the federal AWPL].”¹¹⁴ DIR Fees decrease the net reimbursement rates received by Pharmacy Providers, resulting in unreasonably low reimbursement.

Thus, PBMs are not only compelled by Federal law to allow access to providers that are willing to meet the network’s terms and conditions, but the reimbursement terms for providers in the networks must be reasonable and relevant. As noted in section 5.4 above, the imposition of DIR Fees upon Medicare Part D providers circumvents the reasonable reimbursement requirements and effectively renders the Pharmacy Provider’s reimbursement rates unreasonable, as DIR Fees often result in Pharmacy Providers being reimbursed at rates at or below their acquisition cost, sometimes causing them to lose money by dispensing medications to Medicare enrollees. As a result, DIR Fees may oftentimes be in violation of the Federal AWPL, as they undoubtedly render many Pharmacy Providers’ reimbursement rates unreasonable low.

7.4 DIR Fees Violate Prompt Payment Laws

DIR Fees similarly violate the Federal Prompt Payment law.¹¹⁵ Generally, under the Prompt Payment law, a Part D plan sponsor must issue or otherwise transmit payment on all clean claims to a network pharmacy within (i) 14 days after the date of an electronic claim is received, or (ii) 30 days after the date on which any other claim is received.¹¹⁶ A “clean claim” is a claim that has no defect, impropriety, or particular circumstance requiring special treatment that prevents timely payment of the claim from being made.¹¹⁷ Critically, “a claim submitted to a Part D sponsor that is not paid by the Part D sponsor within the timeframes specified in paragraphs (a)(1)(i) and (ii) or contested by the Part D sponsor within the timeframe specified in paragraph (c)(1)(i) and (ii) of this section must be deemed to be a clean claim and must be paid by the Part D sponsor...”¹¹⁸ DIR Fees violate the clean claim rules.

As noted above, PBM-imposed DIR Fees based on performance metrics generally occur on either a flat fee or percentage basis. Flat fee performance-based DIR Fees are conducted in violation of the Prompt Payment law, as the PBMs assessing these fees are failing to remit full payment on clean claims within the timeframes outlined in the Prompt Payment law and similarly not alleging that the claims are not clean claims.

¹¹³ CMS, *Letter to Medicare Part D Plan Sponsors Regarding Compliance with Any Willing Pharmacy Requirements* (Aug. 13, 2015), available at <http://www.amcp.org/workarea/downloadasset.aspx?id=20065>.

¹¹⁴ CMS, Medicare Prescription Drug Benefit Manual, Chapter 5, Section 50.3.

¹¹⁵ 42 U.S.C. § 1395w-112; 42 C.F.R. 423.520

¹¹⁶ 42 C.F.R. § 423.520(a)(1).

¹¹⁷ 42 C.F.R. § 423.520(b).

¹¹⁸ 42 C.F.R. § 423.520(c)(3).

When the PBM adjudicates the claim at the point-of-sale and identifies the negotiated price, it is obligated to pay that full negotiated price as prompt payment of the clean claim. Any failure to pay that full amount within the statutory timeframe constitutes a violation of the Federal Prompt Payment law.

Likewise, percentage-based DIR Fees similarly violate the Federal Prompt Payment law. As described in detail above, percentage-based DIR Fees involve the assessment of fees against providers in connection with clean claims that have already been paid to providers. Thus, percentage-based DIR Fees are a retroactive reduction of clean claims that have been previously paid. These types of post-adjudication DIR Fees similarly violate the Federal Prompt Payment law, as the PBMs are not ultimately paying clean claims in full. There is no allegation that these claims are not “clean claims.” Thus, by clawing back a portion of the adjudicated, negotiated price previously paid, the PBM fails to render full payment within the timeframes outlined in the regulation.

8 Conclusion

The PBM industry’s imposition of unreasonable DIR Fees is another example of a policy implemented to increase PBM profits at the expense of the Medicare program, patients, and Pharmacy Providers. These DIR Fees—particularly those based on provider performance—find absolutely no basis in Medicare regulation or law and may actually violate Federal law and guidance.

In fact, the PBMs’ use of DIR Fees actually increases the overall costs to patients and the Medicare program, which is ultimately paid for by taxpayers. DIR Fees obfuscate the accurate reporting of prescription drug reimbursement rates, leading to artificially inflated “negotiated prices” and subsequently higher administrative costs to the Medicare program upon reconciliation. The PBMs’ ability to hide the true cost of drugs at the point-of-sale causes a detriment to the Medicare program as a whole, including patients and taxpayers, who have to front higher copayments or premiums to fund the Medicare Part D program because of the PBMs’ lack of transparency. Additionally, indications are that DIR Fees are fueling higher Medicare Part D drug prices.

Ultimately, more can, and must be, done to address DIR Fees. This includes legislative and regulatory action to correct this out-of-control problem. While CMS, under the Obama Administration, has already weighed and considered several proposed clarifications on the subject, CMS, under the Trump Administration, must go further in reining in this practice, increasing transparency and reducing costs both to Medicare and beneficiaries. CMS should start by adopting guidance clarifying the definition of “negotiated price” to prevent improper manipulation by PBMs and Part D plan sponsors. CMS has already noted the immense negative financial impact of traditional DIR on both beneficiaries and the Medicare program, and now CMS, under the Trump Administration, must continue these efforts and take steps to scrutinize and examine the actions of PBMs and Part D plan sponsors, particularly in their assessment and reporting of DIR Fees clawed back from Pharmacy Providers.

Likewise, Congress must take specific legislative action to put an end to retroactive DIR Fees. There were two bills in the 114th Congress (companion bills in the House and Senate) that would effectively eliminate retroactive DIR Fees in most circumstances. The “Improving Transparency and Accuracy in Medicare Part D Spending Act” (H.R. 5951 and Senate companion bill S. 3308) should be re-introduced in the 115th Congress. Senators and Representatives are urged to support both bills in the 115th Congress and to take swift legislative action to ***stop the opaque and costly practice of PBM-imposed DIR Fees.***