



COMMUNITY ONCOLOGY ALLIANCE
Innovating and Advocating for Community Cancer Care

1225 New York Avenue, NW, Suite 600
Washington, D.C. 20005
(202) 729-8147 | communityoncology.org

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March 7, 2022

Submitted electronically to: <http://www.regulations.gov>

The Honorable Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4192-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: *CY 2023 Medicare Advantage and Part D Proposed Rule (CMS-4192-P)*

Dear Administrator Brooks-LaSure:

On behalf of the Board of Directors of the Community Oncology Alliance ("COA"), we are pleased to offer comments on policies outlined in the *CY 2023 Medicare Advantage and Part D Proposed Rule (CMS-4192-P)* (the "Proposed Rule").

As you know, COA is an organization dedicated to advocating for the complex care and access needs of patients with cancer and the community oncology practices that serve them. COA is the only nonprofit organization in the United States dedicated solely to independent community oncology practices, which serve the majority of Americans receiving treatment for cancer. COA's mission since its grassroots founding close to 20 years ago has been to ensure that patients with cancer receive quality, affordable, and accessible cancer care in their own communities where they live and work, regardless of their racial, ethnic, demographic, or socioeconomic status.

Achieving this goal requires federal policies to correct misaligned financial incentives that drive spending and costs for some of the most vulnerable cancer patients: Medicare beneficiaries. For these reasons, COA is pleased to see provisions in the Proposed Rule to include pharmacy price concessions in the definition of "negotiated price" and clarify the definition of "price concessions." We believe these provisions would increase transparency for both beneficiaries and pharmacy providers, lower beneficiary out-of-pocket costs, and provide greater clarity for pharmacy providers on expected final reimbursement. **However, COA remains extremely concerned that the Proposed Rule does not go far enough to protect pharmacy providers, including retail pharmacies and community oncology, urology, and other medical practices with pharmacies and/or in-office dispensing facilities (collectively "Pharmacy Providers"). In the Proposed Rule, Centers for Medicare & Medicaid Services ("CMS") must close any loopholes and unintended consequences of regulatory changes to prevent the top pharmacy benefit managers ("PBMs") from using their concentrated market dominance to game the system for their own profits, while threatening the existence of Pharmacy Providers. Additionally, COA asks that CMS ensures that reimbursement provided to Pharmacy Providers is "reasonable and relevant."**

COA is also extremely concerned with proposals by the CMS to give Part D plan ("PDP") sponsors ("PDP Sponsors") and their PBMs flexibility about whether to apply pharmacy

price concessions to negotiated prices in the coverage gap and about CMS’ clarification regarding pharmacy administrative service fees. Given the unchecked behavior of PBMs, it is likely that they will simply substitute inordinately high “administrative fees” for “direct and indirect remuneration” (“DIR”) fees based on so-called “quality performance programs” such that net reimbursement to Pharmacy Providers will be even lower than it is now, which is why independent Pharmacy Providers are being driven out of business by PBMs. Likewise, with respect to the treatment of negotiated prices during the coverage gap, given the track record of PBMs, we are very concerned that the lack of specific CMS directive related to this issue will allow PBMs to abuse the flexibility CMS proposes. As such, COA believes that additional policies – specifically explained in this comment letter – are necessary to address the negative impact that certain PBM practices have had on Pharmacy Providers and, very importantly, their patients. ***It is critical that CMS in its well-intended proposal to address the problems of DIR fees in artificially fueling drug costs for Medicare beneficiaries does not make the situation worse for Pharmacy Providers.***

Comments on the Proposed Rule

In this letter, COA will provide specific comments, concerns, and recommendations on the following topic areas in the Proposed Rule:

- **Inclusion of Pharmacy Price Concessions in Negotiated Price**
- **Lowest Possible Reimbursement Amount at Point-of-Sale**
- **Definition of Negotiated Price in the Coverage Gap**
- **Clarification of Pharmacy Administrative Service Fees and Price Concession**
- **Clarification on Any Willing Provider Law**
- **Proposed Enhancements to CMS Dispute Resolution Process**
- **Updated Pharmacy Quality Measures**

Inclusion of Pharmacy Price Concessions in Negotiated Price

COA supports CMS’ proposal to amend the definition of negotiated price in Part D to include all pharmacy price concessions and require that those price concessions be passed through to beneficiaries at the point-of-sale (“POS”). **However, we believe that this provision does not go far enough in addressing the financial solvency of Pharmacy Providers.** We also offer additional recommendations on this topic.

As we have stated in comments to CMS on the *Contract Year 2019 Policy and Technical Changes to the Medicare Advantage and Medicare Part D Proposed Rule*¹, the Part D and Medicare Advantage Modernization proposed rule², the Stark/Anti-Kickback Statute (“AKS”) Rebate proposed rule³, and the 2021 letter to the House Energy and Commerce Committee leadership on DIR fees⁴, we believe that changing the definition of negotiated price will increase transparency and provide clarity on expected reimbursement for dispensed medications.

¹ COA. “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.” January 2018. Available [Here](#).

² COA. “Re: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses.” January 2019. Available [Here](#).

³ Community Oncology Alliance. “Re: Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees.” April 2019. Available [Here](#).

⁴ COA. “Re: Direct and Indirect Remuneration Fees (DIR fees).” April 2021. Available [Here](#).

COA believes that the Proposed Rule’s provision to amend the definition of negotiated price in Part D will provide needed transparency and clarity to Pharmacy Providers on expected final net reimbursement, which could make payments to Pharmacy Providers more predictable. DIR fees create extreme financial risks for Pharmacy Providers because the amount owed is assessed retrospectively – or “claw-backed” – by PBMs, and, in many cases, fail to compensate Pharmacy Providers for their drug acquisition costs, let alone the professional services required in dispensing medications and managing patients. In some cases, murky DIR fees can subject Pharmacy Providers to legal risks. For example, in *Zimmerman v. Diplomat Pharmacy*, a PBM changed how it assessed DIR fees in a manner that caused Diplomat, a specialty pharmacy then traded as a public company, to owe higher than expected DIR fees, resulting in a lack of control over its financial reporting and allegations of securities fraud.⁵ COA believes that Pharmacy Providers should not be subjected to this lack of transparency and clarity which results in financial and legal risks.

COA supports accounting for pharmacy price concessions in the Part D negotiated price as it could also lower patient out-of-pocket (“OOP”) costs for high-cost specialty drugs to treat cancer and other complex diseases by eliminating the ability for PDP Sponsors and PBMs – often part of the same corporation – to account for pharmacy price concessions as DIR. However, COA remains concerned that especially the top three PBMs, accounting for 79 percent of prescription drug activity,⁶ will seek alternative ways to leverage their market dominance with Pharmacy Providers and make up for lost DIR fees by narrowing pharmacy networks, which would decrease access to medications for patients.

Especially with cancer and other specialty drugs, pharmacy DIR fees are typically based on a percentage of drug list prices, which creates an incentive for PBMs to seek increasingly larger amounts of pharmacy price concessions in the form of percentage-based fees, often to the detriment of patients in the form of higher OOP costs at the POS. For example, a \$40,000 high-cost specialty drug prescribed to treat Hepatitis C with a 5.5 percent DIR fee would result in the PBM clawing back over \$2,000 on that one claim.⁷ Given the high price of many specialty treatments, these DIR fees often place Pharmacy Providers underwater on each claim, especially those that involve high-touch care management services required by patients with complex medical needs.

It is also important for CMS to understand that PBMs charge DIR fees on all prescription drug claims while only “measuring” performance of Pharmacy Providers on as little as one percent of all claims. CMS needs to investigate the methodology of each PBM in calculating DIR fees that are “reasonable and relevant.”

Furthermore, pharmacy DIR has skyrocketed in recent years, subjecting Pharmacy Providers to increasingly high levels of financial risk. According to CMS, pharmacy DIR grew 107,400 percent between 2010 and 2020. Much of this growth occurred after 2012, when performance-based payment arrangements between PDP Sponsors and Pharmacy Providers became more prevalent.⁸ Additionally, pharmacy DIR in Part D totaled \$11.2 billion in 2020, an increase of \$2.1 billion from 2019 and an \$11 billion increase from 2013.⁹ The *Medicare Prescription Drug Benefit Manual* makes it clear that PBMs cannot require network

⁵ Ahmad, Zahra. “Diplomat Pharmacy in Flint Settles Class Action Lawsuit for \$14.1M.” M Live. Accessed February 14, 2022. Available [Here](#). Of note, Diplomat Pharmacy has since been acquired by UnitedHealthcare, the largest health insurer in the country (including Medicare Part D Plans) and owner of the third largest PBM (OptumRx).

⁶ Mader, Josh. “Pharmacy Benefit Managers: Market Landscape and Strategic Imperatives.” Health Industries Research. Accessed February 14, 2022. Available [Here](#).

⁷ COA. “PBM DIR fees Costing Medicare and Beneficiaries: Investigative White Paper on Background, Cost Impact, and Legal Issues.” January 2017. Available [Here](#).

⁸ Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs. CMS. Available [Here](#).

⁹ Adam Fein, PhD, *The 2021 Economic Report on U.S. Pharmacy Providers and Pharmacy Benefit Managers* (Philadelphia: Drug Channels Institute, 2021), 301.

pharmacies to accept insurance risk as a condition of participation in their networks.¹⁰ The *Medicare Prescription Drug Benefit Manual* also makes clear that PDP Sponsors administering Part D benefits may not engage in sub-capitation arrangements with pharmacies.¹¹ It is clear that PDP Sponsors are supposed to bear insurance risk; not Pharmacy Providers. We encourage CMS to take action to prevent PDP Sponsors from subjecting Pharmacy Providers to this type of risk.

We also appreciate the Biden administration's focus on promoting competition in the prescription drug market discussed in Executive Order 14036 *Promoting Competition in the American Economy*.¹² While CMS believes that this Proposed Rule would address competition issues among PDP Sponsors, it does not address the anticompetitive results of vertical integration among payers, where PDP Sponsors, PBMs, and retail and specialty pharmacies are vertically integrated under a single corporate structure. This vertically integrated corporate structure often creates narrower networks that frequently exclude Pharmacy Providers through restrictive fees and pharmacy "quality performance" programs that are inapplicable to specialized Pharmacy Providers, such as oncology and urology practices, resulting in pharmacy access issues for patients and higher OOP costs. **We ask CMS to investigate whether PDP Sponsors award PBM contracts to their corporate affiliates without the type of bidding required for federal contracts.**

COA appreciates the continued attention from both the Biden administration and Congress on the problems associated with the growth in pharmacy DIR fees and the need for reform. In 2021, House¹³ and Senate¹⁴ legislators introduced the *Pharmacy DIR Reform to Reduce Senior Drug Costs Act* to require price concessions, payments, and fees that are negotiated with a pharmacy to be included in a drug's negotiated price (excluding incentive payments) and be provided to patients at the POS.

COA encourages CMS to address overall pharmacy underpayment concerns, ensure that terms, conditions, and quality performance metrics are both "reasonable and relevant," and address loopholes in PDP Sponsors' and their PBMs' interpretations of network adequacy. **We also request that CMS investigate how PBMs set reimbursement rates, especially for specialty drugs.**¹⁵ As the definition of negotiated price has a downstream effect on administrative costs and pharmacy quality metrics, we ask CMS to ensure that Pharmacy Providers are sufficiently protected against unfair financial exposure, as underpayment increases the concentrated power of PBMs and PBM-owned specialty pharmacies, which causes widespread industry harm by consolidation. We also encourage CMS to close PBM loopholes that harm the financial health of Pharmacy Providers, raise patient drug costs, and create narrower pharmacy networks that limit patient access. CMS has long viewed it as having the ability to undertake this action regarding the definition of "negotiated prices."¹⁶

Recommendations

- **COA generally supports CMS' proposal to redefine negotiated price that accounts for pharmacy price concessions.** Redefining negotiated price in this manner would provide Pharmacy Providers with much-needed transparency and greater clarity on expected financial reimbursement, potentially making payments more predictable and creating greater financial stability.

¹⁰ Medicare Prescription Drug Benefit Manual, Chapter 5, Section 50.8.2. Available [Here](#).

¹¹ *Id.*

¹² Executive Order 14036, Promoting Competition in the American Economy. 2021. Available [Here](#).

¹³ HR 3554, Pharmacy DIR Reform To Reduce Senior Drug Costs Act. 2021. Available [Here](#).

¹⁴ S 1909, Pharmacy DIR Reform To Reduce Senior Drug Costs Act. 2021. Available [Here](#).

¹⁵ 42 U.S.C. § 1395w-104(b), et seq.

¹⁶ See, e.g., 79 FR 1918 at 1971; 83 FR at 16590; 82 FR 56336 and 83 FR 62152.

- COA also encourages CMS to consider the implementation of guardrails that would ensure PBMs do not design overly narrow preferred networks or assess new administrative fees to offset any perceived losses associated with the proposed changes to pharmacy DIR reporting.

Lowest Possible Reimbursement Amount at Point-of-Sale

COA is largely supportive of the Proposed Rule’s provision to redefine negotiated price as “*the lowest possible reimbursement a network pharmacy will receive, in total, for a particular drug, taking into account all pharmacy price concessions*”¹⁷. However, this should in no way be interpreted that PBMs can use their market dominance to low-ball reimbursement to the point that Pharmacy Providers are driven out of business, as is happening now. COA also supports the proposed definition of negotiated price to include all pharmacy price concessions that could flow from network Pharmacy Providers to PBMs in addition to dispensing fees. While we are supportive of price concession transparency at the POS and claim level regarding the net amount of reimbursement, **we are concerned that, absent other protections for Pharmacy Providers, this provision could result in increased downward pressure on reimbursement to Pharmacy Providers. As it currently stands, DIR fees can result in total reimbursement that is lower than acquisition costs for many Pharmacy Providers. Further lowering reimbursement would be catastrophic for Pharmacy Providers.**

While we support CMS’ lowest possible reimbursement provision insofar as it reduces uncertainty around the final reimbursement amount,¹⁸ **we believe that this provision may have unintended consequences that could harm Pharmacy Providers.** Under CMS’ proposal, pharmacy payments to PBMs under a performance-based reimbursement arrangement would no longer be reported as DIR outside of the coverage gap, and any positive adjustments to Pharmacy Providers above the lowest possible reimbursement amount that may occur after the POS would be reported as negative DIR. As a result, PDP Sponsors and their PBMs may seek to offset upward premium pressure by using their leverage to drive even lower total reimbursement or exploit loopholes to levy punitive new fees on Pharmacy Providers. In fact, many DIR fee programs already contemplate this, with tentative lower “default” reimbursement rates in the event that DIR fees are prohibited. These “default” rates are significantly lower than current reimbursement rates and will put even more pressure on Pharmacy Providers.

Excessive DIR fees harm the financial health of Pharmacy Providers. For example, a pharmacy could see a 47 percent lower margin on average per prescription, and a low performing pharmacy could see an 81 percent lower margin on average per prescription due to DIR fees.¹⁹ Since specialty Pharmacy Providers, such as oncology and urology practices, dispense high levels of expensive brand drugs that have slimmer margins, a lowest possible reimbursement provision would put Pharmacy Providers that dispense high levels of specialty drugs at risk of receiving low reimbursement. In some cases, specialty Pharmacy Providers may receive reimbursement well below a drug’s acquisition cost. ***As noted below, CMS has the authority to ensure reimbursement to Pharmacy Providers is “reasonable and relevant,” which does not in any way conflict with the “non-interference clause.”***

Congress enacted the “Any Willing Provider Law” (“AWP Law”) as part of the Social Security Act and CMS, through rulemaking, established that Plan Sponsors must contract with any pharmacy that meets the Plan Sponsor’s standard terms and conditions for network participation.²⁰ The law also requires that Plan Sponsors offer a standard contract with “reasonable and relevant” terms and conditions of participation, where any

¹⁷ 87 FR 1842

¹⁸ “Reforming Pharmacy Direct And Indirect Remuneration In The Medicare Part D Program”, Health Affairs Blog, July 19, 2021. Available [Here](#).

¹⁹ February 2022, Avalere Health Analysis, Pharmacy DIR Fees

²⁰ 42 CFR § 423.120(a)(8)(i)

willing pharmacy may access the standard contract and participate as a network pharmacy.²¹ Additionally, CMS has noted that “[i]t is within [CMS]’ authority and appropriate for CMS to provide additional clarification of these regulatory requirements when necessary to help ensure they are being effectuated in accordance with the statutory requirement.”²² **It is therefore well-within CMS’ authority to ensure that reimbursement rates are both “reasonable and relevant” for Pharmacy Providers.** CMS should use this authority to improve the financial health of Pharmacy Providers since there is virtually no meaningful negotiation occurring between PBMs and Pharmacy Providers. In fact, it is a complete fallacy to even use the word “negotiation” – the dominant market power of the top PBMs is simply “take our terms and conditions or you don’t participate in our network.”

As we noted to CMS in 2019, when COA provided comments on the Part D and Medicare Advantage Modernization proposed rule²³ and the Stark/AKS Rebate²⁴ proposed rule, we believe that upfront POS reimbursement should be “reasonable and relevant,” and not be structured in a way that fails to compensate Pharmacy Providers for acquisition costs, particularly for expensive specialty drugs.

CMS previously noted²⁵ that unreasonably low reimbursement rates for specialty drugs may not be used to circumvent convenient access standards, and we encourage the agency to adopt reforms to protect Pharmacy Providers. Since Pharmacy Providers bear a significant amount of financial risk, we encourage CMS to enforce this provision, which forbids Plan Sponsors from requiring participating Pharmacy Providers to bear risk as a condition of participation in their networks.²⁶

Finally, the current lack of specificity within the Proposed Rule leaves open the possibility that, while Plan Sponsors would be required to **report** the lowest possible reimbursement amount at the point-of-sale, nothing in the Proposed Rule requires Plan Sponsors’ PBMs to **provide** pharmacies with that reported reimbursement amount, thereby opening a loophole for Plan Sponsors and their PBMs to pay Pharmacy Providers even lower amounts and/or higher amounts to pharmacies affiliated with Plan Sponsors and PBMs.

Recommendations

- COA requests that CMS ensures that overall reimbursement to Pharmacy Providers is “reasonable and relevant.” CMS can accomplish this goal by addressing network adequacy, increasing the use of guardrails on PDP flexibility for narrower networks, and closing additional loopholes that PDP Sponsors and their PBMs use to extract price concessions from Pharmacy Providers.
- COA recommends that, in establishing reimbursement rates for specialty medications (given their unique distribution and handling complexities), CMS required that PDP Sponsors and their PBMs account for specific metrics, including (without limitation) acquisition cost, cost to dispense, and some reasonable margin.
- COA wants to underscore that although we support that CMS adopts a lowest possible reimbursement approach to make clear to Pharmacy Providers what the reimbursement will be at the POS – and, very importantly, lower patients’ OOP costs at the POS – this cannot provide a way

²¹ 42 § 423.505(b)(18) and 83 FR at 16590

²² 83 FR at 16590

²³ COA. “Re: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses.” January 2019. Available [Here](#).

²⁴ COA. “Re: Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees.” April 2019. Available [Here](#).

²⁵ Medicare Prescription Drug Benefit Manual, Chapter 5, Section 50.5.3

²⁶ 42 U.S.C. § 1395w-104(b)(1)(E)

for PBMs to low-ball reimbursement. PBMs are masters at finding loopholes and ways of profiting to the detriment of patients and Pharmacy Providers.

Definition of Negotiated Price in the Coverage Gap

COA opposes the Proposed Rule’s provision to provide PDP Sponsors and their PBMs flexibility on whether to apply pharmacy price concessions to negotiated prices in the coverage gap for applicable drugs. We are adamant that the definition of negotiated price should remain consistent throughout all stages of the prescription drug benefit. CMS must understand that granting PDP Sponsors and their PBMs flexibility in the treatment of pharmacy price concessions for applicable claims in the coverage gap undermines a key goal of the policy in the first place by allowing patient OOP costs to remain high. This provision also perpetuates the problems associated with PBM “claw-backs” for applicable claims in the coverage gap that financially strain Pharmacy Providers.

Additionally, COA is very concerned that this proposed provision would create unnecessary operational complexities for Pharmacy Providers, as they would be required to track two separate applications of negotiated price. These complexities will increase administrative and financial burdens for Pharmacy Providers, which already have to comply with arbitrary requirements imposed by PDP Sponsors and their PBMs.

We reiterate that the PBM market is essentially an oligopoly with three major corporations controlling nearly 80 percent of total PBM market share. CVS Caremark represented 34 percent of total adjusted claims in 2020, followed by Express Scripts (24 percent) and OptumRx (21 percent).²⁷ As stated above, the top PBMs use this dominant market power to extract – some would say “extort” – unsustainable and unpredictable price concessions from Pharmacy Providers, who need sufficient protection from overly punitive network agreements. CMS has taken a positive first step in curtailing some of this behavior in the Proposed Rule but giving Plan Sponsors and PBMs flexibility to continue these extortionary practices in the coverage gap undermines the intent of the policy and dilutes the value of lower OOP costs to patients at the POS. COA believes that the Proposed Rule’s provision would create additional operational complexities for Pharmacy Providers, as well as harm their financial health. **Therefore, CMS should not grant Plan Sponsors and PBMs flexibility on whether to apply pharmacy price concessions to negotiated prices in the coverage gap.**

Recommendation

- COA strongly requests that CMS not finalize its proposal to provide Plan Sponsors and PBMs flexibility on whether to apply pharmacy price concessions to negotiated prices in the coverage gap. Instead, the proposed definition of negotiated price to include all pharmacy price concessions should be applied to all phases of the Part D benefit.

Clarification on Pharmacy Administrative Service Fees and Price Concessions

COA opposes language that would include administrative service fees as price concessions and recommends that service fees only be accounted for as administrative costs that are factored into the Part D bid. The proposed definition of price concessions would create a significant risk for Pharmacy Providers by allowing PBMs to respond to DIR reform by replacing DIR fees with dramatic increases to service fees. It is critical for CMS to understand that a specific and limited definition of administrative

²⁷ Mader, Josh. “Pharmacy Benefit Managers: Market Landscape and Strategic Imperatives.” Health Industries Research. Accessed February 14, 2022. Available [Here](#).

service fees would prevent this type of potential abuse. Treating administrative fees as an administrative cost that is accounted for in the Part D bidding process could mitigate the risks associated with this proposal.

CMS' proposed definition of administrative service fees is too broad, putting Pharmacy Providers at risk for untenable increases in fees from PBMs. If PBMs can contrive administrative fees as a network fees, it would allow PBMs to make pharmacy network access contingent on payment of administrative fees operating under the guise of network fees. Taken to the extreme, these practices can be extortionary and abusive to Pharmacy Providers. An analysis conducted by the National Community Pharmacists Association ("NCPA") found that PBMs have already increased DIR 1,600 percent between 2015-2020, which exceeds any possible increase to administrative costs.²⁸ Additionally, PBMs maintain the ability to charge general compliance fees of up to \$500 per day until the PBM determines a pharmacy is sufficiently compliant with the terms and conditions of its contract. PBMs also extract other "fees" from Pharmacy Providers, such as assessing audit fees up to 20 percent of any discrepancies identified by the PBM or requiring Pharmacy Providers to place \$50,000 in escrow as a pre-condition to begin disputes against them. **COA strongly advocates for CMS action to limit the use of these exorbitant and unfair fees, which allow PBMs to wield a disproportionate amount of power against Pharmacy Providers.**

Furthermore, the definition of price concession in the Proposed Rule would include "*all forms of discounts, direct or indirect subsidies, or rebates that serve to reduce the costs incurred under Part D plans by Part D sponsors.*" The lack of specificity in this definition could create a situation where PBMs seek new fees outside of the definition to offset the loss of DIR fees associated with the proposed policy. As a result, a clearer, more specific definition that explicitly excludes post-POS quality program discounts is necessary.

COA implores CMS to further clarify the definition of price concessions due to the financial strain it places on Pharmacy Providers. For example, research conducted by the law firm Frier Levitt found that a five percent DIR fee on a \$2,000 specialty drug nets PBMs \$100 every time the drug is dispensed.²⁹ Pharmacy Providers should not be subject to this extreme financial risk.

Recommendations

- COA recommends amending the definition of price concessions to treat all pharmacy administrative service fees as administrative costs that are accounted for in the Part D bid.
- A clearer, more specific, definition of "price concession" is needed to explicitly exclude post-POS "quality program" discounts. CMS must be aware that PBMs will look for any way to recoup lost revenue from current DIR fees by creating new administrative fees, network access fees, and similar contrived fees. This is exactly what they did when creating these "quality performance" programs as a mechanism of protecting DIR fees from Pharmacy Providers.

Clarification on Any Willing Provider Law

COA encourages CMS to strengthen interpretation and enforcement of the AWP Law, as COA is concerned that PBMs may respond to this policy by effectively narrowing pharmacy networks, which could limit beneficiary access to medications, especially drugs used to treat cancer and other serious diseases.

CMS has stated in Section 50.8.1 of Chapter 5 of the *Medicare Prescription Drug Benefit Manual* that Plan Sponsors must allow any pharmacy to participate in its plan network so long as the pharmacy is willing to

²⁸ NCPA. "Payers and PBMs Profit From Obscure Pharmacy Fees, While Seniors See No Relief in Prescription Costs." February 2020. Available [Here](#).

²⁹ Frier Levitt, LLC. "PBM DIR fees Costing Medicare and Beneficiaries: Investigative White Paper on Background, Cost Impact, and Legal Issues." Jan 2017. Available [Here](#).

accept the Plan Sponsor’s standard contracting terms and conditions, which must be “reasonable and relevant.”³⁰ Plan Sponsors have circumvented this provision and established obstructive terms and conditions to exclude pharmacy participation and establish narrow networks. For example, in recent years, CVS Caremark refused to admit 35 Pharmacy Providers into its network even though they were willing to meet their terms and conditions.³¹

In addition to limiting patient access and placing additional hurdles for care on individuals experiencing devastating diseases like cancer, narrow pharmacy networks imposed by PBMs with concentrated market power are anticompetitive. Overly narrow pharmacy networks run counter to President Biden’s goal of ensuring competition in the prescription drug market discussed in Executive Order 14036 *Promoting Competition in the American Economy*.³² By enforcing provisions that are not “reasonable and relevant” in the network contracts for Pharmacy Providers, PBMs can drive business to retail and specialty pharmacies in which they have a corporate affiliation or other financial interest. This effectively creates a market of vertical monopolies, to the detriment of Pharmacy Providers and their patients.

The recent consolidation among insurers and PBMs provides unprecedented market clout allowing Plan Sponsors and their PBMs to virtually do whatever they want in the prescription drug market. They are fueling drug prices and driving retail pharmacies out of business by hiding behind the Part D “non-interference clause” and essentially ignoring the AWP Law. They have become a law unto themselves.

CMS has clear authority to act regarding the AWP Law. The “non-interference clause” does not prohibit CMS from setting rules around how DIR fees can be assessed or calculated. As CMS has stated, *“since the statute requires [CMS] to regulate many aspects of how drug costs are made available and displayed to beneficiaries and treated in Part D bidding and payment processes, it is clear that [it has] an important role to play in establishing rules for consistent treatment of drug costs in the program.”*³³ Most notably and importantly, CMS has expressly noted that *“[i]t is within [CMS’s] authority and appropriate for CMS to provide additional clarification of these regulatory requirements when necessary to help ensure they are being effectuated in accordance with the statutory requirement.”*³⁴ In line with the statutory mandate that CMS ensure Plan Sponsors offer a standard contract with “reasonable and relevant” terms and conditions of participation whereby any willing pharmacy may participate,³⁵ CMS is more than authorized to take these additional and necessary steps to address unintended consequences of the Proposed Rule.

Recommendations

- COA recommends CMS solicit input from Pharmacy Providers and implement guardrails that would tailor terms and conditions to specific pharmacy types in order to ensure that pharmacy networks are not further restricted through PBM exploitation of the interpretation of the AWP Law. CMS has the authority to address the negative ramifications of AWP Laws by providing additional oversight of network terms and conditions during bid reviews to prevent overreach and ensure the AWP Law is being interpreted as intended.
- COA urges CMS to investigate how PDP Sponsors and their PBMs set reimbursement rates for specialty medications and its impact on negotiated prices and the requirements under 42 U.S.C. § 1395w-104(b). In no way would any investigation as to the “reasonableness and relevance” of reimbursement rates conflict with the “non-interference clause.”

³⁰ CMS. “Medicare Prescription Drug Benefit Manual – Chapter 5.” September 2011. Available [Here](#).

³¹ COA. “COA Demand Letter to CVS Caremark.” September 2020. Available [Here](#).

³² The White House. “Executive Order on Promoting Competition in the American Economy.” July 2021. Available [Here](#).

³³ 79 FR 1918 at 1972

³⁴ 83 FR at 16590

³⁵ 42 C.F.R. § 423.505(b)(18)

- COA recommends that CMS issues warning letters, levy fines, and seek injunctive relief against Plan Sponsors and their PBMs for offering unreasonably low reimbursement that violates the AWP Law.

Proposed Enhancements to the CMS Dispute Resolution Process

Although CMS is not proposing a change to the current dispute resolution process, COA believes CMS has a duty to ensure that Plan Sponsors and their PBMs are acting within the scope of Medicare regulations.

As it stands, Plan Sponsors and their PBMs wield a disproportionate amount of power in doing whatever they want with Pharmacy Providers. We reiterate that there are no “negotiations” between PBMs and Pharmacy Providers. For example, in 2018, CVS Caremark increased its “audit chargeback” fee by 33 percent, which served as a tax on Pharmacy Providers within its network.³⁶ PBMs typically ignore complaints from Pharmacy Providers about disparities in negotiating power through overzealous enforcement of confidentiality provisions. PBMs also limit the ability of Pharmacy Providers to bring legal disputes, such as arbitrations or litigations, through unreasonably short statutes of limitations, onerous arbitration costs for multiple arbitrators, requirements to post bonds in order to bring an action, and limitations on the scope and nature of permissible discovery, all of which prevent Pharmacy Providers from resolving disputes with PBMs. **Given the unfair balance of power by PBMs, CMS needs to establish a more equitable dispute resolution process.**

CMS has noted that its ability to intervene is limited to situations involving “negotiating parties” due to the “non-interference clause” and that it may, in “rare exceptions,” choose to involve itself in the process. However, consistent with CMS’ guidance, which states, *“Part D sponsors must offer reasonable and relevant reimbursement for all Part D drugs”* as required under the AWP Law, CMS can intervene to promote competition among Pharmacy Providers and protect patients’ rights to use a pharmacy of their choice. ***CMS’ actions to ensure Plan Sponsors’ terms are “reasonable and relevant” would therefore not violate the “non-interference clause.”***

Recommendation

- COA recommends that CMS implement policies that strengthen process requirements for dispute resolution between Plan Sponsors and their PBMs and Pharmacy Providers. For example, CMS could allow Pharmacy Providers to appeal decisions made in disputes between Plan Sponsors and Pharmacy Providers and publish annual reports to identify how decisions were made and how the process could be improved.

Updated Pharmacy Quality Measures

COA believes that Pharmacy Providers should be assessed using quality measures relevant to the pharmacy type and drugs dispensed and also that reflect actions that Pharmacy Providers can truly take to influence patient behavior to adhere to their medications. In line with this, many existing quality metrics included in the Star Rating System simply do not apply to certain specialty Pharmacy Providers. CMS must stop Plan Sponsors, and their PBMs from assessing specialty Pharmacy Providers with performance measures focused on primary care – having nothing at all to do with specialty care, such as with cancer treatment – to justify extracting performance-based DIR fees. Senate Finance Committee Chairman Ron Wyden (D-OR) recently commented on the complicated nature

³⁶ COA. “United States of America v. CVS Health Corporation and Aetna Inc.” December 2018. Available [Here](#).

of quality measures in which “the rules are so vague and so inconsistent,” PBMs regularly implement arbitrary policies to siphon funds from Pharmacy Providers.³⁷

We want to make this very clear – the top PBMs use “quality performance” as simply a front to extort DIR fees from Pharmacy Providers. This is a rigged game, just like 3-Card Monte, where Pharmacy Providers cannot possibly win. PBMs overwhelmingly penalize Pharmacy Providers for poor performance versus those few (and we would guess Pharmacy Providers under the same corporate umbrella as the PBMs) that are rewarded for superior performance. CMS must understand the rigged nature of this “quality performance” sham by PBMs. ***We challenge CMS to understand the attached actual “quality performance” report sent by CVS Caremark to a community oncology practice!***

CMS must also understand the profit-seeking strategies and tactics pursued by the top PBMs. As drug rebates have come under employer, state, and federal government scrutiny, PBMs have gone “downstream” to Pharmacy Providers to make up for, and even increase, lost revenue from rebates. They first did this by assessing all types of network “access and administrative” fees on Pharmacy Providers. However, as these fees came under the spotlight (see the attached report from Frier Levitt, the first to publicly disclose DIR fees) and increased scrutiny, the top PBMs started implementing “quality performance programs” to justify extracting DIR fees from Pharmacy Providers. However, the rigged, sham nature of these programs is evidenced by the huge imbalance of penalties to Pharmacy Providers versus rewards. As CMS notes in the Proposed Rule, “sponsors and PBMs have been recouping increasing sums from network pharmacies after the point-of-sale (pharmacy price concessions) for “poor performance,” sums that are far greater than those paid to network pharmacies after the point-of-sale (pharmacy incentive payments) for “high performance.”

Additionally, specifically to cancer treatment, the quality measures tied to adherence with oral cancer drugs are unsuitable for cancer patients, as their drugs are often changed to align with their dosage or therapy. If practices change their prescribing practices to meet adherence metrics, it could cause patients harm when medications are not stopped after experiencing side effects, potentially violating instructions on drug labels. Tying adherence to DIR fees is unsuitable for oncology and urology practices treating cancer patients because adverse health outcomes tied to oral cancer drugs may lead to short-term discontinuation of a treatment, which is used as lack of adherence by PBMs. This results in measurements of poor performance as justification for penalties in the form of DIR fees.³⁸ As we have previously indicated, CMS acknowledges in the Proposed Rule that DIR data reports and stakeholder feedback indicate Pharmacy Providers seldom receive an incentive payment above the original rate of reimbursement, which may be caused in part by the inability of most Pharmacy Providers to achieve the performance scores needed for significantly reduced penalties.

CMS noted that under the *Contract Year 2022 Medicare Advantage and Part D Final Rule*, plans are required to disclose pharmacy performance measures to CMS.³⁹ While this is a positive first step in making measures more transparent, the AWP Law explicitly calls for “reasonable and relevant” terms and conditions of participation in a standard network contract.⁴⁰ COA believes that current pharmacy performance measures utilized by Plan Sponsors and PBMs are not “reasonable and relevant” for different

³⁷ Oregon Public Broadcasting. “Rural Oregonians struggle to get medications as Pharmacy Providers close.” February 2022. Available [Here](#).

³⁸ Hassett, Brianna Willyard, Darrel. and Oncology Today. “The DIR Labyrinth: How Conflicting Adherence Rules Hamper Mid Clinics.” Spring 2021.

³⁹ CMS. “Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly.” January 2021. Available [Here](#).

⁴⁰ 83 FR at 16590

pharmacy types. This is specifically true in cancer care where adherence measures are often counterproductive.

Given that CMS has stated the “non-interference clause” does not prohibit CMS from establishing requirements necessary for implementing the AWP Law, the agency has a duty to ensure that Pharmacy Providers are subject to “reasonable and relevant” quality measures.⁴¹ In a September 2019 letter, the Senate Finance Committee encouraged CMS to accompany DIR reform with a standardized set of quality metrics.⁴² CMS must intervene and ensure Plan Sponsors and PBMs are implementing the AWP Law as it was intended.

Recommendations

- COA encourages CMS to adopt requirements for pharmacy performance measures that Plan Sponsors and their PBMs may use and ensure that performance is measured against similarly situated providers and is relevant to the type of care provided.
- COA requests that CMS evaluate how Plan Sponsors and their PBMs calculate adherence scores on specialty drugs, such as oncology drugs, to ensure compliance with the requirements for “reasonable and relevant” terms and conditions, as well as ensuring that quality metrics are aligned with patients’ safety and efficacy of treatment.

Conclusion

COA appreciates the opportunity to comment on the Proposed Rule and CMS’ efforts to lower OOP costs for beneficiaries and increase system transparency by requiring pharmacy price concessions to be included in the definition of negotiated price. We believe that these provisions are only a first step in leveling the playing field between Plan Sponsors and PBMs and Pharmacy Providers, which will decrease drug costs for patients, including those with cancer.

However, we remain very concerned that the Proposed Rule does not provide enough protection against loopholes PBMs use to extract unfair and unsustainable price concessions from Pharmacy Providers. Specifically, we are concerned with CMS’ provision to give plans flexibility on whether to apply pharmacy price concessions to negotiated prices in the coverage gap and the agency’s proposed definition of pharmacy administrative service fees. Due to substantial insurer and PBM consolidation in recent years, true “negotiation” between Plan Sponsors and Pharmacy Provider is simply a myth. As we have noted, 79 percent of prescription drug claims are processed by three PBMs, but if you add the next three largest PBMs, the top six PBMs control a staggering 97 percent of prescription drugs.⁴³ And to make matters worse, the top PBMs are now vertically integrated with the largest health insurers, as well as with specialty and mail order pharmacies. This extraordinary market power prevents Pharmacy Providers from negotiating at all with Plan Sponsors and their PBMs, which is jeopardizing the financial health of Pharmacy Providers and fueling drug prices for Medicare seniors. Pharmacy Providers are unable to say “no” to PBMs and their punitive DIR fees and administrative burdens, any more than a deli owner is unable to say no to “protection” payments demanded by organized crime.⁴⁴ If you think this is an absurdly hyped statement, please talk to Pharmacy Providers, especially independent retail pharmacies that are increasingly

⁴¹ 83 FR at 16592

⁴² Senate Finance Committee. “Letter to Secretary Azar and Administrator Verma.” September 2019. Available [Here](#).

⁴³ Mader, Josh. “Pharmacy Benefit Managers: Market Landscape and Strategic Imperatives.” Health Industries Research. Accessed February 14, 2022. Available [Here](#).

⁴⁴ <https://www.youtube.com/watch?v=YZBWSAFCrU>

going out of business and specialty pharmacies that are being acquired by PBMs and/or their corporate owners.

COA applauds⁴⁵ the Biden administration for its commitment to relaunching the Cancer Moonshot to end cancer in our lifetime and we look forward to collaborating with the President and his Moonshot team on this important initiative. However, to ensure that cancer patients receive timely and affordable access to prescription drugs, CMS must strengthen the Part D program and level the playing field for community oncology and urology Pharmacy Providers. This can be accomplished by addressing the deleterious effects of unchecked growth in DIR fees, closing loopholes that allow PBMs and Plan Sponsors to use their competitive advantage to assess new fees and further suppress overall pharmacy reimbursement, and by providing stronger oversight of quality metrics used by PBMs to ensure they are fair, relevant, and customized to a specific pharmacy type.


Importantly, CMS clearly has the authority not only to take the steps in the Proposed Rule, but also to adopt the policy recommendations set forth herein. While CMS has historically eschewed directly “interfering” in sponsor-pharmacy “negotiations,” CMS maintains a longstanding ability to set appropriate guardrails and rules around the nature of the relationship between Plan Sponsors and Pharmacy Providers. In this vein, CMS has highlighted numerous statutory provisions that require the agency to directly intervene in the contractual relationship between Plan Sponsors and Pharmacy Providers, including (relative to drug-cost-related issues) *“Interpretation of what ‘access to negotiated prices’ means, any-willing-pharmacy standard terms and conditions, prohibition on any requirement to accept insurance risk, prompt payment, and payment standard update requirements.”*⁴⁶ ***The actions we propose fall squarely in line with this legislative mandate.***

Ultimately, these policy changes are critical not only to supporting the ability of community oncology and urology practices to provide the highest quality, most affordable care to vulnerable cancer patients but also to protecting the nation’s backbone of independent retail pharmacies, which are vanishing from the landscape, especially in rural and underserved areas.

We stand ready to answer any questions about our comments.

Thank you.

Sincerely,



Kashyap Patel, MD
President



Ted Okon
Executive Director

CC: Federal Trade Commission
Hon. Richard Neal, Chair, House Committee on Ways and Means
Hon. Frank Pallone, Chair, House Committee on Energy and Commerce
Hon. Ron Wyden, Chair, Senate Committee on Finance
Hon. Kevin Brady, Ranking Member, House Committee on Ways and Means
Hon. Cathy McMorris Rodgers, Ranking Member, House Committee on Energy and Commerce
Hon. Michael Crapo, Ranking Member, Senate Committee on Finance

⁴⁵ COA. “Statement from Community Oncology Alliance Executive Director Ted Okon on the Cancer Moonshot Relaunch.” February 2022. Available [Here](#).

⁴⁶ 79 FR 1918 at 1971

“Performance” Based DIR Fees: A Rigged System with Disparate Effect on Specialty Pharmacies, Medicare Part D Beneficiaries and the U.S. Healthcare System

Prepared by

Frier Levitt, LLC

Commissioned by the National Association of Specialty Pharmacy

March 2017

FRIER LEVITT
ATTORNEYS AT LAW

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1 Executive Summary

Over the past year, an alarming trend has emerged in the healthcare context that threatens to disrupt the entire delivery model for a large subset of our nation’s most vulnerable patients – seniors enrolled in the Medicare Part D Program receiving complex medications for life-saving treatments. This trend – unilaterally-imposed by vertically-integrated health plans and pharmacy benefits managers – jeopardizes patient access to these critical drugs. This trend is the advent of performance-based “DIR Fees.”

The management and administration of pharmacy claims in the United States is a process largely unfamiliar to the public. Unbeknownst to many, the administration of pharmacy claims is oftentimes not done by a patient’s insurance company, but is rather delegated by the patient’s insurance company to a pharmacy benefit manager, or “PBM.” These PBMs may consist of massive companies that act as middlemen between “Plan Sponsors,” such as health insurance companies and government programs, and healthcare providers, such as pharmacies. However, through a series of mergers and acquisitions the PBM industry’s power has grown tremendously, and with their power has come the implementation of policies that have caused shockwaves throughout the pharmacy industry. The focus of this White Paper is on one such policy, a policy which, if allowed to continue, will result in incalculable damage to the Medicare Part D program and, more importantly, Medicare beneficiaries.

In 2016, a significant change was noted in the administration of “direct and indirect remuneration” or “DIR” fees by select PBMs and plan sponsors against a plethora of pharmacies, including Specialty Pharmacies, that participate in Medicare Advantage and Medicare Part D pharmacy networks. The concept of DIR is not new to Medicare. Indeed, DIR was a term that originated from the Centers for Medicare and Medicaid Services (“CMS”) in an effort to capture in the “actual cost” of a prescription drug and any post point-of-sale price concessions. However, beginning in 2016 select PBMs and Medicare Part D Plan Sponsors began assessing retroactive fees to pharmacies participating in Medicare Part D networks. These fees are charged against pharmacies based on their performance in a number of primary-care focused “quality metric” categories, which are totally unrelated and irrelevant to Specialty Pharmacies and specialty pharmacy patients. These “DIR Fees” have upended the pharmacy industry, clawing back the funds dedicated to the cost of comprehensive, coordinated patient care and support services, and stand to threaten the continued ability of Specialty Pharmacies participating in Medicare Advantage and Part D networks to provide patient-necessary services which ensure optimal clinical outcomes.

As a whole, the PBM industry’s assessment of DIR Fees is wholly improper. However, this White Paper focuses on a subset of pharmacies, known as Specialty Pharmacies, where the effect of DIR Fees has been far more disparate. Specialty Pharmacies predominately provide medications for people with serious health conditions which require complex therapies, including cancer, hepatitis C, rheumatoid arthritis, and multiple sclerosis. Due to the complexity of the medications, Specialty Pharmacies provide services well beyond simply providing prescription drugs to their patients, but rather offer a number of “high touch” services and also assist patients with special administration requirements (such as injectable medications or infused medications). The Specialty Pharmacy business model is critical to the healthcare system, as they provide services for oftentimes the sickest and most vulnerable portions of the patient population – Medicare beneficiaries. However, the Specialty Pharmacy business model is also the most susceptible to the negative impacts of DIR Fees.

PBMs have recently begun to tie DIR Fees to a pharmacy's performance in a number of "quality metric" categories established by that PBM. The categories include a variety of different areas of performance, including, but not limited to diabetes adherence, statin adherence, and formulary compliance. Critically, the "quality metrics" utilized by many PBMs to assess a pharmacy's performance are retail pharmacy-centric, meaning that they focus on retail medications and therapies for commonplace disease states. As such, the criteria reviewed by PBMs are limited in their applicability to pharmacies that dispense retail medications and, as a result, are wholly inapplicable to the business model of Specialty Pharmacies. Rather than simply refrain from assessing DIR Fees on Specialty Pharmacies in light of the inapplicability of the "quality metrics," PBMs have opted to assign the average score of network pharmacies in each "quality metric" category to Specialty Pharmacies and calculate the DIR Fee accordingly. Said another way, PBMs are imposing crippling DIR Fees on Specialty Pharmacies based on the average performance of other network retail pharmacies, which have a much different drug mix, and patient and disease-management focus. The effects of these actions have been monumental.

In light of the complex and serious conditions treated, the products dispensed by Specialty Pharmacies are often more expensive than typical retail medications. The medications, however, are not only expensive on the sale-side, but are also incredibly expensive on the acquisition-side. Indeed, mark-ups between what Specialty Pharmacies acquire medications for versus the benchmark prices at which they are reimbursed by PBMs often range between less than 1% to 6%. Thus, Specialty Pharmacies generally dispense medications with only a 2% to 5% gross margin, with no additional reimbursement received for the comprehensive patient care services critical to ensuring optimal patient clinical outcomes. DIR Fees, however, can range from 3% to greater than 5%, and can thus wholly eradicate any profits to be made by Specialty Pharmacies, and in many instances actually result in Specialty Pharmacies losing money when dispensing their medications. What's worse, Specialty Pharmacies are, in many instances, hamstrung from improving their overall performance score because the "quality metrics" utilized by PBMs are inapplicable because Specialty Pharmacies may only have a small handful, or no, patients to be measured by the quality metrics. Therefore, they are given the network "average" score causing their perceived quality to be lowered and their DIR Fees to increase. The Specialty Pharmacies have no ability to influence quality metrics scores when they do not have patients in the scored categories.

These performance-based DIR Fees threaten not just the ability of Specialty Pharmacies to continue to provide the required patient care support services to Medicare Part D plan participants, but directly harm patients and the Medicare program as a whole by reducing competition and beneficiary access. As confirmed in recent CMS reports, DIR Fees have the effect of shifting financial liability from PBMs and Part D Plan Sponsors to beneficiaries, and ultimately the Medicare program, through higher point-of-sale prices, despite the fact that the PBM claws back a portion of the negotiated price from the pharmacy. In addition, by rendering Specialty Pharmacy's wholly underwater and forcing them to lose money on every single Medicare claim, PBMs and Part D Plan Sponsors will make it untenable for Specialty Pharmacies to continue to offer the necessary support services for Medicare Part D plan participants, leaving the sickest patients with few alternatives for their live-saving medications and management of their condition.

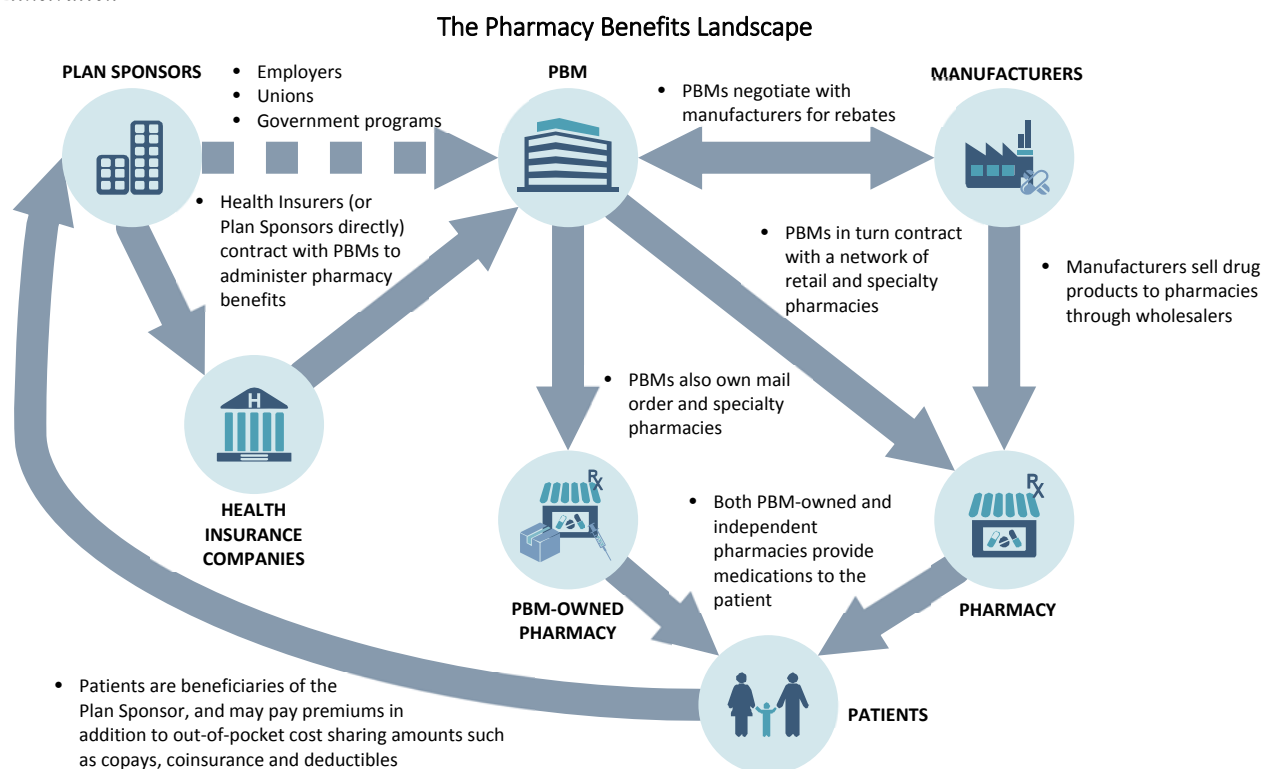
As a result of the impact DIR Fees have had on Specialty Pharmacies throughout the country, members of the media and the pharmacy industry have begun scrutinizing PBMs and the practice of assessing DIR Fees. The United States Senate and House of Representatives have each

introduced proposed legislation aimed at addressing DIR Fees and CMS has issued reports commenting on the impact DIR Fees have on the Medicare Part D program and Medicare beneficiaries. However, more can and must be done to curtail the assessment of DIR Fees, or else patients and taxpayers alike will continue to suffer.

2 Introduction

Perhaps more so than any other segment of the U.S. healthcare system, the coverage, management, and reimbursement of prescription drugs in this country is incredibly complex. The management and administration of pharmacy claims is controlled by a handful of companies known as pharmacy benefit managers, or “PBMs.” Essentially middleman, these companies contract with “Plan Sponsors” such as health insurance companies, large employers, union groups and government programs (such as TRICARE) to administer the “pharmacy benefits” for these plan sponsors— with the medical benefits typically being managed separately. In turn, PBMs contract with a network of retail and specialty pharmacies, and negotiate with and process pharmacy claims submitted by these providers. PBMs also negotiate directly with manufacturers for rebates or other pricing concessions, in exchange for placing a particular manufacturer’s drug on the PBM’s formulary. These PBMs (such as Express Scripts, Humana, CVS Caremark, and OptumRx) are often massive companies, that strangely most Americans have never even heard of.

Illustration 1



Among the “Plan Sponsors” that PBMs contract with are Medicare part D Plan Sponsors. Medicare Part D Plan Sponsors may be insurance companies, managed care organizations, or other entities that create and manage a Prescription Drug Plan made available under the Medicare Part D

Program. As noted below, many Part D Plan Sponsors are owned or affiliated with the PBMs with whom they contract.

Medicare Part D was created following the Medicare Modernization Act of 2003 (“MMA”), and established for the first time comprehensive outpatient prescription drug coverage for Medicare Part D beneficiaries. Under Medicare Part D, the Centers for Medicare & Medicaid Services (“CMS”) contracts with Part D Plan Sponsors to administer the Medicare drug benefit. Part D Plan Sponsors in turn contract with PBMs (many of whom may own, are owned by, or are affiliated with Part D Plan Sponsors) to administer the plans. PBMs in turn contract with pharmacies to provide services to plan beneficiaries. In addition to contracting with independently owned pharmacies, many PBMs also own their own retail, mail order, or specialty pharmacies. These wholly-owned pharmacies service the public, but benefit from PBM underwriting to directly compete with independently owned pharmacies. DIR Fees ultimately have the effect of steering business to the PBM wholly-owned specialty pharmacies allowing the PBM to capture DIR Fees at the plan level as increased profits.

Among the pharmacy providers with whom PBMs contract include retail pharmacies and specialty pharmacies. Retail pharmacies are generally defined as duly-licensed community pharmacies that primarily fill and sell a wide array of brand and generic prescription medications via retail storefront. Retail pharmacies – which may be chains or independents – provide general prescription drug services to general populations customers (walk-in or serviced through local delivery), and dispense commonly prescribed drugs and medication therapies, based on the habits of local prescribers and/or local plan formularies.

Meanwhile, Specialty Pharmacies are state-licensed pharmacies that predominantly provide medications for people with serious health conditions requiring complex therapies. These include conditions such as cancer, hepatitis C, rheumatoid arthritis, HIV/AIDS, multiple sclerosis, cystic fibrosis, organ transplantation, human growth hormone deficiencies, and hemophilia and other bleeding disorders. The specialty medications used to treat these conditions are often more complex than most prescription medications, and may have special administration requirements (such as injectable medications or infused medications), in addition to special storage and delivery requirements. The complexity of these medications may be due to the drugs themselves, the way they are administered, the management of their side effect profiles, or issues surrounding the access to those medications.

In addition to being state-licensed and regulated, Specialty Pharmacies are also often accredited by one or more independent third parties, such as URAC, the Accreditation Commission for Health Care (“ACHC”), the Center for Pharmacy Practice Accreditation (“CPPA”) or the Joint Commission, and often employ Certified Specialty Pharmacists to deliver care. Specialty Pharmacies also provide a variety of clinical and support services that retail pharmacies are not equipped nor prepared to provide. This includes providing patient care services required for certain complex specialty medications (i.e., nursing support), providing patient training on how to administer specialty medications (i.e., instructions on how to self-administer injectable medications), assisting with patient support services for patients who are facing reimbursement challenges for these life-saving but often costly medications, ensuring special handling of certain specialty medications with

unique requirements, and engaging in ongoing patient monitoring based on medication and therapy requirements.¹

The heightened services and customer care provided by Specialty Pharmacies has undoubtedly had an extraordinary impact on patients and physicians alike. For instance, one testimonial recently received by a Specialty Pharmacy reads:

I want to put a very special word in for [a Specialty Pharmacist] and how kind and helpful she is and how much easier she made what could've been a confusing first (and second experience) when ordering through a specialty pharmacy, which I had never done before. She was able to explain everything about the drug to me (something I had never taken before and was quite nervous about starting due to it being a strong narcotic) and answer all my questions and by the time we were finished I was quite comfortable with the idea of the new medication I would soon be starting.

A medical provider recently submitted a testimonial with similar sentiments:

Always mindful of side effects, [Specialty Pharmacy A] always keeps me informed of patient interactions, or when a patient may need something that they have not reported directly to me...the patient is educated in office and over the phone by [the Specialty Pharmacy's] pharmacists. The patients hearing the information twice helps adherence...

Simply put, the services provided by Specialty Pharmacies have an overwhelming impact on patient adherence. It has been documented that only 50% of patients with chronic conditions take their medication as directed.² There are a multitude of reasons why Medicare patients suffer from nonadherence, including forgetfulness, a desire to avoid adverse medication side-effects, and high cost.³ Estimates indicate that nonadherence to prescription drug regimens cost \$105 billion in annual avoidable health care costs.⁴

However, the approaches utilized by Specialty Pharmacies when assisting their patients have demonstrably decreased the nonadherence rates for patients taking specialty medications. One study revealed that patients who exclusively used Specialty Pharmacies had a 60% higher adherence rate when compared with patients using retail pharmacies, while another study found that Specialty Pharmacies, on average, had a 8.6% higher adherence rate when compared to retail pharmacies.⁵ Specifically, studies show that adherence rates in specific specialty therapies are far greater than the average adherence rate for retail medications, with multiple sclerosis at 95.33%, rheumatoid arthritis at 94.65%, HIV at 97%, and Crohn's disease at 95.68%.⁶ This is due in no small part to the expert services that Specialty Pharmacies provide, with no additional reimbursement, which drive

¹ <http://naspnet.org/wp-content/uploads/2017/02/NASP-Defintions-final-2.16.pdf>

² Jessica Williams, US National Library of Medicine, Cost-Related Nonadherence by Medication Type Among Medicare Part D Beneficiaries with Diabetes, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3780603/> (last visited March 14, 2017).

³ Id.

⁴ Optum, How to Increase Adherence to Specialty Drugs, <https://www.optum.com/resources/library/increase-adherence-specialty-drugs.html> (last visited March 14, 2017)

⁵ Maryann Dowd, R.Ph., Specialty Pharmacy Times, The Role of Specialty Pharmacy in Medication Adherence, <https://www.specialtypharmacytimes.com/publications/specialty-pharmacy-times/2016/july-2016/the-role-of-specialty-pharmacy-in-medication-adherence/P-2> (last visited March 14, 2017).

⁶ Id.

adherence and persistency, proper management of medication dosing and side effects, and ensure appropriate medication use, while supporting the needs of some of our nation's highest risk patients.

The businesses of specialty pharmacy and retail pharmacy operate very differently, both in terms of operational margins, ancillary services provided, and infrastructure required to support the complex medications and disease states associated with the specialty pharmacy business model.

Why Don't Retail Pharmacies Dispense Specialty Medications?

Overall, retail pharmacies do not dispense medications that are used to treat patients afflicted by conditions requiring these complex specialty drugs and biologics because these conditions are not widely prevalent in the general population serviced by retail pharmacies. Additionally, the specialty medications that are dispensed by Specialty Pharmacies carry high overhead cost, and require additional technical capabilities. Costs incurred by Specialty Pharmacies include extremely expensive inventory, additional infrastructure (i.e., 24-hour telephone access to pharmacists and temperature controlled storage/shipping), and additional staffing to assist with administration of specialty medication (i.e., skilled nursing network and patient training professionals). Specialty Pharmacies must also closely coordinate with physician offices to monitor patient conditions/adverse effects, aid in completing prior authorization requirements imposed by insurance companies, and ensure adherence to complete treatment regimens. Retail pharmacies cannot justify making the related investment if specialty medications that require these costs make up only a small percent of their normal customer base. Instead, Specialty Pharmacies are better equipped to be implement the structural requirements to dispense specialty medications and engage in the required close coordination with the physicians' offices to function within the healthcare continuum for these complex disease states.

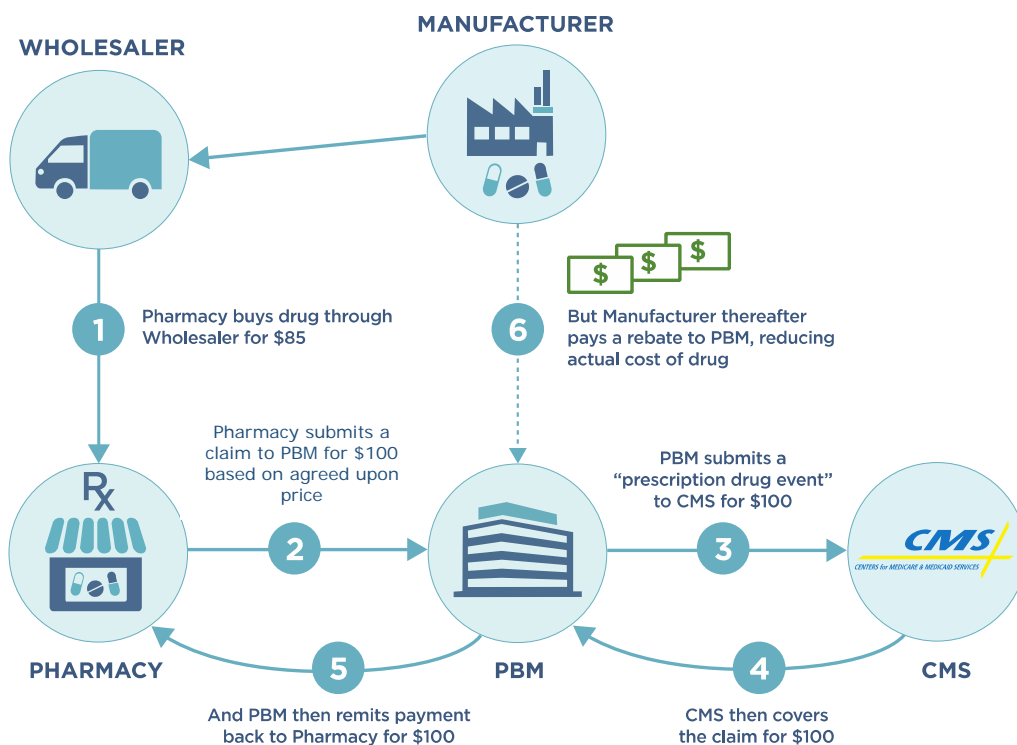
Recently, within the Medicare Part D Program⁷, many PBMs and Part Plan Sponsors have begun to introduce and expand "fees" being charged to pharmacies under the guise of "network rebates," "performance variable rates," or "direct and indirect remuneration" – or "DIR" – Fees. As noted below, many of these DIR Fees have had a grossly disproportionate impact on Specialty Pharmacies with percentage-based fees being particularly damaging.

As part of the Part D program, plan sponsors must report actual costs of all drugs covered under Part D, inclusive of all "direct" and "indirect" remuneration received from third-parties. Historically, the bulk of DIR received by plan sponsors and their agents was made up of manufacturer rebates that could not reasonably be calculated at the point-of-sale for the Part D covered medication. CMS wanted to ensure that it knew of and could share in part of the savings realized from manufacturer rebates. CMS also contemplated scenarios where providers, such as pharmacies, might actually be entitled to *additional* compensation based on performance. Overall, the original purpose of the DIR calculation and report was intended to provide the true cost of medication dispensed to Medicare beneficiaries, as evidenced below in the simplified illustration.

⁷ Although certain payers have begun making these fees applicable across the board for commercial and Medicare plans alike.

Illustration 2

Impact of Manufacturer Rebate on Prescription Drug Event



However, many PBMs have taken this framework and used it to justify the assessment of after-the-fact “DIR Fees” against network providers, including Specialty Pharmacies. These DIR fees charged to pharmacies are distinct from the original DIR as contemplated under the MMA. Instead of incentivizing increased performance, many PBMs have manipulated DIR to instead extract additional monies from pharmacies, including on high cost specialty medications. Such DIR Fees can take the form of either a flat fee per prescription based fee, or may be a percentage-based DIR Fee that is calculated using the ingredient cost of the dispensed medication.

Both percentage-based and flat rate DIR Fees pose serious problems and questions for pharmacies, who are assessed these murky fees either at the time of reimbursement or sometimes months after the fact, but the percentage-based fees have an increased propensity for serious consequences as these fees can be 1,000% to 10,000% higher than flat rate DIR Fees. Many DIR Fee constructs are nothing more than a “tax” on pharmacies, or a fee paid by providers for the privilege of participating in the PBM’s network, regardless of whether they are cast as flat fee or percentage-based DIR.

However, under the guise of “performance-based” fees, some PBMs have levied an extraordinary cost on Specialty Pharmacies in particular by calculating DIR Fees as a *percentage* of gross drug reimbursement per claim. This type of percentage-based fee is a particularly egregious example of PBM-imposed DIR Fee constructs, and imposes an exceptionally high and burdensome cost on Specialty Pharmacies, as the predominance of their dispensing volume is expensive medication. The disparate impact on specialty pharmacies becomes especially clear when fees

extracted from specialty pharmacies, sometimes months after medication is purchased and dispensed to patients, result in the pharmacy being reimbursed below the acquisition cost of the medication. This extraordinary result stems from the fact that Specialty Pharmacies operate in a market where the expected profit margin is a small percentage of the total cost of the medication. Further, the calculation of the DIR Fee relates primarily to qualitative measures that are not applicable to specialty pharmacies.

In this White Paper we will explore the impact DIR Fees have on one subset of healthcare providers, Specialty Pharmacies. We will explain how performance-based DIR Fees, particularly those calculated as a percentage of drug cost, have a disproportionate impact on Specialty Pharmacies and the expensive medications they dispense. This disproportionate impact is compounded, as the “quality metric” categories utilized in calculating DIR Fees review categories of information that are distinctly irrelevant to the drugs dispensed and services provided by Specialty Pharmacies. Specialty Pharmacies are further disproportionately impacted by such unreasonable and irrelevant DIR Fees because of the high concentration of specialty medications they dispense, compared to their retail counterparts (for whom DIR Fees were primarily designed). This White Paper will also explore the impact that such DIR Fees – when applied in the Specialty Pharmacy context – have on Medicare Part D beneficiaries and the Program alike. In particular, it will examine the shifting of financial liability from PBMs (including those owned or aligned with Part D Plan Sponsors) to taxpayers and beneficiaries (many of whom are among the most vulnerable population). Finally, we examine the current state of affairs of DIR Fees, as it relates to Specialty Pharmacies and their patients, and what more can and must be done to curb this abusive and destructive practice.

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3 Performance-Based DIR Fees

DIR Fees can encompass a number of charges to Specialty Pharmacies, including “pay-to-play” fees for preferred pharmacy networks, network access fees, and administrative fees. However, the type of DIR Fees that have created recent shockwaves throughout the specialty pharmacy industry are the “performance-based” DIR Fees. Indeed, performance-based DIR Fees have effectively clawed back millions of dollars from Specialty Pharmacies nationwide, and have detrimentally impacted Medicare Part D and its beneficiaries, and threaten the future of patient care access and choice.

Performance-based DIR Fees are often based on a pharmacy’s performance in a number of “quality metric” categories, established by the PBM. The categories can include a variety of different areas of performance, including ACE/ARB adherence, statin adherence, diabetes adherence, Comprehensive Medication Review (“CMR”) completion rate, and formulary compliance. Under performance-based DIR Fee programs, the amount of DIR Fees assessed against a pharmacy depends on the pharmacy’s performance in these categories, with lower performing pharmacies

being assessed a higher percentage-based DIR Fee and better performing pharmacies being assessed lower DIR Fees. Importantly, the quality metric categories are weighted, which means that certain quality metric categories count more toward the overall performance of the pharmacy than others. Some categories can weigh as much as 25%, whereas other categories can weigh as little as 5%. Regardless, the quality metric categories are virtually inapplicable to Specialty Pharmacies.

Performance-based DIR Fees can be assessed one of two ways: flat fee or percentage. An example of a flat-fee performance-based DIR Fee would have the PBM withhold \$5.00 from each claim submitted by a pharmacy to the PBM. Thereafter, the PBM will review the pharmacy's performance in three categories. For each category the Specialty Pharmacy scores in at least the 50th percentile but below the 80th percentile, the pharmacy will be refunded \$0.50. For each category the pharmacy scores above the 80th percentile, \$2.25 will be refunded. As such, the pharmacy stands to potentially pay a \$5.00 DIR Fee on each claim if its performance score is below the 50th percentile in all three categories, but can potentially receive a DIR "bonus" of \$1.25 if its performance score is above the 80th percentile in all three categories. 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
<i>Net Reimbursement to Pharmacy</i>	<i>\$95.00</i>	<i>\$96.50</i>	<i>\$101.25</i>

Notwithstanding the proposed availability of a "bonus," there is limited evidence that bonuses are paid out, particularly in the specialty pharmacy context. As noted above, these flat rate DIR Fees can pose serious problems for retail and specialty pharmacies alike, particularly where there is little actual ability for the provider to influence the performance scores.

However, performance-based DIR Fees may also be percentage-based. If such DIR Fees are percentage-based, a percent of the total claim submitted by the pharmacy to the PBM will be recouped by the PBM as a DIR Fee. The percentage clawed back by the PBM is calculated using the pharmacy's performance in quality metric categories. While in prior years, non-performance-based DIR Fees were retracted at the time of initial payment by the PBM (typically within the same 14-day claims cycle during which pharmacy claims were normally paid in the first case), more recent performance-based DIR Fees are not calculated or assessed until months later, leaving the pharmacy totally clueless as to the true "net amount" they would ultimately be paid for the claim. Similar to the flat-fee model explained above, pharmacies are assessed a lower percentage DIR Fee if they perform "better" in the quality metric categories. However, under certain models, a certain minimum percentage DIR Fee will be assessed by the PBM, regardless of how well the pharmacy performs in the quality metrics. These percentage-based DIR Fees usually range from 0% to 9%,

with many falling in the range of 3% to greater than 5% of the total claim submitted. This is illustrated in Table 2 (below).

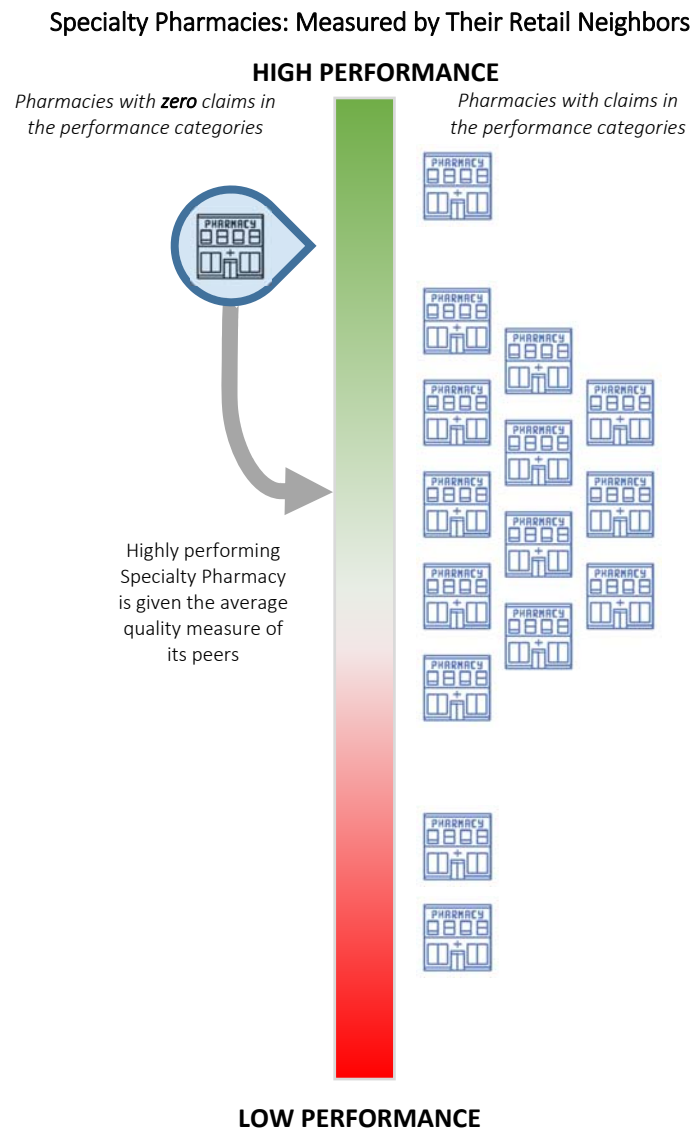
Table 2⁸

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

Most critically, as it applies to Specialty Pharmacies, each pharmacy will generally be assessed DIR Fees based on these fixed “quality metric” categories, irrespective of whether the pharmacies have any claims subject to the reporting and measurement criteria. Said another way, each pharmacy – including Specialty Pharmacies – will be judged by select PBMs using the same set of “quality metric” categories, even if the Specialty Pharmacy’s business model renders the “quality metric” categories wholly inapplicable. What’s worse, in a circumstance where a Specialty Pharmacy does not fill claims that fall within a particular “quality metric” category, the Specialty Pharmacy will receive the Part D plan’s representative performance score for that “quality metric” category for that particular review period. Thus, a Specialty Pharmacy’s performance score in a particular “quality metric” category is often dictated by average performance scores of the other retail pharmacies within the network on products that the Specialty Pharmacy generally does not dispense at all. Ultimately, and as detailed below, based on the imposition of the average performance scores of other retail pharmacies within the network, the DIR Fees imposed on Specialty Pharmacies in these cases are largely unrelated to the Specialty Pharmacy’s performance, medications dispensed or services provided.

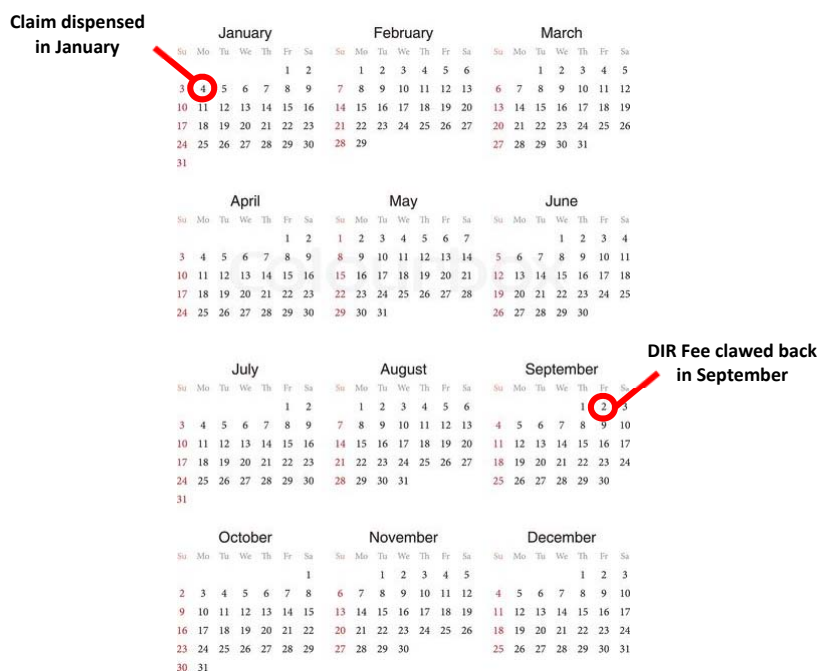
⁸ Melanie Maxwell, *Understanding Pay for Performance and DIR Impact to Pharmacy Reimbursement RxSelect Pharmacy Services*, 20, 22 (Sept. 12, 2015), <http://www.morx.com/assets/docs/2015AC/9-12-15%20%20415%20pm%20%20%20%20mapc%202015%20third%20party%20landscape%20maxwell.pdf> (last visited Mar. 9, 2017).

Illustration 3



The PBMs' timing of assessing DIR Fees is also a huge problem. Aside from the tremendous costs charged by PBMs to Specialty Pharmacies in connection with DIR Fees, the method PBMs use to calculate DIR Fees serve to add "insult to injury." DIR Fees are calculated retrospectively, which, in effect, means they are assessed against Specialty Pharmacies many months after the drug has been dispensed to the patient and the Specialty Pharmacy has been reimbursed. For example, a prescription dispensed in January may not have a DIR Fee assess until as late as September.

Illustration 4



This creates immense uncertainty at the time the medication is dispensed as to how much the Specialty Pharmacy will ultimately be reimbursed for the product (not to mention for CMS to know exactly how much is actually being paid for the drug). The inability to understand true reimbursement for medications dispensed makes it nearly impossible for the Specialty Pharmacy to properly account for projected revenues and cash flows, particularly where it is expected to provide substantial ancillary services to patients (i.e., training, adherence monitoring, and collaboration with other healthcare providers) in order to ensure a high level of patient care on complex disease states. Overall, this lack of visibility jeopardizes the ability of Specialty Pharmacies to continue to provide the necessary comprehensive patient support services to ensure maximal therapeutic outcomes to Medicare Part D plan participants, thereby greatly diminishing the level of care and treatment of some of our country's sickest and most vulnerable patients. Unfortunately, as set forth in greater detail below, it appears that this murky construct may be by design.

4 The Negative Impact of DIR Fees on Specialty Pharmacies

Specialty Pharmacies operate as a niche provider in the healthcare space and serve a critical role in the country's healthcare continuum. These pharmacies provide medication to the sickest and most vulnerable members of society. The medications utilized by this population are almost all extremely complex and typically require special handling both in processing claims (as the dispensing of the medications needs Prior Authorization beyond merely a prescriber's prescription), as well as provision of the medication to the patient (such as maintenance of medication at a cold temperature from manufacture until patient administration). The complexities related to Specialty Pharmacies highlight the important role of these healthcare providers and explain why the application of DIR Fees to this segment of the healthcare system must be analyzed accurately and practically. Failing to

do so will result in a plethora of unintended consequences that will be detrimental to the healthcare system as a whole, and to Medicare in particular.

Unfortunately, PBM-imposed performance-based DIR Fees have had a severe and disparate impact on Specialty Pharmacies. Specialty Pharmacies have no ability to influence, control, or drive the quality measurements utilized by PBMs in many of their current DIR Fee programs, yet PBMs nevertheless assess DIR Fees – whether flat-fee or percentage-based – against Specialty Pharmacies for measures they have no ability to control. Moreover, given the unique nature of the specialty pharmacy industry and alternative distribution framework for many specialty medications, the result of these *post-hoc* DIR Fees has often led to unreasonable, below-acquisition reimbursement rates which severely negatively impact Specialty Pharmacies’ ability to continue to provide the critical support services to Medicare Part D plan participants, seriously jeopardizing the health and welfare of Medicare Part D beneficiaries. Finally, this disproportionate and unreasonable impact on Specialty Pharmacies is exacerbated by the fact that such Specialty Pharmacies have a higher percentage of high-cost specialty medications (which are sometimes limited distribution in nature), given the patient populations they serve.

Far beyond merely reducing profits, DIR Fees force Specialty Pharmacies to often times dispense drugs far below their acquisition costs. This section endeavors to explore the nature and scope of that negative impact on Specialty Pharmacies.

4.1 DIR Fees’ Effect on Specialty Pharmacy Reimbursement

An understanding of how DIR Fees impact reimbursements for Specialty Pharmacies requires first an understanding of the economics of the specialty pharmacy drug distribution channel. The manufacture, sale, and distribution differ markedly for specialty products, as compared to the distribution of traditional brand and generic retail medications.

First, specialty products (whether drugs or biologics) often treat serious, critical, complex, rare, and life-threatening conditions, such as cancer, Hepatitis C, HIV, and Multiple Sclerosis. As such, specialty products are often newer, breakthrough products, with little or no generic alternatives available. Given that they are primarily branded medications, manufacturers have a substantially greater amount of control over the distribution and pricing of these products.

In addition, specialty products differ from their retail counterparts in terms of supply chain and distribution channels. The distribution channels for specialty medications can be widely divided into three categories: (i) specialty medications in a “limited distribution” framework; (ii) specialty medications accessible through a “specialty contract” only; and (iii) specialty medications with traditional accessibility.

Many specialty medications are dispensed through a limited distribution network and are referred to as “limited distribution drugs” or “LDDs.” LDDs could include products that are sold directly from the manufacturer to a select number of specialty pharmacies. Specialty medications acquired directly from the manufacturer represent an estimated 10% of the market.⁹ Certain medications are dispensed in this limited fashion for a multitude of reasons, including a need for special handling (i.e. medications that require temperature controlled transportation), requirement

⁹ <http://www.drugchannels.net/2016/10/the-top-specialty-drug-distributors-in.html>

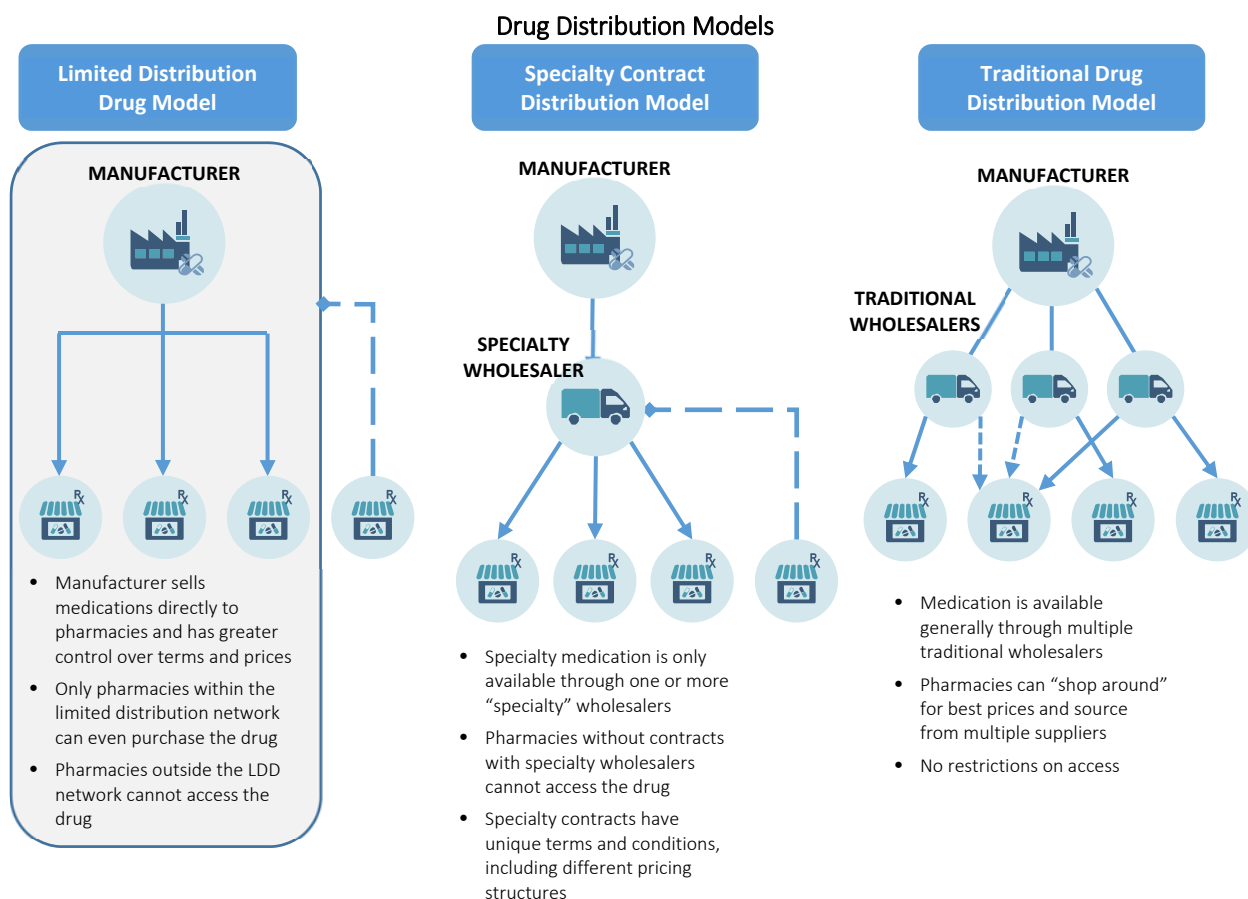
for manufacturers to maintain data regarding patient receipt and utilization (i.e. medications that are subject to an FDA Risk Evaluation and Mitigation Strategies (“REMS”)), and overall marketability of dispensing information (i.e. utilization of dispensing data to evaluate distribution strategies). The distribution network of a single LDD could be so constrained that it is available only from one or two Specialty Pharmacies nationwide. Often, even the PBM-owned specialty pharmacies do not have access to specific LDDs. LDDs often have higher cost of handling and even lower margins, as compared to other specialty and retail medications.

Other specialty medications may not be distributed directly from manufacturers, but nevertheless are still distributed in a limited fashion as compared to widely accessible medications (such as retail brand and generic medications like Pfizer’s Lipitor or generic omeprazole). These medications typically require access to specialty medication wholesalers/distributors or through a large wholesaler’s specialty contract. Access to this subset of distribution contract is not widely available and include distributors such as ASD Healthcare, Oncology Supply or Besse Medical (all three owned by AmerisourceBergen Corp.), McKesson Specialty (owned by McKesson, Corp.), CuraScriptSD (owned by Express Scripts, Inc.), and Specialty Solutions (owned by Cardinal Health Corp.) This marketplace is highly concentrated in the three largest drug wholesalers, AmerisourceBergen, Corp., Cardinal Health, Corp. and McKesson, Corp. with estimated shares of the specialty distribution market of 34%, 41% and 19%, respectively.¹⁰

Lastly, many drugs categorized as specialty medications by PBMs and/plan sponsors are more widely available through the same distribution market as retail medication. These can include medications such as Humira and Enbrel. Medications acquired through the standard distribution chain may still be unable to be dispensed by retail pharmacies that do not participate in the specialty pharmacy network, depending on the plan sponsor, or may also be subject to different credit and pricing terms.

¹⁰ Id.

Illustration 5



These alternative distribution strategies limit a Specialty Pharmacy’s ability to “shop around” for lower acquisition costs, and reduce a Specialty Pharmacy’s leverage to negotiate with wholesalers and manufacturers for lower prices. As such, specialty products are not only generally much more expensive as compared to retail drugs (sometimes upwards of \$30,000 for a 30-day supply), but the available margins or mark-ups for the products are often much lower than retail drugs, with most specialty products having margins no greater than 6%¹¹. These smaller profit margin percentages are often a function of the fact that specialty medications tend to be very expensive, so a smaller percentage margin is more acceptable. As set forth in greater detail below, small margins combined with higher drug costs means that percentage-based DIR Fees often eliminate any profit and put Specialty Pharmacies into the red, driving Specialty Pharmacies out of the Medicare Part D marketplace. This has the effect of decreasing competition for PBM-owned specialty pharmacies and ultimately increases Medicare’s drug spend, all while restricting medication access and limiting beneficiaries’ freedom of choice. Where these practices push out Specialty Pharmacies that have access to LDD, it could even create a serious patient care crisis, where such restricted medications are simply unavailable in the marketplace to certain beneficiaries.

¹¹ <http://www.drugchannels.net/2015/03/diplomat-shows-specialty-pharmacies.html>

Mark-ups between what Specialty Pharmacies acquire drugs for versus the benchmark prices at which they are reimbursed by PBMs (typically a function of AWP¹² minus a certain percentage, or WAC¹³ plus or minus a certain percentage) often range between less than 1% up to 6%. Meanwhile, the mark-ups for retail drugs range from 10% to 30% for brand drugs and can range from 30% to over 1,000% for generics.¹⁴ These differences in distribution frameworks and profit margins pose real difficulties for Specialty Pharmacies once after-the-fact percentage-based DIR Fees are introduced.

In this vein, Specialty Pharmacies often times dispense medication with only a 2% to 5% gross margin to begin with, thus, a retroactive DIR Fee of 3% to greater than 5% may not just eat up their profits, it may (and often does) put the Specialty Pharmacy underwater entirely. These economics present dire realities for Specialty Pharmacies, even if they can manage to obtain the best performance score (and in turn, lowest minimum DIR Fee) possible.

Consider the below example of a Specialty Pharmacy dispensing Drug A¹⁵, an oral medication prescribed for the treatment of lung cancer for a Medicare Part D participant.

Example 1

DIR Fees on a Claim for Drug A

Acquisition	\$13,514.99	Acquisition	\$13,514.99
AWP	\$16,217.99	AWP	\$16,217.99
Contracted AWP Discount	-15.10%	Contracted AWP Discount	-15.10%
Reimbursement Amount	\$13,769.07	Reimbursement Amount	\$13,769.07
Initial Gross Profit Above Acquisition	\$254.08	Initial Gross Profit Above Acquisition	\$254.08
DIR Fee (Lowest End -3.00%)	\$(413.07)	DIR Fee (Highest End -5.00%)	\$(688.45)
NET REIMBURSEMENT	\$(158.99)	NET REIMBURSEMENT	\$(434.37)

In the above example, every Specialty Pharmacy losses money on every claim for Drug A. With per claim DIR Fees of up to \$688.45, the best the Specialty Pharmacy can hope for is to cap their losses at \$158.99 per claim. With this reimbursement, the Specialty Pharmacy is operating at negative margins of between -1.2% and -3.2%. This is before taking into account any costs for overhead, such as payroll, professional fees, and rent, let alone the unique and high-touch services Specialty Pharmacies provide.

The economics of these reimbursements are particularly egregious for LDDs, to which large chain pharmacies and even many PBM-owned specialty pharmacies have no access, and which often require substantial additional administrative and clinical services as part of the dispensing process. By way of illustration of actual harm to Specialty Pharmacies, consider the following example

¹² “Average Wholesale Price.”

¹³ “Wholesale Acquisition Cost.”

¹⁴ <http://www.thepharmaletter.com/article/1-000-pharmacy-mark-up-on-generics>

¹⁵ This example of “Drug A,” and all other examples contained in this White Paper, are based off of actual real-world examples. However, specific identifiers have been removed, and certain data may have been changed slightly, to avoid providing any information that could be deemed proprietary or confidential. However, in each case, the import of the example and the impact on the Specialty Pharmacy or the patient remains the same.

involving a prescription for Drug B, a “high-touch,” life-supporting oral oncolytic, classified as a limited distribution drug.

Example 2

DIR Fees on a Claim for Drug B

Acquisition	\$10,037.70	Acquisition	\$10,037.70
AWP	\$12,291.06	AWP	\$12,291.06
Contracted AWP Discount	-15.49%	Contracted AWP Discount	-15.49%
Reimbursement Amount	\$10,386.95	Reimbursement Amount	\$10,386.95
Initial Gross Profit Above Acquisition	\$349.25	Initial Gross Profit Above Acquisition	\$349.25
Cost of Services Per Specialty Claim <i>(Includes intake, processing, clinical services, courier/delivery and dispensing costs)</i>	\$(150.00)	Cost of Services Per Specialty Claim <i>(Includes intake, processing, clinical services, courier/delivery and dispensing costs)</i>	\$(150.00)
Initial Net Profit	\$199.25	Initial Net Profit	\$199.25
DIR Fee (Lowest End -3.00%)	\$(311.61)	DIR Fee (Highest End -5.00%)	\$(519.35)
NET REIMBURSEMENT	\$(112.36)	NET REIMBURSEMENT	\$(320.10)

These “high touch” services provided by Specialty Pharmacies are critical and necessary, and are what set Specialty Pharmacies apart in functioning as high-level healthcare providers. It can require several man-hours per fill in order for Specialty Pharmacies to process and dispense these medications to their patients. These services could include enhanced patient consultation, obtaining additional information from the prescriber (including clinic notes and records), consulting with nursing staff, completed REMS program reporting, sensitive packaging based on special medication, and finding charitable funding support for patients in financial need. Often times, many of these services are required as part of the Specialty Pharmacy’s mandatory accreditation in order to receive licensing, access to drugs or admission to payor and PBM networks. By creating a reimbursement system that puts Specialty Pharmacy below water – particularly on LDDs to which PBM-owned pharmacies do not have access – PBMs are essentially shifting the financial liability for providing services ancillary to filling the prescription to independent Specialty Pharmacies, forcing them to do it at a loss or not at all. In short, Specialty Pharmacies are losing money treating the most vulnerable Medicare patient population, directly as a result of PBM imposed DIR Fees.

Importantly, however, the disproportionate negative impact on Specialty Pharmacies created by DIR Fees is not limited to LDDs. Many other specialty medications and products that are subject to an open distribution model, such as Enbrel, Humira or Harvoni, are subject to the excessively high and unreasonable percentage-based DIR Fees, putting Specialty Pharmacies underwater and threatening their ability to continue to provide these critical, high touch, patient-centric services to drive patient compliance, persistency and optimal clinical outcomes.

What’s worse, for Specialty Pharmacies, a higher percentage of their patient population receive high-cost specialty medications, which leads to DIR Fees having a disparate impact on accredited Specialty Pharmacies as compared to other providers.

This is illustrated with an example. Consider two pharmacies, Pharmacy A, a retail pharmacy, and Pharmacy B, a Specialty Pharmacy who has devoted substantial resources to invest in Hepatitis C therapies, clinical protocols and treatments, and who has forged relationships with

prescribing physicians and Hepatitis patient groups alike. If Pharmacy A fills 100 prescriptions in a given month, 98 of the prescriptions would likely be for traditional retail medications at \$100.00 per fill, and perhaps 2 of the prescriptions would be for Drug Y, a specialty oral hepatitis medication for the treatment of Hepatitis C, for \$25,000 per fill. Meanwhile, when Pharmacy B fills 100 prescriptions in a given month, it is possible that 98 of them would be Drug Y, and only 2 of them might be traditional retail medications.

If both Pharmacy A and B are assessed the same DIR Fee of 4.5%, Pharmacy A's total DIR Fee clawbacks would be \$2,691.00, while Pharmacy B's clawbacks would be \$110,259.00. Of course, if the DIR Fees were a flat fee, or were capped at a rate in line with other PBMs, the total DIR Fees for both pharmacies would only be \$500.00. In either event, however, these fees are based on performance and quality measures irrelevant to specialty pharmacy outcomes, and regardless of the formula used to calculate the fees, these fees are levied with no added value delivered by the PBM to the Part D beneficiary or the Medicare Part D program.

These trends are only more pronounced in cases where Specialty Pharmacies have access to limited distribution drugs. In those cases, Specialty Pharmacies receive an *even higher* percentage of prescriptions for those limited therapies, to which they are often one of only a handful of pharmacies with access to sell the product, and such Specialty Pharmacies regularly receive referrals from other providers (including PBM-owned specialty pharmacies who do not even have access to certain medications). Penalizing Specialty Pharmacies whose clinical systems are designed to handle rare medications, so that PBMs can reap staggering profits on DIR Fees, is unconscionable and ultimately hurts Medicare patients and the Medicare system generally.

In addition, many of the conditions requiring specialty medications tend to have higher incidences in the Medicare Part D population, where performance based DIR Fees have been most heavily implemented.¹⁶ For example, cancer and rheumatoid arthritis are conditions with a variety of high cost specialty medications available in the marketplace, and which have a higher incidence among seniors.¹⁷ Medicare patients have a much higher chance of having these diseases than younger patients covered by commercial policies, where these performance-based DIR Fees do not generally apply.

These factors only serve to compound an already precarious and unsustainable position for Specialty Pharmacies' ability to serve patients and provide the critical support services in certain Medicare Part D networks. The severe, negative economic impact on Specialty Pharmacies caused by DIR Fees compromises the access and choice of our most vulnerable patient population – Medicare Part D beneficiaries. If Specialty Pharmacies are forced to discontinue providing these support services and specialty medications to Medicare Advantage and Medicare Part D participants, Medicare beneficiaries will not have access to a broad selection of willing providers to service their critical medication needs. As a result, DIR Fees may effectively steer Medicare beneficiaries toward a small subset of PBM and payor-owned specialty pharmacies with few incentives to achieve optimal clinical outcomes and patient service. As noted below, this narrowing of Medicare Part D Specialty

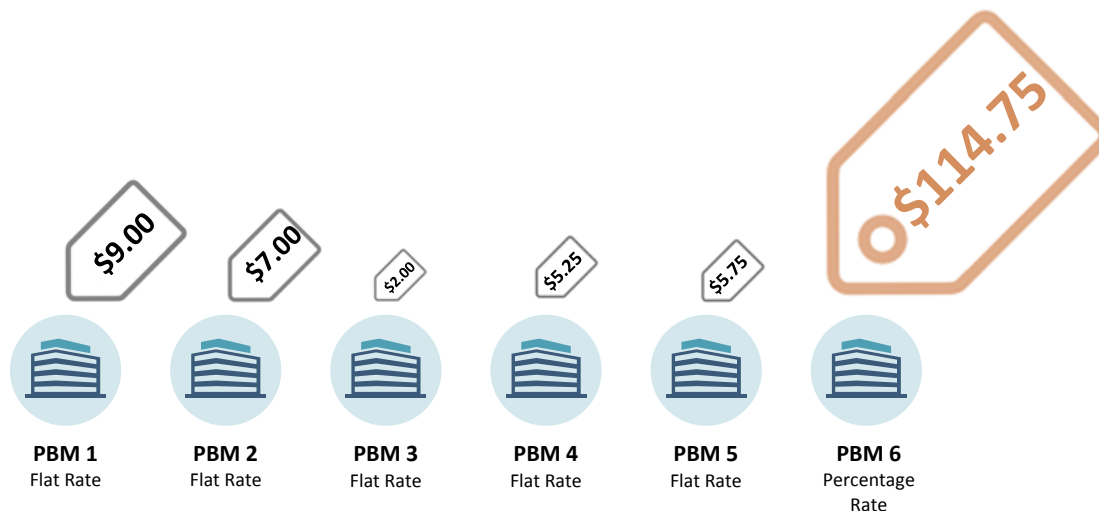
¹⁶ <http://www.unitedhealthgroup.com/~media/uhg/pdf/2014/unh-the-growth-of-specialty-pharmacy.ashx>

¹⁷ <https://www.acscan.org/sites/default/files/2013-Medicare-Chartbook-Online-Version.pdf> (“In 2012, more than 1.6 million new cases of cancer were diagnosed in the United States. Fully half of those individuals –880,000—were over the age of 65”; <http://www.modernhealthcare.com/article/20160401/NEWS/160409993> (“A substantial number of rheumatoid arthritis patients are Medicare enrollees...”);

Pharmacy networks circumvents the intent of the Medicare Any Willing Provider Provisions and seriously threatens beneficiary access and choice.

Case Study: Flat Fee DIR Fees vs. Percentage Based DIR Fees

Without commenting on the propriety of any one format, or even of any DIR Fee construct as a whole, it is important to recognize that percentage-based DIR Fees are not the only format in existence in the Medicare Part D marketplace. Many PBMs employ DIR Fee programs that encompass a fixed dollar amount per claim. Utilizing information across the pharmacy industry it is clear that the utilization of percentage based DIR Fees ultimately has a disproportionate impact on Specialty Pharmacies. An industry wide example of different PBM programs illustrates the disproportionate impact of percentage based DIR Fees on Specialty Pharmacies. The chart below illustrates the enormous fee associated with percentage-based DIR Fees as compared to Flat Rate DIR Fees.



Percentage-based DIR Fees result in assessments against Specialty Pharmacies nearly 20-times the average of other industry flat-rate DIR Fees. Of note, with the average cost of a generic retail drug is a little more than \$280 per year.¹⁸ A 4.5% DIR Fee on a generic retail medication would result in a clawback of approximately \$12.60, or 1.06 per prescription, a number more in line with other flat rate DIR Fees. The flat rate DIR Fee imposed on a generic drug illustrates and further confirms the inappropriateness of percentage-based DIR Fees in the context of Specialty Pharmacy.

Moreover, the disproportionate impact on Specialty Pharmacies is often larger than the average listed above, as many Specialty Pharmacies often dispense much more expensive products. For example, Specialty Pharmacies dispense certain medication with costs above \$30,000. The DIR Fee for these medications are well above \$1,000 per prescription per month when calculated on a percentage basis as oppose to fees that max out around \$9.00 under flat rate DIR Fee programs with other PBMs. This is nearly a 20,000% increase over the average DIR Fees in flat fee programs.

¹⁸ <http://www.aarp.org/health/drugs-supplements/info-2015/prices-spike-for-generic-drugs.html>

4.2 Inapplicability of Performance Metric Criteria to Specialty Pharmacies

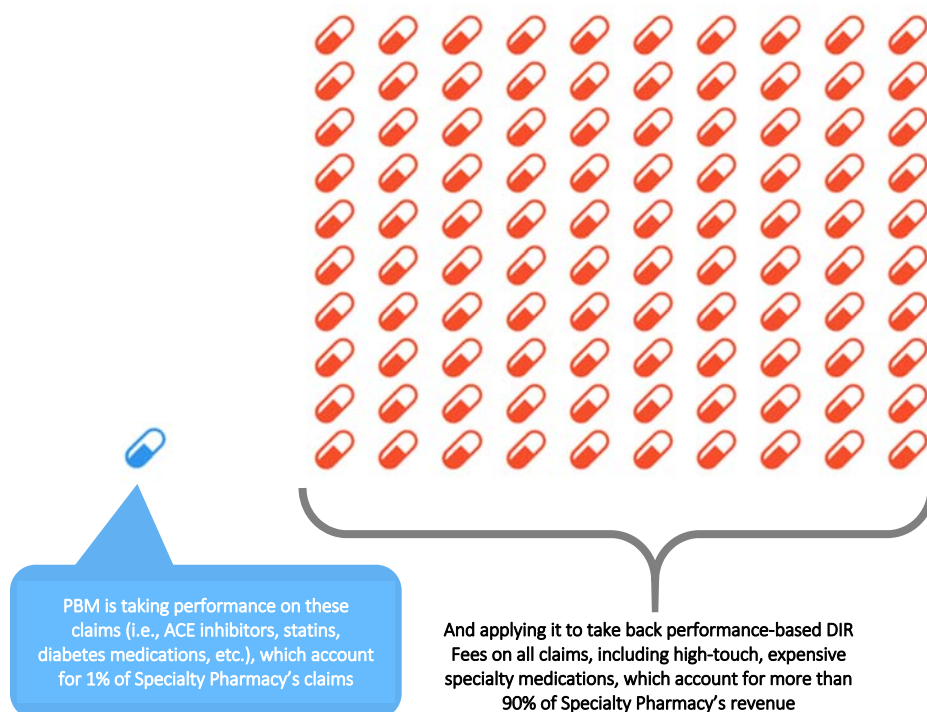
The disparate impact of DIR Fees on Specialty Pharmacies goes beyond solely the economics of percentage-based DIR Fees applied to high-cost specialty drugs. Specialty Pharmacies face a “double whammy” when percentage-based DIR Fees are calculated based on quality metric categories that have nothing to do with the products and services provided by Specialty Pharmacies, and over which Specialty Pharmacies have no ability to influence performance scores. Overall, the quality metric categories, as implemented and applied by PBMs, do not provide an adequate basis of measuring Specialty Pharmacies’ impact on patient care.

Quality metric categories utilized by PBMs to calculate DIR Fee are largely inapplicable to Specialty Pharmacies. In many early DIR Fee programs, PBMs have adopted the CMS Star Ratings System to develop performance metrics. There’s good reason they do this, as PBMs and Part D sponsors themselves receive a financial bonus with the achievement of higher Star Ratings from CMS. As a result, these quality metric categories often include individual patient adherence to certain treatment regimes in specific categories such as: 1) heart disease (Angiotensin-converting enzyme (“ACE”) inhibitors / angiotensin receptor blockers (“ARB”) adherence); 2) treating high cholesterol (statin adherence); 3) managing high blood sugar levels (diabetes adherence). Putting aside the mechanics of how these metrics are calculated (which is a discussion for another day, given the murkiness of PBM contracts), these quality metric categories are primarily retail pharmacy driven, and are largely inapplicable to Specialty Pharmacies as these pharmacies do not focus on the treatment of the few above-mentioned medical conditions.

Specialty Pharmacies instead focus on providing medication for the sickest members of the population that face incredibly complex, serious, and often rare medical conditions. The inapplicability of limited quality metric categories is best viewed through a real-life example. During the period of time that Specialty Pharmacy A is reviewed to assess its score of the quality metrics, Specialty Pharmacy A dispensed 1,800 prescriptions. Of those 1,800, only 1% or 18 individual prescriptions fit into the PBM’s above-mentioned performance categories because Specialty Pharmacies do not dispense ACE/ARB, statins, or diabetes medications. Nevertheless, the PBM will assess percentage-based DIR Fees on Specialty Pharmacy A on all 1,800 claims based on “performance” on only 18 claims.

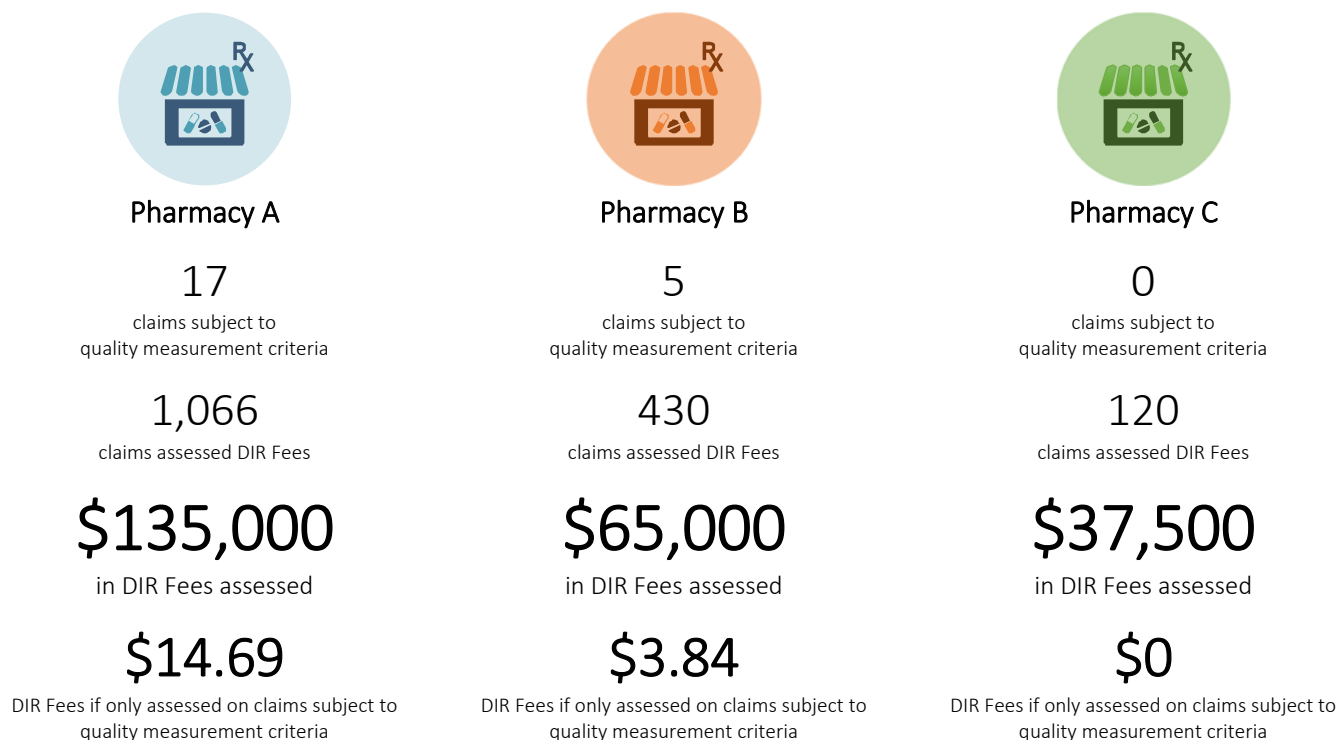
Illustration 6

Claims Subject to Reporting Requirements vs. Claims Subject to Performance-Based DIR Fees



The experiences of Specialty Pharmacy A are not unique within the specialty pharmacy industry.

Illustration 7






Pharmacy C's experience in the scenario above raises an important question about what happens when a pharmacy does not have sufficient claims volume in the various performance criteria. Many PBM contracts may state that in such cases, the pharmacy will neither be advantaged nor disadvantaged by this scenario. However, in practice, such Specialty Pharmacies are ultimately assigned the average score for that particular Part D plan and penalized.

This is perhaps the most egregious aspect of how DIR Fees are applied and weighted in the Specialty Pharmacy context. In these situations, Specialty Pharmacies may often find themselves being ascribed the average performance of other pharmacies for the various categories (such as, diabetes adherence), within that particular Part D plan during that assessment period. These categories tend to make up the bulk of the weighting (around 95%) for the performance score, leaving Specialty Pharmacies with control of only minimal components of the performance criteria (such as formulary compliance, which appears to simply list all claims dispensed by a pharmacy in that plan during that time period). This design and application flies in the face of not only the concept that Specialty Pharmacies will neither be harmed nor helped by not having claims in a given category, but also the concepts of overall fairness and equity. In fact, these network average scores often prove to be much less than scores that are or could be obtained by Specialty Pharmacies, who are often best-equipped to obtain positive patient outcomes for the diseases and medical conditions of which each Specialty Pharmacy specializes in.

Consider the following three examples of Specialty Pharmacies, who had no claims subject to any of the reporting criteria, *except* for the Formulary Compliance metric.

Illustration 8

Network "Averages" vs. Actual Metrics of Performance

								
PHARMACY 1			PHARMACY 2			PHARMACY 3		
Overall Performance Score (Based Primarily on Network Averages)	Formulary Compliance Score (Based on Pharmacy's Actual Performance)	DIR Fee Assessed	Overall Performance Score (Based Primarily on Network Averages)	Formulary Compliance Score (Based on Pharmacy's Actual Performance)	DIR Fee Assessed	Overall Performance Score (Based Primarily on Network Averages)	Formulary Compliance Score (Based on Pharmacy's Actual Performance)	DIR Fee Assessed
84%	96%	4%	83%	94%	4%	82%	94%	4.8%

In each of the above cases, the Specialty Pharmacies are ascribed a performance score based on the network averages that is substantially lower than the scores the pharmacies *did achieve* in the Formulary Compliance category that is applicable to their Medicare patient population. As is demonstrated in Pharmacy 3's example, this Specialty Pharmacy had zero claims in any of the quality metric categories, other than the "Formulary Compliance" metric. As noted, the Specialty Pharmacy

scored exceedingly well on those claims, with a score of 94%, but was nevertheless assigned the “average” performance score of all pharmacies in the other quality metric categories, which dramatically reduced its overall performance score to 82%. Thus, the Specialty Pharmacy obtained a score more than 14% higher based on metrics against which it was actually measured. Such a significant improvement in performance scores could put the pharmacy in a different DIR Fee tier altogether, as compared to the 4.80% that the Specialty Pharmacy was assessed. Even the difference of one percentage point in DIR Fee rates (assuming they could even be applied in the first place) could result in decreased costs to some Specialty Pharmacies of hundreds of thousands of dollars in one trimester alone.

Moreover, because the Star Ratings system is essentially a retail pharmacy construct, DIR Fee performance metrics based on this system are focused on retail pharmacy functions, and overlook the superior performance and quality measures demanded and routinely attained by accredited Specialty Pharmacies. For example, while Specialty Pharmacies do not create policies and protocols around maintaining diabetes or statin adherence (since they very rarely dispense those types of products), they do develop and maintain a robust series of procedures and workflows surrounding other quality measures more applicable to specialty pharmacy. These include measurements of Proportion of Days Covered (“PDC”), Drug Safety, Dispensing Accuracy and Patient Satisfaction, just to name a few. These metrics are carefully tracked real-time by Specialty Pharmacies (often as part of their accreditation requirements), and are far better indicators of the performance level of Specialty Pharmacies compared to Star Ratings. Most critically in this regard, however, is the fact that for these measurement criteria, Specialty Pharmacies seek and attain performance rates far in excess of the network average scores they are ascribed through many PBM-imposed DIR Fee programs. For example, Specialty Pharmacies routinely strive for and actually meet compliance rates of either 90% or better, 98% or better, or even 99.8% or better. Thus, the performance metrics used by PBMs have *no bearing whatsoever* on the services and products actually provided by Specialty Pharmacies.

The methods in which DIR Fees are assessed against Specialty Pharmacies are at best puzzling, and at worst illogical and capricious. What’s worse, the method of calculating DIR Fees is completely divorced from the overall purpose of the program: to reward pharmacies for performing well, and to punish pharmacies for performing poorly. Rather, these performance-based DIR Fee programs have devolved into economically punishing pharmacies for the poor performance of their competitors.

5 The Negative Impact of DIR Fees Is Not Limited to Specialty Pharmacies as DIR Fees Push Medicare Part D Beneficiaries into the Coverage Gap Prematurely and Increase Overall Costs to Beneficiaries and the Government

Contrary to many recent statements in the marketplace and by the PBM lobby, the expansion of DIR Fees has had a substantial negative impact on both Medicare beneficiaries and the Program as a whole. As confirmed in recent CMS studies, DIR Fees ultimately shift financial liability from the Part D Plan Sponsor to the patient, then ultimately to Federal government,

through Medicare’s catastrophic coverage framework. The shifting of financial liability away from the Part D Sponsor and to Medicare and the patient is even more pronounced in the context of specialty medications. An understanding of this phenomenon requires first an understanding of the Medicare Part D coverage breakdown.

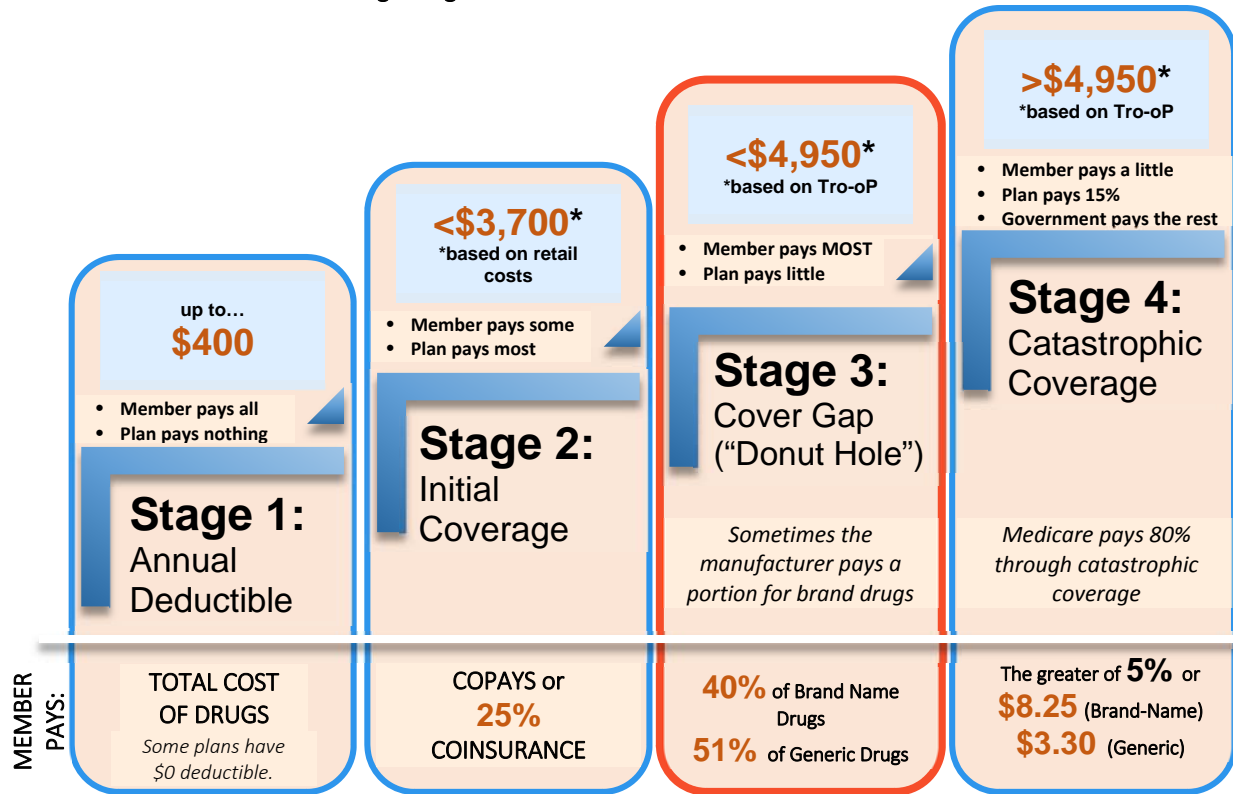
Most Medicare Part D prescription drug benefit plans have three stages: (1) initial coverage, (2) the coverage gap, or “donut hole,” and (3) catastrophic coverage. Each stage has different limits or thresholds, which are updated from year-to-year. In 2017, the initial coverage for a Medicare Part D beneficiary was \$3,700¹⁹. As illustrated in detail in the table below, this means that for the first \$3,700, the beneficiary, under most Part D plans, will have minimal out-of-pocket costs, which are usually limited to the beneficiary’s deductible (in plans that have a deductible component), copayments, and potentially coinsurance for their prescription drugs (coinsurance is often 25% of the drug cost). Once the beneficiary and the Medicare Part D plan spend \$3,700 collectively on covered drugs, the beneficiary enters stage 2, known as the “coverage gap” or “donut hole.” When a Medicare beneficiary is within the “donut hole,” they are responsible for up to 40% of the plan’s cost for brand-name drugs, and up to 51% of the plan’s cost for generic drugs (importantly, Part D Plan Sponsors are only responsible for 10% of brand-name medications and 49% of generic medications in the donut hole, as compared to 75% during the initial coverage stage²⁰). Thus, the Part D Plan Sponsor has a financial incentive to move Medicare beneficiaries into the Donut Hole. A Medicare beneficiary remains in the “donut hole” until the beneficiary and Part D plan have spent \$4,950 collectively in 2017. Once the beneficiary and plan’s cost exceed \$4,950, the beneficiary enters stage 3, “catastrophic coverage.” In stage 3, a beneficiary’s out-of-pocket costs greatly decrease, as they are capped at either 5% or \$3.30 (whichever is greater) for generic or preferred medications, and 5% or \$8.25 (whichever is greater) for all other drugs. Most critically, the Part D Plan Sponsor’s share decreases to 15% during the catastrophic coverage stage – this is 5-times less than their responsibility during the initial coverage stage. This three-stage process is illustrated in Illustration 9 below.

¹⁹ <https://q1medicare.com/PartD-The-2017-Medicare-Part-D-Outlook.php>

²⁰ <https://www.segalco.com/media/2521/me-5-4-2016.pdf>

Illustration 9²¹

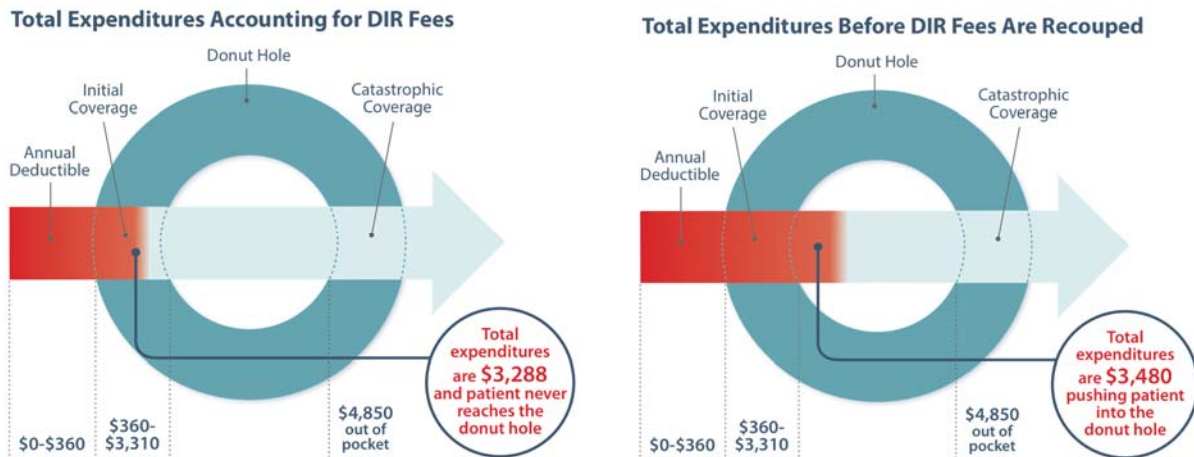
Coverage Stages of Medicare Part D and the “Donut Hole”



Ultimately, the post point-of-sale imposition of DIR Fees may result in Medicare beneficiaries entering the donut hole prematurely. For example, Patient A receives a prescription drug once a month with a negotiated price of \$290 per month. Patient A will enter the “donut hole” after twelve fills, and will thus be responsible for an increased level of cost sharing until Patient A reaches catastrophic coverage limits. If, however, the negotiated price for the drug charged at the point of sale had reflected a 5.5% DIR Fee (instead of the PBM subsequently assessing such fee on the Specialty Pharmacy after the Medicare beneficiary enters the Donut Hole), the costs charged to Patient A would dramatically decrease. In fact, Patient A would have never entered the “donut hole” in the first place. This is shown in the illustration below based on 2016 limitations.

²¹ <https://www.senior-advisors.com/medicare-blog/changes-upcoming-to-part-d-of-medicare-in-2017>

Illustration 10



Additionally, the out-of-pocket costs for Medicare beneficiaries in the coverage gap and in the catastrophic coverage phase are based on a percentage of the total cost of the prescription drug. In the coverage gap phase, a beneficiary's out-of-pocket cost can be as high as 51% of the cost of the drug, whereas in the catastrophic coverage phase the beneficiary's out-of-pocket cost can be as high as 5% of the cost of the drug. Said another way, a beneficiary's out-of-pocket cost in stage 2 and stage 3 (and oftentimes in stage 1, as well) is directly dependent on the actual point-of-sale cost of the drug (as opposed to other forms of beneficiary cost sharing, such as copayments, where the amount stays fixed). So, when the actual cost of the drug changes after the point of sale, only the PBMs charging such fees benefit.

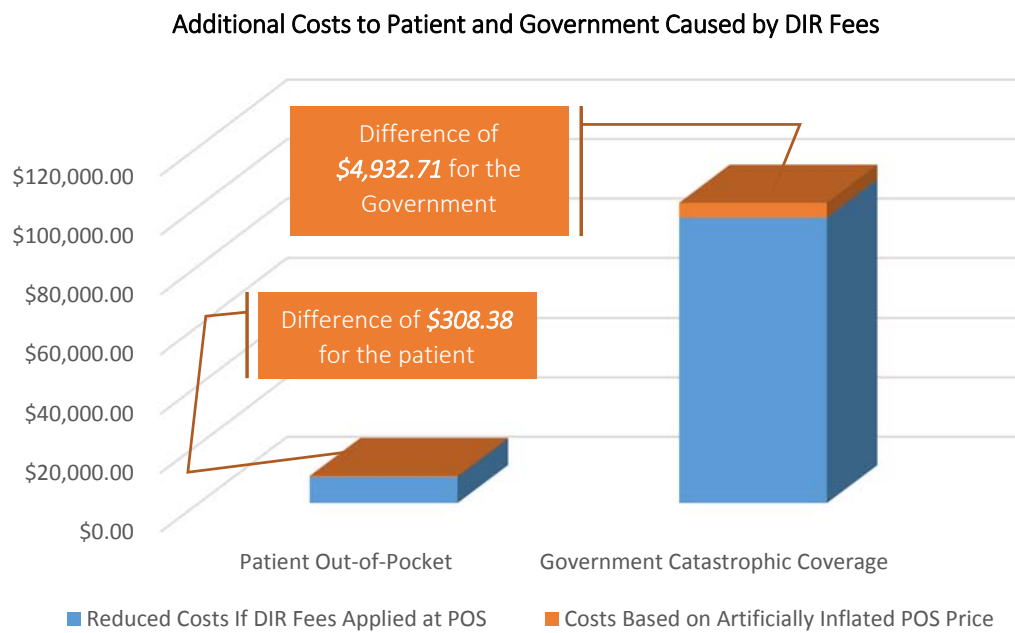
DIR Fees, whether percentage-based or flat fee, undoubtedly increase the ultimate costs borne on Medicare beneficiaries, as the cost of a prescription drug at the point-of-sale – which is where beneficiaries' out-of-pocket expenses are determined – are artificially inflated. To illustrate this concept, imagine a prescription drug with a negotiated price of \$500 at the point of sale. If the beneficiary is in the coverage gap, the beneficiary's out-of-pocket expenses could be as high as 51% of the cost of the drug, which would amount to \$255. However, if the actual price of the drug is subsequently lowered 4.5% by a DIR Fee, the cost of the drug would be lowered to \$478.50 and the Medicare beneficiary's out-of-pocket expense would be similarly lowered to approximately \$244. Thus, the retroactive DIR Fee resulted in the beneficiary paying approximately \$11 more out-of-pocket than he/she should have.

The financial harm to Medicare beneficiaries is exaggerated in the specialty drug context, where drug costs are not \$500 per fill, but oftentimes exceed \$10,000 per fill. Consider the following example: Patient A fills a prescription for Drug Y, a specialty medication, once-per-month. The point-of-sale adjudicated price for a prescription of Drug Y is \$11,170.90. During Patient A's first month filling the prescription, the costs to Patient A and her Part D plan result in Patient A speeding through the initial coverage stage as well as the coverage gap stage. Patient A's total out-of-pocket costs for the first fill of Drug Y, which is inclusive of Patient A's deductible, copayment, and cost-sharing, is \$3,067.89. Thereafter, for the next eleven fills, Patient A is in catastrophic coverage, and is paying approximately \$558.55, or 5% of the drug cost. Patient A's total out-of-pocket costs for the year would be approximately \$9,211.93.

Next, consider the impact a 4.6% DIR Fee would have on Patient A's out-of-pocket expenses. Instead of Drug Y costing Patient A and her Part D Plan \$11,170.90 each month, the DIR Fee being charged at the point of sale would result in the actual price of the drug being \$10,657.04, a difference of \$513.86 per month. Accordingly, Patient A's first-fill would cost approximately \$3,042.20, and each subsequent month Patient A would be responsible for approximately \$532.85. Patient A's total out-of-pocket expenses for the year would amount to \$8,903.55. Thus, Patient A paid an additional \$308.38 throughout the course of the year out-of-pocket because Patient A's cost-sharing amounts were based on the drug's cost prior to the PBM's imposition of DIR Fees. In other words, Patient A's out-of-pocket costs were based on an inaccurate, artificially inflated number created by the PBM. In this instance, the PBM and Part D Plan Sponsor effectively shifted \$308.38 of costs from the plan sponsor to the Medicare beneficiary for this one drug. It is important to note that although this is an individual example of the incurred financial harm of one Medicare beneficiary, this cost shifting is happening on all claims in select networks resulting in huge additional profits for the plans (often wholly owned subsidiaries of the PBM's that created the fees), and causing in widespread beneficiary impact and harm.

Unfortunately, this shifting of financial liability does not end here. Because the Medicare Part D Program provides reinsurance payments for catastrophic coverage costs exceeding \$4,950, Part D Plan Sponsors effectively also shift costs from the Part D Plan to the Medicare Program, and ultimately the taxpayer, through these inflated point-of-sale prices. In that same example as above, with 12 fills of Drug Y at an adjudicated cost of \$11,170.90, the Medicare catastrophic coverage would ultimately kick in, and Medicare would pay a total of \$101,037.74 for this patient. However, if the assessment of the 4.6% DIR Fee had been applied at the point-of-sale, Medicare would have only been responsible to pay \$96,105.03. In this instance, the DIR Fee resulted in an overpayment by the Government of \$4,932.71 for this one patient, for this one drug. This serious impact on the Government and the patient is illustrated in Table 3 below.

Table 3



The impact DIR Fees have on Medicare beneficiary coverage is evident. In fact, in a Fact Sheet issued on January 19, 2017, CMS opined on the effects of DIR Fees, and noted that DIR Fees “[do] not reduce the cost of drugs for beneficiaries at the point-of-sale.”²² Moreover, it is critical to note that DIR Fees do not simply result in beneficiaries prematurely entering the donut hole or paying an artificially higher amount of cost-share, but they negatively impact beneficiary adherence to prescription drug treatments and likely increase overall Medicare costs, which include also the health benefit in addition to the drug benefit. Indeed, it is estimated that more than 25% of all Part D beneficiaries that fall into the donut hole will discontinue adherence to their prescription drug regimens.²³ Discontinued patient adherence results in Medicare having to spend more money to remediate poor clinical outcomes, including expensive hospital readmissions.

Is the Money Really Returned?

In recent public communications, several PBMs and their representatives have claimed that DIR Fees do not increase the costs to the Medicare program, claiming that DIR Fees are passed back to Part D Plan Sponsors, and that all DIR Fees are “reported” to CMS. But what does that really mean?

Let’s start with the first point: DIR Fees are passed back to Part D Plan Sponsors. In order to understand the significance of this statement, it is necessary to understand the Medicare Part D Plan Sponsor framework. Part D Plan Sponsors create and fund Part D plans, often taking on insurance risk. Four of the largest Part D Plan Sponsors include: UnitedHealth Group, Humana, SilverScript (CVS Health), and Express Scripts.²⁴ Each of these Plan Sponsors owns, is owned by or is affiliated with its own PBM.

PART D PLAN				
PBM				

So while they may pass a portion of DIR Fees back to the Part D Plan Sponsors (less any DIR Fees reclassified as administrative expense by the PBM), it is more often than not tantamount to the PBM taking money out of one pocket (the PBM) and passing it to its other pocket (the wholly-owned Plan Sponsor).

Moreover, nowhere in these Press Releases do PBMs state that they return the money to Medicare. Rather, they are always cautious to state that DIR Fees are “reported” to CMS. This is an important distinction, because many times, it results in no financial difference whatsoever to the amounts that CMS or beneficiaries ultimately pay for the medications based on the high upfront costs. While Part D Plan bids are “reconciled” once a year in the beginning of the June following the conclusion of the plan year, Plans are not required to pass back – dollar-for-dollar – any overpayments they received from the government. Rather, if it turns out that the bid as submitted was too high based on the net costs as lowered by retroactive DIR Fees, Plans are only required to reimburse any monies to CMS if there is more than a 5%

²² See CMS, Medicare Part D – Direct and Indirect Remuneration (DIR) (Jan 19, 2017), <http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-fact-sheet-items/2017-01-19-2.html>.

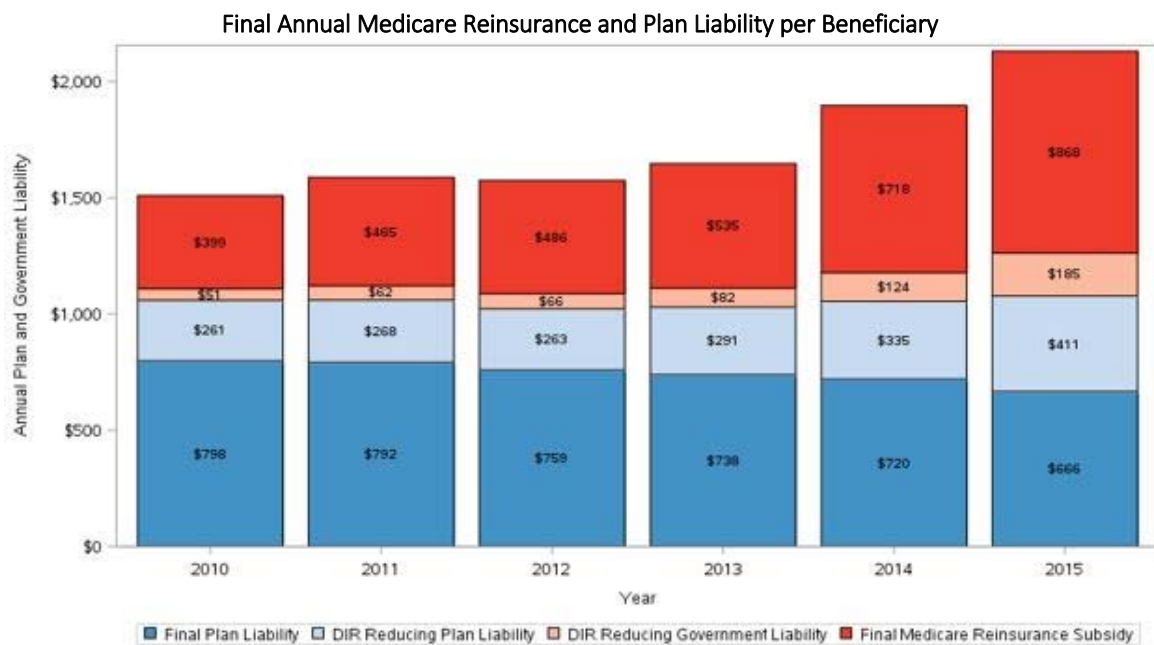
²³ See Jason Claffey, Medicare ‘Donut hole’ Checks in the Mail, *Foster’s Daily Democrat* (Aug. 14, 2010), <http://archive.is/RKP2u> (last visited February 21, 2017).

²⁴ <http://kff.org/medicare/report/medicare-part-d-in-its-ninth-year-the-2014-marketplace-and-key-trends-2006-2014/>; <http://www.fiercehealthcare.com/payer/top-10-insurers-part-d-arena-unitedhealth-at-top>

deviation from the bid and actual costs.²⁵ Even then, the amounts the Plan is required to reimburse are not dollar-for-dollar. Rather, Plans are only required to return a percentage of the excess profits realized under the bid as reconciled.²⁶ PBMs and Plans at times have the ability to lower these numbers further, by allocating certain amounts of DIR Fees to administrative expenses. In either event, none of these excess profits between the increased upfront drug costs, and net costs as lowered by DIR Fees are passed back to patients, who have been forced to pay higher out of pocket amounts. Nor has it been proven that beneficiaries ultimately realize lower plan premiums, as these lower net plan costs generally only impact bid submissions and premium calculations for the following plan year, leaving patients with no immediate relief from being overcharged.

These concepts were borne out in a recent CMS report which noted that 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.”²⁷

Table 4²⁸



Thus, while monies may be passed along to Part D Plan Sponsors, and even “reported” to CMS, there is no evidence that DIR Fees serve to lower overall costs to the Medicare Part D Program or to Medicare patients.

²⁵ 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>. See also, 42 C.F.R. § 423.265.

²⁶ 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>.

²⁷ *Id.*

²⁸ 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).

6 Where Do We Stand?

Increased media and industry attention in DIR Fees has begun to expose the truly egregious impact such fees have had on Specialty Pharmacies participating in Medicare Part D, as well as Medicare beneficiaries and the program as a whole. However, increased attention alone has not had the effect of curtailing the assessment of DIR Fees. DIR Fees remain an existential crisis for Specialty Pharmacies and their ability to deliver the patient care services associated with drug dispensing to Medicare Part D program participants as well as patients with serious medical conditions throughout the United States. Continued delay and inaction only serves to paint the outlook for Specialty Pharmacies and their ability to maintain their current level of engagement with the Medicare Part D program bleaker with each passing day.

Importantly though, various groups, organizations, and key stakeholders have begun to take notice of the flagrance of DIR Fees and their disproportionate impact in certain pharmacy spaces. In response to pressure from pharmacy organizations, CMS made several strides towards clarifying the adjudication in reimbursement structure, including through its January 10, 2014 Proposed Rules set forth in Vol. 79, No. 7 of the Federal Register and its May and September 2014 draft guidances. In May 2014, CMS first attempted to address DIR Fees by revising the definition of “negotiated price.” CMS noted that a Part D plan sponsor’s “negotiated price” is the amount that a Specialty Pharmacy actually receives and retains as payment in connection with a Part D claim.²⁹ CMS was concerned that pricing in bidding and cost reporting across the Part D program had the potential to be inconsistent, as some Part D plan sponsors reported DIR Fees as price concessions and others reported DIR Fees as DIR.³⁰ Specifically, CMS stated that it had learned that some Part D sponsors have been reporting costs and price concessions to CMS in different ways, and that such reporting differential could affect beneficiary cost sharing, CMS payments to plans, and Medicare catastrophic coverage.³¹ CMS also noted that differential treatment of costs could also affect plan bids, and suggested that when Part D sponsors and their intermediaries elect to take some price concessions from pharmacies in forms other than the negotiated price and report them outside the PDE (say, in the context of DIR), “the increased negotiated prices generally shift costs to the beneficiary, the government and taxpayer.” As noted below, this premonition has since come true, as evidenced by CMS’s January 17, 2017 report on the impact of the expansion of DIR Fees and Medicare/beneficiary liability for cost sharing amounts.

CMS attempted to safeguard against this reality by seeking to revise the definition of “negotiated price” to include “all price concessions, except those...that cannot be reasonably determined at the point of sale.”³² CMS released draft guidance on September 29, 2014, which made clear that a broad, inclusive standard should be applied to the “reasonably determined at the point of sale” standard, and indicated that any price concession that could be *reasonably approximated* at the point-of-sale should not be included as DIR, but rather part of the Part D plan sponsor’s

²⁹ 42 C.F.R. § 423.100

³⁰ Cheri Rice, Direct and Indirect Remuneration (DIR) and Pharmacy Price Concessions, Centers for Medicare and Medicaid Services, September 29, 2014.

³¹ Cheri Rice, Direct and Indirect Remuneration (DIR) and Pharmacy Price Concessions, Centers for Medicare and Medicaid Services, September 29, 2014.

³² 42 C.F.R. § 423.100

“negotiated price.”³³ CMS seemed to be cognizant of performance metric DIR Fees, and specifically opined that a basic rate to a Specialty Pharmacy at the point-of-sale, with subsequent enhanced payment rates based on performance in enumerated categories is considered a price concession that could be reasonably determined at the point-of-sale, and should therefore be reported at the point-of-sale.³⁴

In addition to these past efforts at clarifying the PBMs’ obligation with respect to fair and clearly established negotiated prices for Part D providers, CMS has also independently taken note of the substantial negative impact that DIR Fees have had on the financial responsibilities of Medicare beneficiaries and the Medicare program. In a Fact Sheet issued by CMS on January 19, 2017, CMS noted the steady but substantial growth of point-of-sale drug costs, combined with rapid increases in DIR.³⁵ CMS noted that these trends contributed to higher upfront drug costs, which CMS found placed more of the burden on beneficiary cost-sharing, noting 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.”³⁶ Thus, as concluded by CMS, 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.³⁷

CMS was not alone in these observations concerning Medicare and its beneficiaries. As time progressed, more and more organizations and stakeholders began to question and challenge the legitimacy, reasonableness, and legality of PBM-imposed performance-based DIR Fees. The National Community Pharmacy Association (“NCPA”)³⁸, National Association of Specialty Pharmacy (“NASP”)³⁹, Community Oncology Alliance (“COA”)⁴⁰, and AmerisourceBergen⁴¹ have all voiced serious concerns about the appropriateness of such DIR Fees, with COA having commissioned an extensive White Paper analyzing the lawfulness of DIR Fees and how PBMs were utilizing them to increase their profits at the expense of taxpayers and providers.⁴² Overall opposition to DIR Fees has garnered wide support across stakeholders in the healthcare industry as 99 organizations joined in a letter⁴³ supporting Federal legislation aimed at prohibiting DIR Fees.

³³ Cheri Rice, Direct and Indirect Remuneration (DIR) and Pharmacy Price Concessions, Centers for Medicare and Medicaid Services, September 29, 2014.

³⁴ Cheri Rice, Direct and Indirect Remuneration (DIR) and Pharmacy Price Concessions, Centers for Medicare and Medicaid Services, September 29, 2014.

³⁵ 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).

³⁶ *Id.*

³⁷ While CMS’s Fact Sheet accurately stated the impact of DIR on CMS and Medicare beneficiaries, the impact on Specialty Pharmacies was overlooked.

³⁸ <http://www.ncpanet.org/advocacy/pbm-resources/lack-of-transparency-and-higher-costs/dir-fees>

³⁹ <http://naspnet.org/wp-content/uploads/2017/02/12-10-2106-DIR-Presentation-with-data.pdf>;

http://naspnet.org/wp-content/uploads/2017/02/DIR-web_.pdf

⁴⁰ <https://www.communityoncology.org/portfolio-items/pbm-dir-fees-costing-medicare-and-beneficiaries-investigative-white-paper-on-background-cost-impact-and-legal-issues/>

⁴¹ <http://www.amerisourcebergen.com/abcnew/pharmacies/take-a-stand-against-dir-fees.aspx>

⁴² https://www.communityoncology.org/wp-content/uploads/2017/01/COA_White_Paper_on_DIR-Final.pdf

⁴³ <http://www.ncpa.co/pdf/dir-bill-sign-on-letter-signatories-senate.pdf>

Recognizing the seriousness of DIR Fees, several Senators and Representatives introduced Federal legislation aimed at curbing retrospective DIR Fees. The “Improving Transparency and Accuracy in Medicare Part D Spending Act” (H.R. 1038 / S. 413) aims to prohibit the use of retroactive DIR Fees by Medicare Part D plan sponsors and PBMs. 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 claw backs under the guise of DIR Fees. This bill had originally been introduced in the 114th Congress in September 2016 but has since been re-introduced in the 115th Congress on February 14, 2017.

Unfortunately, the recent publicity and notoriety of DIR Fees has also resulted in the PBM industry quickly grabbing their swords to defend DIR Fee programs. In ways not unlike the former CEO of Turing Pharmaceuticals – Martin Shkreli – attempted to defend his company’s 13,000% price hike, so too did the PBM lobby and the CEOs of major PBMs seek to defend the murky and secretive fees. Facing questions from Wall Street analysts about their DIR Fee programs, many PBMs were quick and direct in their efforts to defend and justify the programs in press releases and during earnings calls.

On February 2, 2017, in a swiftly drafted Press Release, CVS Health (NYSE: CVS) responded to questions regarding the lawfulness of DIR Fees just three days before its quarterly earnings. In the Press Release, CVS Health only indicated that a change in the DIR Fee “would not be material to our profitability,” and stated that such DIR Fees “are allowed under CMS regulation, and are fully disclosed as part of the annual bid process.”⁴⁴ During CVS Health’s Fourth Quarter 2016 earnings call on February 9, 2017, its CEO also touched on DIR Fees as the very first issue after reporting basic earning numbers. CVS Health attempted to categorize the existing reporting and comment on DIR Fees as false and misleading, yet CVS Health parsed words in discussing its DIR Fee – or “Performance Network” – program. CVS Health claimed that DIR Fees are utilized to reduce the net cost of the Medicare Part D program, stating that such DIR Fees are “fully passed through from the PBM to its clients [i.e., Part D Plan Sponsors].”⁴⁵ What CVS Health failed to mention, however, is that its single largest “client” in the Medicare Part D space is SilverScript, a wholly-owned subsidiary of CVS Health.⁴⁶ As noted above, this is tantamount to simply moving money from one pocket (i.e., from its PBM arm, CVS Caremark) to another pocket (i.e., to its plan sponsor, SilverScript). Importantly, in its investor presentation, CVS Health stated “*CVS Caremark* [the company’s PBM subsidiary] does not keep or profit from performance network-based DIR.”⁴⁷ The company did not say that CVS Health – the publicly-traded parent corporation – did not benefit from the DIR Fees it extracts from Specialty Pharmacies.

During Express Scripts Holding’s (NYSE: ESRX) Fourth Quarter 2016 earnings call on February 2, 2017, its CEO dismissively concluded that DIR Fees were agreed to by *retail pharmacies* and have no impact on the PBM⁴⁸. The CEO made no mention of the inappropriate impact on

⁴⁴ <https://cvshealth.com/newsroom/press-releases/cvs-health-statement-regarding-direct-and-indirect-remuneration-dir>

⁴⁵ <http://seekingalpha.com/article/4044425-cvs-health-cvs-q4-2016-results-earnings-call-transcript?part=single>

⁴⁶ <https://www.silverscript.com/about-us.aspx>

⁴⁷ <http://seekingalpha.com/article/4044425-cvs-health-cvs-q4-2016-results-earnings-call-transcript?part=single>

⁴⁸ <http://seekingalpha.com/article/4046365-express-scripts-holding-esrx-q4-2016-results-earnings-call-transcript?part=single>

Specialty Pharmacies, and instead, alleged that DIR Fees helped to drive down costs by being passed back to plan sponsors and “reported” to CMS. Express Scripts similarly failed to mention that it too owns a large Medicare Part D plan, Express Scripts Medicare, the exact entity that receives DIR Fees. With little options or room for negotiation or bargaining power, independent pharmacies are often left with no choice but to accept one-sided PBM contracts with ambiguous and unclear terms, which are in turn, used by PBMs to their advantage, at the expense of Specialty Pharmacies, as well as patients and the Federal government.

Of extreme importance in all of these PBM communications, other than a flippant and off-the-cuff remark by CVS Health’s Executive Vice President in response to a question from an analyst, is that nowhere do the PBMs state that any of the monies recouped through DIR Fees actually get passed back *to the Government*. Again, they are all careful to state that the monies are passed back to the Part D Plan Sponsors, but never state that the monies are actually turned over to Medicare. Instead, they use specific language, stating that the DIR Fees are in some capacity “reported” to Medicare. Importantly, even to the extent that these fees are even reported to Medicare, as noted above, it does not mean that they are passed back to the government.

Perhaps some of the strangest defenses of PBM-imposed DIR Fees came from Pharmaceutical Care Management Association (“PCMA”), the powerful lobby for the PBM industry. In response to an earlier published White Paper, PCMA issued a statement attacking the sponsors of the White Paper as a “splinter group of oncologists,” and accusing doctors of being profit hungry, while making odd and ill placed analogies to the costs of drugs under the Medicare part B program (point of fact, drugs under the Medicare Part B program – where PBMs or not involved – are on average 49% lower than drugs reimbursed under Medicare Part D⁴⁹). The PCMA has since refined its positions, and recently stated that DIR Fees “don’t harm the health industry in any way” but that “[t]hey only help it.”⁵⁰ As has been demonstrated over and over again throughout this White Paper, DIR Fees clearly harm Specialty Pharmacies, Medicare beneficiaries and Medicare. These abusive DIR Fees not only regularly put Specialty Pharmacies substantially underwater on their prescriptions, but deny Specialty Pharmacies any meaningful opportunity to influence measured performance outcomes. Moreover, as demonstrated recently through independent reports by CMS, retroactive DIR Fees have the effect of shifting cost from Part D Plan Sponsors to patients and to Medicare. The organization went on, however, suggesting that the reason providers attack DIR is because “they sign a contract to pay for it, and then they don’t want to hold up their end of the bargain.”⁵¹ The truth of the matter, however, is that the retroactive, performance-based DIR Fees, those that are the focus of this White Paper and that pose the most nefarious risk to the industry, are not clearly articulated by contract, especially for Specialty Pharmacies. Such DIR Fee programs are generally included in retail pharmacy agreements and discuss retail pharmacy performance, not Specialty Pharmacy performance. In PCMA’s eyes, Specialty Pharmacies should have somehow predicted that DIR Fees would apply with the same rigor and degree to specialty medications, when the quality metrics apply almost exclusively to retail therapies and offer Specialty Pharmacies no real opportunity to affect performance.

⁴⁹ Office of Inspector General. *Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price*. June 2005. OEI-03-05-00200.

⁵⁰ <http://www.specialtypharmacytimes.com/news/pbms-and-dir-fees-where-the-data>

⁵¹ *Id.*

DIR Fees: Permitted by CMS?

Certain PBMs have also claimed that DIR Fees or performance network-based fees charged to pharmacies are allowed under CMS regulation.⁵² While beyond the scope of this White Paper (see COA's White Paper, entitled "PBM DIR Fees Costing Medicare and Beneficiaries: Investigative White Paper on Background, Cost Impact, and Legal Issues for a more detailed discussion reference"⁵³), this position espoused by the PBMs belies and ignores the overarching weight and authority of Medicare laws and regulations. The concept of "direct and indirect remuneration" started as a CMS construct to account for rebates or other subsidies, discounts and price concessions received from third parties, primarily in the form of manufacturer rebates.⁵⁴ CMS, wanting to ensure that it was able to share in the rebates increasingly being paid out by manufacturers to PBMs and Part D sponsors, sought to ensure that "negotiated prices" was net of any such direct or indirect remuneration. However, as evidenced by the abundance of CMS regulation and guidance on the subject, CMS clearly has a preference towards including as many of such charges and concessions in the point-of-sale price as possible.⁵⁵ There is good reason for this. A number of overarching Federal laws and regulations impose severe limitations and restrictions on PBMs' ability to manipulate prices for Part D drugs.

For example, 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.⁵⁶ The Federal AWPL and accompanying regulations require not only that a Part D plan sponsor admit any pharmacy into its network that is willing to meet the terms and conditions of the network,⁵⁷ but also set forth that the terms must be "reasonable and relevant."⁵⁸ 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, and that "offering pharmacies unreasonably low reimbursement rates for certain 'specialty' drugs may not be used to subvert the convenient access standards."⁵⁹ In other words, Part D sponsors "must offer reasonable and relevant reimbursement terms for all Part D drugs as required by [the federal AWPL]."⁶⁰ By imposing DIR Fees on Specialty Pharmacies that decrease the net reimbursement rates received by providers to well below their acquisition costs, thereby putting them severely underwater, PBMs and Part D sponsors are not offering "reasonable" and "relevant" terms and conditions. This violation of law is compounded by the fact that the manner of calculation and recoupment of performance-based DIR Fees has absolutely no bearing or applicability to the products and services provided by Specialty Pharmacies. A performance-based program upon which Specialty Pharmacies have no ability to influence quality metrics is neither reasonable nor relevant.

⁵² <http://seekingalpha.com/article/4044425-cvs-health-cvs-q4-2016-results-earnings-call-transcript?part=single>

⁵³ https://www.communityoncology.org/wp-content/uploads/2017/01/COA_White_Paper_on_DIR-Final.pdf

⁵⁴ See 42 U.S.C. §1395w-102(d).

⁵⁵ See, e.g., 42 C.F.R. §423.100 (Requiring all price concessions from network pharmacies, except only those that cannot reasonably be determined at the point-of-sale, to be part of a Part D sponsor's "negotiated price"); Cheri Rice, Direct and Indirect Remuneration (DIR) and Pharmacy Price Concessions, Centers for Medicare and Medicaid Services, September 29, 2014, (discussing CMS's proposed rule expanding the definition of "negotiated price" to all price concessions that could be reasonably approximated at the point-of-sale).

⁵⁶ 42 C.F.R. § 423.505(i)(3)(iv).

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

⁵⁸ 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>.

⁵⁹ CMS, Medicare Prescription Drug Benefit Manual, Chapter 5, Section 50.3.

⁶⁰ CMS, Medicare Prescription Drug Benefit Manual, Chapter 5, Section 50.3.

Importantly, despite any PBM claims to the contrary, nothing in the Social Security Act, Medicare Regulations or CMS guidance specifically authorizes charging a variable, performance-based rate of 3% to 5% on *all claims* dispensed by Specialty Pharmacies, particularly when these chargebacks put the pharmacies substantially underwater. Rather, these actions arguably exceed the PBMs' and Plan Sponsors' statutory and legislative prerogative to manage Part D plans. In creating the Medicare Part D program, Congress imbued the Department of Health and Human Services (HHS), and in turn, CMS, with certain authority to effectuate that program. However, CMS's authority to act in this regard is limited by not only the enumerated requirements of the Social Security Act (noted above) but also the Administrative Procedure Act.⁶¹ In turn, PBMs and Medicare Part D Plan Sponsors are similarly 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. Thus, by unilaterally imposing performance-based DIR Fees on Specialty Pharmacies, PBMs have created unreasonable, non-negotiable contract terms which necessarily constitute "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.⁶² This is the very type of administrative action that requires appropriate rulemaking in conformity with the Administrative Procedure Act, which has not occurred.⁶³

These DIR Fees and reimbursement frameworks cannot be sustained by the Specialty Pharmacy industry. If something is not done, more and more Specialty Pharmacies (including many with exclusive access to LDDs that Medicare patients – including those with complex cancer conditions – rely upon for life-saving therapies) will be left with no choice but to leave these Medicare Part D networks. This is likely to create real network access and adequacy issues, and will jeopardize Medicare patients' safety, in addition to posing even further issues with Medicare Part D requirements⁶⁴.

Specialty Pharmacies are not just being denied a reasonable profit on the products and services they provide, but are put squarely underwater on many medications they have no choice but dispense. This jeopardizes Specialty Pharmacies' ability to continue to provide the high touch, patient-centric support services to Medicare Part D plan participants in select networks, and ultimately puts the health and safety of Medicare beneficiaries at risk. While CMS has taken note of the issue and agreed with the impact on providers and patients alike, sweeping regulatory action has yet to come. Likewise, while Federal legislation aimed at addressing these problems has been introduced, there is no assurance that it will pass, and there are questions as to whether it goes far enough to curb PBM abuse and protect patient access. All the while, Specialty Pharmacies, patients and taxpayers suffer in the name of PBM profits.

7 Conclusion

In the Specialty Pharmacy industry, DIR Fees do not just represent a threat to Specialty Pharmacies' profits – DIR Fees represent an existential threat to Specialty Pharmacies' continued ability to deliver the patient care support services required to achieve maximal therapeutic outcomes for Medicare Part D beneficiaries as a class of providers focused on providing high-quality, high-

⁶¹ See generally 5 U.S.C. §§ 551 through 559, *et seq.*

⁶² 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).

⁶³ 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).

⁶⁴ See 42 C.F.R. §423.120(a)(8); 42 C.F.R. §423.505(b)(18); 42 U.S.C. §1395w-104(b)(1)(A); 42 U.S.C. 1395w-104(b)(1)(C)

touch services to the most vulnerable of patient populations. Performance-based DIR Fees as applied and imposed by PBMs puts Specialty Pharmacies severely underwater on their very specialty medications, which are subject to different distribution and reimbursement models than retail pharmacies. Specialty Pharmacies have no ability to control these PBM-imposed performance metrics, and instead, are left in rigged system designed to cause them to fail.

It is not just Specialty Pharmacies that suffer at the hands of these financially-driven DIR Fee programs. If the application and proliferation of these wholly unreasonable DIR Fees is allowed to continue, Specialty Pharmacies will not be able to provide comprehensive, coordinated patient care services with the proven optimal results to Medicare Part D patients. Aside from clinical differences in levels of care, there are many limited distribution drugs to which PBM-owned specialty pharmacies do not have access, and can only be obtained at certain independent Specialty Pharmacies. Medicare beneficiaries and the Medicare program as a whole are harmed by being forced to pay higher upfront costs, pushing patients through the Donut Hole and into catastrophic coverage. As noted by independent CMS reports, this has the effect of shifting costs from PBMs and Part D Plan Sponsors, to beneficiaries (in the form of higher out-of-pocket costs) and to Medicare (in the form of higher catastrophic care payments).

Immediate action is needed to curb these opaque and abusive practices. First and foremost, CMS needs to act to clarify Medicare definitions and reign in this abusive conduct. Virtually all of the PBMs' performance-based DIR Fees as applied to Specialty Pharmacies are known or knowable at the point-of-sale. PBMs refuse to include these as upfront price concessions because they would otherwise pose unreasonable reimbursement terms in violation of applicable Medicare guidance, by plainly reimbursing well below actual, available acquisition costs. These actions can be substantially mitigated through direct and pointed guidance and clarification from CMS. CMS has every right to take decisive action in this context, as the governmental entity tasked with regulating Medicare Part D. CMS has the obligation to ensure plan sponsors and their PBMs are complying with federal regulation, irrespective of the Medicare "noninterference clause."⁶⁵ This includes clear authority requiring CMS to directly intervene in the contractual relationship between Medicare Part D Plan Sponsors and network pharmacies as it relates to any willing pharmacy standard terms and conditions, prohibitions on any requirement for pharmacies to accept insurance risk, prompt payment requirements, the interpretation of "access to negotiated prices," and payment standard update requirements.⁶⁶ Thus, it is well within CMS's ability to review and strike down DIR Fees, given that the disparate impact on Specialty Pharmacies is contrary to CMS regulation of the Medicare Part D program requirements and beyond the scope of limited authority of Medicare Part D Plan Sponsors and their PBMs.

Second, Congress needs to act. Legislation has been introduced aimed at prohibiting retroactive DIR Fees. While this is welcomed assistance in curbing PBM behavior, this legislation can be bolstered and extended by curtailing irrelevant performance metrics and strengthening legal obligations for fair, "above-water" prices.

⁶⁵ 42 U.S.C.A. § 1395w-111(i).

⁶⁶ See, Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 100, 29873 (May 23, 2014).

Finally, stakeholders must act. This includes Specialty Pharmacies faced with unreasonable and unsustainable reimbursement rates, as well as patients forced to pay higher out-of-pocket amounts due to inflated prices. Utmost vigilance is needed by these stakeholders with the respect to their legal and contractual rights vis-à-vis PBMs and Part D Plan Sponsors.

PBMs and Part D Plan Sponsors must not be allowed to use DIR Fees to circumvent the overwhelming body of Federal authority, including the Any Willing Provider laws, that were enacted to protect the Medicare Part D program and its recipients. Without immediate action, patients, taxpayers and the Medicare Part D program alike will suffer.

IMPORTANT! UNDERSTANDING YOUR PHARMACY'S TRIMESTER REPORT

2020 CVS Caremark Medicare Part D Retail Performance Network Program™

Your pharmacy's Trimester Report reflects participation in one or more Medicare Part D Performance Networks for the 2020 plan year. What follows is an explanation of the report's content which primarily consists of:

- **Financial Results** your pharmacy achieved for the trimester
- **Performance Results** your pharmacy achieved for the trimester

Financial Results

CVS Caremark Medicare Part D Retail Performance Network Program™: Trimester Report†					
Financial Results for PHARMACY NAME					
Performance Plan Name	① Final Overall Performance Score	② Network (Variable Rate Range %)	③ Variable Rate	Est Total Ingredient Cost (IC) Paid	④ Est Total IC Paid Times Variable Rate
Plan 1	78.19%				
		XX B (X-X)	6.2%	\$ 4,382	\$ 272
		XX G (X-X)	7.7%	\$ 709	\$ 55
Plan 2	⑤				
Plan 3	81.46%	XX B (X-X)	4.1%	\$ 7,584	\$ 311
		XX G (X-X)	6.1%	\$ 1,950	\$ 119

†For illustrative purposes only.

- ① **Final Overall Performance Score:** This score is used to derive your pharmacy's network variable rate. Individual category scores comprise this performance score and can be found in the Performance Results section of your trimester report.
- ② **Network (Variable Rate Range %):** If your pharmacy has utilization for a Performance Plan; the network, its range, and whether there is a difference between rate ranges for brand and generic drugs will be displayed. If there are different ranges, a 'B' for brand and a 'G' for generic will appear between the network number and its range.
- ③ **Variable Rate:** This is your pharmacy's rate if your pharmacy has utilization.
- ④ **Est Total IC Paid Times Variable Rate:** This is an estimate of the total amount of money to be collected from your pharmacy over the collection period. Details on the amount owed and timing of collections are provided under the **Collection and Reconciliation Information** section.
- ⑤ **Blanks** in the **Final Overall Performance Score**, **Network (Variable Rate Range %)**, **Variable Rate**, **Est Total Ingredient Cost (IC) Paid**, and **Est Total IC Paid Times Variable Rate** columns indicate your pharmacy had no utilization/claims for the network and plan.

Performance Network Program reports are available in electronic format on the CVS Caremark Pharmacy Portal at: <https://rxservices.cvscaremark.com>.

Performance Results

The Performance Results section provides details of each performance category in which your pharmacy had claim utilization. These details include volume, score, criteria weight, and weighted score (criteria weight times score) as depicted below.

CVS Caremark Medicare Part D Retail Performance Network Program™: Trimester Report†									
Performance Results* for PHARMACY NAME									
Performance Plan Name	Category	Medication Adherence				Other Categories			Final Overall Performance Score
	Performance Criteria	RAS Antagonists¹	Statins²	Diabetes³	Overall Adherence Score	Gap Therapy (Statin)⁴	CMR Completion Rate (MTM)⁵	Formulary Compliance⁶	
Plan 1	Volume	108	119	92	319	5		429	
	Score	78.57%	75.36%	76.19%	76.71%	81.25%		97.20%	
	Criteria Weight	28.78%	31.71%	24.51%	85.00%	10.00%		5.00%	
	Weighted Score	22.61%	23.90%	18.67%	65.20%	8.13%		4.86%	

†For illustrative purposes only. If your report includes a Specialty Component, your report may look different. Reference the Specialty Performance information, if applicable.

- ① **Medication Adherence:** Criteria Weight is dependent on patient volume for each adherence category. Refer to the weighted score for each performance criterion to view the weighted score achieved.
- ② **CMR (Comprehensive Medication Review) Completion Rate:** Criteria weight is 10% unless a Part D Plan is not enrolled in the CVS Caremark MTM (Medication Therapy Management) program or participates in the Enhanced MTM pilot in your pharmacy's region. If either condition applies, the **10% weight is re-distributed to Medication Adherence** for a total weight of 85% and the entire CMR column will be blank.
- ③ **Formulary Compliance** is the only category that uses claim volume as its unit of measure instead of patient volume.
- ④ **Final Overall Performance Score** is the sum of the weighted scores for each category.

Note: For all measures, if your pharmacy has zero or negligible volume, the cells will be blank—your pharmacy is neither advantaged nor disadvantaged by this scenario.

Collection and Reconciliation Information

Paper Remittance Advice

The paper Remittance Advice (RA) contains summary and claim-level financial information that reflects 2020 Performance Network Program activity.

During the **collection period**: In the **Adjustments – Caremark-initiated** section, an area called **PNR Collection – Claim Level** will display on your pharmacy's RA that is populated with claim detail for the trimester and the amount of PNR that will be collected for each claim that week.

Electronic Remittance Advice

Three (3) segments of the electronic RA (835) will display information regarding the 2020 Performance Network Program:

1. PLB Segment – Reason Adjustment Codes: 67
2. CLP Segment – Claim-level details are located in this segment
3. CAS Segment – Claim-level adjustments (monetary amounts per claim) are located in this segment

Refer to the notification titled **2019-2020 Program Overview and Comparison** for the **Medicare Part D Retail Performance Network Program** which references the timeline, reconciliation, and reporting information.

2020 CVS Caremark Medicare Part D Retail Performance Network Program™ Specialty Component Report Information

① **Specialty Component:**
Results will populate in this column if a pharmacy has greater than 25% (>25%) claims for specialty drugs in any given trimester for a Part D Plan by network contract. The specialty component will be allocated as a **portion of the overall adherence weight**, proportionate to the percentage of claims for specialty drugs among all claims dispensed for a Part D Plan during a trimester. (For additional information refer to the communication titled “2019-2020 Program Overview and Comparison” for the Medicare Part D Retail Performance Network Program.

CVS Caremark Medicare Part D Retail Performance Network Program™: Trimester Report [†]										
Performance Results* for PHARMACY NAME										
Performance Plan Name	Category	Medication Adherence ②					Other Categories			Final Overall Performance Score ③
	Performance Criteria	RAS Antagonists ¹	Statins ²	Diabetes ³	Non-Specialty Component	① Specialty Component ⁴	Gap Therapy (Statin) ⁵	CMR Completion Rate (MTM) ⁶	Formulary Compliance ⁷	
Plan 1	Volume	108	119	93	320	29	5		429	
	Score	83.33%	80.67%	83.87%	82.50%	82.76%	60.00%		97.90%	
	Criteria Weight	20.08%	22.13%	17.29%	59.50%	25.50%	10.00%		5.00%	
	Weighted Score	16.73%	17.85%	14.50%	49.09%	21.10%	6.00%		4.90%	

[†]For illustrative purposes only. If your report does not include a Specialty Component for a given trimester, your report may look different.

- ② **Overall Adherence Score** is the sum of the weighted scores for each of the individual medication adherence categories (Non-Specialty Component weighted score added to the Specialty Component weighted score).
- ③ **Final Overall Performance Score** is the sum of the weighted scores for each category.

CVS Caremark Medicare Part D Retail Performance Network Program™: Trimester Report											
Specialty Performance Results for PHARMACY NAME											
Performance Plan Name	Category	⑤ Specialty Medication Adherence									
	Performance Criteria	HIV	Immune Inflammatory Disorders	Lipid Disorders PCSK9 Inhibitors	Multiple Sclerosis	Oncology	Osteoporosis	Pulmonary Arterial Hypertension	Renal Disease	Transplant	Specialty Component
Plan 1	Volume	5	4	3	0	10	2	3	0	2	29
	Score	80.00%	75.00%	100.00%	0.00%	80.00%	100.00%	66.67%	0.00%	100.00%	82.76%
	Criteria Weight	4.40%	3.52%	2.64%	0.00%	8.79%	1.76%	2.64%	0.00%	1.76%	25.50%
	④ Weighted Score	3.52%	2.64%	2.64%	0.00%	7.03%	1.76%	1.76%	0.00%	1.76%	21.01%

- ④ As with the Non-Specialty adherence, your pharmacy’s criteria weight is dependent on its patient volume. Refer to the **Weighted Score** for each performance criterion to view the weighted score achieved.
- ⑤ For the nine (9) **Specialty Medication Adherence** therapeutic classes. The list of drugs included in each therapeutic class can be found on the Pharmacy Portal: <https://rxservices.cvscaremark.com>.

2020 CVS Caremark Medicare Part D Retail Performance Network Program™: Trimester 3 Report

Performance Plan Name (Region)	Specialty Component YES/NO	Overall Adherence Score	Gap Therapy (Statin)	CMR Completion Rate (MTM)	Formulary Compliance	Final Overall Performance Score	Estimated Amount to Collect
Overall							\$ 85,351
<i>National Performance Plans</i>							
Aetna	YES	72.55%	8.18%		4.87%	85.60%	\$ 3,384
Anthem Medicare	YES	78.12%	8.19%		4.94%	91.25%	\$ 13,966
SilverScript Choice	YES	68.83%	7.82%	5.03%	4.61%	86.29%	\$ 13,018
SilverScript Plus & Aetna Medicare Rx offered by SilverScript							
WellCare Health Plans	YES	64.59%	8.05%	5.05%	5.00%	82.70%	\$ 54,983
<i>Regional Performance Plans</i>							
ClearStone: BlueCross BlueShield of Arizona (AZ)							
ClearStone: BlueCross BlueShield of Michigan Basic Blue RX (MI)							
ClearStone: Northern Plains Alliance (IA, MN, MT, ND, NE, SD, WY)							
Envolve Pharmacy Solutions (AZ, CA, OR, CT)							
Fallon Senior Plan (MA)							
Healthfirst Medicare Advantage Plans (NY)							
New England Joint Enterprise (CT, MA, RI, VT)							
Premiera BlueCross (WA)							
Tufts Health Plan (CT, MA)							

See notes, at the end of this report, for additional information.

2020 CVS Caremark Medicare Part D Retail Performance Network Program™: Trimester 3 Report

Financial Results	Performance Plan Name	Final Overall Performance Score	Network (Variable Rate Range %)			Variable Rate	Est Total Ingredient Cost (IC) Paid		Est Total IC Paid Times Variable Rate		
	Aetna	85.60%	Standard Brand	(3.0-5.0)		4.0%	\$ 84,603		\$ 3,384		
Performance Results	Category	Medication Adherence					Other Categories		Final Overall Performance Score		
	Performance Criteria	RAS Antagonists ¹	Statins ²	Diabetes ³	Non-Specialty Component	Specialty Component ⁴	Gap Therapy (Statin) ⁵	Formulary Compliance ⁷			
	Volume							75			
	Score				84.84%	85.98%	81.78%	97.33%			
	Criteria Weight				46.04%	38.96%	10.00%	5.00%			
	Weighted Score				39.06%	33.49%	8.18%	4.87%	85.60%		
Specialty Performance Results	Category	Specialty Medication Adherence									
	Performance Criteria	HIV	Immune Inflammatory Disorders	Lipid Disorders PCSK9 Inhibitors	Multiple Sclerosis	Oncology	Osteoporosis	Pulmonary Arterial Hypertension	Renal Disease	Transplant	Specialty Component ⁴
	Volume										
	Score										85.98%
	Criteria Weight										38.96%
	Weighted Score										33.49%

2020 CVS Caremark Medicare Part D Retail Performance Network Program™: Trimester 3 Report

Financial Results	Performance Plan Name	Final Overall Performance Score	Network (Variable Rate Range %)			Variable Rate	Est Total Ingredient Cost (IC) Paid		Est Total IC Paid Times Variable Rate		
	Anthem Medicare	91.25%	75 B (3.0-5.0)			3.6%	\$ 200,007		\$ 7,200		
			75 G (14.0-16.0)			14.6%	\$ 46,340		\$ 6,766		
Performance Results	Category	Medication Adherence					Other Categories		Final Overall Performance Score		
	Performance Criteria	RAS Antagonists ¹	Statins ²	Diabetes ³	Non-Specialty Component	Specialty Component ⁴	Gap Therapy (Statin) ⁵	Formulary Compliance ⁷			
	Volume					9		157			
	Score				84.15%	96.52%	81.92%	98.73%			
	Criteria Weight				31.70%	53.30%	10.00%	5.00%			
	Weighted Score				26.67%	51.45%	8.19%	4.94%	91.25%		
Specialty Performance Results	Category	Specialty Medication Adherence									
	Performance Criteria	HIV	Immune Inflammatory Disorders	Lipid Disorders PCSK9 Inhibitors	Multiple Sclerosis	Oncology	Osteoporosis	Pulmonary Arterial Hypertension	Renal Disease	Transplant	Specialty Component ⁴
	Volume	0	0	0	0	9	0	0	0	0	9
	Score	0.00%	0.00%	0.00%	0.00%	96.52%	0.00%	0.00%	0.00%	0.00%	96.52%
	Criteria Weight	0.00%	0.00%	0.00%	0.00%	53.30%	0.00%	0.00%	0.00%	0.00%	53.30%
	Weighted Score	0.00%	0.00%	0.00%	0.00%	51.45%	0.00%	0.00%	0.00%	0.00%	51.45%

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Financial Results	Performance Plan Name	Final Overall Performance Score	Network (Variable Rate Range %)			Variable Rate		Est Total Ingredient Cost (IC) Paid		Est Total IC Paid Times Variable Rate	
	SilverScript Choice	86.29%	71 B (5.0-7.0)			5.3%		\$ 213,565		\$ 11,319	
			71 G (8.5-10.5)			8.8%		\$ 19,307		\$ 1,699	
Performance Results	Category	Medication Adherence						Other Categories			Final Overall Performance Score
	Performance Criteria	RAS Antagonists ¹	Statins ²	Diabetes ³	Non-Specialty Component	Specialty Component ⁴	Gap Therapy (Statin) ⁵	CMR Completion Rate MTM ⁶	Formulary Compliance ⁷		
	Volume					5			77		
	Score				83.29%	95.08%	78.17%	50.31%	92.21%		
	Criteria Weight				21.00%	54.00%	10.00%	10.00%	5.00%		
	Weighted Score				17.49%	51.34%	7.82%	5.03%	4.61%	86.29%	
Specialty Performance Results	Category	Specialty Medication Adherence									
	Performance Criteria	HIV	Immune Inflammatory Disorders	Lipid Disorders PCSK9 Inhibitors	Multiple Sclerosis	Oncology	Osteoporosis	Pulmonary Arterial Hypertension	Renal Disease	Transplant	Specialty Component ⁴
	Volume	0	0	0	0	5	0	0	0	0	5
	Score	0.00%	0.00%	0.00%	0.00%	95.08%	0.00%	0.00%	0.00%	0.00%	95.08%
	Criteria Weight	0.00%	0.00%	0.00%	0.00%	54.00%	0.00%	0.00%	0.00%	0.00%	54.00%
	Weighted Score	0.00%	0.00%	0.00%	0.00%	51.34%	0.00%	0.00%	0.00%	0.00%	51.34%
Financial Results	Performance Plan Name	Final Overall Performance Score	Network (Variable Rate Range %)			Variable Rate		Est Total Ingredient Cost (IC) Paid		Est Total IC Paid Times Variable Rate	
	SilverScript Plus & Aetna Medicare Rx offered by SilverScript										
Performance Results	Category	Medication Adherence						Other Categories			Final Overall Performance Score
	Performance Criteria	RAS Antagonists ¹	Statins ²	Diabetes ³	Non-Specialty Component	Specialty Component ⁴	Gap Therapy (Statin) ⁵	Formulary Compliance ⁷			
	Volume										
	Score										
	Criteria Weight										
	Weighted Score										
Specialty Performance Results	Category	Specialty Medication Adherence									
	Performance Criteria	HIV	Immune Inflammatory Disorders	Lipid Disorders PCSK9 Inhibitors	Multiple Sclerosis	Oncology	Osteoporosis	Pulmonary Arterial Hypertension	Renal Disease	Transplant	Specialty Component ⁴
	Volume										
	Score										
	Criteria Weight										
	Weighted Score										

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Financial Results	Performance Plan Name	Final Overall Performance Score	Network (Variable Rate Range %)			Variable Rate	Est Total Ingredient Cost (IC) Paid		Est Total IC Paid Times Variable Rate		
	WellCare Health Plans	82.70%	72 B (7.5-9.5)			8.3%	\$ 87,102		\$ 7,229		
			72 G (14.0-16.0)			14.8%	\$ 403		\$ 60		
			73 B (10.0-12.0)			10.7%	\$ 445,690		\$ 47,689		
			73 G (8.0-10.0)			8.7%	\$ 52		\$ 5		
Performance Results	Category	Medication Adherence					Other Categories			Final Overall Performance Score	
	Performance Criteria	RAS Antagonists ¹	Statins ²	Diabetes ³	Non-Specialty Component	Specialty Component ⁴	Gap Therapy (Statin) ⁵	CMR Completion Rate MTM) ⁶	Formulary Compliance ⁷		
	Volume					8			177		
	Score				84.78%	86.93%	80.52%	50.55%	100.00%		
	Criteria Weight				28.13%	46.88%	10.00%	10.00%	5.00%		
	Weighted Score				23.84%	40.75%	8.05%	5.05%	5.00%	82.70%	
	Specialty Performance Results	Category	Specialty Medication Adherence								
Performance Criteria		HIV	Immune Inflammatory Disorders	Lipid Disorders PCSK9 Inhibitors	Multiple Sclerosis	Oncology	Osteoporosis	Pulmonary Arterial Hypertension	Renal Disease	Transplant	Specialty Component ⁴
Volume		0	0	0	0	8	0	0	0	0	8
Score		0.00%	0.00%	0.00%	0.00%	86.93%	0.00%	0.00%	0.00%	0.00%	86.93%
Criteria Weight		0.00%	0.00%	0.00%	0.00%	46.88%	0.00%	0.00%	0.00%	0.00%	46.88%
Weighted Score		0.00%	0.00%	0.00%	0.00%	40.75%	0.00%	0.00%	0.00%	0.00%	40.75%
Weighted Score		0.00%	0.00%	0.00%	0.00%	40.75%	0.00%	0.00%	0.00%	0.00%	40.75%

Summary Results:

Specialty Component YES/NO: For pharmacies with **greater than 25% (>25%) claims** for specialty drugs in any given trimester for a Part D Plan by network contract, the Overall Adherence Score will include a specialty drug component (using specialty drug adherence criteria based on therapeutic classes). The specialty drug component will be allocated as **a portion of the overall adherence weight**, proportionate to the percentage of claims for specialty drugs among all claims dispensed for a Part D Plan during a trimester.

Overall Adherence Score is the sum of the weighted scores for each of the individual medication adherence categories (Non-Specialty Component weighted score added to the Specialty Component weighted score, if applicable).

Gap Therapy (Statin), CMR Completion Rate (MTM), and Formulary Compliance see Performance Results Other Categories below for additional information.

Final Overall Performance Score: The sum of the weighted scores from each performance category that is compared among all other pharmacies for each Performance Plan by network contract to determine your pharmacy's relative performance and derive your pharmacy's Network Variable Rate.

Overall Estimated Amount to Collect: Summarizes the total across all clients as an estimated amount to collect.

Financial Results:

Final Overall Performance Score: The sum of the weighted scores from each performance category that is compared among all other pharmacies for each Performance Plan by network contract to determine your pharmacy's relative performance and derive your pharmacy's Network Variable Rate.

Network (Variable Rate Range %): The network and rate range (or ranges if the network has separate brand/generic rates) that applies to a network in which your pharmacy has a paid claim in the trimester. A 'B' for brand and a 'G' for generic between the network number and its range identifies the rates for networks which have separate brand/generic rates.

Variable Rate: *A component of your pharmacy's overall contracted reimbursement rate* that is derived from your pharmacy's performance relative to all other pharmacies within each Performance Plan/Network and is applied to your pharmacy's applicable paid claims for the trimester indicated for each Performance Plan/Network in which your pharmacy had claims utilization.

Est Total Ingredient Cost (IC) Paid: A summary of your pharmacy's total IC on applicable paid claims dispensed within the indicated trimester as of the date/time this report was run that is subject to the variable rate associated with your pharmacy's performance. The point-in-time values in this report may vary from those reported in your pharmacy's Remittance Advice (RA) as additional claim processing may have occurred.

Est Total IC Paid Times Variable Rate: The amount calculated by multiplying the Variable Rate (based upon your pharmacy's final overall performance score for each Performance Plan/Network) by the Est Total IC Paid that will be collected from your pharmacy to satisfy the contractual terms associated with each network. The Estimated amount will be collected from individual paid claims based on their date of fill over the collection period.

Blank values indicate that your pharmacy had no utilization for the Performance Plan/Network in the indicated trimester.

Performance Results:

For all measures:

- Pharmacies are scored **individually** for each Performance Plan by network contract in which a pharmacy has paid claims utilization within the trimester.
- **Blank cells mean your pharmacy had zero or negligible volume.** Your pharmacy is neither advantaged nor disadvantaged by this scenario.
- Criteria **Scores** are multiplied by their **Criteria Weights** to determine their **Weighted Scores**.
- **Weighted Scores** reflect how your pharmacy performed on a criterion.

Medication Adherence: Criteria weight is divided among its subcomponents based upon their patient volumes.

Overall Adherence Score is the sum of the weighted scores for each of the individual medication adherence categories

- The **Specialty Component** along with the **Non-Specialty Component** comprise the **Overall Adherence Score** (found on the Summary page).

Other Categories weight (25%) includes measures for GAP (10%), CMR (10%), and Formulary Compliance (5%). These weights are multiplied by the category scores to yield the weighted scores that sum to the **Final Overall Performance Score**.

If a Part D Plan does not enroll in the CVS Caremark MTM (Medication Therapy Management) program or participates in the Enhanced MTM pilot in your pharmacy's region, the **CMR (Comprehensive Medication Review) Completion Rate** measure will be eliminated, and the **10% weight is re-distributed to Medication Adherence**, for a total weight of 85%.

Final Overall Performance Score: The sum of the weighted scores from each performance category that is compared among all other pharmacies for each Performance Plan by network contract to determine your pharmacy's relative performance and derive your pharmacy's Network Variable Rate.

Scoring: 1, 2, 3, 5 - PQS provides the measurement and displays in the EQuIPP dashboard approximately 45 days after the close of each trimester; 6 - OutcomesMTM® provides the measurement for CMR completion rate; 4 (Specialty only), 7 - CVS Caremark provides the measurement.

Specialty Performance Results:

Your pharmacy's specialty performance is reported in this section for all Performance Plans in which your pharmacy has the Specialty Component (see **Summary Results**). For the nine (9) **Specialty Medication Adherence** therapeutic classes, your pharmacy's criteria weight is dependent on its patient volume. Refer to the **weighted score** for each performance criterion to view the weighted score achieved.

The list of drugs included in each of the therapeutic classes can be found on the Pharmacy Portal: <https://rxservices.cvscaremark.com>