April 7, 2021

The Honorable Frank Pallone  The Honorable Cathy McMorris Rodgers
Chairman  Ranking Member
Committee on Energy and Commerce  Committee on Energy and Commerce
United States House of Representatives  United States House of Representatives
2125 Rayburn House Office Building  2322 Rayburn House Office Building
Washington, D.C.  20515  Washington, D.C.  20515

Re: Direct and Indirect Remuneration Fees (DIR Fees)

Dear Chairman Pallone and Ranking Member McMorris Rodgers:

We are writing this letter on behalf of the Board of Directors of the Community Oncology Alliance (COA) respectfully requesting that the Energy & Commerce Committee investigate and hold a hearing on so-called “DIR Fees” used by pharmacy benefit managers (PBMs) to extract – some would say “extort” – additional revenues for PBMs from pharmacy providers. DIR Fees are increasing the costs of prescription drugs for Americans, especially those relying on cancer medications and other specialty therapies, and are fueling consolidation of the pharmacy market, which further increases cost for patients and payors.

All forms of direct and indirect remuneration (DIR) received by Medicare Part D plan sponsors must be reported to the Centers for Medicare & Medicaid Services (CMS). This DIR includes rebates paid by pharmaceutical manufacturers to Medicare Part D plan sponsors and to their PBMs charging pharmacy providers various administrative and “quality-based” DIR Fees. We are focusing our request to the Energy & Commerce Committee specifically on the DIR Fees clawed back from pharmacy providers, which include independent pharmacies and community oncology practices with affiliated retail pharmacies or dispensing facilities.

In the case of community oncology practices, where an estimated 55 percent of Americans with cancer are treated, more chemotherapy and related cancer therapies are available in oral formulations (pills). This has attracted PBMs to find “creative” ways of extracting DIR Fees as a percent of the list price of these very expensive specialty drugs. To do this, PBMs “administer” so-called mandatory “quality” programs to community oncology pharmacy providers that measure drug “adherence” and base DIR Fees on the list prices of these drugs. There are several problems with these so-called “quality” programs and the clawback of DIR Fees associated with them:

- **DIR Fees fuel the prices of already expensive specialty drugs for patients.** These DIR Fees are implemented as a percentage of the list prices of expensive oral specialty drugs. These percentage-based DIR Fees are increasingly in excess of 10 percent of specialty cancer medications, which can cost in the tens of thousands of dollars per fill. PBMs are therefore highly incentivized to fuel drug list prices higher, off of which they extract rebates from drug manufacturers and then charge the pharmacy a percentage of the list price as a DIR Fee. The higher the drug price, the more the PBM makes off of rebates and DIR Fees. The result is that patients pay more for drugs because their out-of-pocket costs are based on the PBM-
inflated list prices of drugs, not the net cost to the PBM. The higher the price the more the PBM profits, but the more it costs the patient.

- **These PBM so-called “quality” programs are a complete sham and utilize measures that are irrelevant and can even be dangerous for patients with cancer.** Attached is an actual report provided by the PBM CVS Caremark to a community oncology practice. First, we defy anyone to understand this convoluted report. Unlike real quality programs – such as the Medicare Oncology Care Model – that provide an increase in payment for high-quality performance and a deduction for poor performance, the so-called PBM “quality” programs are one-sided – they are set up to almost always deduct DIR Fees. Similar to the street hustler version of Three-Card Monte, it is set up for the practice to always lose; meaning, PBMs always claw back funds as a percentage of each prescription. In the report provided, the practice is assessed DIR Fees in excess of $85,000. This is based in part on adherence to non-specialty drugs (irrelevant in cancer care) and specialty drugs. The problem of measuring adherence in cancer treatment is that in many cases, it is meaningless and can actually be dangerous. For example, cancer drugs are often changed as to dosage or therapy, depending on the response of the tumor and the patient to the dosage and/or drug. If a community oncology practice were to change its clinical practices to align with CVS Caremark’s adherence metrics, it could cause real harm to patients and possibly violate the instructions contained in FDA-approved drug labels.

- **DIR Fees are illegal.** In establishing cost sharing obligations for beneficiaries, CMS has stated that “[b]eneficiary cost sharing is a function of the negotiated price” paid by Part D plan sponsors, noting that “[w]hen pharmacy price concessions and other price concessions are not reflected in the negotiated price at the point of sale (that is, are applied instead as [Direct and Indirect Remuneration] at the end of the coverage year), beneficiary cost-sharing increases.”¹ To that end, CMS defined “negotiated prices” as the price that the “Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug ... inclusive of all price concessions from network pharmacies except those contingent price concessions that cannot reasonably be determined at the point-of-sale.” With DIR Fees tied to these sham “quality” programs, PBMs take advantage of and manipulate this exception to the “negotiated price” definition. Worse yet, with CVS Caremark’s program in particular, there will always be a set minimum or “floor” amount of DIR Fees, making a significant portion of their price concessions very clearly able to be “determined at the point of sale.” In fact, a federal court recently confirmed an arbitrator’s award that found CVS Caremark’s DIR Fee program “imputation of irrelevant metrics was a violation of the [Federal Any Willing Provider] law requirement that contracts have relevant terms and conditions....”² Most importantly, every dollar that PBMs shift to being applied after the point of sale means that the Federal government and patients have to pay more.

We note that the National Community Pharmacists Association (NCPA) has filed a lawsuit against the Department of Health and Human Services maintaining that DIR Fees are without reasonable transparency and conceal the true cost of prescription drugs. According to NCPA CEO Doug Hoey, “Pharmacy clawbacks are fundamentally dishonest and unfair for patients and pharmacies, and they make it impossible

for pharmacies to predict their costs.” NCPA maintains that 60 percent of community pharmacies believe they will go out of business in the next two years if DIR Fees are not addressed.

To give you an order of magnitude of the problem of DIR Fees, the net value of pharmacy-related DIR Fees has grown significantly, from $229 million in 2013 to an estimated $9.1 billion in 2019. Pharmacy DIR Fees accounted for more than 18 percent of total DIR paid to Medicare Part D plans in 2019. The same analysis also notes that the Government Accountability Office (GAO) reported that Part D plan sponsors received $2.3 billion from pharmacies in 2016 but paid only $211 million to pharmacies. The deck is clearly being stacked by PBMs to extract more and more DIR Fees, thus increasing the costs of prescription drugs for Americans.

Attached are letters sent to CVS Caremark and Express Scripts on behalf of COA by our law firm Frier Levitt. They explain in greater detail the problems with DIR Fees touched upon in this letter. You are both copied on those letters and have already received copies. Our law firm has not received any substantive response from either CVS Caremark or Express Scripts.

You ask how PBMs can get away with “extorting” DIR Fees from pharmacy providers? The answer, displayed in this chart, is simple: market leverage. The top three PBMs control 77 percent of the prescription drug claims and the top six percent almost 100 percent. You cannot operate a pharmacy of any type without dealing with PBMs and paying their DIR Fees to stay in-network.

We implore the Energy & Commerce Committee to hold a hearing on these out-of-control DIR Fees and how they fuel drug costs for patients and are severely damaging pharmacy providers, threatening to consolidate the pharmacy market even further.

We are available to answer any questions in detail.

Sincerely,

Kashyap Patel, MD
President

Ted Okon
Executive Director

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3 https://www.drugchannels.net/2020/02/pharmacy-dir-fees-hit-record-9-billion.html

4 https://www.drugchannels.net/2021/04/the-top-pharmacy-benefit-managers-pbms.html
# 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

<table>
<thead>
<tr>
<th>Performance Plan Name</th>
<th>① Final Overall Performance Score</th>
<th>② Network (Variable Rate Range %)</th>
<th>③ Variable Rate</th>
<th>④ Est Total Ingredient Cost (IC) Paid</th>
<th>⑤ Est Total IC Paid Times Variable Rate</th>
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<tbody>
<tr>
<td>Plan 1</td>
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<td>XX B (X-X)</td>
<td>6.2%</td>
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<td>$272</td>
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<td></td>
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<td>XX G (X-X)</td>
<td>7.7%</td>
<td>$709</td>
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<td>Plan 2</td>
<td>⑤</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plan 3</td>
<td>81.46%</td>
<td>XX B (X-X)</td>
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<td>$311</td>
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<td></td>
<td></td>
<td>XX G (X-X)</td>
<td>6.1%</td>
<td>$1,950</td>
<td>$119</td>
</tr>
</tbody>
</table>

†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](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.

†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.
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.

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).

Final Overall Performance Score is the sum of the weighted scores for each category.

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.

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

<table>
<thead>
<tr>
<th>Performance Plan Name (Region)</th>
<th>Specialty Component YES/NO</th>
<th>Overall Adherence Score</th>
<th>Gap Therapy (Statin)</th>
<th>CMR Completion Rate (MTM)</th>
<th>Formulary Compliance</th>
<th>Final Overall Performance Score</th>
<th>Estimated Amount to Collect</th>
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<tr>
<td>Overall</td>
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<tr>
<td>Aetna</td>
<td>YES</td>
<td>72.55%</td>
<td>8.18%</td>
<td>4.87%</td>
<td>85.60%</td>
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<td>8.19%</td>
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<td>SilverScript Choice</td>
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<td>68.83%</td>
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<td>5.03%</td>
<td>4.61%</td>
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<td>$ 13,018</td>
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<tr>
<td>SilverScript Plus &amp; Aetna Medicare Rx offered by SilverScript</td>
<td>YES</td>
<td>64.59%</td>
<td>8.05%</td>
<td>5.05%</td>
<td>5.00%</td>
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<td>WellCare Health Plans</td>
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<td>8.05%</td>
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<td><strong>Regional Performance Plans</strong></td>
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<td>ClearStone: BlueCross BlueShield of Arizona (AZ)</td>
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<td>ClearStone: BlueCross BlueShield of Michigan Basic Blue RX (MI)</td>
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<td>ClearStone: Northern Plains Alliance (IA, MN, MT, ND, NE, SD, WY)</td>
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<td>Enolve Pharmacy Solutions (AZ, CA, OR, CT)</td>
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<td>Fallon Senior Plan (MA)</td>
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<td>New England Joint Enterprise (CT, MA, RI, VT)</td>
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<td>Premera BlueCross (WA)</td>
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</table>

See notes, at the end of this report, for additional information.
<table>
<thead>
<tr>
<th>Performance Plan Name</th>
<th>Final Overall Performance Score</th>
<th>Network (Variable Rate Range %)</th>
<th>Variable Rate</th>
<th>Est Total Ingredient Cost (IC) Paid</th>
<th>Est Total IC Paid Times Variable Rate</th>
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</thead>
<tbody>
<tr>
<td>Aetna</td>
<td>85.60%</td>
<td>Standard Brand (3.0-5.0)</td>
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<td>$ 84,603</td>
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### Performance Results

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<th>Category</th>
<th>Medication Adherence</th>
<th>Other Categories</th>
<th>Final Overall Performance Score</th>
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<tbody>
<tr>
<td>Volume</td>
<td></td>
<td></td>
<td>75</td>
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<tr>
<td>Score</td>
<td>84.84%</td>
<td>85.98%</td>
<td>97.33%</td>
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<tr>
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### Specialty Performance Results

<table>
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<th>Performance Criteria</th>
<th>Specialty Medication Adherence</th>
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</tr>
<tr>
<td>Score</td>
<td>85.98%</td>
</tr>
<tr>
<td>Weight</td>
<td>38.96%</td>
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<tr>
<td>Weighted Score</td>
<td>33.49%</td>
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</table>
## 2020 CVS Caremark Medicare Part D Retail Performance Network Program™: Trimester 3 Report

### Financial Results

<table>
<thead>
<tr>
<th>Performance Plan Name</th>
<th>Final Overall Performance Score</th>
<th>Network (Variable Rate Range %)</th>
<th>Variable Rate</th>
<th>Est Total Ingredient Cost (IC) Paid</th>
<th>Est Total IC Paid Times Variable Rate</th>
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</thead>
<tbody>
<tr>
<td><strong>Anthem Medicare</strong></td>
<td>91.25%</td>
<td>75 B (3.0-5.0)</td>
<td>3.6%</td>
<td>$ 200,007</td>
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<td></td>
<td></td>
<td>75 G (14.0-16.0)</td>
<td>14.6%</td>
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### Performance Results

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<thead>
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<th>Category</th>
<th>Medication Adherence</th>
<th>Other Categories</th>
<th>Final Overall Performance Score</th>
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<tr>
<td></td>
<td>RAS Antagonists¹</td>
<td>Statins²</td>
<td>Diabetes³</td>
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<tr>
<td>Volume</td>
<td></td>
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<td>Score</td>
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### Specialty Performance Results

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<thead>
<tr>
<th>Category</th>
<th>Specialty Medication Adherence</th>
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<td>HIV</td>
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<td>Weighted Score</td>
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## Financial Results

<table>
<thead>
<tr>
<th>Plan Name</th>
<th>Final Overall Performance Score</th>
<th>Network (Variable Rate Range %)</th>
<th>Variable Rate</th>
<th>Est Total Ingredient Cost (IC) Paid</th>
<th>Est Total IC Paid Times Variable Rate</th>
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<tbody>
<tr>
<td>SilverScript Choice</td>
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<td></td>
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## Performance Results

### Category
- **Medication Adherence**
- **Other Categories**

<table>
<thead>
<tr>
<th>Performance Criteria</th>
<th>RAS Antagonists(^1)</th>
<th>Statins(^2)</th>
<th>Diabetes(^3)</th>
<th>Non-Specialty Component</th>
<th>Specialty Component(^4)</th>
<th>Gap Therapy (Statin)(^5)</th>
<th>CMR Completion Rate MTM(^6)</th>
<th>Formulary Compliance(^7)</th>
<th>Final Overall Performance Score</th>
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<td>Volume</td>
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<td></td>
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</tr>
<tr>
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<td>86.29%</td>
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## Specialty Performance Results

### Category
- **Specialty Medication Adherence**

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<th>Performance Criteria</th>
<th>HIV</th>
<th>Immune Inflammatory Disorders</th>
<th>Lipid Disorders PCSK9 Inhibitors</th>
<th>Multiple Sclerosis</th>
<th>Oncology</th>
<th>Osteoporosis</th>
<th>Pulmonary Arterial Hypertension</th>
<th>Renal Disease</th>
<th>Transplant</th>
<th>Specialty Component(^4)</th>
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<tr>
<td>Score</td>
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<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>95.08%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>5.0%</td>
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<tr>
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<td>54.00%</td>
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## Financial Results

<table>
<thead>
<tr>
<th>Plan Name</th>
<th>Final Overall Performance Score</th>
<th>Network (Variable Rate Range %)</th>
<th>Variable Rate</th>
<th>Est Total Ingredient Cost (IC) Paid</th>
<th>Est Total IC Paid Times Variable Rate</th>
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<tr>
<td>SilverScript Plus &amp; Aetna Medicare Rx offered by SilverScript</td>
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## Performance Results

### Category
- **Medication Adherence**
- **Other Categories**

<table>
<thead>
<tr>
<th>Performance Criteria</th>
<th>RAS Antagonists(^1)</th>
<th>Statins(^2)</th>
<th>Diabetes(^3)</th>
<th>Non-Specialty Component</th>
<th>Specialty Component(^4)</th>
<th>Gap Therapy (Statin)(^5)</th>
<th>Formulary Compliance(^7)</th>
<th>Final Overall Performance Score</th>
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<tr>
<td>Volume</td>
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## Specialty Performance Results

### Category
- **Specialty Medication Adherence**

<table>
<thead>
<tr>
<th>Performance Criteria</th>
<th>HIV</th>
<th>Immune Inflammatory Disorders</th>
<th>Lipid Disorders PCSK9 Inhibitors</th>
<th>Multiple Sclerosis</th>
<th>Oncology</th>
<th>Osteoporosis</th>
<th>Pulmonary Arterial Hypertension</th>
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<tr>
<td>Weighted Score</td>
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### Financial Results

<table>
<thead>
<tr>
<th>Network</th>
<th>Variable Rate</th>
<th>Est Total Ingredient Cost (IC Paid)</th>
<th>Est Total IC Paid Times Variable Rate</th>
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<tbody>
<tr>
<td>72 B (7.5-9.5)</td>
<td>8.3%</td>
<td>$ 87,102</td>
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<tr>
<td>72 G (14.0-16.0)</td>
<td>14.8%</td>
<td>$ 403</td>
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**WellCare Health Plans** 82.70%

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<tr>
<th>Network</th>
<th>Variable Rate</th>
<th>Est Total Ingredient Cost (IC Paid)</th>
<th>Est Total IC Paid Times Variable Rate</th>
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</thead>
<tbody>
<tr>
<td>73 B (10.0-12.0)</td>
<td>10.7%</td>
<td>$ 445,690</td>
<td>$ 47,689</td>
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<tr>
<td>73 G (8.0-10.0)</td>
<td>8.7%</td>
<td>$ 52</td>
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### Performance Results

#### Medication Adherence

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<tr>
<th>Performance Criteria</th>
<th>RAS Antagonists¹</th>
<th>Statins²</th>
<th>Diabetes³</th>
<th>Non-Specialty Component</th>
<th>Specialty Component⁴</th>
<th>Gap Therapy (Statin)⁵</th>
<th>CMR Completion Rate MTM⁶</th>
<th>Formulary Compliance⁷</th>
<th>Volume</th>
<th>Score</th>
<th>Criteria Weight</th>
<th>Weighted Score</th>
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<td>100.00%</td>
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<tr>
<td>Final Overall Performance Score</td>
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### Specialty Performance Results

<table>
<thead>
<tr>
<th>Performance Criteria</th>
<th>HIV</th>
<th>Immune Inflammatory Disorders</th>
<th>Lipid Disorders PCSK9 Inhibitors</th>
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<th>Oncology</th>
<th>Osteoporosis</th>
<th>Pulmonary Arterial Hypertension</th>
<th>Renal Disease</th>
<th>Transplant</th>
<th>Specialty Component⁴</th>
<th>Volume</th>
<th>Score</th>
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<td>86.93%</td>
<td>46.88%</td>
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<tr>
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<td>86.93%</td>
<td>46.88%</td>
<td>40.75%</td>
<td>40.75%</td>
</tr>
</tbody>
</table>
**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.

**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.

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

**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 redistributed 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.cvshealth.com
Via Overnight Mail

Caremark
Attn.: General Counsel
9501 East Shea Boulevard
Scottsdale, AZ 85260

Re: Caremark’s PNR Program and Community Oncology Practices

Dear Sir/Madam:

This office represents the Community Oncology Alliance (“COA”). In case you are not familiar with the organization, COA is a non-profit organization dedicated to advocating for community oncology practices and the patients they serve, including Medicare beneficiaries. COA is the only organization dedicated solely to independent community oncology where the majority of Americans with cancer are treated. The mission of COA is to ensure that patients with cancer receive quality, affordable, and accessible cancer care in their own communities. For close to 20 years, COA has built a national grassroots network of community oncology practices to enhance the effectiveness and efficiency of cancer care, as well as to advocate for public policies that benefit patients with cancer. Individuals from all perspectives of the cancer care delivery team – oncologists, administrators, pharmacists, mid-level providers, oncology nurses, patients, and survivors – volunteer their time on a regular basis to lead COA and serve on its committees. Many community oncology practices provide the highest quality, most affordable, and accessible cancer care to patients who are part of networks managed by CVS Caremark (“Caremark”).

We write on behalf of the community oncology practices COA represents nationwide (the “Practices”) regarding Caremark’s Performance Network Rebate Program (“PNR Program”), under which Caremark assesses direct and indirect remuneration (“DIR”) fees from pharmacies and community oncology practices participating in certain Medicare Part D networks. The assessment of DIR fees against the Practices fails to comport with applicable Medicare Part D rules and guidance. More specifically, Caremark’s DIR fees do not comport with the clear guidance set forth under federal law, which requires “reasonable and relevant” terms and conditions for participation in Medicare Part D pharmacy networks. As it relates to cancer care, the PNR Program’s terms and conditions are at best irrelevant and at worst, if followed, harmful to cancer patients, particularly as it relates to the “adherence” PNR metrics. Caremark’s unreasonable terms and conditions have disproportionately impacted the Practices. Simply put, Caremark’s PNR Program violates federal law.

Caremark’s PNR Program, disguised as a “quality-based” initiative, is in fact, simply a way for Caremark to charge community oncology practices unreasonable and irrelevant fees. It is a “Three Card Monte” rigged game that guarantees Caremark yet another source of revenue from community oncology practices and other specialties relying on high-priced specialty medications to treat their patients.
And perhaps most audaciously, Caremark has brazenly violated Medicare’s definitions regarding “negotiated price”, requiring that all discounts that are “reasonably determined” be applied at the point of sale. Apart from the unfair and untoward impact, this conduct has had on community oncology practices, Caremark’s decision to ignore the law has resulted in increased costs to the Medicare program and increased out-of-pocket costs to patients. These actions stand as yet another PBM moneymaking tactic that only places additional upward pressure on already out-of-control drug prices.

On behalf of COA and the Practices, we demand that Caremark cease utilizing its PNR Program to impose DIR fees on community oncology practices. We hope that, by way of this correspondence, the parties can work together to resolve the issues identified below.

I. THE ISSUE

The Practices constitute a broad cross-section of community oncology practices currently in Caremark’s networks and subject to Caremark’s PNR Program. The Practices are located throughout the country and represent some of the largest, most clinically progressive oncology practices in the industry, which dispense oral cancer and related drugs through in-office dispensing under physicians’ plenary medical licenses or through a practice-owned licensed retail pharmacy (the dispensing type depends in part on rules imposed by state boards of medicine and boards of pharmacy, and related state laws). As more cancer medications are available in oral formulations, providing these therapies at the point-of-care, along with necessary education of adherence and side effects, is critical. The Practices range in size from just a few physicians to several hundred. Regardless of their size or makeup, however, these Practices and their patients all face negative consequences from Caremark’s problematic program.

Caremark’s quality metrics are neither “reasonable” nor “relevant” to oncology and in violation of federal law. Beginning in 2016, Caremark created and implemented the PNR Program, whereby it assesses the Practices’ performance in a number of “quality metric” categories. Depending on the Practices’ performance in these “quality metric” categories, Caremark assesses DIR fees and effectively claws back anywhere between 3% and 16% of the providers’ “ingredient cost.” The Practices had their performance reviewed by the “quality metric” categories such as ACE inhibitor/ARB (angiotensin receptor blockers) adherence, statin adherence, diabetes adherence, GAP therapy, comprehensive medication review (CMR) completion rate, percentage of high-risk medications, and formulary compliance. These “quality metric” categories reviewed by Caremark were not weighted equally, and the Practices were assessed DIR fees based on these categories despite the fact that most of the Practices do not have underlying claims volume of dispensed medications in the quality metric categories. As community oncology practices dispense medications only to their own patients, the Practices generally dispensed few, if any, drugs that met any of the performance criteria in the PNR Program. The “quality metrics” had no bearing whatsoever on the high-touch cancer medications being dispensed by the Practices.

For that reason and because of written complaints issued by providers (including many community oncology practices), under Caremark’s PNR Program for the 2018 and 2019 plan years, Caremark revised its terms and conditions of participation to take into account a “specialty adherence component” for providers that have a certain percentage of specialty claims for a plan by the network in any given trimester. The “specialty adherence component” purports to include “quality metric” categories that are allegedly relevant to providers who dispense specialty medications, with a

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3 It is generally understood that “ingredient cost,” the term used by Caremark, represents the full approved amount at the point-of-sale, inclusive of any cost sharing obligations from the patient.
4 It is understood that GAP Therapy is another form of essentially measuring adherence in statin regimens.
specific weighted value of the provider’s overall performance score. The “specialty adherence component” of Caremark’s PNR Program has continued to be in use since it was implemented in 2018. However, despite this effort to include specialty medications as one criterion to assess performance, there are still many, many flaws with Caremark’s PNR Program.

Most notably, the PNR Program’s focus on adherence, even in the specialty oncology space, creates perverse incentives and poses real dangers to patients, especially Medicare beneficiaries. Simply put, given the unique nature of cancer care and cancer medications, adherence is not an appropriate tool to measure quality, and community oncology practices should not be judged based on medication adherence. By doing so, Caremark has created incentives that can be seriously detrimental to patients’ health. As described in greater detail below, DIR fees tied to adherence are especially problematic in cancer treatment because adverse events experienced by these medications often call for a temporary discontinuation of therapy until a patient’s status returns to an acceptable level (sometimes even directed within the medication’s FDA-approved package insert). The period during which the drug is “held” is perceived by Caremark as a lack of adherence, causing the performance rating to decrease and DIR fees to increase. This creates a perverse financial incentive that could not only harm the patient but ultimately cost the system more money, not only through wasted medications but through increased medical costs stemming from patient harm.

As Caremark is aware, the Practices dispense many expensive cancer medications. Dispensing expensive specialty medications increases financial exposure in Caremark’s PNR Program, as PNR fees are calculated on a percentage of “ingredient costs” paid. Caremark’s post-hoc DIR fees result in unreasonable, below-acquisition cost reimbursement rates in violation of federal law, as set forth below. The assessment of DIR fees on the Practices by Caremark is effectively bringing the Practices’ reconciled reimbursement rates below the cost to even acquire the drugs. The resulting net reimbursement leaves the Practices with a difficult choice of losing money and dispensing medications or directing their patients to another pharmacy (which would not only violate the Practices’ contracts with Caremark but result in worse care for the patient).

As such, Caremark is not only assessing Practices’ performance under the PNR Program based on a metric that is wholly antithetical to high-quality cancer care, but is fueling the increase in drug prices, while jeopardizing patients’ access to community oncology practices.

II. CAREMARK’S PNR PROGRAM IS INAPPLICABLE TO THE PRACTICES IN VIOLATION OF FEDERAL LAW

The metrics utilized by Caremark in carrying out its PNR Program are completely inapplicable to the Practices and thus are not “reasonable and relevant terms and conditions” for the Practices to participate in Caremark’s networks. Specifically, as COA members are community oncology practices, they dispense primarily (and almost exclusively) specialty medications for cancer patients. As such, they had virtually no ability to influence their performance upon which Caremark’s post-hoc and unilaterally imposed DIR fees were based for the years 2016 to 2017. They had no such ability because their business model rendered nearly all of Caremark’s “quality metric” categories largely inapplicable because the categories mostly graded performances in the treatment of high cholesterol, heart disease, and diabetes and thus were geared toward the dispensing of retail medications, and not the dispensing of specialty medications. In addition, if a Practice did dispense even an insignificant number of medications falling within the largely inapplicable “quality metric” categories, such as statin adherence or diabetes adherence, the Practice’s overall performance score was largely based on its performance on those claims, despite the fact that the vast majority of the Practice’s measured claims fell within another quality category (e.g., “formulary compliance”), but such other categories compromised a very small percentage of the Practices’ overall performance score due to the PNR Program weightings. The Practices’ performance scores were artificially brought down due to their assigned scores in categories in which they have no claims data. The method used by Caremark to assess DIR fees stacks the deck against the Practices because Caremark
has imposed, and continues to impose, low-performance scores on the Practices based on network averages of other pharmacies on “quality metric” categories that are entirely inapplicable to the Practices and which are entirely unrepresentative of the Practices’ actual performance.  

Similarly, the changes to Caremark’s 2018 and 2019 PNR Program are still largely inapplicable to the Practices and have resulted in the Practices being reimbursed even less by Caremark. Overall, Caremark’s DIR fees not only render the Practices’ reimbursement rates unreasonably low, but the methods utilized by Caremark in implementing its DIR fee program have made it impossible for them to have satisfactory performance scores, much less performance scores that actually reflect their performance.

Worse yet, and as noted above, adherence-based metrics are particularly problematic and wholly inapplicable in the oncology setting. Community oncology practices are extremely vigilant about monitoring their patients’ medication regimens and may temporarily discontinue or “hold” medications until a patient’s status returns to an acceptable level. The period during which medication is “held,” or therapy is temporarily discontinued, is wrongly and obtusely perceived by Caremark as a lack of adherence in one of the few areas where the Practices may have claims volume, ultimately causing the Practices’ performance to decrease, and the DIR fee assessment to subsequently increase.

Consider, for example, Imbruvica (ibrutinib), which is dispensed by many community oncology practices to treat mantle cell lymphoma (MCL) and chronic lymphocytic leukemia (CLL). Studies have shown that Imbruvica tends to cause hematologic effects such as neutropenia and thrombocytopenia in MCL and CLL. If these adverse events occur at certain levels, the standard of care – as articulated directly by the FDA-approved package insert – is to hold the medication until the patient’s lab values return to normal ranges. This can happen in as many as 46% of cases, resulting in discontinuing the patient’s medication for up to a month. If community oncology practices are required to continue to dispense this medication, it will result in additional (and avoidable) costs to Medicare for the discontinued fills, as well as potential harm to the patient (along with potentially increased costs to Medicare for associated medical costs).

Further, due to the high cost of specialty drugs, and in particular, oncology medications, any small change in perceived adherence rates due to the purposeful physician-directed temporary discontinuation of therapy results in unreasonably low reimbursement rates. According to Caremark, its DIR fee program is designed to influence providers to deliver great care to patients in Caremark’s provider network. On that clinical basis, if our clients were to be “influenced” by Caremark’s metrics by adhering to a medication when the FDA-approved label calls for the therapy to be held, patients would die. Caremark’s adherence metrics are not “reasonable and relevant” to oncology providers, and for that reason, Caremark should cease and desist from further DIR fees for our clients and return fees unilaterally recouped.

III. CAREMARK’S VIOLATIONS OF FEDERAL LAW AND MEDICARE REGULATIONS

Caremark’s conduct by way of its PNR Program violates an array of federal laws and regulations, including CMS’ guidance documents and the Medicare Part D Any Willing Provider Laws, as detailed below. Far beyond the financial implications to these community oncology practices, these actions affect patient access and choice. As a

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5 It is important to note that neither these metrics, nor the methodology in determining the performance scores (including the use of what is in essence, “mean imputation,” are approved by CMS, and in fact, are not permitted by Medicare regulations.

6 IMBRUVICA (ibrutinib) [package insert]. Sunnyvale, CA; Pharmacyclics LLC; Revised April, 2020.


8 Notably, most cancer medications entering the market cost more than $100,000 per year of treatment.
multitiered healthcare conglomerate, CVS Health’s CVS Caremark Specialty Pharmacy is a direct competitor to the Practices and stands to benefit directly by unduly narrowing the networks via negatively impacting reimbursement rates, resulting in the Practices being reimbursed below cost for a host of specialty medications they dispense. In this vein, Caremark’s PNR Program constitutes a flagrant violation and circumvents the intent of the Medicare Any Willing Provider Provisions and seriously threatens beneficiary access and choice.

As a threshold matter, Federal Law protects the Practices from abhorrently low reimbursement – which essentially constitutes exclusion – from Medicare networks. Pursuant to 42 U.S.C. § 1395w-104(b)(1)(A), the Any Willing Provider Law (“AWPL”) states that “[a] prescription drug plan shall permit the participation of any pharmacy that meets the terms and conditions under the plan.” The Centers for Medicare & Medicaid Services (“CMS”) has enacted regulations to ensure the “terms and conditions for participation” in Medicare Part D networks are “reasonable and relevant” to ensure that pharmacies are not only generally willing to participate in Medicare Part D, but also to participate under objectively reasonable terms. The AWPL requires Part D plan sponsors and PBMs to have “a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy.” 42 C.F.R. §423.505(b)(18). Unreasonable reimbursement rates and DIR fees based solely upon inapplicable “quality metrics” violate that standard because they are not “reasonable” and are also not “relevant.” In short, “Part D sponsors must offer reasonable and relevant reimbursement terms for all Part D drugs as required by [the Medicare AWPL].” Medicare Prescription Drug Benefit Manual, Chapter 5, Section 50.3. How Caremark calculates performance are material terms and conditions for which the law sets a “reasonable and relevant” benchmark of judgement. Caremark failed to abide by that standard of law as it relates to oncology care.

Caremark’s PNR Program is neither reasonable nor relevant because it ties the Practices’ reimbursement to metrics not relevant at all to whether the Practices have, in fact, performed well in treating Caremark’s members or provided care under their contracts with Caremark. Caremark’s assessment of the Practices’ performance does not actually reflect the Practices’ true performance and is entirely unrepresentative of actual performance. Instead, it actually risks driving patient harm. Thus, as applied to the Practices, the PNR Program cannot be deemed reasonable or relevant.

More specifically, Caremark must offer contract terms to the Practices that are reasonable and relevant to the operation and functions performed by the Practices, and the terms and conditions under Caremark’s PNR Program are completely irrelevant to their operation and functions. CMS explicitly stated that contract terms and conditions are not reasonable and relevant when they are “based upon outdated pharmacy classifications that do not accurately reflect today’s pharmacy business model(s) and practices.” Here, the terms and conditions in Caremark’s PNR Program are unreasonable and irrelevant because they do not reflect Practices’ business model.

Even further, Caremark’s actions are a clear-cut breach of each and every contract Caremark has with Medicare Part D Plan Sponsors. Pursuant to 42 C.F.R. § 423.505(i)(4)(iv), each contract between a Part D Plan sponsor and Caremark must contain language obligating Caremark to abide by all applicable federal laws and regulations, including the AWPL. As a result, the Practices have inherent rights against Caremark as third-party beneficiaries under such agreements, as well as claims against Caremark and its Plan Sponsor customers.

Finally, Caremark’s PNR Program flouts Medicare regulations aimed at controlling patient out-of-pocket amounts through the definition of “negotiated price.” In establishing “cost sharing” obligations for beneficiaries, CMS has stated that “[b]eneficiary cost sharing is a function of the negotiated price” paid by Part D plan sponsors, noting

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10 74 Fed. Reg. 1,494, 1,505 (Jan. 12, 2009) (emphasis added)
that “[w]hen pharmacy price concessions and other price concessions are not reflected in the negotiated price at the point of sale (that is, are applied instead as [Direct and Indirect Remuneration] at the end of the coverage year), beneficiary cost-sharing increases.”\(^{11}\) To that end, CMS defined “negotiated prices” as the price that the “Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug … inclusive of all price concessions from network pharmacies except those contingent price concessions that cannot reasonably be determined at the point of sale.”\(^{12}\) Through the PNR Program, Caremark has sought to take advantage of and manipulate this exception to the “negotiated price” definition. For one, the minimum level of DIR fees that Caremark assesses to every provider is 3% of the “ingredient cost.” This 3% clawback is certainly known or knowable at the point-of-sale, and Caremark’s failure to include this in the negotiated price and pass along the savings to the patients flies in the face of the regulation. More sinisterly, though, Caremark appears to have designed its PNR Program to appear as though there will be some level of variability in how DIR fees are assessed (i.e., through retrospective clawbacks and variable network rebates), but in reality, Caremark has a clear “target” of what it expects its effective DIR fee rate to be across each network and can predict with extreme accuracy and precision where a provider will fall on the spectrum of potential DIR fee rates. As such, Caremark’s PNR Program further directly violates 42 C.F.R. § 423.100, and unlawfully forces patients to pay substantially more out-of-pocket for their drugs, especially their expensive cancer medications.

IV. CONCLUSION

For all the foregoing reasons, Caremark’s PNR Program and fees are not reasonable and relevant terms and conditions for the Practices’ participation in Caremark’s pharmacy networks because the PNR Program is wholly inapplicable and even harmful to cancer care. We are attempting to resolve this issue in good faith on behalf of the Practices and COA and, in that vein, we seek a meeting with Caremark to forge a workable solution for the community oncology practices represented by COA. While we would prefer to resolve this matter amicably, should a resolution not be reached, the Practices are seriously contemplating filing for arbitration, alleging a variety of meritorious causes of action, including, but not limited to violations of state and federal law, violation of any willing provider laws and violation of unfair trade and competition laws. The Practices are prepared to seek all other legal and equitable relief to which they are entitled, including attorneys’ fees. Additionally, the Practices are prepared to press for regulatory and/or congressional action to address the problem of patient deficits.

In light of the serious issues set forth in this letter, we would expect and appreciate a prompt response from Caremark. If we do not hear a response from Caremark by March 22, 2021, the Practices will assume that Caremark does not wish to engage in good faith discussions to resolve this dispute short of arbitration or litigation and will be guided accordingly.

\(^{12}\) 42 C.F.R. § 423.100 (emphasis added).
This letter is being sent for settlement purposes only and shall not be used for any other purpose pursuant to Fed. R. Evid. 408 and corresponding State rules of evidence.

Very truly yours,

FRIER & LEVITT, LLC

/s/ Jonathan E. Levitt

Jonathan E. Levitt, Esq.

cc: Norris Cochran, Acting Secretary of Health and Human Services
    Liz Richter, Acting Administrator, Centers for Medicare & Medicaid Services
    Cheri Rice, Acting Deputy Administrator, Centers for Medicare & Medicaid Services
    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
    Kashyap Patel, M.D., President, Community Oncology Alliance
    Ted Okon, MBA, Executive Director, Community Oncology Alliance
    Community Oncology Alliance Board of Directors
    COA Oncology Pharmacy Association Board of Directors
March 1, 2021

Via Overnight Mail and Email (EDoerhoff@express-scripts.com)

Erica A. Doerhoff
Senior Legal Counsel
Express Scripts, Inc.
One Express Way
St. Louis, MO 63121

Re: Express Scripts, Inc.’s DIR Fee Programs and Community Oncology Practices

Dear Ms. Doerhoff:

This office represents the Community Oncology Alliance (“COA”). In case you are not familiar with the organization, COA is a non-profit organization dedicated to advocating for community oncology practices and the patients they serve, including Medicare beneficiaries. COA is the only organization dedicated solely to independent community oncology where the majority of Americans with cancer are treated. The mission of COA is to ensure that patients with cancer receive quality, affordable, and accessible cancer care in their own communities. For close to 20 years, COA has built a national grassroots network of community oncology practices to enhance the effectiveness and efficiency of cancer care, as well as to advocate for public policies that benefit patients with cancer. Individuals from all perspectives of the cancer care delivery team – oncologists, administrators, pharmacists, mid-level providers, oncology nurses, patients, and survivors – volunteer their time on a regular basis to lead COA and serve on its committees. Many community oncology practices provide the highest quality, most affordable, and accessible cancer care to patients who are part of networks managed by Express Scripts, Inc. (“ESI”).

We write on behalf of the community oncology practices COA represents nationwide (the “Practices”), regarding ESI’s Medicare Part D Performance Network Protocol for 2020 (“Network Protocol”) and Broad Medicare Part D Performance Network (“Performance Network Protocol”), under which, ESI assesses direct and indirect remuneration (“DIR”) fees. The assessment of DIR fees against the Practices fails to comport with applicable Medicare Part D rules and guidance. More specifically, ESI’s DIR fees do not comport with the clear guidance set forth under federal law, which requires “reasonable and relevant” terms and conditions for participation in ESP’s pharmacy networks. As it relates to cancer care, the Network Protocol and Performance Network Protocol’s terms and conditions are at best irrelevant and unclear, and at worst, if followed, harmful to cancer patients, particularly as it relates to “adherence.” ESI’s unreasonable terms and conditions have disproportionately impacted the Practices. Simply put, ESI’s DIR fee programs violate federal law.

ESI’s DIR fee programs, disguised as “quality” value-based initiatives are, in fact, simply a way for ESI to charge practices unreasonable and irrelevant fees. They are a “Three Card Monte” rigged game that guarantees ESI yet another source of revenue from community oncology practices and other specialties relying on high-priced specialty medications to treat their patients.
And perhaps most audaciously, ESI has brazenly violated Medicare’s definitions regarding “negotiated price” by requiring that all discounts that are “reasonably determined” be applied at the point of sale. Apart from the unfair and untoward impact, this conduct has had on community oncology practices, ESI’s decision to ignore the law has resulted in increased costs to the Medicare program and increased out-of-pocket costs to patients. These actions stand, as yet another PBM moneymaking tactic that only places additional upward pressure on already out-of-control drug prices.

On behalf of COA and the Practices, we demand that ESI cease utilizing the Network Protocol and Performance Network Protocol to impose DIR fees on community oncology practices. We hope that, by way of this correspondence, the parties can work together to resolve the issues identified below.

I. **THE ISSUE**

The Practices constitute a broad cross-section of community oncology practices currently in ESI’s networks and subject to ESI’s Network Protocol and Performance Network Protocol. The Practices are located throughout the country and represent some of the largest, most clinically progressive oncology practices in the industry, which dispense oral cancer and related drugs through in-office dispensing under physicians’ plenary medical licenses or through a practice-owned licensed retail pharmacy (the dispensing type depends in part on rules imposed by state boards of medicine and boards of pharmacy, and related state laws). As more cancer medications are available in oral formulations, providing these therapies at the point-of-care, along with necessary education of adherence and side effects, is critical. The Practices range in size from just a few physicians to several hundred. Regardless of their size or make up, these Practices and their patients all face negative consequences from ESI’s problematic program.

ESI’s quality metrics are neither “reasonable” nor “relevant” to oncology and in violation of federal law. Beginning in 2020, ESI created and implemented its updated DIR fee programs, whereby it either assesses practices’ performance based on adherence to an extremely high “Generic Dispense Rate” (“GDR”) under the Network Protocol, or unknown and ambiguous metrics under the Performance Network Protocol. Specifically, under the Network Protocol, ESI assesses DIR fees in a range that comprises a substantial percentage of the “ingredient cost” based on a practice’s GDR, which measures the percentage of generic drugs a pharmacy dispenses relative to its overall claims volume. In this framework, for every 100 claims, a practice must dispense almost all generic drugs to avoid the DIR fee. Critically, due to the Practices’ treatment of cancer patients, they by necessity dispense almost exclusively branded specialty medications for cancer patients where no generic alternative exists, and thus, they cannot possibly dispense generic drugs to the extent required to meet the GDR percentage stated in the contract. Simply put, whereas an extremely high GDR percentage may be appropriate for certain pharmacy types or areas of medicine, it is totally inappropriate in cancer care. The Practices are therefore without control over their GDR, and the imposition of this metric to measure their performance is neither reasonable nor relevant to their operations as specialty oncology providers. Most specialty oncology drugs are not available in generic form, and thus, ESI is imposing a totally unrealistic mandatory fine of a significant percentage of ingredient cost for every drug one of the Practices dispenses.

Likewise, the proposed formulas for calculating DIR fees under the Performance Network Protocol are vague and ambiguous, and, to the extent they can be discerned, measure factors equally outside of the Practices’ control. For

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3 This is especially true for community oncology practices, who are legally restrained from dispensing to any patients who are not also patients of the practice.
example, but without limitation, ESI states it will measure performance based upon CMS star metrics or metrics modeled after adherence, though it gives no indication of what those metrics will actually measure, thus providing the Practices with no notice of their likely exposure. ESI states that if the metric measure is inapplicable to the Practices, they may be assessed in the most punishing tier. Since most of the CMS star metrics relate to concepts such as generic dispensing or adherence to certain maintenance medications, the Practices (who dispense few generics and zero maintenance medications) will presumably be forced to pay the most punishing DIR fees based upon a measure that is inapplicable to the Practices. In short, the Performance Network Protocol is entirely unclear and lacks any transparency, such that the Practices do not know how to measure and calculate their performance upon which a DIR fee is based.

Largely irrelevant metrics aside, the Performance Network Protocol poses an additional and more dangerous problem, that community oncology practices should not be judged based on medication adherence, which in many instances is not relevant in cancer care and can, in fact, be seriously detrimental to patients’ health. As described in greater detail below, DIR fees tied to adherence are especially problematic in cancer treatment because adverse events experienced by these medications often call for temporary discontinuation of therapy until a patient’s status returns to an acceptable level. The period during which the drug is held could be perceived by ESI as a lack of adherence, causing the performance rating to decrease and DIR fees to increase. This creates a perverse financial incentive that could not only harm the patient but ultimately cost the system more money.

As ESI is aware, the Practices dispense many expensive cancer medications. Dispensing expensive specialty medications increases financial exposure in ESI’s DIR fee programs, as DIR fees are calculated on a percentage of “ingredient costs” paid. ESI’s post-hoc DIR fees result in unreasonable, below-acquisition cost reimbursement rates in violation of federal law, as set forth below in this letter. As such, ESI is assessing Practices’ performance under the Network Protocol based on a metric that is wholly inapplicable to high-quality cancer care and under the Performance Network Protocol, under which the metrics are entirely unknown.

The assessment of DIR fees on the Practices by ESI is effectively bringing the Practices’ reimbursement rates below the cost to even acquire the drugs. The resulting net reimbursement leaves the Practices with a difficult choice of losing money and dispensing the medications or directing their patients to another pharmacy (which would not only violate the Practices’ contracts with ESI but result in worse care for the patient).

II. ESI’S DIR FEE PROGRAMS ARE NEITHER REASONABLE NOR RELEVANT TO THE PRACTICES IN VIOLATION OF FEDERAL LAW

The metrics utilized by ESI in carrying out its DIR fee programs are either completely inapplicable to the Practices, patently unclear, or both, and thus are not “reasonable and relevant terms and conditions” for the Practices to participate in ESI’s networks. Specifically, as COA’s members are community oncology practices, they dispense primarily (and almost exclusively) specialty medications for cancer patients. As such, they have virtually no ability to influence their performance upon which ESI’s ex post facto, and unilaterally imposed DIR fees are based. The method used by ESI to assess DIR fees stacks the deck against the Practices because ESI has imposed, and continues to impose, low-performance scores on the Practices based on either an unknown metric or an inapplicable metric, and which is entirely unrepresentative of the Practices’ actual performance. Overall, ESI’s DIR fees not only render the Practices’ reimbursement rates unreasonably low, but the methods utilized by ESI in implementing its DIR fee program have made it impossible for them to have satisfactory performance scores, much less performance scores that actually reflect their performance.

Worse yet, and as noted above, adherence-based metrics are particularly problematic and wholly inapplicable in the oncology setting. Community oncology practices are extremely vigilant about monitoring their patients’ medication regimens and may temporarily discontinue or “hold” medications until a patient’s status returns to an acceptable level.
The period during which a medication is “held,” or therapy is temporarily discontinued, is often perceived by ESI as a lack of adherence, ultimately causing the Practices’ performance to decrease and the DIR fee assessment to subsequently increase.

Consider, for example, Imbruvica (ibrutinib), which is dispensed by many community oncology practices to treat mantle cell lymphoma (MCL) and chronic lymphocytic leukemia (CLL). Studies have shown that Imbruvica tends to cause hematologic effects such as neutropenia and thrombocytopenia in MCL and CLL. If these adverse events occur at certain levels, the standard of care is to hold the medication until the patient’s lab values return to normal ranges. This can happen in as many as 46% of cases, resulting in discontinuing the patient’s medication for up to a month. If community oncology practices are required to continue to dispense this drug continuously, it will result in additional costs to the health plan for the discontinued fills, as well as potential harm to the patient.

Further, due to the high cost of specialty drugs, and in particular, oncology medications, any small change in perceived adherence rates due to the purposeful, physician-directed temporary discontinuation of therapy results in unreasonably low reimbursement rates. According to ESI, its DIR fee programs are designed to influence providers to deliver great care to patients in ESI’s provider network. On that clinical basis, if our clients were to be “influenced” by ESI’s metrics by adhering to a medication when the FDA-approved label calls for the therapy to be held, patients would die. ESI’s unknown and known adherence metrics are not “reasonable and relevant” to oncology providers, and for that reason, ESI should cease and desist from further DIR fees for our clients and return fees unilaterally recouped.

III. ESI’S VIOLATIONS OF FEDERAL LAW AND MEDICARE REGULATIONS

ESI’s conduct by way of its DIR fee programs violates an array of federal laws and regulations, including CMS guidance documents and the Medicare Part D Any Willing Provider Laws, as detailed below. Far beyond the financial implications to these community oncology practices, these actions affect patient access and choice. As a multitudinous healthcare conglomerate, ESI’s specialty pharmacy, Accredo, is a direct competitor to the Practices and stands to benefit directly by unduly narrowing the networks via negatively impacting reimbursement rates, resulting in the Practices being reimbursed below cost for a host of specialty medications they dispense. In this vein, ESI’s DIR fee programs constitute a flagrant violation and circumvent the intent of the Medicare Any Willing Provider Provisions and seriously threaten beneficiary access and choice.

As a threshold matter, Federal Law protects the Practices from abhorrently low reimbursement – which essentially constitutes exclusion – from Medicare networks. Pursuant to 42 U.S.C. §1395w-104(b)(1)(A), the Any Willing Provider Law (“AWPL”) states that “[a] prescription drug plan shall permit the participation of any pharmacy that meets the terms and conditions under the plan.” The Centers for Medicare & Medicaid Services (“CMS”) has enacted regulations to ensure the “terms and conditions for participation” in Medicare Part D networks are “reasonable and relevant” to ensure that pharmacies are not only generally willing to participate in Medicare Part D, but also to participate under objectively reasonable terms. The AWPL requires Part D plan sponsors and PBMs to have “a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy.” 42 C.F.R. §423.505(b)(18). Unreasonable reimbursement rates and DIR fees based solely upon an inapplicable metric, and those that are based on unknown and unclear metrics, violate that standard because they are not “reasonable” and are also not “relevant.” In short, “Part D sponsors must offer reasonable and relevant reimbursement terms for all Part D drugs as required by [the Medicare AWPL].” Medicare

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7 Notably, most cancer medications entering the market cost more than $100,000 per year of treatment.
Prescription Drug Benefit Manual, Chapter 5, Section 50.3. How ESI calculates performance are material terms and conditions for which the law sets a “reasonable and relevant” benchmark of judgement. ESI failed to abide by that standard of law as it relates to oncology care.

ESI’s DIR fee programs are neither reasonable nor relevant because they tie the Practices’ reimbursement to a metric not relevant at all to whether the Practices have in fact performed well in treating ESI’s members or providing care under their contracts with ESI. In the Network Protocol, ESI has tied reimbursement to the percentage of generics a practice has dispensed – something community oncology practices have no meaningful ability to impact. Likewise, in the scant details provided in the Performance Network Protocol, the Practices are left guessing between adherence metrics that will penalize them for “holding” medications when it is in the best interests of the patient, or wholly unknown measurement criteria, in determining how their performance will be measured. ESI’s assessment of the Practices’ performance does not actually reflect the Practices’ and is entirely unrepresentative of actual performance. Thus, as applied to the Practices, the DIR fee programs cannot be deemed reasonable or relevant.

More specifically, ESI must offer contract terms to the Practices that are reasonable and relevant to the operation and functions performed by the Practices, and the terms and conditions under ESI’s DIR fee programs are completely irrelevant to their operation and functions. CMS explicitly stated that contract terms and conditions are not reasonable and relevant when they are “based upon outdated pharmacy classifications that do not accurately reflect today’s pharmacy business model(s) and practices.” Here, not only are vague terms and conditions in ESI’s DIR fee programs unreasonable and irrelevant because they are indecipherable, but the terms that are decipherable do not reflect Practices’ business model.

Even further, ESI’s actions are a clear-cut breach of each and every contract ESI has with Medicare Part D Plan Sponsors. Pursuant to 42 C.F.R. § 423.505(i)(4)(iv), each contract between a Part D Plan sponsor and ESI must contain language obligating ESI to abide by all applicable federal laws and regulations, including the AWPL. As a result, the Practices have inherent rights against ESI as third-party beneficiaries under such agreements. Indeed, ESI has incorporated the AWPL into its Agreement, at Section 7.1 of its PBM Provider Manual, as an enforceable term, expressly stating ESI’s “Medicare Prescription Drug Plan . . . retain[s] ultimate responsibility to comply with the terms of its CMS contract,” and further incorporating 42 CFR 423.505(i). That provision, in turn, states at subsection (3)(iv), “Each and every contract must specify that first tier, downstream, and related entities must comply with all applicable Federal laws, regulations, and CMS instructions.” Thus, ESI has included a negotiable and enforceable contractual term making ESI responsible to the Practices to comply with the AWPL.

Finally, ESI’s DIR fee programs flout Medicare regulations aimed at controlling patient out-of-pocket amounts through the definition of “negotiated price.” In establishing “cost sharing” obligations for beneficiaries, CMS has stated that “[b]eneficiary cost sharing is a function of the negotiated price” paid by Part D plan sponsors, noting that “[w]hen pharmacy price concessions and other price concessions are not reflected in the negotiated price at the point of sale (that is, are applied instead as [Direct and Indirect Remuneration] at the end of the coverage year), beneficiary cost-sharing increases.” To that end, CMS defined “negotiated prices” as the price that the “Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug . . . inclusive of all price concessions from network pharmacies except those contingent price concessions that cannot reasonably be determined at the point-of-sale.” Through its DIR program, ESI has sought to take advantage of and manipulate this exception to the “negotiated price” definition. For one, it is essentially impossible for providers to avoid a minimum

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9 74 Fed. Reg. 1,494, 1,505 (Jan. 12, 2009) (emphasis added)
11 42 C.F.R. § 423.100 (emphasis added).
level of DIR fees, which inevitably will be assessed on all claims. These clawbacks are known or knowable at the point-of-sale, and ESI’s failure to include this in the negotiated price and pass along the savings to the patients flies in the face of the regulation. More sinisterly, though, ESI appears to have designed its DIR programs to appear as though there will be some level of variability in how DIR fees are assessed (i.e., through retrospective clawbacks and variable DIR fee claw back rates), but in reality, ESI has a clear “target” of what it expects its effective DIR fee rate to be across each network, and can predict with extreme accuracy and precision where a provider will fall on the spectrum of potential DIR fee rates. As such, ESI’s DIR programs further directly violate 42 C.F.R. § 423.100 and unlawfully force patients to pay substantially more out-of-pocket for their drugs, especially their expensive cancer medications.

IV. CONCLUSION

For all the foregoing reasons, ESI’s DIR fee programs and fees are not reasonable and relevant terms and conditions for the Practices’ participation in ESI’s pharmacy networks because the DIR fee programs are wholly inapplicable and even harmful to cancer care. We are attempting to resolve this issue in good faith on behalf of the Practices and COA and, in that vein, we seek a meeting with ESI to forge a workable solution for the community oncology practices represented by COA. While we would prefer to resolve this matter amicably, should a resolution not be reached, the Practices are seriously contemplating filing a multi-plaintiff public lawsuit in Federal court, alleging a variety of meritorious causes of action, including, but not limited to violations of state and federal law, violation of any willing provider laws and violation of unfair trade and competition laws. The Practices are prepared to seek any other legal and equitable relief to which they are entitled, including attorneys’ fees. Additionally, the Practices are prepared to press for regulatory and/or congressional action to address the problem of patient deficits.

In light of the serious issues set forth in this letter, we would expect and appreciate a prompt response from ESI. If we do not hear a response from ESI by March 22, 2021, the Practices will assume that ESI does not wish to engage in good faith discussions to resolve this dispute short of litigation and will be guided accordingly.

This letter is being sent for settlement purposes only and shall not be used for any other purpose pursuant to Fed. R. Evid. 408 and corresponding State rules of evidence.

Very truly yours,

FRIER & LEVITT, LLC

/s/ Jonathan E. Levitt

Jonathan E. Levitt, Esq.

cc: Norris Cochran, Acting Secretary of Health and Human Services
    Liz Richter, Acting Administrator, Centers for Medicare & Medicaid Services
    Cheri Rice, Acting Deputy Administrator, Centers for Medicare & Medicaid Services
    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
    Kashyap Patel, M.D., President, Community Oncology Alliance
Ted Okon, MBA, Executive Director, Community Oncology Alliance
Community Oncology Alliance Board of Directors
COA Oncology Pharmacy Association Board of Directors