Submitted Written Testimony on:

Reviewing the Role of Pharmacy Benefit Managers in Pharmaceutical Markets

United States House of Representatives

Committee on Oversight and Reform

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The opinions expressed in this testimony are mine and were prepared by me.

Pharmacy Benefit Managers (PBMs) have had an increasingly devastating impact on cancer patients and their oncology providers. I will summarize that impact during my brief opening remarks to the House Oversight & Reform Committee during the forum being held on November 17, 2021, on *Reviewing the Role of Pharmacy Benefit Managers in Pharmaceutical Markets*. In addition to my opening remarks – submitted in this document for the record – I am also including five volumes describing how PBMs abuse cancer patients. These are real stories affecting the lives of real people – only the identities are concealed. Additionally, although way too numerous, I have also included for the record some important news stories on PBMs and their corporate-affiliated insurers and mail order pharmacies.

Speaking for the Board of Directors of the Community Oncology Alliance (COA), and all independent community oncology practices across the country, we thank Oversight & Reform Committee Ranking Member Comer for holding this important forum on PBMs. Lives are literally at stake. And, as I end my opening remarks, no PBM should rob any American, including cancer patients, of hope. Congress must act – and now – to stop PBMs from adversely impacting the lives of Americans with serious diseases like cancer and from fueling drug prices/costs higher for Americans.

Sincerely,

Ted Okon
Executive Director
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Ranking Member Comer and members of the committee — I thank you for the opportunity to share my views on PBMs.

I'm the Executive Director of the Community Oncology Alliance, a non-profit organization dedicated to cancer patients and their oncologists. It is difficult in my brief opening remarks to describe to you the significant destructive impact PBMs have on cancer care and their role in fueling drug prices for Americans. But I will quickly summarize the toxic influence of PBMs and am happy to answer any questions.

You need to understand that the PBM market has drastically consolidated such that the top three PBMs – CVS, Express Scripts, and OptumRx – control upwards of 80% of the prescription drugs in this county. Consolidation hasn't stopped there as these PBMs own or are owned by the top one, three, and four health insurers. With this near stranglehold on medicine, these companies can dictate what cancer care an oncologist prescribes and how and where cancer patients receive treatment.

PBMs and their corporate insurers use a variety of tactics such as step therapy, formularies, and rebates to dictate treatment decisions by restricting access to optimal cancer therapy to ensure the most profitable drugs to the

PBM/insurer are given. Then, especially in the case of oral cancer drugs, they dictate that patients obtain their drugs via the PBM's mail order pharmacy, rather than at the point-of-care from patients' providers. Not only does this disjoint and uncoordinate the patient's care, but it leads to delays, denials, and waste.

As if this weren't bad enough, PBMs extract rebates – some would say "extort" – from drug makers. I'm not letting drug makers off the hook who try to buy their way unto formularies by offering rebates to PBMs. However, the leverage of the large PBMs is such that they can demand increasingly greater rebates from drug makers, or their drugs don't see the light of day on formularies – or in a recent case, pay a near 50% rebate or the drug will be declared medically unnecessary.

As rebates have come under pressure from employers and governments, PBMs have turned to pharmacies, either free-standing or, in our case, associated with an oncology practice, to extract what have become known as DIR fees under Medicare Part D. These arbitrary, nebulous fees collected three to six months after a drug is dispensed cause drugs to be reimbursed less than cost, which is why so many independent pharmacies are going out of business. However, because of rebates and DIR fees, PBMs have a

vested interest in having drug "list" prices be as high as possible. Although drug makers set the prices, often too high in cases, PBMs make money by fueling them higher for Americans.

I will never forget sitting in Senator Cassidy's office with a sister and brother from Louisiana relating how their mom fought the PBM for 2 months to get her cancer drug, which she could have gotten immediately from her oncologist. A week after being admitted to hospice, their mom finally got her drug, but a week later she died. As the daughter related through tears, we don't know if the drug would have saved her, but the PBM robbed her of hope.

No cancer patient should be robbed of hope by a PBM.

Thank you for listening.

April 2017

Delay, Waste, and Cancer Treatment Obstacles:

The Real-Life Patient Impact of Pharmacy Benefit Managers

Over 15 Years *of* Making a Difference in Cancer Care

There is growing awareness of the problems and pitfalls with Pharmacy Benefit Managers (PBMs) in the United States health care system. Contracted by insurance carriers to negotiate on their behalf with pharmaceutical companies, these 'middle men' corporations have quietly become an unavoidable part of our nation's health care system. Controlling at least 80 percent of drug benefits for over 260 million Americans, PBMs have the power to negotiate drug costs, what drugs will be included on plan formularies, and how those drugs are dispensed. Oftentimes, patients are required to receive drugs through PBM-owned specialty pharmacies.

However, while the role PBMs play in the U.S. health care system is complex and under scrutiny by policymakers and the public, with much of the debate focusing on economics, little discussion takes place of the impact PBMs have on patients.

This paper is the first in a series that will focus on the serious, sometimes dangerous, impact PBMs are having on cancer patients today. These are real patient stories but names have been changed to protect privacy.

AN AVOIDABLE DEATH?

Derek, a young husband, was diagnosed with advanced melanoma with brain metastases. Prognosis was grim, yet a ray of light appeared in the form of a new drug prescribed by his doctor. Proven to have the potential of significantly extending life, the drug offered Derek and his wife real hope. Located in his doctor's office was the clinic's pharmacy, where this potentially life-prolonging medication was simply waiting on the pharmacy shelf— but not for Derek. Derek's PBM mandated that Derek purchase his meds from one of their own mail-order specialty pharmacies. The clinic immediately faxed to the PBM all the necessary information for receiving prior authorization, and for the next ten days, Derek and his wife waited to hear that the prescription had been approved. Upon receiving the go-ahead, they then faxed the prescription to the PBM's specialty pharmacy, and sat back to wait again.

One week later, the drug still had not appeared; instead, the couple was notified that they first had to remit the drug's $1,000 co-pay, an amount they were unable to afford. Derek's wife now began arranging co-pay assistance, but she had to deal with the matter on her own at this point, because Derek had been admitted to the ICU. Several days later, she received approval for co-pay assistance, and forwarded the information to the PBM's pharmacy, which then FedExed the drug to Derek. The medication finally arrived— only there was no one to take them. By this time, Derek could no longer swallow pills, and sadly, shortly after, he died.

The most common and devastating issue that cancer patients face with PBMs is the fact that they must wait, for weeks or even months, to obtain medication that they could have received within 24 hours, had they been permitted to get it at the point of care from their oncologist. Beyond the stress and aggravation incurred, delays in receiving medication often translate into delayed treatment and worsening of the patient's condition, and in the most tragic of cases, possibly contributing to the patient's death.

TREATMENT DELAYED DUE TO PHARMACY RESTRICTIONS

Bill was prescribed an oral medication that works to prevent his cancer cells from replicating, thus reducing the growth and spread of the disease. His oncologist faxed the prescription to the specialty pharmacy indicated by Bill's PBM. Unfortunately, this particular pharmacy does not carry the medication prescribed, and so they forwarded the script to another specialty pharmacy that does carry it. However, that pharmacy does not accept Bill's insurance.

So, the prescription was forwarded again to yet another specialty pharmacy, which is the preferred pharmacy of Bill's insurance company. However, they don't carry the medication either. By this time, ten days have passed since the medication was first prescribed. Bill's physician, attempting to expedite things, now sends the prescription to a fourth specialty pharmacy that does carry the meds, and personally calls the insurance provider to explain the situation and ask for immediate approval. Five days later, and more than two weeks since the initial prescription was made, Bill receives his medication.

Agreements between insurance carriers and PBMs, which may be part of the same corporation, grant them full authority to determine where patients may or may not purchase their medication. This is carried out regardless of the detrimental effect it often has on patient health and wellbeing. In such a system, one must wonder whether the objective of curing patients from terminal disease has been usurped by that of achieving financial gain.

MEDICATION DELAYED 6 WEEKS DUE TO PBM SPECIALTY PHARMACY INDIFFERENCE

Carol was battling metastatic colon cancer. Unable to receive the same chemotherapy Carol had been treated with initially, her oncologist prescribed a medication to help stop the cancer from spreading any further. Her physician sent all documentation necessary to the specialty pharmacy mandated by Carol's PBM.

One week later, when Carol's oncologist phoned the PBM-mandated pharmacy to check on status of the prescription, again, they were told that nothing had been done— they refused to process the prescription without knowing Carol's current weight. Rather than calling Carol or the doctor to ascertain the necessary information, they had simply done nothing.

Another week went by, and the doctor called in again to check on the prescription. This time she was told that there was a form the doctor needed to fill out, in order to request Prior Authorization from the PBM. The doctor couldn't understand why they hadn't simply sent the form to her— or told her about it a week ago, when she had called. Eventually the doctor received the form, filled it out and submitted it, as Carol continued to wait and her cancer continued its lethal advance. Ultimately Carol received the medication— a full six weeks after it was initially prescribed, the most terrible irony being that had she been allowed to receive the pills at the site of care, she would have had them within a day.

Another serious issue patients and doctors face with PBMs and specialty pharmacies is their passive attitude towards patient care. Time and again, patients and doctors wait for medication that will never arrive. One small detail missing in the documentation is enough to delay its delivery, and the specialty pharmacy staff, who do not see themselves as partners to patient care, also do not see it as their responsibility to take any action to hasten the process.

LIFE-SAVING TREATMENT POSTPONED

Barbara, who was battling brain cancer, was prescribed two drugs: one a form of chemotherapy and the other an antiemetic that would alleviate the symptoms of nausea caused by the chemo. Both were to be taken in conjunction with the radiation treatments scheduled to begin six days later.

At Barbara's clinic, well aware of the urgency of the situation, the nurse on call faxed Barbara's prescriptions over to her PBM-mandated specialty pharmacy, and at the same time, applied for prior authorization from Barbara's PBM. Five days later the nurse called over to the pharmacy, asking for an update, since neither she nor Barbara had heard anything. The pharmacy worker informed the nurse that the prescriptions had indeed arrived and they were now about to enter them into their system to see if prior authorization was necessary.

The nurse was nonplussed— why had the prescriptions not been entered five days earlier, when they were sent and received by fax? And what if the nurse had not called to follow up; how much longer would it have taken? Most importantly, how is it that the PBM-mandated pharmacy staff, who are dispensing medication aimed to keep people alive, do not see it as their duty to provide customers with the very best and fastest service possible? Barbara's radiation treatments, scheduled to begin the next day and already delayed nearly a week, now had to be postponed until the medication could be received.

Multiple cases are reported in which doctors must reach out to PBM-mandated specialty pharmacies to enquire about the status of medication— only to find that while the pharmacy has received the patient's prescription, it's been just sitting on someone's desk, untouched, with no concern for the person on the other end, who is being treated for a life-threatening condition.

PATIENT DENIED MEDS DUE TO TECHNICAL GLITCH

Carl, battling prostate cancer, was prescribed an oral chemotherapy drug to help control his disease. Under his insurance plan, however, the co-pay costs for the medication came to over $4,000 per order. Carl simply could not afford to pay such an exorbitant amount. Fortunately, the pharmaceutical company that manufactures the drug has a co-pay program of its own, for eligible patients, making the drug affordable. Furthermore, the in-house pharmacy at the clinic where Carl receives his treatment benefits from this arrangement, and is able to acquire these and other cancer drugs for the low patient co-pay of $20.

The clinic phoned Carl's PBM on his behalf, explained the situation and asked them to accept the pharmaceutical company's co-pay as a 'secondary insurance.' Their request was promptly denied, as the PBM explained that their system did not have the capability to add in a secondary insurance. When asked if they could then simply authorize the clinic to fill the prescription instead, as they had it right there, this was also refused. Unwilling to believe that his patient was not going to receive this medication because it could not be entered into the PBM's computer system, Carl's physician made repeated calls to the PBM, speaking to one supervisor after another. Ultimately, he was forced to admit defeat, and Carl was denied a treatment that might have extended his life.

Patients who receive medication at their treating physician's in-house pharmacy benefit from the fullest in personal care and attention, and have access to a team that will strongly advocate on their behalf. Patients who are forced to deal with PBMs and specialty pharmacies, on the other hand, are often relegated to numbers and statistics, and if their case requires special attention or extra effort, their needs are likely to go unmet.

BUSY SIGNALS AND PBM SPECIALTY PHARMACY PROTOCOLS DELAY DRUG DELIVERY

PBM specialty pharmacies require patients to schedule delivery of their medications by phone, which seems, on the surface, a simple enough task. John, who was undergoing chemo for bone cancer, tried for an entire week to get through to his specialty pharmacy and schedule the next delivery of his medication, but no matter what time of day he called, the line was always busy. Finally, one day before he was supposed to start a new chemo cycle, and with no medication left, John called the clinic in frustration, and asked if they could intervene in some way.

Calling the specialty pharmacy, John's clinic was able to speak with a representative. "You are lucky you got through! " she was told by the rep. "Our lines are so busy, we cannot make outbound calls because all of our lines are used up. " Their luck ran out fairly quickly however; as the clinic staff member was not on John's list of 'approved' contacts at the pharmacy, she was unable to speak on John's behalf and schedule delivery of the medication. And with the lines tied up throughout the day, the specialty pharmacy rep was unable to call John to verify. The clinic staff hung up, and had to call John back to tell him his only recourse was to continue trying to call in and hope that he will eventually reach someone— before it becomes too late to matter.

Another reason for delays in receiving medication from a PBM specialty pharmacy is the difficulty in adhering to their complex bureaucratic protocols. Pharmacies insist on speaking to the sick patient firsthand, hearing them name the drug, and confirming their shipping details before they will send the medication. However, patients often miss these calls, which are most often automated, and which stop after three missed attempts. In many cases, even when the patient answers the phone, they cannot confirm the name of the drug, causing another cycle of delay to begin.

SPECIALTY PHARMACY TRIES TO STEAL A PATIENT

For two days, a PBM specialty pharmacy had been calling and faxing a doctor's clinic, which offers a pharmacy to provide integrated care to the patients it treats. The specialty pharmacy was claiming that one of the clinic's patients, William, had requested that his lung cancer medication be transferred to their pharmacy, and was demanding the clinic's immediate compliance in the matter.

Surprised by the news, the physician contacted William to enquire about his decision, only to discover that this was the first time William had heard of the matter. "Please do not transfer it anywhere else! " William asked. " I want to get it filled through the dispensary. I did not ask for this. I love being able to get this right away and with no hassles. I was on an oral chemo before and it was filled by a specialty pharmacy and I always was getting it late, missed a few days of medication sometimes and had numerous phone calls from them. They never seemed to know what was going on with my medication."

At first it may seem surprising to hear of a specialty pharmacy resorting to lies in order to steal business from an in-house dispensary. On deeper examination, however, it would seem just the next step in a long line of unethical behaviors resulting from the industrialization of the pharmacy system and the dehumanization of patients seeking medical care.

PATIENT AND CARE PROVIDERS GET THE RUNAROUND

Diana, a patient with metastatic breast cancer living in Ventura County, California, needed to refill her oral medication. On a Thursday, the clinic staff called in to the PBM specialty pharmacy to refill it on her behalf. The specialty pharmacy representative promised to expedite the process and overnight the medication, at no additional cost.

On Monday morning, the staff member walked into her office to find several faxes, e-mails and voicemails from Diana's family, friends and assisted living staff. Apparently, they had received a phone call from the specialty pharmacy on late Friday afternoon, saying that the drug was out of stock in their pharmacy, and suggesting that she call around to local pharmacies to try and find some. Over the weekend, Diana's family and friends called every pharmacy in the county, before starting on those in Los Angeles and Santa Barbara, all with no success.

Hearing the news, the clinic staff immediately contacted the drug manufacturer, who gave her the name of another specialty pharmacy to try. She faxed over the prescription, and then followed up over the next few days, each time being told that the script was being processed. Near the end of the week, the new specialty pharmacy called her to say that they were unable to fill the prescription for at least another month, as it had already been filled by the initial specialty pharmacy— the one that had said they were out of stock. The staff member now called back the first specialty pharmacy, asking that they reverse their claim; however, they reported that the medication had already been shipped out via UPS. Tracking it down, the staff member discovered that indeed the medication was on the truck, ready for delivery.

The cost in hours wasted per patient, per medicine, multiplied by the millions of people living with cancer today in the US, is astronomical. This is in addition to the high toll that the resultant stress takes on patients and their caregivers, as they race through bureaucratic hoops and set off on what often prove to be wild goose chases.

THOUSANDS OF DOLLARS IN WASTED MEDICINE

Laura was prescribed a regimen of drugs to treat her multiple myeloma. She was supposed to take it for three weeks, and then take a break for a week. After two weeks on the medication, Laura began exhibiting symptoms of toxicity, so her oncologist lowered her dosage. However, her specialty pharmacy had already sent her another bottle of the medication in its initial, stronger dosage, to be used the following month. Unable to be returned, the $12,000 worth of medication had to be taken into the clinic and destroyed.

Numerous instances are reported in which patients' therapies have changed, but the specialty pharmacy continues to send the medicine anyway. For expensive anti-cancer drugs and therapies each wasted delivery can be worth tens of thousands of dollars. Each time, the medicine must be brought in and destroyed— a shameless waste of money, time and medicine.

About the Community Oncology Alliance

The Community Oncology Alliance (COA) is the only non-profit organization dedicated solely to preserving and protecting access to community cancer care, where the majority of Americans with cancer are treated. COA helps the nation's community cancer clinics navigate a challenging practice environment, improve the quality and value of cancer care, lead patient advocacy, and offer proactive solutions to policymakers. To learn more, visit www.CommunityOncology.org

May 2017

Unaccountable Benefit Managers:

Real Horror Stories of How PBMs Hurt Patient Care

Over 15 Years *of* Making a Difference in Cancer Care

There is no shortage of horror stories associated with the increasingly large role that Pharmacy Benefit Managers (PBMs) play in the United States' health care system. With their numerous offshoots and service lines, PBMs have managed to take on an oligopolistic presence that adversely impacts patients receiving treatments, their health care providers, and everyone else in between.

Originally created to lower prescription drug costs, it has become clear that these multibillion dollar PBM corporations have transformed into gargantuan and almost completely unaccountable arbiters of the care that cancer patients receive. As this story series demonstrates, the dangerous combination of PBM unaccountability, opacity, and lack of oversight have resulted in benefit managers that are focused on their profits and not patient care.

This paper is the second in a series from the Community Oncology Alliance (COA) that focuses on the serious, sometimes dangerous, impact PBMs are having on cancer patients today. These are real patient stories but names have been changed to protect privacy.

PBM KNOWS BETTER THAN THE DOCTOR?

A community oncology and hematology clinic in Pennsylvania was being forced to use a specific PBM specialty pharmacy for their patients' oral chemo prescriptions, despite the practice having its own in-office dispensary. They had actually applied to the PBM two years earlier for the right to dispense drugs; however, approval was still "pending."

Frank was one of the clinic's patients battling rectal cancer. His oncologist prescribed an appropriate medication and submitted it to the PBM specialty pharmacy for filling. Soon after, the PBM called the clinic and announced that approval was denied for the submitted diagnosis, however if the oncologist were to change the diagnosis to one of several other cancers, they would then approve it. The clinic responded by noting that this would be a fraudulent change, that they refused to comply with it, and would be reporting it to the State of Pennsylvania. Within ten minutes of that call, Frank's medication was approved without any changes.

Edward was another of the clinic's patients, also battling rectal cancer. He had been prescribed the same drug, with a specific dosage, to be taken twice daily, seven days a week, for five weeks. However, when the medicine arrived, the PBM specialty pharmacy had changed the dosage and instructions. This was done despite the fact that a pharmacy is forbidden to change prescription instructions without the approval of the prescribing physician. To make matters even worse, the quantities sent to Edward were incorrect, even for the adjusted regimen.

Chris was another patient at the practice battling with rectal cancer and prescribed the same medication with the same dosage. He too found that his prescription had been changed by the PBM specialty pharmacy—from seven days per week to five days per week. When the PBM specialty pharmacy called Chris to schedule shipment he refused because the instructions were different from those he'd been given at the doctor's office. At this point, the PBM specialty pharmacy called the patient's physician, who had to reinstate the original prescription.

Because of the constant, unauthorized changes to the details of prescriptions made by oncologists, this practice worries that patients' care is in danger. And these changes are not isolated to just this PBM or practice—specialty pharmacies seem to be playing it fast and loose with the oncologists' directed treatment plans. Details, such as number of dosages and their size, are crucial life-and-death matters, and PBMs and their specialty pharmacies should not be changing them.

NEARLY A MONTH OF DELAYS

James, a 73-year old husband, father and grandfather, had been battling metastatic non–small cell lung cancer (NSCLC) for a while, when his oncologist prescribed a new medication that was FDA approved for cases like James', in which the cancer was "locally advanced or metastatic."

On November 13th, James' doctor submitted a request for prior authorization to the PBM. The first sign that things were not as they should be was when the request was denied—in a way that made absolutely no sense; they were demanding the results of his blood tests for jaundice. His doctor was incensed. How could the PBM deny someone an FDA-approved medication that was indicated for their illness and prescribed by an oncologist? They resubmitted the request, and for the next three weeks, waited in vain for the determination, with the doctor occasionally calling for status, only to be disconnected or told to call back.

On December 4th, as the doctor waited on hold with James' insurance company, James' family called to say that James had died. They would never get a chance to see if the medicine would have prolonged his life.

PBMs, by giving decision-making power to administrative workers with no medical background and little to no patient contact, have created a system that often results in treatment delays and, in worst-case scenarios, the patient's untimely death. In contrast to this, when patients are permitted to purchase their medication from a physician-owned pharmacy, they are spared the crippling bureaucracy of the PBM system.

REFILLING MEDICATION TO TREAT THE DECEASED

A practice in California began receiving request after request from a particular PBM for prior authorization to initiate a refill—what was unusual was that they were for a variety of expired prescriptions. What was going on? None of the practice's patients had been prescribed these drugs recently. In fact, some were for drugs that patients had stopped taking months earlier, while others were for patients who had died.

The practice was puzzled at first, but then came to the following conclusion: "It seems they [the PBM] are just going through their files, and when a prior authorization expiration date pops up for prescriptions filled through their pharmacy at one time, they are automatically sending out prior auth requests."

An amusing anecdote on the surface, stories such as this reveal the wholesale approach taken by the PBMs, in which patients are viewed not as individuals in need of medical care, but rather as a potential market of consumers. Spread across the entire health care system with drug benefits managed by PBMs for millions of patients, this scenario also potentially means millions, if not billions, of dollars of wasted costs in cancer medications.

THE BUREAUCRACY KNOWS BETTER THAN DOCTORS' ORDERS?

George, a patient with multiple myeloma, was prescribed two specific medications that work in conjunction with each other. It was thus a great surprise when the specialty pharmacy refused to send his medication, saying that they wanted to discuss with his oncologist the drug interaction between the two medicines. His oncologist was also perplexed; it was common knowledge that these two drugs are always prescribed together, as the second medicine provides a key part of the maintenance for the first drug, a fact that was not only clinically known but actually spelled out clearly on the manufacturer's website. George had also been on the medication combination for nearly 18 months at that point without problems.

After over a month of delays, the oncologist and PBM finally got this sorted out, but George's fiasco wasn't over. The specialty pharmacy then caused further delay, as they insisted upon speaking again to the doctor, this time to ascertain how many refills were needed. The irony of this was that this particular medication cannot be refilled, so it was simply additional time wasted, while George's treatment cycle was again delayed.

PBM specialty pharmacies have a long list of complex bureaucratic protocols. While they may be designed to prevent mistakes and ensure patient safety, the result is just as often unnecessary, time-consuming delays that in fact endanger the patients they are trying to protect.

MANY PATIENTS… ONE PBM SPECIALTY PHARMACY FULL OF PROBLEMS—A PRACTICE DOCUMENTS CHRONIC DELAYS

A community oncology clinic became so fed up with the problems and delays their patients faced in dealing with a PBM specialty pharmacy that they opened a dedicated file to document each case.

Michelle, a patient at a Florida community oncology practice, had arranged for the PBM specialty pharmacy to ship her medication to one of their local branches, for easy pickup. However, when Michelle arrived at the store, she discovered that they had thrown away her prescription. She now had to request a new prescription from her doctor, get a new prior authorization from her insurance carrier, and then have the medication shipped again—all of which resulted in a two-week delay of treatment.

Diane, another patient at the clinic, had her prescription faxed to the same PBM specialty pharmacy. The pharmacy confirmed it had received the prescription. However, 50 days later, the medication had still not arrived. Clinic staff called the pharmacy, who then claimed they had never received the prescription. By the time it was all sorted out, Diane had been left two months behind in treatment.

The following month, another patient of theirs, Juan, came home to find that his medication had been delivered and left in the middle of the road. Exposed to the Florida heat and rain, the drugs were ruined and had to be reordered—subjecting him to another round of authorizations, delay of his life-saving treatment, and unnecessary cost for the health care system.

No system is perfect. But when a PBM specific pharmacy is repeatedly documented making life-threatening mistakes with no accountability, and cancer patients are forced to remain with them, unable to choose another pharmacy, it would seem that something needs to change.

NEARLY THREE WEEKS OF BROKEN PROMISES AND SHIPPING DELAYS

On January 12th, the clinic treating Liane, a cancer patient, submitted a prescription to her PBM's preferred specialty pharmacy. On January 19th, the day Liane was scheduled to begin treatment, her insurance company notified the clinic that even though they already had prior authorization, they were now requiring a new prior authorization.

Liane was understandably upset by the news; why had the insurance company not contacted them a week ago, when the prescription was first sent? This would now delay her treatment unnecessarily. Later that day, the clinic's pharmacist ascertained that the additional approval required was related to the medication's cost, which had been put under a separate review. Over the next five days, the clinic's authorization specialist, Barbara, was in constant contact with the PBM, who assured her that the medication would be going out at any moment.

A week later, Barbara discovered that this was not true, for when she finally reached a PBM supervisor, Barbara learned that authorization was still pending. She was told that it could take another seven business days or more, before a decision was made.

Barbara's call must have made a difference however, because later that day the PBM faxed over a form to the clinic, to be filled out and returned to them. The following day approval was granted, albeit for the mail order specialty pharmacy. It took another two days for the specialty pharmacy to receive the prescription, another day to process it, and then the pharmacy contacted the patient to arrange for shipping. All together it took nearly three weeks from the original prescription being submitted to the PBM for the patient to receive it.

"Approval of your medication is pending" may well join the list of phrases that savvy consumers have long-since stopped believing, such as "Your call is important to us" and "The check is in the mail." Too many patients and physicians have been promised things too many times by PBM and specialty pharmacy reps, only to find those promises unfulfilled or completely contradicted.

DATA MIGRATION OR PATIENT NEGLECT?

Cathy was one of the fortunate ones; after seven and a half years, she was among the 22% of patients diagnosed with Stage IV cancer who had made it past five years. Unfortunately, Cathy's survival was dependent upon the specialty pharmacy her PBM had mandated she use—despite the fact that her oncologist had an in-house pharmacy that she would prefer to use. The problem was that every month, Cathy had to engage in a battle with the PBM pharmacy just to obtain her oral chemo medication.

As an example, on October 12th, Cathy called the PBM specialty pharmacy to verify that they were planning to over–night the oral chemo medication to her, so she could stay on schedule. The PBM specialty pharmacy told her that her oncologist had not sent in the renewal subscription. Cathy then called the pharmacy manager at her oncologist's office, who assured her that the prescription had indeed been faxed over one week earlier.

Trying to help Cathy out, the practice pharmacy manager then called up the PBM specialty pharmacy, who placed her on hold until they eventually located the script, which indeed had arrived a week before. "Why was the medicine not shipped? " the pharmacy manager asked. "Data migration," she was told; this meant that the PBM specialty pharmacy was in the middle of reorganizing its filing system, and had failed to take proper precautions to ensure that no patient care information was lost or misplaced along the way.

Had Cathy not called up the specialty pharmacy, she would never have received her medicine in time. Furthermore, the pharmacy manager at her oncologist's office informed Cathy that while she had been talking with the PBM specialty pharmacy, another patient had called her with the exact same issue. Every month, without exception, Cathy has had difficulty getting the medicine shipped on time from the PBM specialty pharmacy. No matter what, whenever her oncologist calls it in, the PBM specialty pharmacy manages to misplace the order.

Customer satisfaction, integrity, and commitment are important qualities for any profession or field. Yet, they are even more crucial in those professions that deal directly with people's lives. As PBM specialty pharmacies deal in products that have the potential to lengthen the time another person has on Earth, there must be a different standard to which their employees are held, and clearly indifference, apathy and carelessness should have no place.

PATIENT AND CARE PROVIDERS GET THE RUNAROUND

One serious complication that often results from chemotherapy and radiation treatments is a condition called neutropenia, in which there is a significant reduction of the white blood cells that provide essential first line of defense against infections. Neutropenia can lead to sepsis, organ failure, and death; however, it need not progress this far, if properly treated in time.

Marvin, a cancer patient being treated by a community oncology clinic, had developed neutropenia, and his oncologist prescribed a medication that helps the body to produce more white blood cells. His PBM indicated that, in order for Marvin to receive this particular medication, it had to be mail ordered from a specific PBM specialty pharmacy.

The clinic where Marvin was being treated faxed the prescription over to the specialty pharmacy on February 27th. Three days later, they called to check on status, and were told that the prescription was in the 'benefits verification stage,' in which the PBM pharmacy confirms that the patient's insurance provider will indeed cover the medication's costs. The clinic asked if prior authorization was required, but the PBM specialty pharmacy representative was unable to say; she promised to call back with that information. Two days later, having heard nothing, the clinic called again, and a PBM specialty pharmacy representative told them that indeed prior authorization was required. That same day, the clinic arranged for prior authorization, called the PBM specialty pharmacy back, told them the medication had been approved, and requested that they now call the patient and arrange for delivery. The PBM specialty pharmacy representative refused, however, stating that the prescription was still 'being processed.'

Having had enough, the clinic manager asked to speak with a supervisor, who under pressure, agreed to deliver Marvin's medication on March 7th. However, the date came and went, without any medicine being delivered; nor did Marvin or his clinic receive any phone calls from the PBM or specialty pharmacy, to let them know about or explain the additional delay. When the clinic called back the next day, the PBM specialty pharmacy representative told her that the medication was out of stock, but they would arrange for delivery on March 9th.

Because of the PBM delays and runaround, Marvin's neutropenia continued to go untreated for nearly two weeks, leaving him vulnerable to any number of infections and diseases that his body was unable to fight off on its own.

Dealing with PBM bureaucracy often feels like being trapped on a merry-go-round, with no way off. Every issue is handled by a different person or entity, each with its own agenda and protocols, and there is no one person who has a bird's-eye view of the patient's situation. Nor is there any accountability or certainty that the promises made will be met.

PBM SPECIALTY PHARMACY INDIFFERENCE DELAYS MEDICATION FOR TWO MONTHS

Darla had been taking a medication to treat her thyroid cancer since June. Then, in January her insurance provider changed to a new PBM, although they assured Darla that she would be able to continue filling her prescription at her doctor's in-house pharmacy. However, when it came time for her January refill, the PBM denied the clinic authorization to fill the script, saying it had to be filled at their own specialty pharmacy.

Despite being a federal government-supported plan under Obamacare, which mandated that the PBM consent to any

"willing provider," Darla never received her January refill. By the time the PBM contacted her for benefits verification, an entire month had gone by. Another week passed, and then another, without Darla ever receiving her medication.

Six weeks later, on March 7th, the PBM called Darla to schedule delivery, but there was more to come. Now her case was passed on to the PBM clinical department, where they needed to verify the dose, diagnosis, allergies, and drug interactions, despite the fact that Darla had been on the medication already for nearly ten months.

Once everything was verified, someone at the PBM realized that the medication was being used off-label. They called up Darla's oncologist, who confirmed that the patient had received prior authorization back in June to use the drug for thyroid cancer. He also asked the PBM specialty pharmacy representative for an explanation as to why it had taken so long to get Darla her medicine, and why there had been so many lags in communication, but the PBM representative had none to offer. As the call came to an end, the physician asked if Darla could now finally get her medicine. "No," the specialty pharmacy representative said. "Now we forward to the payment verification center. Once complete, it will be forwarded to the dispensing center. Then we can ship it out."

If Darla had been allowed to purchase her meds from the in-office pharmacy at her oncologists practice, she would have had them within 48 hours at the most. With the PBM specialty pharmacy, it took closer to two months.

Even when PBM specialty pharmacies are unable to provide a patient with the necessary medicine, they still will not release that patient so he or she can purchase it where it is available. The greed is so deep that they would rather risk a patient's life than allow another pharmacy to profit in their stead.

About the Community Oncology Alliance

The Community Oncology Alliance (COA) is the only non–profit organization dedicated solely to preserving and protecting access to community cancer care, where the majority of Americans with cancer are treated. COA helps the nation's community cancer clinics navigate a challenging practice environment, improve the quality and value of cancer care, lead patient advocacy, and offer proactive solutions to policymakers. To learn more, visit www.CommunityOncology.org

September 2017

Bureaucracy, Deadly Delays, and Apathy:

Pharmacy Benefit Manager Horror Stories — Part III

Over 15 Years *of* Making a Difference in Cancer Care

The dire consequences of having Pharmacy Benefit Managers (PBMs) within the United States' health care system continue to be seen, especially by the millions of cancer patients across the nation who must interact with them to access life-saving drugs.

Initially established as a way for insurance companies to outsource the management of drug benefits, PBMs have slowly morphed from simply handling prescription transactions to managing pharmacy benefit plans, negotiating with drug manufactures for discounts, and determining which drugs a patient will receive and from whom they will receive them. It's even reached the point where PBMs have become so bold as to usurp physicians' treatment decisions without consulting or notifying them of their actions.

This paper is the third in a series from the Community Oncology Alliance (COA) that focuses on the severe impact PBMs are having on cancer patients today. The stories are all real and provided by community oncology practices; only the patient names have been changed, to protect their privacy.

The vast number of horror stories from PBM abuses that are being reported by COA and others, shows the devastating result these institutions are having on patient care. From medication never sent or never received and mistaken dosages, to insurmountable red tape erected between the patient and their treatment, the problems are numerous and lead to one incontrovertible conclusion: action must be taken to stop PBM abuses.

PBM-PHARMACY ERROR NEARLY KILLS PATIENT

Carla, a colorectal cancer patient, was prescribed a common oral medication that has been on the market for nearly 20 years. Carla's PBM mandated that she fill the prescription at a large, well-known specialty pharmacy. Each time, the pharmacy had the medicine auto-shipped to Carla, with no patient contact or instructions.

Carla's oncologist prescribed the medication to be taken in rounds with the following specific instructions: 'two weeks on, one week off.' The PBM mail-order pharmacy, unfortunately, neglected to include the 'one week off' part of the instructions on the label. After her third refill, Carla ended up in a hospital's intensive care unit, fighting for her life.

Carla's experience was the straw that finally broke the camel's back, and the practice established its own oncology pharmacy with a pharmacist-managed program. However, many of their patients are still required to purchase their drugs from PBM-mandated, mail-order specialty pharmacies.

PBM pharmacies have been repeatedly documented making life-threatening mistakes; yet patients are forced to remain with them, unable to receive their medication at their physician-managed pharmacy, where they would receive the close, personalized care and monitoring that would easily prevent such potentially fatal occurrences from happening.

A PBM BUREAUCRACY FAILS TO HELP PATIENTS

Dylan had been on a specific medication for several years to manage his chronic cancer. Each time, he would simply fax the refill script to his pharmacy and the prescription would be filled with no glitches. Dylan's new insurance policy, however, required him to now fill his prescriptions at a specific PBM specialty pharmacy.

As usual, the clinic treating him faxed his refill prescription over to the new pharmacy in mid-May and Dylan waited for his medication to arrive. He waited and waited. In fact, over

the next few weeks, Dylan's wife began calling the pharmacy on a daily basis, asking them when the medication would arrive. Each time, she was told there was some issue delaying delivery, but that it would be resolved in just a day or two, not to worry. Every few days, she would call back to say it had still not arrived, only to have the same conversation with a different person.

Finally, after over a month of waiting, Dylan's wife asked his oncology clinic to intervene and one call from them determined the actual problem. Apparently, the prior authorization for the medication had expired, something no one at the specialty pharmacy had bothered to inform Dylan, and no one his wife had spoken to had bothered to check what the real issue was holding up delivery. The clinic handled the situation, arranging for authorization and for the medicine to finally be shipped.

Patients and practices often find their efforts to be futile in trying to overcome the massive bureaucracy morass they face with PBM-mandated specialty pharmacies. This creates a costly burden on the physician offices throughout the country, who must now take up the task of contacting pharmacies, resubmitting medication approval, locating missing prescriptions, questioning holdups, and more. But what of the thousands of patients out there with no one in their corner, who are forced to fight these battles on their own?

ONE-SIZE FITS ALL IS NO WAY TO TREAT A CANCER PATIENT

About a year ago, Darlene was diagnosed with multiple myeloma and prescribed a particular medication. Single and living alone, Darlene decided she would continue to work full-time while being treated for the disease.

The first hurdle Darlene met was getting her 21-day supply of medication filled by the mail-order pharmacy mandated by the PBM. The pharmacy called her while she was in a meeting at work and insisted that she listen to the mandatory recital of the "Patient Understanding." They promised it would take no longer than five minutes, yet forty-five minutes later, having been transferred to four different representatives as part of the process, Darlene finally hung up the phone.

While confused and upset, Darlene also felt relieved that the PBM ordeal was over, and all she had to do now was to wait for the medication to arrive. She could not have been more wrong. Although Darlene had made it very clear that she arrives home every day from work at 4:30pm, two days later Darlene arrived home to find a note on her door that UPS had tried to deliver her medicine at 2pm. She spent the rest of the day trying to locate the medicine.

After a great deal of effort, Darlene managed to schedule future deliveries of her medication for Saturdays before 1pm. Darlene is hard of hearing, so that Saturday, she sat in her front room from 8am to 1pm, afraid to even go to the bathroom lest she miss the knock on the door. At 2pm, she opened her front door and found a note from the UPS driver that he had attempted to make the delivery but found no one at home. Again, she had to chase down the package and finally ended up retrieving her drugs from a drop center twenty-five miles away from home.

As time went on, Darlene's situation only worsened, becoming more and more time-consuming for this elderly woman who was already contending with a fatal cancer. Each time she attempted to speak to a PBM representative to resolve the issue, she was passed to a new person who refused to listen to what Darlene had to say, but rather droned on repetitively that Darlene must "follow procedures" or she would not receive her medication.

Not every cancer patient has a vast network of family and friends who are there to assist them in their time of need. Often the elderly, or those living alone without close friends nearby, are forced to handle everything by themselves. While a physician-managed pharmacy would be able to adjust to such a patient's needs and assist them in easily accessing their medication, PBM mail-order pharmacies are not set up to handle the requirements of individuals. Patients must comply with their procedures and regulations, regardless of the personal cost.

POTENTIALLY FATAL DELAY IN DELIVERY

Bertrand was diagnosed with renal cell carcinoma and prescribed a specific oral medication by his doctor. The oncology clinic sent out his prescription to the PBM-mandated specialty pharmacy on February 4th. Four days later, the clinic called the pharmacy to follow up, and was told that the pharmacy was waiting for additional information from Bertrand. Ten days later, they called again to see where things stood, and were told that while the pharmacy had tried to call the patient and schedule delivery, they had been unsuccessful in reaching him. The

patient's clinic asked why the pharmacy had not tried to call the patient's doctor; were they not aware that Bertrand was suffering from renal cell carcinoma, and that it was quickly progressing without medication?

Another eleven days passed — nearly one month from the initial prescription — and Bertrand informed the clinic that the medication had still not arrived. The clinic once again called the pharmacy and were told that the pharmacy had closed the patient's account there, having been unable to reach him and verify his information in order to schedule shipment. The clinic then called Bertrand and asked him to contact the pharmacy in order to re-open his account and immediately schedule delivery.

Nearly forty days since being prescribed the medication, Bertrand had still not received it. The oncology clinic ultimately filed a formal complaint with the insurance company and is waiting for a resolution. Meanwhile, Bertrand continued to wait, though his cancer did not; in fact, between Stage I and Stage IV of renal cell carcinoma, five-year survival rates go from 90% down to 10%.

Time and again, patients wait for medication from PBMs that will never arrive — because of a small detail missing in the documentation, or a situation that requires the specialty pharmacy worker to take some proactive measure. These workers, with their passive attitude towards patient care, unfortunately, do not see themselves as partners to the process, nor do they see it as their responsibility to shorten the time needed to deliver patients' medication.

COMPLETE INDIFFERENCE TO A SITUATION'S URGENCY

Lorraine, a multiple myeloma patient, was being denied by her insurance company the medication prescribed by her doctor. A worker at the clinic where she was being treated called Lorraine's PBM to sort the matter out. She got through to a company representative and began reviewing the situation until, at some point, the call was disconnected. Upon calling back, the worker had to start all over from the beginning with a different customer service representative.

A few days later, she called the PBM a third time, reaching yet another representative, who seemed unable to understand the situation. The clinic worker asked to speak to a supervisor, yet she turned out to be even more abysmal than the prior three representatives, both in terms of her attitude and her inability to understand the situation. The supervisor transferred the matter over to someone in appeals.

Now, the clinic worker found herself speaking to a fifth employee of the PBM who became even more aggressive, and questioned the worker's role in the doctor's office and her right to be making the call. When the worker began to conference the doctor in, so he could participate in the phone call, the PBM representative hung up on them.

As a last resort, the worker tried reaching someone in the PBM investor relations department, and had the call transferred over to the executive escalation team. She began by emphasizing the urgency of the matter; the longer it took to get Lorraine her medication, the worse her prognosis. She added that their office would be contacting both Medicare and the Insurance Commissioner's office in Maryland, to complain about the unprofessional handling of the matter with a patient's life on the line. Within twenty-four hours, there was a case worker assigned to Lorraine's case, yet no knowledge yet of how long it would be before — or even if — Lorraine would receive authorization for the lifesaving treatment she needed.

Dealing with PBM bureaucracy often feels like being trapped on a merry-go-round with no way off. Every issue is handled by a different person or entity, each with its own agenda and protocols. Patients must wait for weeks or even months, to obtain medication that they could have received within twenty-four hours, had they been permitted to get it at the point of care from their oncologist. These delays often translate into delayed treatment and worsening of the patient's condition, and in the most tragic of cases, possibly contribute to the patient's death.

BUREAUCRACY LEAVES A PATIENT IN LIMBO

Janine, a 22-year-old woman with Hodgkin's lymphoma, was prescribed a specific medication for fertility preservation. Her clinic's representative contacted the PBM specialty pharmacy to determine if prior authorization was required for the drug, and what Janine's co-pay would be.

The PBM pharmacy representative rudely responded that Janine's doctor needed to follow the proper procedures: send in the prescription and wait the necessary two days before obtaining the benefits information. The clinic representative explained that they only wanted the benefit information in order to make a treatment decision; that without knowing the co-pay they didn't know if Janine

could afford the medication, and therefore didn't know whether or not to prescribe it.

The response was that the PBM specialty pharmacy could in no way help in this, nor could they refer them anywhere for more information. As a result, the clinic's hands were tied; they had no idea if the insurance company would authorize the medication, and if not, if Janine would be able to afford them on her own.

PBM specialty pharmacies have a long list of complex bureaucratic protocols, but shouldn't they be able to help patients and practices make cost saving decisions? Unfortunately, PBM bureaucratic protocols are often harmful to the very patients they are meant to help.

ONE DANGEROUS MISTAKE AVERTED… HOW MANY AREN'T?

Maria was a colon cancer patient prescribed several rounds of chemotherapy. For her first round of treatment, all went smoothly; she was permitted to fill the drug prescription right there at her clinic's physician-run pharmacy. However, for the second round of treatment, her insurance company mandated that she use one of the large, well-known PBM specialty pharmacies.

The problems began when the specialty pharmacy delivered Maria's medicine late, which delayed the beginning of her second treatment round. The following month, things worsened. Maria had suffered profound side effects from the medication, causing her oncologist to lower the dose for her third round of treatment. When Maria called the pharmacy, however, they said they had no record of the new prescription on file — though it had been sent and received.

Confusingly, shortly after the call, the PBM pharmacy called Maria back and said the medicine was about to be shipped. Upon her inquiry, the pharmacy informed her of the dosage; it was the same dosage and instructions as the previous two rounds, which had caused the intolerable side effects. Maria proceeded to spend the next several hours on the phone with the pharmacy to correct the situation. In addition, her physician's office called and spent time clarifying the matter with them. Had Maria been any less vigilant, her health could have been severely compromised by such sloppy drug administration.

With PBM specialty pharmacies being run completely separately from the point of care and physicians, patients must be extremely vigilant at all times to ensure they receive the correct medication. For cancer patients who are already dealing with a life-threatening disease and a range of debilitating side effects of the toxic medications they are on, this additional burden can be very costly — and for some, simply not feasible.

TOTAL INDIFFERENCE TO PATIENT'S PROGNOSIS

James was a patient in his late 50s, suffering from advanced renal cell carcinoma. On May 18th, his oncologist prescribed a particular medication, and they began a two-week wait for his insurance company to approve usage. Upon receiving approval, the doctor's office sent the prescription over to James' PBM-mandated pharmacy, with a request that it be handled ASAP, as the patient's situation was dire.

One week after making the urgent request and having heard nothing, the practice followed up to ascertain the status of his prescription. A few days later, a response came back from the pharmacy that they had attempted to contact James twice, but had not succeeded to reach him. They asked the doctor's office to have the patient call the pharmacy himself. The office asked the pharmacy if and when they had been planning to contact them, to notify them that there was an issue with delivering James' medication. The pharmacy responded that their policy is to try phoning the patient three times, and then they either contact the prescribing doctor's office or simply mail the prescription back to the patient.

While the PBM bureaucracy failed to try to remedy the situation, James' cancer continued to spread, untreated, leaving him no closer to receiving his medication than he had been three weeks earlier. As for the PBM pharmacy, they seemed completely unconcerned, despite the fact that the five-year survival rate for advanced renal cell carcinoma goes from 53% down to 8%, if it passes from Stage III to Stage IV.

Time and again, doctors reach out to PBM-mandated specialty pharmacies to enquire about the status of medication— only to discover that the process is stuck, and no one at the pharmacy feels any sense of urgency, despite the fact that the patient in question is being treated for a life-threatening condition in which time is of the absolute essence.

THE HORROR IS NOT LIMITED TO CANCER DRUGS

Carl was prescribed regular injections of anticoagulant medication. The initial prescription was sent off to the local branch of a major pharmacy and filled without issue. Three weeks later, however, when Carl tried to refill his medication, the pharmacy charged him a $700 co-pay. They explained that they could not offer refills; they must go through his PBM-mandated specialty pharmacy. Now there was an emergent situation because Carl needed those syringes immediately.

Carl paid the high price to obtain four syringes, which was all he could afford, while his doctor contacted the insurance company, who said that if the local pharmacy would call them, they could offer an override. The doctor called the pharmacy with the terrific news, only to hear them refuse the request, outright. "We don't have time for this," they said. "If the customer wants an override, he needs to make the call himself."

Several hours later, Carl received a call from the local pharmacy, saying that they had spoken with his insurance company, and that the mail-order pharmacy will need a new prescription. No word about the override — they hadn't even bothered to enquire about it while on the phone with the insurance company. Three hours later, the mail-order pharmacy sent Carl's doctor a request… only it was for a refill on medication used to prevent side effects caused by chemo and radiation — not for the anticoagulant meds that Carl actually needed.

At this point, Carl was twenty-four hours away from being out of medication. Adding to the absurd irony of the situation, Carl's doctor actually had an in-house pharmacy that stocked the necessary medicine. However, while the pharmacy was once part of the network of Carl's insurance company, in 2011 their contract had been cancelled, as they presented competition to the PBM's specialty pharmacy.

Even when PBM specialty pharmacies are unable to provide a patient with the necessary medicine, and even when the situation is urgent to the point of life and death, they still will not release that patient so he or she can purchase it where it is available. The greed is so deep that they would rather risk a patient's life than allow another pharmacy to profit in their stead.

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August 2018

Danger, Delay, Denial:
Pharmacy Benefit Manager Horror Stories — Part IV

The cautionary tale of the Pharmacy Benefit Manager (PBM) system is a lesson not yet learned. The United States' health care system continues to be strangled by the dark presence of these ever-growing corporate middlemen, siphoning off billions of dollars in profits while leaving behind pain, suffering, anxiety, and despair for the millions of cancer patients.

This is the fourth paper in a series from the Community Oncology Alliance (COA) that focuses on the very real and negative impact PBMs continue to have on cancer patients today. This impact threatens to grow even stronger under recent proposals put forth by the Centers for Medicare & Medicaid Services and in President Trump's Blueprint. Rather than heed warnings about abusive PBMs and limit their influence, the current administration has proposed to do the exact opposite and increase the role PBMs play in our health care.

Today, while PBMs are contracted to handle Medicare Part D, which includes self-administered medications such as pills, they are not involved in Medicare Part B, which covers all doctor- administered drugs, such as infused chemotherapy. The government is now proposing a slew of changes, including that some, or all, of Part B medications be shifted to fall into Part D. It has also dictated that insurance middlemen, some of which own PBMs, can require step therapy for Part B medications in Medicare Advantage.

These proposals have been put forth to lower drug prices. Unfortunately, they ignore the vast evidence that the incompetence and greed of middlemen has not only failed to reduce drug prices but has ironically caused them to increase thanks to the network of shadowy rebates and discounts siphoned off by these middlemen. And, as these horror stories clearly demonstrate, this has all been done at the expense of cancer patients.

The following PBM horror stories have been provided to COA by community oncology practices. While patient names have been changed to protect privacy, the terrifying stories and details are unfortunately very real.

BUREAUCRATIC MADNESS AND A GAME OF TELEPHONE

Donald, an electrical engineer, husband and father of two college students, had been diagnosed with colorectal cancer and was scheduled for radiation treatments. His doctor prescribed an oral chemotherapy to be taken alongside the radiation and faxed the prescription off to Donald's PBM-mandated specialty pharmacy. Three days later, the pharmacy contacted Doreen at the clinic treating Donald, to clarify his prescription. Doreen handled the matter without delay, and then, four days later, called to ask when the medicine had shipped… only to discover that due to 'issues' it had not yet gone out.

The pharmacy transferred Doreen to the Medicare department, and after a lengthy wait, a representative came on, to whom Doreen explained that Donald was in fact not a Medicare patient. After another lengthy wait, the silence was broken only by the occasional interjection of "One moment," the representative explained that regardless of the patient's coverage, this particular medication ordered for him needed to be 'released' from the Medicare Part B department.

The representative informed Doreen that the next step was for her to call Donald and ask him to call them – the pharmacy – to schedule delivery, as the pharmacy was not able to make outbound calls. However, she said, another option was for Doreen to bring Donald in on a third-party call and then wait on the line while the pharmacy verified the entire shipping process with him.

A very frustrated Doreen hung up and called Donald to explain the situation. By now it was Friday afternoon, and Donald was scheduled to begin radiation treatments on Monday, accompanied by the oral medication. It was looking more and more unlikely that Donald would have his medication in time. Adding to the absurdity of the situation was the fact that Doreen had plenty of the medication Donald needed – right there in the in-house pharmacy, and could easily have filled Donald's prescription herself, had the PBM allowed her to do so.

Countless times, bureaucratic PBM delays mean that patients must postpone treatment – or begin, but without the right combination of medicine – that will give them their best chance at battling this devastating disease. Yet, even when the situation has become a matter of life and death, patients have no recourse other than to wait it out, as the bureaucratic machinery of the PBM is not programmed to make any kind of exception.

SHAMELESS BLAME GAME WHILE THE PATIENT SUFFERS

James, a third-grade teacher in his early 40s, has lived with leukemia for many years, keeping it in remission with a daily oral medication. In November, his insurance provider notified James' doctor that a new prior authorization was required to continue receiving his medication. There was no time to lose; James had just finished his last bottle and needed an immediate refill. The authorization was immediately obtained, and the clinic forwarded it on to the PBM-mandated specialty pharmacy.

Four weeks went by, yet no medication arrived. Brenda, a clinic worker, contacted the specialty pharmacy, and a voice on the other end stated that a new prior authorization was needed. Confused, Brenda again faxed the approval letter to the pharmacy, while continuing to wait on hold. After a considerable wait, the pharmacy worker came back on the line and told Brenda that this letter was already in the patient's file, but that a new prior authorization was needed.

What on earth for? Brenda wondered to herself, as she hung up the phone. They were in February, so perhaps it was because the previous prior authorization had been sent in 2017? Yet, according to the insurance company, the old prior authorization was still in effect. She called the specialty pharmacy back, and this time a different representative answered. He looked up James' case and stated that all was well; in fact, the medication should arrive in just a few days.

Brenda hung up and called James to let him know he should expect his medication any day now. Answering the phone, James told Brenda that for the past four weeks, going without medication, he'd been frantically calling the pharmacy on a regular basis, trying to order it. They had told him each time that they'd been unable to contact Brenda, despite many attempts, and that his being without medication was due to the clinic's negligence.

Meanwhile, during those same four weeks, while James' blood counts were reaching horrific levels, Brenda was able to fill five prescriptions of the same drug for other patients, whose PBM allowed them to receive their medications in-house.

Dealing with PBM bureaucracy can be frustrating to say the least. Getting the runaround… being told one thing by a representative, only to have that information contradicted the next moment by someone else… having the person on the other end of the phone lie to you… these are the things patients and clinic workers meet time and again. And, as if lying about the status of a drug's delivery wasn't bad enough, to add insult to that situation by implying the delay is the fault of the very people treating the patient, is unconscionable.

TROLLING FOR BUSINESS

The pharmacist of an in-house clinic at a community oncology practice was going over patient files one day when the phone rang.

The caller politely introduced herself as an employee of a well-known PBM specialty pharmacy, and then abandoned all niceties as she proceeded to ask why the pharmacist was filling a prescription for a patient that by all rights belonged to them. The in-house pharmacist pulled up the

file for the patient in question, who was battling advanced stage ovarian cancer. Not seeing any conflict of interest, he requested further details.

In clipped tones, the caller explained that his filling of this script was "outside of the manufacturer's contract, and illegal." Unfazed, the pharmacist responded by saying that there was no law preventing them from filling it. At this point, realizing that her strong-arm tactics were getting her nowhere with the pharmacist, she changed tactics; perhaps the doctor would be an easier target. "Did the patient's physician intentionally send the script to you?" she asked, to which the pharmacist replied, "Of course he did. Our pharmacy is located inside of the practice."

With no wiggle room left, the caller said that she would be informing the patient of all this, and abruptly ended the call. The pharmacist was left to marvel at the audacity of trying to intimidate him into handing over a patient – and the corporation that clearly couldn't care less about what was best for her.

When that corporation's income is derived from 'trolling' the system to collect more profit-generating patients receiving treatment for life-threatening ailments, we realize things have gone way too far. At some point, something must be done to rectify the perverse profit-motives and incentives behind the corporate PBM approach patient care.

CAN'T BE BOTHERED TO GET THE PRESCRIPTION RIGHT

Annabelle, a retired cosmetician and widow, had been diagnosed with Philadelphia chromosome-positive + chronic myeloid leukemia. Her community oncologist tried her out on 180mg of a particular medication, and Annabelle's response was highly positive. Her blood work showed immediate improvement, and she showed no significant side effects.

The doctor wrote out a prescription for the medication, which according to Annabelle's PBM had to come from their mandated mail order specialty pharmacy. As the medicine does not come in pills of 180 mg, the prescription clearly stated: one 100 mg tablet and one 80 mg tablet. Nevertheless, over the following months, each time Annabelle had her prescription renewed, she was given either 100 mg or 80 mg – never both. This meant that she was not only taking the wrong dosage, but also her dosage was changing each month, according to the whim of the pharmacy and whoever happened to be filling her prescription.

Annabelle did not do well with the incorrect dosing; her laboratory results showed dangerous levels in her blood work, again.

Despite the clinic's repeated attempts to get the PBM to deliver the right medication, the PBM specialty pharmacy refused to take the necessary measures to ensure that Annabelle received the proper dosage. When the doctor tried to have the script filled in the in-house pharmacy at his clinic, it was denied. Meanwhile, Annabelle continues to be improperly dosed, impacting her opportunity for remission.

This story exemplifies the constant dangers patients are in at the hands of incompetent, faceless PBM pharmacy workers. Removed several times from the patients they are meant to serve, their inattention to crucial detail is not what we should expect from a company in the business of caring for patient lives.

PBMs STANDING IN THE WAY OF TIMELY STANDARD OF CARE TREATMENT

Rhonda, a 55-year-old wife, mother, grandmother, nurse, world traveler and self-described Disney expert had been diagnosed with Her2-negative breast cancer. She was receiving treatment at a local community oncology center. Her physician prescribed treatment and attempted to fill it on the same day at the in-house pharmacy; however, the co-pay was too high for Rhonda's limited means.

The clinic's financial assistance coordinator went to bat and, six days later, had secured a co-pay card from the drug manufacturer. Two days later, however, when the practice tried to fill Rhonda's script, her PBM rejected the use of the co-pay card at the practice pharmacy. Instead, the PBM required the script to go out to its own specialty pharmacy. Not wanting to delay her treatment, the practice quickly faxed the prescription over.

Another six days passed before the specialty pharmacy notified the clinic that the prescription must first go

through the specialty pharmacy connected with the patient's PBM, regardless of who would ultimately fill it. The clinic staff filled in all the additional forms and handled all new bureaucratic measures, and then proceeded to wait. Three days later, a clinic RN called the specialty pharmacy to ask for an update. The representative who answered told her that all was well, and that no prior authorization would be needed. She then placed her on hold. Ten minutes later, the representative returned, only to say that actually prior authorization was needed. With the greatest of patience, the nurse filled out all the new forms and faxed all relevant records necessary for the prior authorization, over to the specialty pharmacy.

Later that day, the pharmacy contacted the RN to inform her that the prescription had been denied, based on the patient's Her-2 positive status. The RN again sent the patient's records to the pharmacy, highlighting the fact that she was, and had always been, since she was first diagnosed Her-2 negative. Two days later, the medicine finally arrived.

All-together, Rhonda's therapy was delayed 19 days, which, had she been permitted to fill her prescription in-house, would never have happened. In total, the clinic staff spent five hours dealing with red tape.

Worst of all, Rhonda never had the opportunity to take the first pill. The night before the medication arrived at her home, she was hospitalized for complications of her metastatic disease. After a lengthy hospital stay she was discharged home to hospice.

While the physicians caring for Rhonda were busy trying to "march to the beat of the PBM's drum", this sweet, young, vibrant woman's window of opportunity closed. How many other scenarios involving pointless deterioration, hospitalization, and death from PBM incompetence are there? When reflecting on the life and care of the patients, PBMs should not be part of the conversation.

WOULD IT KILL YOU TO WAIT?

In 2012, a 45-year-old salesman named Bill was diagnosed with colorectal cancer. Bill had a good job working for a large office supply manufacturer based in the Midwest, a loving wife and two small children, and he decided to fight with everything he had. Following surgery, Bill was treated with IV chemotherapy, but with negligible results. The cancer progressed over the next year, and his doctor changed to a different IV chemotherapy. This time his response was very good, and for the next four years things were fairly quiet.

In 2017, tests showed that Bill's cancer was back, and this time he was treated with yet a third kind of IV chemotherapy. His response seemed good at first, but by the following year, the cancer had progressed to Stage IV and metastasized to his liver. At this point, Bill's oncologist ordered an oral medication specially prescribed for relapsed or metastatic colon and rectal cancers.

Bill's physician at the community oncology practice sent the prescription over to the in-house pharmacy to fill. Unfortunately, according to Bill's new insurance plan, his prescription could only be filled by a PBM-mandated pharmacy. Despite the facts that Bill's Stage IV cancer was aggressive, that his doctor wanted to get him started on the medication that very same day, and that the medication was sitting on the shelf of the in-house pharmacy, Bill had to wait. Even the option sometimes given to have a 'one-time fill' that would let him get started while waiting for the PBM pharmacy to mail him his medication was denied. Thus, with the drug's prohibitive list price (over $10,000/month), Bill had no option but to wait.

The doctor sent his prescription on to the new pharmacy, along with Bill's contact details, so that they could arrange for delivery. Meanwhile, Bill went to his clinic and received detailed in-person counseling on how to take the drug, since it was a somewhat complicated regimen. There were specific directions on how to take the medication, what side effects to expect, and how to ensure the proper dosing. The latter could be confusing, since the drug is taken in multiple tablets twice daily on days 1-5 and 8-12 of a 28-day cycle.

After seven full days of waiting to start his therapy regimen, Bill finally received his medication in the mail. Opening the box, he began to read the label, and found to his great surprise, that it stated: "take once a day." Picking up the phone, Bill checked in with his oncologist

to report the change in instructions. The clinic pharmacist confirmed that the instructions were wrong, and reached out to the PBM pharmacy, which promised to contact Bill about clearing up the matter.

Bill received a call from the PBM-mandated pharmacy representative, who apologized for having sent the wrong prescription with the wrong amount of medication. They assured Bill he would receive an additional supply of medication. First, however, they asked Bill to please return the medication he had been sent, so it could be properly labeled. Now Bill, with Stage IV metastatic cancer and his treatment already having been delayed a week, was being asked that rather than take his life-saving medicine, he ship it back to the warehouse for proper labeling and reshipping.

This was not the last time the PBM pharmacy impacted and delayed Bill's care. Later, when it came time to refill his medication, Bill's treatment was again delayed. The PBM pharmacy, it seemed, decided that before filling his prescription, it had to first clarify the dosage. It then claimed to have had difficulties in contacting Bill's community oncology clinic, despite having been provided with all the correct contact details. Ultimately, Bill had to call his local clinic and ask for the in-house pharmacist to call the PBM to confirm dosage, before they would ship it out. And while he waited, his cancer was allowed to progress, unchecked.

One of the most dangerous parts of PBM-mandated pharmacies is the distance between the pharmacy and patient. In this, we are speaking not only of geographical distance, but also of when patients are forced to wait for medicine to be shipped, rather than walk across a hallway to purchase it. More to the point, however, is the situation in which the patient becomes a name or number on a call sheet, rather than an actual human being facing a life-threatening illness; rather than a patient for whom there is care and endearment. That distance is at the core of many PBM mistakes and apathy.

About the Community Oncology Alliance

The majority of Americans battling cancer receive treatment in the community oncology setting. Keeping patients close to their homes, families, and support networks lessens the impact of this devastating disease. Community oncology practices do this while delivering high-quality, cutting-edge cancer care at a fraction of the cost of the hospital setting.

The Community Oncology Alliance (COA) advocates for community oncology and on policy issues that affect patient care. Our members include patients in active treatment, cancer survivors, caregivers, family members, medical and oncology professionals, and members of the general community. For more than 15 years our members have advocated for smart public policy that ensures the community cancer care system remains healthy and able to provide all patients with access to local, quality, affordable cancer care. Learn more at www.CommunityOncology.org

May 2019

Dangerous Health Care Middlemen & Bureaucracies:

Pharmacy Benefit Manager Horror Stories — Part V

The Pharmacy Benefit Manager (PBM) industry lobby claims that it successfully achieves drastic price reductions on medications. They say this comes from PBMs negotiating with competing drug companies and by "encouraging consumers to use the most cost-effective drugs."

Setting aside clear evidence that secretive PBM rebates and fees are actually driving drug prices higher, the last claim should give all Americans pause. How exactly does a PBM "encourage" a treating physician to use cost-effective but life-saving drugs? How do they know what is right for each individual patient and disease? What tactics or methods do PBMs use to do this? And are the changes in the patients' best interests, or simply to save money for PBM profit margins?

Unfortunately, time after time, PBMs have been exposed for abusing their position to do this, getting between the patient with cancer and their physician to dictate care. All too often, the PBM bureaucracy does this by simply and heartlessly delaying or denying patients' access to needed medications. Perhaps most egregiously for patients facing a ticking clock of cancer, PBMs deny prescribed treatments and demand that patients first fail on a list of 'approved' drugs before receiving the medication that their physician prescribed in the first place.

For patients with cancer, this intrusion into their care plans is painful, potentially life-threatening, and unnecessarily stressful. For oncologists it is yet another bureaucratic burden placed between them and caring for a patient, wasteful of scarce health care resources, and insulting to the doctors that went to medical school and prescribe treatment plans.

These and other monstrous by-products of the PBM system are further exposed here, as the Community Oncology Alliance (COA) presents the fifth in a series that focuses on the very real and negative impact PBMs continue to have on patients with cancer today. The infuriating stories presented here are real but made anonymous with personal details changed to protect the privacy of the patients.

A NARROW WINDOW FOR TREATMENT

Brian, a married social worker with two young children, was in his early 30s in February 2014, when he was diagnosed with a relatively rare form of cancer in his appendix. Brian underwent surgery and chemo at a large hospital system, and for the next few years, his life went back to normal.

In late 2017, however, Brian suffered a relapse. He underwent surgery to remove all traces of the cancer, and his oncologist followed up with a round of chemotherapy. Despite the metastasis, Brian's doctors thought he had a good chance at survival and recommended that he immediately begin a six-month regimen of oral medication to help keep the cancer at bay. He was young, strong, and had everything to live for; they were optimistic the cancer might never return.

On February 8th, Brian's oncologist sent a prescription for the pills to the local pharmacy his clinic worked with. They informed him that while they had the medicine in stock, Brian's insurance and PBM prohibited them from filling the prescription. Instead, they forwarded the prescription to a PBM-mandated specialty pharmacy to receive prior authorization.

The PBM-mandated specialty pharmacy granted the prior authorization, but was also unable to fill the prescription, so it was forwarded to yet another PBM specialty pharmacy. By this point, 11 days had passed. After another few days of silence, the second PBM pharmacy sent a message that they were unable to fill the prescription; it had to be done by the first PBM specialty pharmacy. It seemed that no one really knew who was responsible or able to fill the script.

On February 23rd, the same day that Brian finally received his oral anti-cancer medications, he was rushed to the emergency room for severe pains in his abdomen. There they discovered he had contracted an infection that necessitated surgery to repair his abdominal wall. The pills in his hand were no longer relevant.

Today, Brian must remain on chronic antimicrobial therapy pills to ward away abdominal infection; should he stop, it might easily return. Unfortunately, this precludes any further chemotherapy, and Brian's once promising prognosis has been replaced by one far direr. In effect, Brian missed his very narrow window and it is likely that he will never get well again.

Oncologists are on the front lines treating patients with cancer who have complex needs – they know the exact state of their patients, and how very precious even a day can be. PBMs and their mandated specialty pharmacies are several times removed from the exam room, and as a result, their lack of urgency and inability to cut through bureaucratic red tape can easily become an indirect – or even direct – cause of patient suffering.

NOT A HEALTH CARE PROFESSIONAL? YOU DON'T STAND A CHANCE

After having survived her battle with thymus cancer in 2015, Rachel was surviving with several autoimmune disorders, including myasthenia gravis, a condition in which the body attacks its own neuromuscular connections. After utilizing several immunosuppressants, Rachel has managed to keep the illness in remission for the past two years, by taking a wonder drug that works as an immunosuppressant, maintaining a low volume of antibodies in her system.

An advanced oncology certified nurse at a community oncology clinic, Rachel knows her condition well and how to stay healthy. For two years she has been taking her medication faithfully every day, working to care for her patients, and living life as normally as could be.

Then, at the beginning of 2019, her employer changed insurance carriers. When it came time one Friday for Rachel to refill her meds, she went to the local pharmacy to pick them up, only to be told that there were 'issues.' The pharmacist was confused and said he would look into it.

Two hours later, the pharmacist called to say that from now on, Rachel must obtain her medication through the PBM's specialty pharmacy. She immediately called the new pharmacy's number, where she waited a long time until she was connected. After trying fruitlessly to locate Rachel in the system, he put her on hold for 10 minutes. When someone else finally came back on the line, Rachel, again, had to tell her entire story from the beginning. This happened several times, with Rachel's blood pressure rising exponentially. It was Friday afternoon and she had six pills left – enough for two days.

Rachel hung up the phone; this had been a dead end. Falling back on a trick she had learned after dealing with countless PBM bureaucracies on behalf of patients, Rachel called the member services number on the back of her insurance card. After being passed around from representative to representative, she reached "Brian," who promised to establish a new member's account for her. However, as to her refills, he insisted he first needed to call her doctor to get prior auth.

Rachel began to see red. It was Friday afternoon and her neurologist's office was closed. Trying to remain calm, Rachel explained to Brian that she still had several refills left. Brian promised he would contact her pharmacy and have the refills transferred over. "Call me in the morning," he said. Saturday morning, at 7:30 am, she called the specialty pharmacy, where she was told that no one named Brian had been in touch, and there was nothing in the computer about her issues. However, this new representative was the real deal. She handled everything over the next few hours and arranged for the meds to arrive by Monday – which they finally did – just as Rachel's pills had run out.

Infinite patience, coupled with buckets of determination and self-control, seem to be de rigueur when it comes to dealing with PBM Specialty Pharmacy bureaucracies holding one's life-saving medicine hostage. If it was this difficult for a seasoned, tough-as-nails, advanced oncology nurse to get her own meds, what is going to happen to the other 99.9% of the population?

CLERICAL ERRORS MARRIED WITH INCOMPETENCE

Paula was a very intelligent company executive battling breast cancer. Her oncologist prescribed a particular medication and she faced no issues in having it filled or refilled the first time. When it came time for the second refill, however, she met a PBM roadblock. Despite several calls to the PBM, and speaking with several different people, all the patient could get them to explain was that there were insurmountable "insurance issues." Not knowing what else to do, she came into the oncologist's office so they could call the PBM together to resolve the matter.

After a long wait on hold, the doctor and his patient finally reached a representative who informed them that they were unable to fill the prescription because it could have a negative interaction with another medicine she was currently taking. The doctor and the woman looked at each other for a moment, before asking the rep, "What medicine?" The patient was not taking any other medication. This was, however, not what the PBM had in their records. It took quite a bit of additional convincing by the patient and her doctor before the PBM would believe them and agree to provide authorization.

By this point, due to clerical error and the absence of anyone to take responsibility, the patient had already gone 10 days off her regimen, something which never should have happened.

Practices report that they spend an absolutely 'ridiculous' amount of time trying to obtain prior authorizations from PBMs – well beyond any reasonable expectancy. Even getting to the point where there is another human being on the other end of the phone to talk to is an achievement in and of itself. This, of course, is only the beginning of the PBM process that is fraught with errors and poor record keeping, all of which can add up to dozens of hours of staff time wasted dealing with bureaucracy, and drag on over days, weeks, even months. In the meantime, patients with cancer are left waiting without the treatment that they need.

PBMs SERVING THEIR OWN BOTTOM LINE

Gordon, a retired FBI agent with a distinguished record of security service on behalf of the United States, was diagnosed with an aggressive form of lung cancer. Proving resistant to the drug regimen his oncologist initially prescribed, the cancer metastasized to his brain and he was immediately started on radiation therapy. It was at that point that his doctors made an important discovery: Gordon's cancer had the EGFR mutation, which indicated he would do better with oral medication than infusion chemotherapy. More importantly, there was a new drug that had just been approved by the FDA as the first-line treatment for EGFR-mutated non-small cell lung cancer. This gave Gordon and his cancer care team a window of hope.

Gordon's oncologist prescribed the new medication, but the PBM denied authorization, providing the name of an alternative drug they wanted him to try first. His doctor argued that his original prescription would be better for the patient; It had been shown to have far higher efficacy for patients whose cancer had metastasized to the brain. The PBM argued back that it had been initially approved for a different EGFR mutation than the one Gordon had. His doctor argued back that this was irrelevant, as it was effective for Gordon's mutation as well, and was now FDA approved.

Back and forth, the fight went on for an entire month, with the doctor providing data and rationale to support his clinical decision making. Meanwhile the cancer grew inside Gordon, unchecked. He began to feel increasingly fatigued, and a man who had remained very active throughout his cancer battle began to deteriorate.

Ultimately, after more than 30 days of wasted time, the PBM approved the doctor's original prescription. Upon beginning the regimen, Gordon's condition began to slowly improve, but it never should have been allowed to reach such a low state.

Again and again, we see PBMs playing doctor, choosing to authorize one medication and not another, for reasons that have nothing to do with patient care. From pushing the drugs from pharmaceutical companies with which they have made "sweetheart" deals, to demanding patients be

prescribed lower-cost medication, their actions are profit-driven and often in complete contradiction to what the patient actually needs to get well.

PBM APATHY LEAVES BOY IN DANGER OF BLEEDING TO DEATH

Diagnosed with hemophilia, 15-year old Jason had to simultaneously contend with his blood's inability to form clots and the danger of bleeding uncontrollably. Jason's oncologist had him on a once-daily oral medication that can slow the spread of his disease by blocking a specific protein it needed to thrive.

One day, Jason missed his footing on the stairs at home. Falling, he hit his thigh and developed a significant hematoma, common with hemophiliacs. He now urgently needed a specific recombinant factor injection to help his blood clot, and quickly.

Jason's oncologist quickly prescribed the necessary self-injected medication to be taken at home. Prior authorization was received, however the PBM handling Jason's case refused to allow the practice's pharmacy to fill the script, so they forwarded it to the PBM-mandated pharmacy. Unfortunately, they could not fill the prescription, and without informing Jason or his doctor, they outsourced the prescription to yet another pharmacy.

Recognizing the urgency of the situation, Jason's mother, a full-time nurse, stepped in to see how things could be expedited. She made numerous phone calls, verifying that the pharmacy she used to work with before her insurance changed had the medication in stock and, due to a contract with the PBM, was able and willing to ship it out the next day. Not wanting to lose out on the business, the original PBM-mandated pharmacy stepped in and vetoed the plan, stating that as it had already been ordered from them, there could be no cancellations.

Adding another layer of unnecessary problems to the mix, the PBM suddenly claimed that there had been no prior authorization filed for the prescription. Undeterred, the practice pharmacist spent hours trying to get it all done as soon as possible, so that Jason could get the medicine he needed.

Finally, just when it felt like the situation was starting to be resolved, the PBM pharmacy representative on the phone belatedly realized that the medication in question was for injection and stopped the process. Prescriptions for injections, she said, had to go through a different department. Unfortunately, it was now 5 pm on a Friday and the PBM offices were closed for the weekend, so they would have to wait to submit the prescription until Monday. Because of his hemophilia, young Jason was now in danger of developing a dangerous complication that could require emergency surgery and a long hospital stay if not treated immediately.

With no alternative, the doctor sent Jason to the hospital emergency department to receive the necessary injection. While this prevented any life-threatening occurrences, it incurred an enormous expense for his family and insurer, one that could easily have been avoided. Due to the astonishing bureaucracy, a patient fell through the cracks, with no one outside his personal doctor standing up to take responsibility or showing the slightest concern.

Patients do not walk off the pages of a textbook or an encyclopedia of illnesses and their recommended treatment. Each case is individual and ought to be treated as such, in a thoughtful, intelligent, holistic manner. Additionally, patients do not stop treatment just because it is the weekend or after the phone lines shut down. The more control PBMs are given over patient care, the more sweeping and infuriating their bureaucracies become, and, ultimately, the more dangerous their decisions and actions prove to be.

WOULD YOU LIKE SOME KIDNEY FAILURE WITH YOUR CANCER?

In the Fall of 2012, Trisha, a medical software instructor in her early 60s, suffered renal failure and was rushed to the hospital. Diagnosed with Multiple Myeloma, she underwent dialysis and was referred by her community oncologist to a Myeloma specialist at the nearby hospital system. The specialist recommended a particular regimen of chemotherapy to keep the disease in check, and Trisha was released.

A few months later, tests revealed that the cancer was progressing. Her chemo was clearly not working; a new

medication had to be tried. This would not be simple, for following Trisha's renal failure, her kidneys had never returned to normal. This meant her doctors had to be extremely careful about what drugs they prescribed, as certain medications for Myeloma are known to take a heavy toll on the kidneys.

Trisha's oncologist, in consultation with the hospital specialist, decided to prescribe a particular drug that could slow the progression of her disease, without having any adverse effects on her already stressed kidneys. Her oncologist sent in the prescription to the PBM mandated specialty pharmacy, which promptly sent back a notice denying the request.

At first, the pharmacy said that prior authorization was needed. Her doctor said, "No problem," and instructed the in-house clinic to fill out all the necessary forms and fax them over. This was followed by a second denial, which stated that the patient did not meet "the proper requirements" to receive the requested drug. What were those requirements? Trisha had to first have tried two other drugs, one after the other, and to prove that either her body had been unable to tolerate them, or that they had failed to slow the cancer's advancement.

Of those two drugs that the PBM demanded Trisha try – and fail – the first one was the very same drug she had been prescribed the previous year that had already failed to slow the cancer's progression. The second was a medication that, had she taken it, would have seriously damaged her kidneys and likely put her back into renal failure.

Over the next two months, Trisha's oncologist appealed the PBM's decision, and a long series of communications ensued between the oncologist, the Multiple Myeloma specialist, and the PBM specialty pharmacy. Trisha, meanwhile, watched with increasing anxiety as her myeloma protein markers quadrupled, indicating that the cancer was gaining ground. The appeal turned into a letter of medical necessity, and ultimately, after more than two months of delay, the correct medicine was finally approved by the PBM.

PBMs have been given enormous amounts of control over what doctors may and may not prescribe. They try to strong-arm doctors into prescribing the medicine that the PBMs choose, even though they have never met the patient, and often have no medical background to support the decisions they are making.

PBM DELAY TACTICS VICTIMIZE PATIENTS

Belinda, a kindergarten teacher and mother of two, was fighting thyroid cancer. Her oncologist had her on a particular medication that was approved for off-label use on thyroid cancer; she'd been taking the medication for seven months and was doing well.

In January, Belinda's insurance carrier moved to a new PBM, which required her to fill her prescriptions at their mandated specialty pharmacy. They assured Belinda that it would be no trouble for them to continue filling her medication. So, that same month, when it came time for Belinda's refill, her oncologist sent the e-prescription directly to the new pharmacy and called Belinda to confirm.

When Belinda tried to pick up the prescription, however, the PBM-mandated pharmacy said they were unable to process it "at that time." She waited an entire month before being contacted by the PBM pharmacy to verify benefits and schedule delivery. After another week went by with no medication, a very frustrated Belinda called her oncologist to see if they could dispense the medication directly to her. Unfortunately, according to Belinda's insurance policy, they were not allowed to do that.

Another week passed, and, after six weeks of delays, the PBM-mandated pharmacy contacted Belinda. They wanted now to schedule delivery – again. The prescription was then sent to PBM's clinical department to verify dose, diagnosis, allergies, and drug interactions.

At this stage, someone at the PBM finally noticed that the drug was being prescribed for an off-label usage and called her oncologist to verify the diagnosis. The oncologist spoke to the PBM pharmacist, explaining that the drug had been approved for nearly a year, with the patient taking it all that time, to very beneficial results. It had always been for off-label usage, and the insurance company had always agreed to it. What was the matter?

The PBM pharmacist had no explanation for the time lag, nor was there any documentation to explain why more than two months had passed. At the end of the

conversation, the doctor asked if Belinda could finally expect to receive her medication now. "No," the pharmacist replied. "Now, we forward the matter to the payment verification center. After that stage, it will be forwarded to the dispensing center. Then we can ship it out."

Had Belinda been authorized to purchase her medicine from the in-house pharmacy at her doctor's office, the entire process would have taken a single day.

The larger an organization, the more complex the bureaucratic procedures. This is often done under the guise of ensuring safety. However, how far do things need to go before it can be said that the harm to patients has greatly surpassed any intended good? At what point do the PBMs themselves become accountable to a certain standard of care – even in terms of something as simple as response time?

IT IS TIME TO STOP PBM ABUSES!

While much of the debate over PBMs focuses on economics, there is often not enough discussion about the impact PBMs have on patients. The sad fact is that PBMs make more money by delaying or denying patients access to necessary medications. Every pill they stop from being dispensed is money they can pocket. COA has documented real-life patient horror stories from practices and physicians about patients battling cancer who have suffered at the hands of PBMs due to delayed coverage decisions, denial of coverage, arguments with physicians over proper treatment, and failure to receive medications in a timely manner.

Read our other PBM Horror Stories papers at https://www.communityoncology.org/category/horror-stories/

About the Community Oncology Alliance

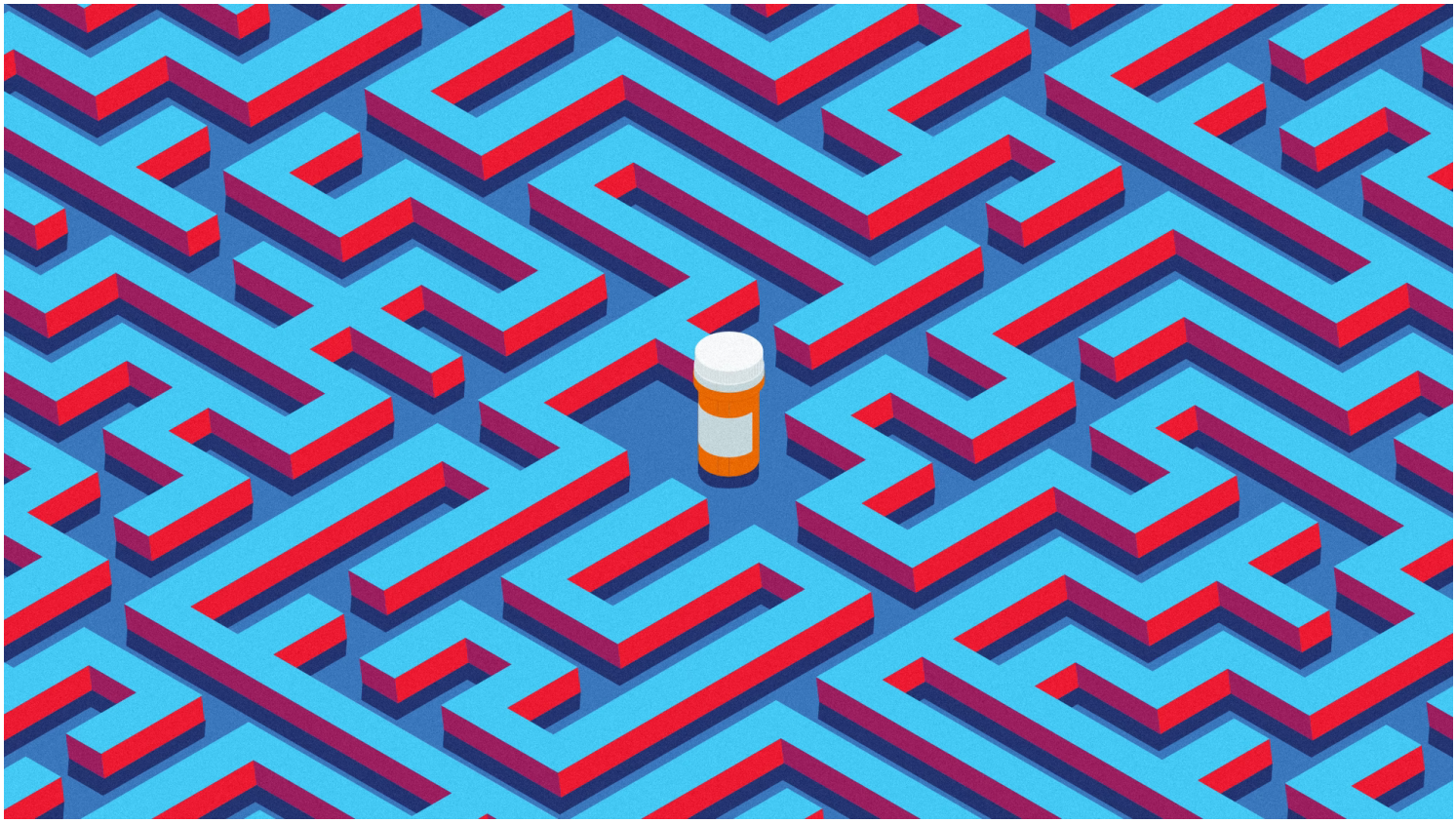
The majority of Americans battling cancer receive treatment in the community oncology setting. Keeping patients close to their homes, families, and support networks lessens the impact of this devastating disease. Community oncology practices do this while delivering high-quality, cutting-edge cancer care at a fraction of the cost of the hospital setting. The Community Oncology Alliance (COA) advocates for community oncology and smart public policy that ensures the community cancer care system remains healthy and able to provide all Americans with access to local, quality, affordable cancer care. Learn more at www.CommunityOncology.org

HEALTH

Invisible Middlemen Are Slowing Down American Health Care

Nurses spend 16 hours on the phone, medications take months to arrive, and patients suffer as they wait.

By Olga Khazan



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APRIL 9, 2019

Lynn Lear finished her final round of chemotherapy for breast cancer in December. To help keep the cancer from coming back, Lear's doctor told her about a new

medication she could take called Nerlynx. Lear, who is 46, wanted to do everything she could to remain healthy, so she asked her doctor to order the drug for her.

Unlike, say, an antibiotic or an antidepressant, a Nerlynx prescription can't be filled at a neighborhood CVS or Walgreens. Instead, Nerlynx is dispensed either through certain doctors' offices or through specialty pharmacies, which exist specifically to process expensive drugs for difficult conditions and often deliver medications by mail. On December 18, 2018, Cheri Bateman, a nurse in Lear's doctor's office near Virginia Beach, Virginia, sent the prescription to Accredo, the specialty pharmacy that worked with Lear's insurance.

So began Lear's Kafkaesque journey to getting this life-saving drug, which she wouldn't be able to start taking until nearly two months later. Accredo had a prior-authorization process, in which companies called pharmacy benefit managers ask questions of doctors before they will release medications to patients. Accredo's pharmacy benefit manager is called Express Scripts. Like all pharmacy benefit managers, Express Scripts negotiates drug prices with drug manufacturers on behalf of insurance plans, determines which drugs are covered, and conducts the prior-authorization process for certain cancer drugs.

The problems began with an error on Bateman's end. During the prior authorization for Lear's Nerlynx, Bateman accidentally answered a question wrong—she thought the person on the phone was asking whether Lear had ever been on an antiemetic medicine rather than an antidiarrheal—and Express Scripts promptly denied approval for the drug. The very same day, Bateman appealed the denial and provided the correct information, but she had to wait nearly a month before the medication was finally approved, according to clinical notes she provided to *The Atlantic*.

Then there was a new complication. Bateman called Accredo, the specialty pharmacy, which agreed to set up the delivery of Lear's medication, Bateman says. But after more than a week of phone tag, neither Bateman nor Lear had heard from the pharmacy. Bateman realized there might be an issue with Lear's insurance, which had changed on January 1. Bateman called the new insurer, Optima Health, who said the prescription had been transferred to a different specialty pharmacy, Proprium—though according to Bateman, she had never been notified about this. An Optima representative gave Bateman a new number to pass on to Lear so that Lear could set up the delivery of the Nerlynx.

Bateman was a busy nurse at a busy practice just trying to get one tiny thing taken care of. At this point, in her clinical notes, Bateman spewed a frustrated, punctuation-

free stream: "[Lear] called me back at 4:40 pm and stated that Proprium pharmacy stated to her that the medication needed a prior authorization ..." Bateman had already been told that a prior authorization would not be necessary, she says. When she called to clarify, Optima told her she was right, but there was yet another problem: The medication had a bank-breaking $1,367 co-pay.

Read: Big pharma's go-to defense of soaring drug prices doesn't add up

A spokesperson for Sentara, the parent company of Optima and Proprium, said in an email that Lear's previous insurer appeared to be the "primary hold up" in this case, and that it was a "a highly unusual set of circumstances which resulted in an unfortunate delay."

Bateman usually encounters some hurdles in getting cancer medications to her patients, but she told me this was one of the worst cases she'd ever had. At the end of her note on January 22, Bateman wrote that she had spent more than 16 hours on the phone attempting to get Lear her medication. And Lear still didn't have it. The way Lear was ultimately able to secure it and avoid the high co-pay was by canceling her primary insurance, making her secondary plan her primary one, and filling the prescription with Accredo after all. On February 6, she was finally able to start taking Nerlynx.

Citing patient privacy, Express Scripts declined to comment on Lear's specific case. In an emailed statement, a spokesperson told me that "sometimes patients have primary and a secondary benefit plans. The differences in those plans, and the timing of plan-year changes, can lead to confusing situations." They said that in cases where Accredo is an in-network pharmacy, patients are generally able to get their medications.

Lear told me she initially blamed herself for the delays. "As a cancer survivor, you wonder every day if it's gonna come back," she said, breaking into sobs. "It's difficult to feel like I don't have that control and power to use every tool possible to help me stay healthy, and to help me not have to go through all of this again."

RECOMMENDED READING

The 3 Reasons the U.S. Health-Care System Is the Worst

OLGA KHAZAN

The Drug With a 5,000 Percent Markup

JULIE BECK

How Climate Change Is Challenging American Health Care

VANN R. NEWKIRK II

In the sea of America's health-care system, pharmacy benefit managers tend to be seen as destructive leviathans. Invisible to everyday patients, PBMs lurk beneath health-insurance companies and swim through nearly every prescription-drug transaction. They squeeze rebates out of drug manufacturers, pass most—but not all—of those rebates on to health insurers, pay the pharmacy for the drugs, and collect payments from the insurer. In doing so, they subtly shape the currents of American health care.

Because of their outsize influence, pretty much everyone in the health-care system who isn't a PBM likes to blame PBMs for high drug prices. The fact that some of them own specialty pharmacies—like Express Scripts does with Accredo—has not done much to improve their image. Recently, policy makers have taken aim at PBMs in an attempt to rein in drug prices. Draft rules announced by the Department of Health and Human Services earlier this year, if finalized, would make it so that drugmakers can no longer offer rebates to PBMs working for government insurance plans. The Senate Finance Committee has also set its sights on PBMs, dragging them before the committee for the latest in a series of hearings that aim to get to the bottom of why Americans pay so much for their drugs. The heads of five PBMs will testify on Capitol Hill about high drug prices this week.

Ted Okon, the executive director of the Community Oncology Alliance, a group of community-based cancer doctors, hates pharmacy benefit managers. COA is one of several doctors' groups that accuse these middlemen of causing delays like the one Lear experienced and of driving up drug prices. Okon, whose group introduced me to Lear and the other patients and doctors in this article, claims that high prices are in PBMs' financial interest: They get rebates from the drug companies and fees from pharmacies as a percentage of list prices, so the higher the drug's price, the larger their payout. (PBMs have argued that their rebates don't affect drug prices.)

Beyond raising prices, COA says that PBMs hinder the treatment of patients with complicated ailments such as cancer. PBMs gum up the process, they argue, through prior authorizations and the use of inaccessible specialty pharmacies. COA loathes the PBMs' practice of using what's called step therapy—forcing patients to try and fail at using cheaper drugs first—which COA says can lead to even further delays. Okon thinks the problem will only get worse now that insurers are buying up PBMs in order to have more control over drug prices. For instance, Cigna, a major insurer, recently bought Express Scripts.

"Would you trust your doctor to make the decision about your chemotherapy, or a corporation?" Okon told me indignantly between bites of arugula pizza recently. "It's just not acceptable when a cancer patient, especially someone who is in dire need of treatment, doesn't understand why they can't get the drug."

Okon thinks—"as crazy as this sounds"—that PBMs actually delay sending medication to patients in order to save money, since they are rewarded by insurers for controlling drug costs. And because PBMs are such a hidden part of the process—most patients don't even know they exist—no one, ultimately, gets held responsible.

Read: What's actually wrong with the U.S. health system

Specialty pharmacies, Okon and others say, are part of the problem. Okon told me stories of hemophilia patients having to be admitted into the hospital because a specialty pharmacy wouldn't dispense the drugs the patients needed in time. Since some specialty pharmacies don't have storefronts, they often deliver directly to patients. If a patient is at work when a $10,000 medication is dropped off, it could be stolen. Or, COA says, patients might be asked to spell the names of their medications by phone before they will be delivered—a near-impossible task, in the case of drugs such as Alemtuzumab and Tisagenlecleucel.

PBMs "earn a higher profit when they go to a specialty pharmacy," says Gerard Anderson, a professor at the Johns Hopkins Bloomberg School of Public Health. "But if you need that drug on a Saturday or Sunday, you're probably not going to get it."

Accredo does not have any retail locations, but in a statement, the National Association of Specialty Pharmacy, the specialty pharmacy's trade group, claimed that "there are retail locations and store fronts affiliated with most specialty pharmacies." However, a spokeswoman added, patients usually prefer to have medications sent directly to their home. The group says that speciality pharmacies coordinate the delivery window with patients, and that they would already have the name and spelling of the drug prescribed on file "at the time of the initial contact with the patient." The group also countered that restrictions imposed by insurance companies might be what's impeding medication delivery on weekends, but that specialty pharmacies do routinely deliver medications on Saturdays.

Still, some patients do fall through the cracks of this system. Cindy Adams, who lives in Benton, Arkansas, found herself writhing in pain after some injections she needs to take in tandem with her chemotherapy were delayed for three weeks. As she slipped in and out of consciousness, "I was begging for God to take me," she told me. Her

doctor, Fred Divers, claims the delay was caused by an issue with the specialty pharmacy and PBM. "This kind of thing happens all day, every day," he says.

The doctors I spoke with said that they have full-time employees whose job it is to do daily battle with PBMs and specialty pharmacies. David Oubre, the managing physician of the Pontchartrain Cancer Center in Louisiana, gave me the clinical notes of one woman whose breast-cancer drug was delayed by nearly a month because of what the office says is a misunderstanding of the patient's diagnosis by the PBM, as well as by a long exchange of faxes, some of which were simply "blank pages." "If you have swimmer's ear, you can pick up the script on your way home and start the medicine," Oubre told me. "Why do we have to wait four or six weeks?"

These delays might be happening because "there's no downside" for PBMs in reducing the number of expensive medications sent to patients, says Kevin Schulman, a professor of medicine at Stanford University. "They're not responsible for the poor care the patient is getting."

The argument for PBMs is that some drugs are so expensive—Nerlynx has an average co-pay that starts at $3,600—that PBMs must ensure they aren't going to patients who won't benefit from them. You don't need a PBM for aspirin, because aspirin costs pennies. The cancer drug Kymriah costs nearly half a million dollars.

In response to the criticisms of PBMs, a spokesperson for the Pharmaceutical Care Management Association, the national PBM association, said that they provide a crucial check on drugmakers' prices. "When more affordable, clinically appropriate, treatment options are available, employers, unions and public programs choose to use prior authorization to lower costs and improve patient safety," the spokesperson said.

To make matters more complicated, pharmaceutical companies have joined some doctors' groups in blaming high drug prices on PBMs, which creates a potential conflict of interest. COA has pharmaceutical companies as corporate members, which give money to the group, and on the PBM issue, at least, COA appears to be aligning with the message of its corporate sponsors—something it has been accused of doing in the past. The two COA-affiliated doctors, Divers and Oubre, have both received money from drug and device companies, according to the CMS Open Payments Database. (Both Divers and Oubre said pharma payments do not influence their stance on PBMs.) In our interview, Okon denied the suggestion that COA is toeing the party line of its corporate sponsors. He claimed that if the PBM rebates go away,

he will turn his ire on pharmaceutical companies if they don't lower drug prices in turn. "I'll be the first in line basically damning pharma," he told me.

COA might also oppose step therapy—the practice of trying and failing at cheaper drugs—because oncologists stand to benefit from prescribing more expensive drugs, Anderson says. Okon denies this, and says that the drugs PBMs pick are often not even the cheapest drugs.

Read: How two common medications became one $455 million specialty pill

It remains unclear whether PBMs are the only, or even the true, culprit in cancer-drug delays. The pharmaceutical companies, after all, are the ones setting prices so high. Insurers also use prior authorizations, and surveys suggest that the practice is growing more widespread. Though Schulman says that Lear's medicines did seem to have been stalled by PBMs, Anderson disagrees. A good doctor, Anderson says, would be able to anticipate the PBM delays and order the medication in advance. (Okon called this idea "absurd," saying it's simply not something oncologists are able to do.) In Lear's case, Anderson says, "none of this was really the PBM doing something bad": Every player in the process seemed to have failed.

In stories about PBMs, the word *shadowy* comes up, as does *cockamamie*. They don't disclose publicly how much they profit from rebates, and there are so many players in any given health transaction that the buck is very easily passed on to someone else. The health-care sea is treacherous in other ways, after all, so vanquishing PBMs might not end cancer-medication delays. But the problems these patients experienced nevertheless point to a common pattern when it comes to American health care: Companies charge exorbitantly high prices, mysterious intermediaries stand to benefit, and patients are caught in the cross fire. In some cases, families are left wondering what, exactly, went horribly wrong with a relative's care.

On April 17 of last year, Oubre's office issued a prescription for Verzenio, a breast-cancer medication, for a 55-year-old patient named Jamie Spada. Spada was a cheerful mom who volunteered at the Red Cross and ran charity drives for children. Knowing her time might be short, she took 30 vacations in four years until doctors told her she could no longer travel.

More than a month after the medication was ordered, the specialty pharmacy informed Oubre's office that they could not fill the prescription, and that it would

have to be sent to a different pharmacy. The new pharmacy said it required a prior authorization.

On May 24, Spada's patient notes suggested a confused nurse trying to determine whether a prior authorization was required or not: "Received letter saying no auth was needed. Called to see when it would be dispensed was told by Rachel that an auth is needed." Two days later, the medication finally arrived at Spada's home. But it was too late. Spada was too far gone for the medication to do any good, and she had already been admitted to the hospital.

"She lost six weeks or so of time that she could have been taking medication. Maybe her quality of life would have been better," Spada's daughter, Gabriella Burst, told me. As for the reason for the delay, Burst said, "we never got a true explanation."

On June 25, Oubre's office made a final note in Spada's file: "Patient expired."

Olga Khazan is a staff writer at *The Atlantic* and the author of *Weird: The Power of Being an Outsider in an Insider World*.

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EDITORIAL

A Fresno woman with cancer had to fight for key drugs. This must be reformed.

BY THE FRESNO BEE EDITORIAL BOARD

Norma Smith has struggled to stay upbeat in the face of life-threatening cancer — multiple myeloma, a blood disease.

As if having a rare form of the illness was not bad enough, the challenge before the Fresno woman and her husband Rod grew exponentially harder when the medicine prescribed by their doctor was denied by their insurance company's pharmacy.

Unfortunately, the Fresno couple became all too familiar with an arcane term — pharmacy benefit manager. It was this bureaucratic-sounding entity that denied treatment requests of the Smiths and Dr. Ravi Rao, Norma's oncologist who prescribed the treatments.

And why did the denial occur? Because Rao wanted to use drugs in a different sequence and combination than the pharmacy benefit manager had listed as the usual protocol.

What followed for the Smiths was a months-long battle to overcome that duplicitous decision making by the pharmacy benefit manager, a company called CVS Caremark. By the month, Norma got weaker and her husband's frustration, anger and despair grew. What should shock anyone reading Carmen George's account of the Smiths' experience is that such a situation could easily occur to any of us, given how drugs are dispensed today.

As if there needed to be another example of why health care reform must occur, the Smiths are it. Far from the health insurance company or pharmacy benefit manager providing exactly what they are supposed to — appropriate care to help a critically ill 62-year-old woman — the companies very nearly engaged in medical malpractice.

Who controls the drugs

Most patients and their family members think doctors make the call on what medicines are needed. Wrong. As George's story showed, pharmacy benefit managers are the faceless layer in the health care system that actually determines what medicines are available to health care plans.

Insurers use PBMs to negotiate drug purchases from pharmaceutical companies. The PBM will draft a list of drugs for the insurer to review, then go to the drug company and offer to include its medicines on the list. The drug company will offer a rebate — hypothetically, $10 off on a drug that normally sells for $100. The PBM then nabs the rebate; the customer gets charged full price.

A PBM sets forth a sequence of drugs to be used when a patient like Norma has a complicated illness. When Rao wanted to prescribe a drug beyond the approved order, the PBM denied the request. Rao did that because he felt the next-level treatment would help her more. Norma's health got so bad last spring that she nearly died. CVS Caremark took two months to approve one of the treatments.

PBMs are not accountable to anyone. Rao, however, must be licensed by the state to practice medicine and must have malpractice insurance in case a patient dies and he is sued.

PBMs were created to stem the accelerating cost of medicines. One study found that prices of many brand-name drugs increased more than 120 percent since 2008. But what has developed is a system of middle reviewers with little to no medical training. PBMs are making decisions that literally have life-or-death implications.

What is needed

Bills have been introduced in Congress to deal with drug pricing and making that information public. Currently, pharmacy benefit managers and the pharmaceutical companies can keep their agreements a secret.

A group representing cancer patients and their doctors also wants Congress to eliminate the ability of pharmacy benefit managers to create "steps" in how drugs are dispensed so doctors can get what they think is most needed for their patients.

Jim Costa, TJ Cox, Devin Nunes, Kevin McCarthy, take note: As the Valley's representatives in the House, read the story about the Smiths. Then work to reform this part of the medical system because it badly needs fixing.

Norma Smith is alive today and improving, but only because her husband and doctor refused to give up the fight against a company that seemingly puts profits ahead of patients.

LETTERS TO THE EDITOR

Logic and indicting the president

Pardon me. Did I hear correctly? A sitting president cannot be indicted? But he could be after he leaves office? Logic! Come to my aid:

If a sitting president murders someone, can he not be indicted? If a sitting president robs a bank, can he not be indicted? If a sitting president kidnaps the daughter of a rich man, can he not be indicted?

No one is above the law, even temporarily.

– *Wayland Jackson, Fresno*

Drivers, careful on right turns, please

Fresno drivers who are making a right turn on a red light need to make sure that no one is trying to complete a U-turn into their direction of travel, in addition to making sure no traffic is coming from their left.

Almost every day, I see drivers check to their left, but almost become involved in a collision when they do not make sure that there are no cars trying to make a U-turn into their direction of not have the right-of-way.

If people exercised more caution and were not in such a hurry, our roads would be a lot safer.

– *Jordan Edginton, Fresno*

Time for Slatic to withdraw

Terry Slatic is consistent. When he first became a Fresno Unified trustee, he was invited to meet with me and another board member from the League of Women Voters. We wanted to hear more about his views on Fresno Unified schools, and we wanted him to learn about the league's interest in education.

He told us that he was the boss of the superintendent because if the superintendent was having a meeting and he (Slatic) wanted to meet with him, the superintendent would have to leave his meeting and see him. When we said we did not think this was a board member's privilege, he was condescending, rude and used foul language directed at us. His arrogance and misperception of his role were striking. We left the meeting disturbed.

Future behavior showing combativeness and poor judgment demonstrated that our concerns were justified. Whether in public or in a private meeting, he consistently exhibits these character traits.

As Marek Warszawski said in a recent column, his actions give no reason to think Slatic will change in his misguided thinking and behavior. As a military veteran, he should know

Nunes and shortcomings of intelligence

Marek Warszaski's commentary on Devin Nunes (July 26, The Bee) gives testimony to District 22nd congressman's complete ineptitude. And why, it's my conclusion, that Devin Nunes is only there for a paycheck.

During the Mueller hearings, Nunes theorized that "Democrats colluded with the Russians to get mine Trump's presidency" Is this plausible? This can only be the thinking of a crazy man. But who would vote for a candidate like this? Let's see ... surely not those voters from Tulare.

His supporters are Sean Hannity-educated. They will believe whatever Sean Hannity spins their way. If Sean Hannity reported the sun will not rise tomorrow, Nunes and his supporters would all run out

YOUR OPINION

Please include an address and a daytime phone number for verification; limit to 200 words. Readers may submit their stories of life in the Valley to be considered for Valley Voices. Include address and daytime phone number. Limit: 700 words. Email submissions to **letters@fresnobee.com** (no attachments.) Submissions may be edited and republished in any format, and become the property of The Fresno Bee.

Americans because they think and look different from them. Only the white supremacist, neo-Nazis, the KKK, and other forms of racists are the true Americans.

I guess what I infer here is that logic, to Nunes and his supporters, is beyond their understanding. Facts are ineffective to them, while lies are what they listen to, and more readily accept.

And now, according to what Marek Warszaski stated, Nunes might be chosen to be national intelligence director. This means he'll be listening to Vladimir Putin more than his intelligence agencies. Well, I agree with what Marek said: Dare we hope?

Millions of Americans receive drugs by mail. But are they safe?

Many mail-order pharmacy customers feel trapped in a system that has left them with crushed pills, damaged vials and lifesaving drugs exposed to extreme weather.

Bianca Bagnarelli / for NBC News

By Adiel Kaplan, Kenzi Abou-Sabe, Kit Ramgopal and Cynthia McFadden
December 8, 2020

One evening in mid-June, Megan Becker stepped outside of her Las Vegas home and scooped up a package containing her medication, a monthly injection to prevent debilitating migraines.

It was a sweltering night - the temperature hovered just below 95 degrees. When Becker opened up the package, which arrived a day late, she found that the ice packs were melted and the medicine, which is supposed to be refrigerated, was warm to the touch.

“They literally just dump the box on my front stoop, regardless of the weather,” Becker, an English professor at the University of Nevada, Las Vegas, said. “It’s just such expensive medication and it seems like such a careless way to deliver it.”

A shipment of Megan Becker's migraine medication left at her door in late August. (Megan Becker)

Shortly after the drug, Aimovig, hit the market, Becker began picking it up from a nearby pharmacy. But last year, her health insurance confronted her with a choice: switch to the Express Scripts mail-order pharmacy and get it for roughly $50 per month, or pay out of pocket for the more than $600-per-dose medication.

Becker fought to keep picking it up locally, but said she gave up after two months of what she described as maddening calls with Express Scripts.

"I really, really, really did not want to get it this way and I was not given an option," she said.

Millions of Americans receive their medications by mail but many, like Becker, find themselves forced to do so by their insurance plans or face the prospect of paying exorbitant amounts for the same drugs.

An NBC News investigation found the growth of mail-order pharmacies has caused many people to feel trapped in a system that has left them with crushed pills, damaged vials and lifesaving drugs exposed to extreme weather.

Millions receive medication by mail with little regulation for mail-order pharmacies

Interviews with more than 65 mail-order pharmacy customers across the nation revealed deep worries over how their medication is delivered – and no affordable alternatives. Many reported receiving drugs in flimsy packaging without temperature indicators, which can cost as little as a dollar per package. Others have had to plead with pharmacies to send them replacement drugs after receiving medication they thought arrived too warm or cold.

The industry is massive, generating billions in annual sales, but it occupies a gray area with little regulation and even less enforcement, NBC News found.

“It’s a quagmire,” said Georgia state Rep. Ron Stephens, a pharmacist, who has sponsored multiple bills to increase patient choice when it comes to pharmacies. “If they’re sending it without a temperature strip, and you’re the recipient of insulin or a lifesaving drug, you’re taking your life into your hands,” the Republican said.

Extreme temperatures can degrade medications, potentially rendering them unsafe or ineffective for patients. Industry guidelines make clear that pharmacies should package and ship medications in accordance with their recommended temperature range. But many mail-order pharmacy customers have no way of knowing whether their medicine has gone too far outside that range for too long.

“[Patients] just might think that they're getting sicker or that it might be their fault,” said Erin Fox, director of drug information at University of Utah Health, who researches drug quality and shortages. “But it's important to think about, ‘Could it be my medicine that is maybe not of high quality or potentially got ruined with high temperatures?”

After receiving organ transplant medication that felt hot, a mail-order pharmacy customer posted a photo to social media of a home thermometer reading inside the pill bottle. (Obtained by NBC News)

Proving that a drug had become ineffective or made someone sicker because it was exposed to extreme temperatures is nearly impossible, experts say. By the time such a possibility is considered, the medication itself would likely have already been consumed or thrown away, preventing it from ever being tested. Plus, experts say, without temperature tracking during shipment, there's no way to know how the medication may have been affected by the conditions inside a delivery truck or the temperature outside someone's home.

But some people believe they or their loved ones have experienced a decline in health after receiving medications through the mail, including the family of a young girl from North Carolina.

‘You’re not a pharmacist, ma’am.’

Shortly after she was born, Sophie Dean was diagnosed with cystic fibrosis.

She was two weeks old when doctors put her on a lifesaving pancreatic enzyme to help her digest food and absorb nutrients. The medication worked, allowing Sophie to gain weight and grow.

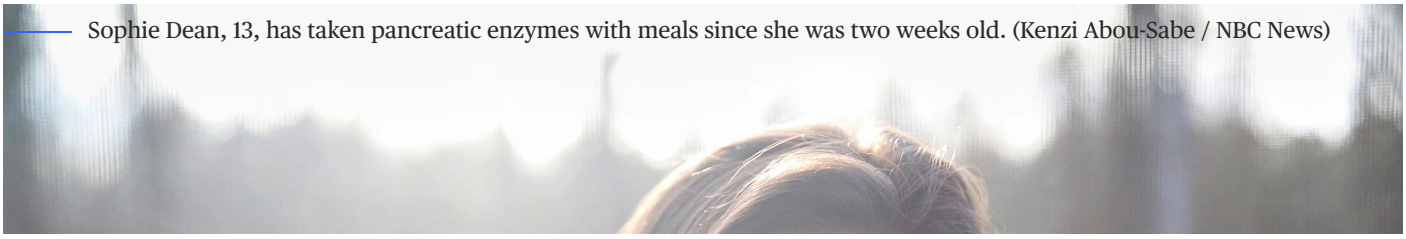
But in 2015, when she was eight, her parents’ health insurance started requiring that they receive her medication through Express Scripts mail-order pharmacy rather than the specialty pharmacy that had been sending it to them previously.

Watch the investigation on TODAY (https://www.today.com/video/do-mail-order-pharmacies-deliver-drugs-safely-nbc-news-investigates-97396805689)**.**

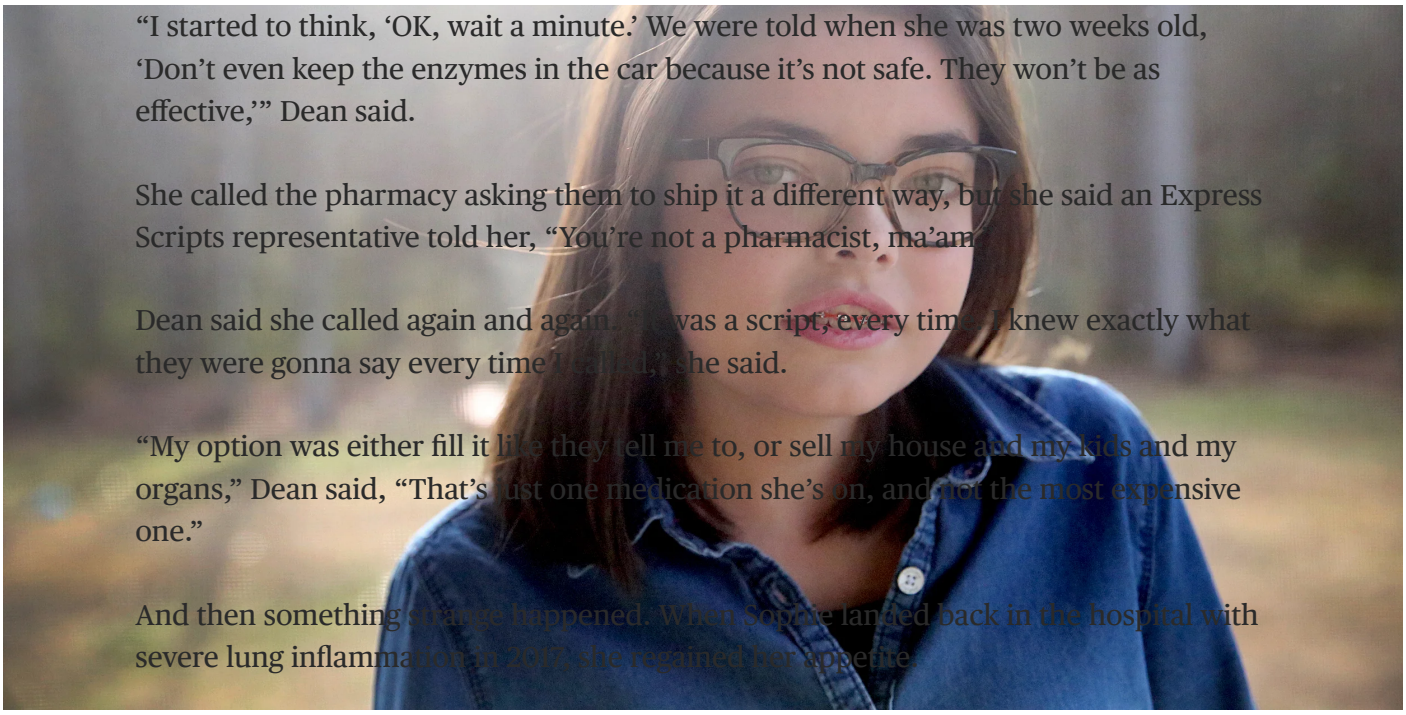
Instead of receiving the medication in an insulated box with a device that indicated if it was exposed to potentially harmful temperatures, as her family had done previously, Express Scripts sent it without any kind of temperature indicator in a cardboard box or often just a thin, gray plastic bag, Erica Dean, Sophie’s mother, said.

And because the mail-order pharmacy didn’t notify them when the package arrived or provide them with a tracking number, the package would sometimes sit on the family’s porch for hours, baking under the North Carolina sun.

Sophie began suffering from debilitating stomach aches. Her appetite evaporated, her mother said, and her body mass index plummeted.



Sophie Dean, 13, has taken pancreatic enzymes with meals since she was two weeks old. (Kenzi Abou-Sabe / NBC News)



“I started to think, ‘OK, wait a minute.’ We were told when she was two weeks old, ‘Don’t even keep the enzymes in the car because it’s not safe. They won’t be as effective,’” Dean said.

She called the pharmacy asking them to ship it a different way, but she said an Express Scripts representative told her, “You’re not a pharmacist, ma’am.”

Dean said she called again and again. “It was a script, every time. I knew exactly what they were gonna say every time I called,” she said.

“My option was either fill it like they tell me to, or sell my house and my kids and my organs,” Dean said, “That’s just one medication she’s on, and not the most expensive one.”

And then something strange happened. When Sophie landed back in the hospital with severe lung inflammation in 2017, she regained her appetite.

“The doctor is baffled,” Dean recalled. “And he comes in and he says, ‘Ms. Dean, I don't understand. Enlighten me. What's going on?’”

Dean explained that after Sophie was placed on the hospital’s supply of enzymes, her discomfort during mealtimes had all but disappeared.

“At that time, my take was the enzyme source needed to be reviewed,” Dr. Patrick Sobande, Sophie’s then-doctor, said in an email.

Soon after, Sophie’s family secured an exception allowing them to fill the prescription at a local pharmacy. She continued gaining weight, and in the last three years, her mother says she hasn’t had the same digestive issues.

A bottle of Sophie Dean’s pancreatic enzymes, which she takes to help treat cystic fibrosis. (Kenzi Abou-Sabe / NBC News)

Definitively linking Sophie’s digestive problems with how her medication was delivered would be nearly impossible, multiple pharmacological experts said. The medication is gone – ingested by Sophie long ago – and can’t be tested for changes in potency before

and after transit. And there are other potential explanations for her discomfort that aren't easily disproved.

Cystic fibrosis specialists have long warned families about pancreatic enzymes' sensitivity to heat.

"Even before mail-order pharmacies, when it came to enzymes, we very explicitly told families never to leave them in their cars, never to leave them in a hot spot in the house," said Dr. Greg Sawicki, an associate professor of pediatrics at Harvard Medical School who runs the Cystic Fibrosis Center at Boston Children's Hospital. "It could have very much been that the enzymes were denatured or not working effectively because they were not being stored or shipped properly."

When asked about Dean's and Becker's cases, a representative for Express Scripts Pharmacy said that when patient issues arise, "our team works quickly to resolve them, just as we did with these patients."

In an interview, Wendy Barnes, Express Scripts' head of home delivery, said all medications are shipped with tracking information and if a patient's drug is damaged during transit, the company will expedite a replacement to them, which is what happened with Becker's warm migraine medication.

"Everything we do is to serve our patients. We want nothing more than for them to have the medication that they need in a timely and efficacious manner," she said.

"While we are getting it right the majority of the time, any time we're not, we absolutely need to do better," she added.

As for Dean's and Becker's inability to fill their prescriptions locally without paying out of pocket, Barnes said Express Scripts is not the one imposing the requirement to fill long-term medications by mail. "Those decisions are ones that are often made by someone's employer or their health plan," she said.

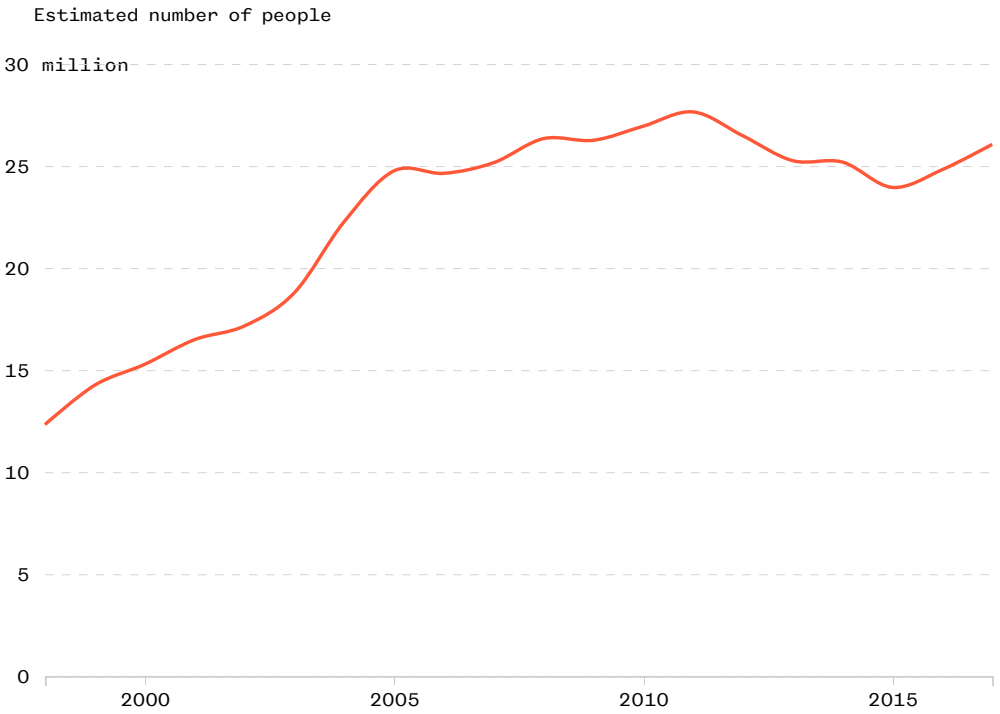
In a statement, Express Scripts said that only about six percent of its patients are in plans like Dean's where patients have to use mail service for maintenance medications or pay out of pocket. The rest can choose to fill prescriptions at a local pharmacy, Express Scripts said, but it will likely cost about 30 percent more than doing so by mail.

'Sorry for the inconvenience'

Sending drugs by mail is not new. The Department of Veterans Affairs has been shipping prescriptions since the 1970s. But in the last 20 years, the number of users nationwide has roughly doubled, with federal data showing an estimated 26 million people receiving their medication by mail.

Number of Americans receiving their prescriptions by mail

Between 1998 and 2017, the number of people using mail-order pharmacy in the U.S. more than doubled, according to federal survey data.



Source: Analysis of the Medical Expenditure Panel Survey (MEPS) data for years 1998 to 2017 by the Center for Financing, Access and Cost Trends, Agency for Healthcare Research and Quality.

Much of how prescriptions work in the U.S. is now determined by companies like Express Scripts – called pharmacy benefit managers – which work with insurers and employers to negotiate drug prices, and often operate their own mail-order pharmacies. Many patients are effectively forced onto their services, particularly those with long-term prescriptions for chronic conditions, either by financial incentives to fill those prescriptions by mail or because coverage is withheld if they don't.

NBC News reviewed letters like this one from Express Scripts, dotted with notes a patient took during phone calls, informing them that their prescription would no longer be covered by their health insurance unless filled through the company's mail-order pharmacy.

"For these medications, convenient home delivery is required by your plan. If you choose to continue filling the medications above at a retail pharmacy every month, unfortunately, you'll have to pay the full cost."

This one informing a patient they would pay full cost unless they switched to OptumRX's home delivery or withdrew from the program.

"After 2 refills, you will have to pay the full cost, if you don't switch to a 3-month supply and fill through

The ability to receive drugs by mail is a lifeline f
the elderly and rural residents. Some customers

first, they now prefer the convenience of getting

door.

But pharmacy experts said the safety of mail-or
particularly because few regulators and academ

“Nobody has performed a systematic study to know whether those medications are effective or not,” said Mansoor Khan, a professor of pharmaceutical sciences at the Texas A&M College of Pharmacy and a former Food and Drug Administration director of product quality research.

The pharmacy benefit managers that operate the three largest mail-order pharmacies – Express Scripts, CVS Caremark, and OptumRx – took home 72 percent of mailed prescription revenue in 2019, to the tune of $113 billion, according to one industry analysis (https://drugchannelsinstitute.com/products/industry_report/pharmacy/).
They all ship drugs through regular delivery ser
conditioned trucks, which can hit temperatures

A delivered package of refrigerated medication in M

Like Express Scripts, CVS Caremark and Optum
cheaper, more convenient and provide longer-te
leading to more patients taking medication pro

The companies all said they also use specific packaging for temperature-sensitive medication which protects against extreme highs and lows on the medication’s journey to a patient’s door.

The Pharmaceutical Care Management Association, a trade group that represents pharmacy benefit managers, said that its members use proprietary software to monitor weather and map the potential temperatures a sensitive package may be exposed to on its delivery route, and that their mail-order pharmacies are safe, convenient and reliable.

Patients told a different story.

OptumRx home delivery. You can continue to fill a 1-month supply at your current retail pharmacy, but you must disenroll from the Mail Service Member Select program.”

studied the effects.

And another from CVS Caremark, announcing that, going forward, refills for a long-term medication could only be filled by mail or at CVS pharmacies.

“We are writing because you have reached your 30-day refill limit and must start filling the medications listed below in 90-day supplies at CVS Pharmacy or through CVS Caremark Mail Service Pharmacy. If you fill them anywhere else, or in 30-day supplies, they will no longer be covered and you'll have to pay 100 percent of the cost.”

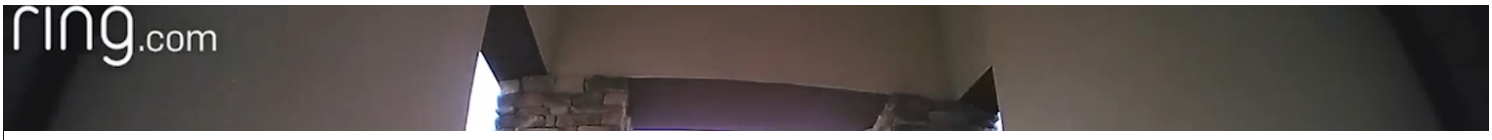
‘Incredibly infuriating’

Ten local pharmacists in eight states said they also frequently deal with the consequences of forced mail order. The pharmacists described longtime customers coming into their stores to ask why their insurance will no longer cover in-person refills. Others ask if it is safe to take medication left on a doorstep for hours, or beg for emergency refills while waiting on a delayed delivery.

“I do everything I can to help patients avoid mail order,” Terry Traster, who owns a pharmacy serving several small towns in rural Illinois, said. “What I am most worried about is they will get drugs that don't work, or – what could even be worse – instead of not working, could actually be harmful because they degrade.”

Most drugs can be subjected to temperatures higher or lower than their labeled guidelines for short periods of time, experts say.

One of the challenges, patients said, is not knowing if a package will arrive when they’re not home, potentially leaving it exposed to the elements for hours. Only about a third of the more than 65 mail-order pharmacy customers interviewed said they were offered signature delivery. Of those, several said that the option cost extra.



A UPS driver, captured by a doorbell camera, leaves a package of refrigerated medication on a Florida doorstep in February 2020. (Denise Church)

Many complained about overly broad delivery windows. People from Minnesota to Florida said they've had to take off work to ensure temperature-sensitive drugs weren't left sitting on a doorstep or a driveway all day, or worse, sent back to a delivery warehouse if they weren't home to sign for the package.

Unopened insulin is supposed to be refrigerated – kept between 36 and 46 degrees Fahrenheit. But Kim Munson, of Lakeview, Minnesota, said she has come home to find her daughter Kinsley's mailed insulin left on a sunny porch in July, or sitting for hours by a pile of snow in January. Express Scripts replaced Munson's January shipment, but after several calls, she gave her daughter insulin from the July shipment and hoped for the best.

"The package could be on the doorstep for hours," Munson said. "I can't just stop my life to be at home because this package is going to come between the hours of 8 a.m. and 8 p.m."

Like other mail-order pharmacies, Express Scripts said that the packaging it uses to keep refrigerated medications within a specific temperature range during shipping will keep those medications within safe ranges even if the package is sitting outside for several hours after delivery.

Kim Munson received a broken vial of insulin in August 2019. (Kim Munson)

But the hours it can take to navigate the customer service system, get a pharmacy representative on the phone, and then convince them to replace a shipment is like having a second job, Munson said. Her daughter's insulin has twice arrived in broken vials. Replacing the first was such a hassle she gave up trying with the second, instead dipping into a stash of spare vials she keeps for emergencies.

When asked about Munson's case, a representative for Express Scripts said, "The safety and satisfaction of our millions of patients is always our top priority," and that as with Dean and Becker, Express Scripts works quickly to resolve any patient issues.

"This is a life-sustaining drug that keeps my child alive," Munson, who had Express Scripts on speed dial, said. "It's incredibly infuriating."

Her frustration was a common refrain among mail-order pharmacy customers.

‘You get tired of fighting with them’

Oversight of mail-order pharmacies rests with state pharmacy boards, but board officials across the country said they rarely, if ever, receive complaints about drugs damaged in delivery.

Interviews with customers revealed that most weren’t aware of their state pharmacy board and simply didn’t know where to complain.

Loretta Boesing’s son Wesley, 11, is on anti-rejection drugs for a liver transplant. When the room-temperature medication arrived on a hot Missouri day in May 2018, she worried it might not be safe to give to him. Dissatisfied with what she said were CVS Caremark’s shifting explanations of why it was shipped without temperature protection, she called the FDA.

Loretta Boesing’s son Wesley had a liver transplant in 2012 at the age of two (top). In May 2018, they received his anti-rejection medication by mail (bottom). (Loretta Boesing)

Wesley Boesing, now 11, with his anti-rejection medication. (Loretta Boesing)

In an audio recording reviewed by NBC News, an FDA drug information specialist explained to Boesing that it was state pharmacy boards, not the agency, which handle issues with mailed prescriptions.

But the FDA specialist also made clear Boesing's comments weren't unusual.

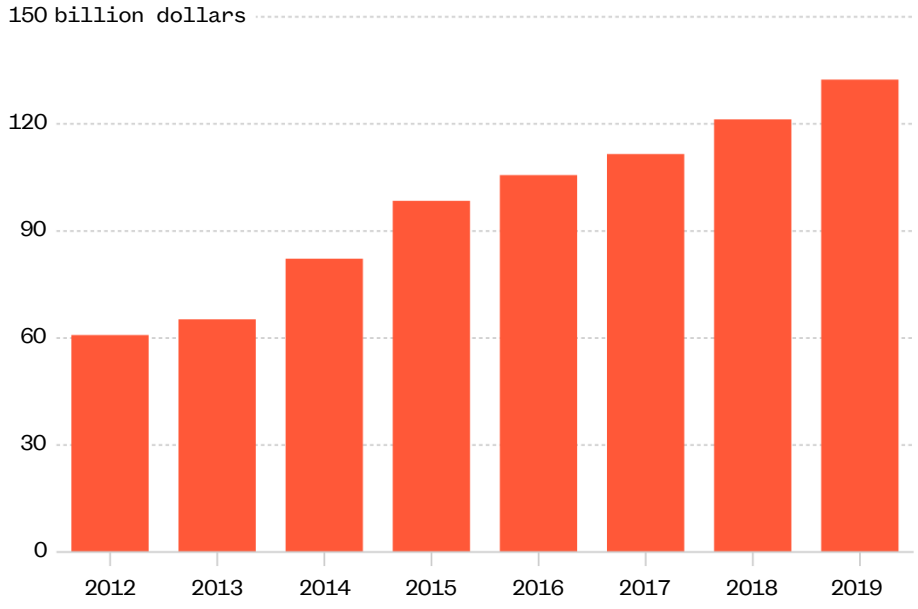
"Every summer and every dead of winter, we get these calls because people's insulin is sitting in their mailbox," the specialist said in the call.

Boesing, who now runs a nonprofit advocacy group focused on improving pharmaceutical safety, also called the Department of Labor, which oversees federally-regulated insurance plans. She was told that, while her complaint about being forced to get medications this way was a common one, the agency could not do anything for her.

"It's just unfortunately the nature of the industry right now," the agency representative said in another audio recording that was reviewed for this article. "They're not in violation of a law. It might be unethical, it might be unfair, but it's not illegal."

Growth of the mail-order pharmacy industry

The amount of money spent on mail-order prescriptions more than doubled between 2012 and 2019.



Source: IQVIA National Sales Perspectives

Hannah Davis of Panama City, Florida, recalls a UPS driver handing her a hot-to-the-touch package with her oral cancer medication inside on a 97-degree day in September 2018. Worried, she called the drug manufacturer, who said not to take it. She said CVS,

her pharmacy, agreed to send a replacement only after she told them what the manufacturer said.

Davis wrote letters to the National Cancer Institute, the FDA, and the Florida Division of Consumer Services. In responses that were reviewed by NBC News, all referred her elsewhere.

After more than a year of complaints to CVS and her state pharmacy board, and letters to multiple government agencies and elected officials, Davis said, CVS earlier this year began sending the medication to her by courier.

While she's now happy with how her medication arrives, Davis said, the entire experience was disheartening. "You just get tired of fighting with them," she said.

CVS Caremark declined to comment on the particulars of Boesing's and Davis' stories, but said in a statement that both issues had been resolved, and that "the overwhelming majority of members express satisfaction with our service."

'How is this allowed?'

Many large mail-order pharmacies voluntarily meet independent accreditation standards every three years that evaluate their standards for safe medication delivery.

But government oversight of mail-order pharmacies is largely a system of blind trust, experts said. Inquiries to the state boards of pharmacy of all 50 states – the government agencies with enforcement authority over pharmacies – along with records requests for their inspection forms, revealed that most don't have specific rules for how pharmacies should ship customers' medication.

"The responsibility of proper temperature storage and soundness of packaging is largely a gray area," Tracy West, deputy executive director of Washington state's board of pharmacy, said in an email.

Only six states have pharmacy rules explicitly addressing proper packaging or temperature monitoring for home delivery, and just two – Georgia and Utah – have inspection forms that ask if those rules are being followed. Some said they have no authority to regulate delivery at all. Others said that their regulations often go further than what's written on the page, but the vast majority ultimately passed the buck, saying it is up to the pharmacy to ensure safe shipping.

Local pharmacists around the country said that temperature oversight from pharmacy boards is strict when it comes to how they store medication, but all that goes out the window when it comes to shipping.

A shipment of Humira sent to an Arlington, Texas home in January 2020. Like many mailed refrigerated medications, it was packaged in a foam cooler with cold gel packs to control its temperature. (Obtained by NBC News)

People who receive room-temperature medications said they often come in plain gray envelopes, like the kind clothing might ship in. An Austin, Texas woman received her medication in these U.S. Postal Service envelopes in August 2020. (Obtained by NBC News)

Teresa Dickinson, an independent pharmacy owner in Arizona and the former president of the advocacy group Pharmacists United for Truth and Transparency, remembers being reprimanded by her state pharmacy board during an inspection because her thermostat read 78 degrees. “The board of pharmacy made a big deal that it needed to be 77,” she said. “If it was such a big deal with the board of pharmacy that I was 1 degree over, then how is this allowed?”

Adding another wrinkle, drugs are often shipped from warehouses outside the state. While boards license out-of-state pharmacies, they typically only inspect facilities physically within their borders.

“We would rely on the home state to be doing effective regulation,” Matt Martineau, executive director of the board of pharmacy in Wyoming, said. “There would be lots of ways for something to fall through the gaps, so to speak.”

A federal investigation

Last summer, an NBC News investigation (https://www.nbcnews.com/business/economy/hot-seat-ups-delivery-drivers-are-risk-heat-stroke-kidney-n1031321) into heat illness among delivery workers found that UPS delivery trucks, which are largely not air-conditioned, can hit temperatures well above 120 degrees. When NBC News sent temperature logging devices across the country, the interior of a standard bubble mailer reached above 104 degrees in four of five packages – generally the hottest temperature that the U.S. Pharmacopeia (USP), a nonpartisan group that sets national standards for drug handling, advises room temperature medicines can be exposed to.

Equally worrying is accidental freezing, packaging experts said. Freezing temperatures or a poorly placed ice pack can freeze a drug, rendering medication like insulin ineffective. And if the package reaches the patient and the drug has thawed, there may be no visible trace of potential harm.

In February, NBC News sent the temperature devices to five cities through UPS, FedEx and the Postal Service. Three went below freezing for hours during transit, and one, sent to Brooklyn from Rochester, New York, spent more than 38 hours below freezing, bottoming out at 9 degrees Fahrenheit for two hours.

One of NBC News' temperature logging packages delivered to a Portland, Maine, home in February 2020. (Michael Gagne)

All three delivery organizations said they offer a range of delivery and signature options to the mail-order pharmacies using their services, with UPS and the Postal Service adding that it is up to the shipper to choose the options right for its products, and to use packaging that sufficiently protects the medications from extreme temperature exposure or damage.

Concerns over the temperature of mailed medication have caught the attention of federal law enforcement. In 2016, the Justice Department demanded CVS Caremark provide documents as part of an investigation into its "handling of certain temperature-sensitive pharmaceuticals," according to a CVS financial disclosure.

Investigators were focused on whether CVS knowingly used ineffective methods to insulate shipments of refrigerated medications to customers as far back as 2010, according to two sources familiar with the investigation. The Justice Department declined to comment on the investigation, but sources say the investigation was still active as recently as 2019.

As part of the investigation, the Justice Department requested documents from a 2014 California lawsuit against CVS Caremark, which alleged the company improperly shipped patients' refrigerated arthritis medication for years.

That case was eventually dismissed, but it revealed that in 2014, a CVS Caremark employee mixed up Celsius and Fahrenheit when dictating freezer temperatures in CVS' specialty mail-order facilities, leading to ice packs kept far colder than intended. Like a misplaced ice pack, an excessively cold one has the potential to flash-freeze a drug, packaging experts said.

The error was not fixed until after the plaintiff brought it up during litigation – roughly two years later – according to a hearing transcript.

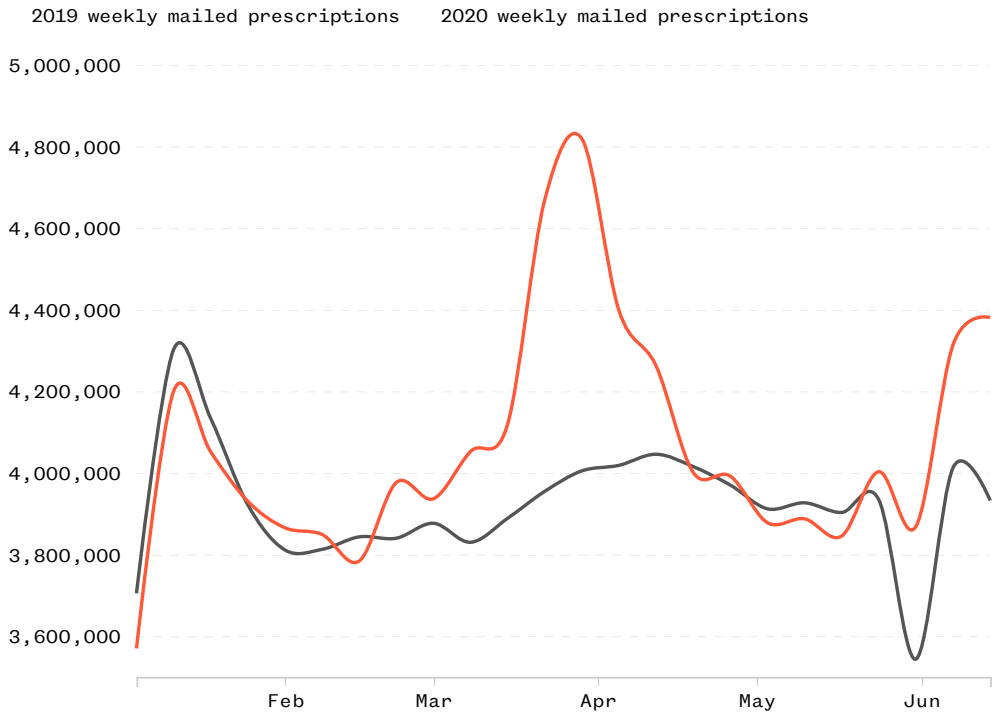
CVS declined to comment on the lawsuit and the investigation.

'There's no way out of this'

Home delivery of medications spiked by 20 percent in March and April, when Covid-19 quarantines began around the country. And experts speculate that more people may choose to get their prescriptions this way as they continue to self-isolate.

Weekly mail-order prescriptions spiked during coronavirus stay-at-home orders

The first six months of 2020 saw several jumps in the number of prescriptions filled by mail per week compared with 2019, according to an analysis by health research firm IQVIA.



Source: IQVIA

But those patients are entering a system plagued by recent postal delays (https://www.nbcnews.com/politics/congress/prescription-deliveries-significantly-delayed-postal-service-senate-democrats-find-n1239649) and increasingly frequent extreme temperatures (https://www.nbcnews.com/news/weather/sweltering-heat-shattering-temperature-records-duration-makes-it-especially-dangerous-n1236775).

“If it is a quick shipment, it’s probably going to be fine,” Fox said. “But when you’re hearing about weeklong delays or just sitting in very hot containers that are not refrigerated or temperature controlled at all, that’s concerning and you should be putting temperature monitoring strips in those shipments.”

Industry practices are changing. Last year, the organization that accredits mail-order pharmacies began inspecting pharmacies’ shipping methods for room temperature medication, which it previously only did for refrigerated medication. USP, the standard setting group, has also updated its guidance to spell out specific ways pharmacies can limit the risk of temperature exposure during transit. The guidance went into effect earlier this month, though its enforcement still falls to state pharmacy boards.

In the past decade, at least 12 state legislatures have passed laws trying to prevent pharmacy benefit managers from incentivizing or forcing consumers to get their prescriptions by mail. But many of those laws have loopholes, experts say, and most

state laws about insurance don't apply to the employer-funded plans common among large companies. Those are regulated federally and cover more than an estimated 73 million Americans.

For patients, it's still an uphill fight. After long battles over insurance coverage, Boesing and Dean no longer get the medications they were concerned about in the mail. But Becker and Munson still do, unhappily and unwillingly.

Kim Munson with her nine-year-old daughter Kinsley, who has Type 1 Diabetes, at their Minnesota home in September 2020. (Courtesy Kim Munson)

"There's no way out of this," said Munson, who can't afford the hundreds of dollars more her daughter's insulin would cost every month if they did not get it by mail.

"All I can do is wish for the best when I open up the styrofoam container and put it in the refrigerator. I just hope and pray that the insulin I eventually will be putting into her body works."

Samantha Springer, Wilson Wong, Kara Stevick, Gretchen Morgenson and Peter Georgiev contributed.
Graphics and development by Robin Muccari, Jiachuan Wu and Charlotte Li;
Photo editing by Elise Wrabetz.

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STAT

Cancer patients should be treated by their doctors, not pharmacy benefit managers

By Jeff Vacirca May 9, 2019

Adobe

When I must tell a patient that she or he has cancer, that diagnosis comes with the explicit promise that I will provide timely treatment, including medicines aimed at curing cancer or extending life as long as possible.

But an insidious interloper now often comes between me and my patients. I'm talking about pharmacy benefit managers (PBMs), the middlemen that have introduced a bureaucratic and nightmarish system of delays and denials into filling prescriptions.

I'm not alone.

An oncologist in Florida determined that her patient with metastatic kidney cancer needed to start taking a standard, first-line oral medication. But the patient's pharmacy benefit manager decided it knew better and refused to authorize the medication unless a surgeon first performed surgery to remove a tumor on the patient's kidney — despite the

fact that the patient's surgeon had already determined that the procedure was too risky and the patient wasn't a candidate for surgery, something the surgeon had previously told the PBM.

For three months, the patient's oncologist and surgeon appealed the pharmacy benefit manager's denial so the patient could receive the treatment he desperately needed. Although the PBM ultimately relented, the patient will never get those three months back. For anyone battling cancer, delaying treatment and allowing the disease to progress by even a week can mean the difference between life and death.

There's the story of a young mother in Tennessee who was beating the odds against stage 4 pancreatic cancer but was left with a dangerously suppressed immune system. She was forced to delay critical treatment because the medicine she needed was on backorder at her pharmacy benefit manager's mail-order pharmacy and the company wouldn't pay for her to get it from her doctor's office.

Working with cancer care providers across the country, the Community Oncology Alliance[4] has compiled hundreds[5] of these horror stories. They demonstrate time and again how pharmacy benefit managers come between patients and their doctors, with little regard for the pain and suffering they inflict.

Pharmacy benefit managers were *supposed* to help bring down the cost of drugs by negotiating with competing drug companies and by "encouraging consumers to use the most cost-effective drugs[6]." But they have done the opposite, fueling higher drug prices through manufacturer rebates and by extorting fees from pharmacy providers.

Those rebates and fees were the focus of a Senate Finance Committee hearing[7] featuring top executives of five pharmacy benefit managers last month. The chair of the committee, Iowa Republican Chuck Grassley, noted that "the current system is so opaque that it's easy to see why there are many questions about PBMs' motives and practices."

For health care professionals on the front lines of delivering timely care to people with cancer, there is no debate about the need for transparency: Pharmacy benefit managers are a roadblock to potentially lifesaving cancer care. For many of our patients, the groundbreaking cancer drugs they see in headlines are often out of reach because of PBM practices that restrict or delay access. While they won't admit it, there is no doubt

that every dollar a pharmacy benefit manager saves by stopping or redirecting a prescription means more upside for their profits.

The pharmacy benefit manager business model is built on a lucrative and shadowy network of drug manufacturer rebates and pharmacy fees squeezed from every level of the health care system. Congress is right to look into these rebates and fees to better understand exactly what roles pharmacy benefit managers play in the complex economics of drug prices.

A veneer of governmental indifference seems to be helping pharmacy benefit managers protect their egregious profits. But the system isn't working for patients with cancer or the millions of other Americans who struggle to overcome red tape to get the medications they need.

Americans deserve better from our health care system and we should be able to count on our elected officials to support affordable, convenient, cutting-edge, patient-centered care. This includes access to the cancer therapies they need, when and where they need them.

The White House, members of Congress, policymakers, and the American public should ask themselves this important question: If your mom was facing breast cancer or your son had brain cancer, do you want a pharmacy benefit manager determining their care, or their doctor?

Jeff Vacirca, M.D., is CEO of New York Cancer and Blood Specialists and the immediate past president of the Community Oncology Alliance. The author reports being medical director of ION Solutions and on the board of directors of OneOncology, Odonate, and Spectrum Pharmaceuticals.

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Why a cancer patient had to wait 3 months to get her medication

Maria Clark, NOLA.com | The Times-Picayune

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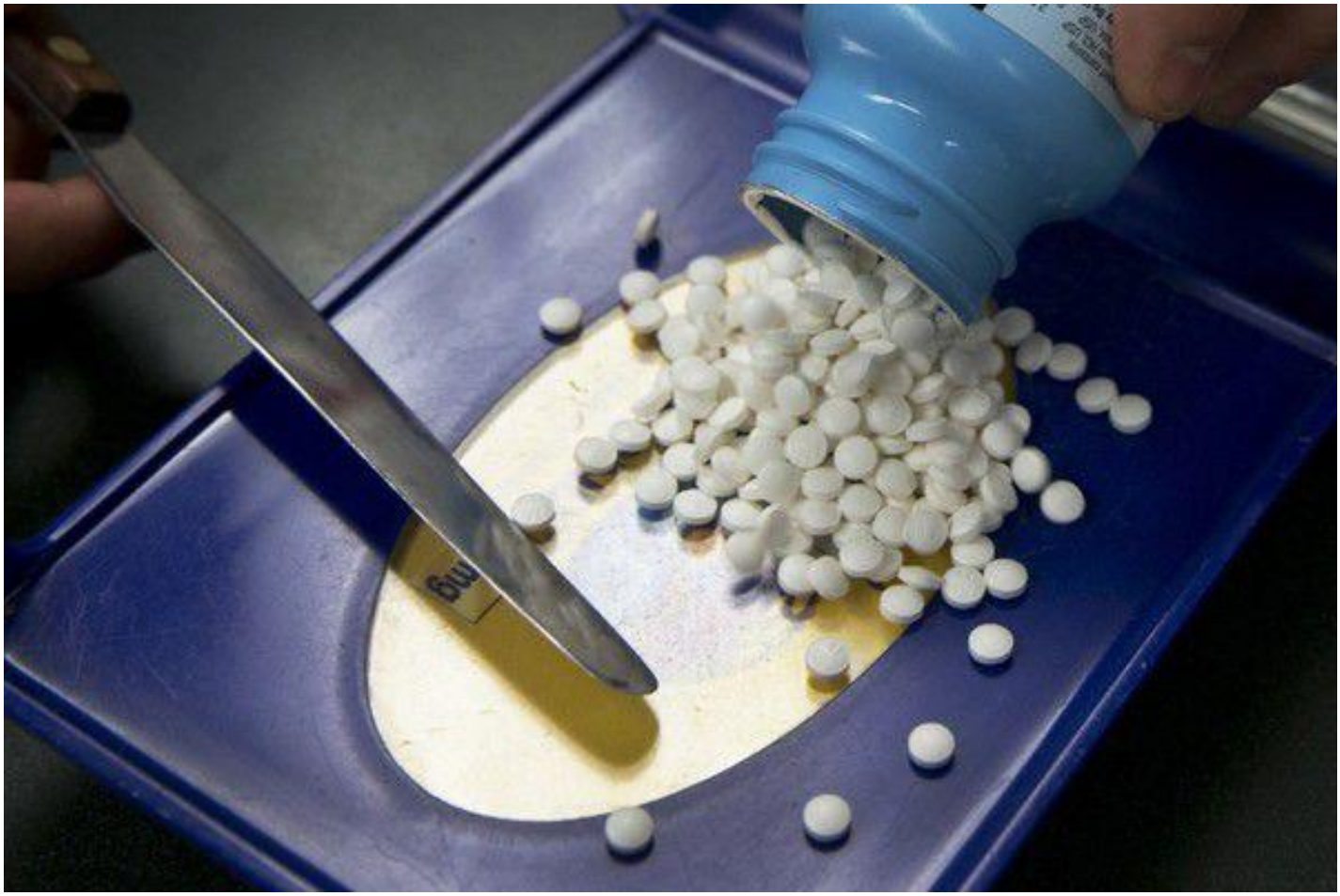

FILE - In this Friday, July 8, 2016, file photo, a prescription is filled at Pucci's Pharmacy, in Sacramento, Calif. (AP Photo/Rich Pedroncelli, File)(Rich Pedroncelli)

Connie Raborn had already survived metastatic breast cancer and a double mastectomy when she was diagnosed with bone cancer on May 4.

The 66-year-old Kentwood, Louisiana resident is a Medicare recipient and has health insurance through the military. So her coverage should have been enough to

ensure she had the medication she needed after her second cancer diagnosis.

What she got instead was a denial letter on June 19 from her mail-order pharmacy Express Scripts, telling her they would not fill her prescription. She said she ultimately had to wait almost three months until she was finally able to access the medication prescribed to slow the growth of cancer cells in her right shoulder.

Raborn's dilemma is far from unusual among oncology patients, who sometimes have to wait days and even weeks to get prescriptions for expensive specialty drugs filled.

"It's a frequent problem in oncology," said Dr. David Oubre, Raborn's oncologist. "The more expensive the medication the more likely there will be a delay."

The decision of whether or not a patient can access a certain medicine often isn't up to the doctor or even the health insurer. Instead, that sometimes life-changing decision falls on the shoulders of the middle-men of the pharmaceutical industry--companies called pharmacy benefit mangers or PBMs.

Express Scripts, the company that initially sent Raborn her denial letter, operates a mail-order pharmacy and is also the largest PBM in the U.S. Raborn receives health insurance through a plan called TriCare, which serves former and current members of the military and their families. The insurer works with Express Scripts to determine what medications can or can't be covered.

Raborn said she appealed the decision on June 19 and was told it could take up to 90 days to get a response. A month later when she called the company to check on her prescription, they told her they had approved the medication, she said. However, neither Raborn nor her doctor both said they were not notified, and she said it wasn't until Aug. 1, nearly three months after her diagnosis, that she was able to access her medication.

"They let me sit for months on this," said Raborn, a retired secretary who lives in Kentwood with her husband Sam, a retired Air Force master sergeant. "I keep thinking how much longer I would have waited if I hadn't called."

Health insurance companies such as TriCare hire PBMs to manage how much they pay for prescription drugs, how much pharmacies are reimbursed for the cost of the drug, and what drugs are available on formularies. A formulary is the list of medications covered by specific insurance plans.

The Pharmaceutical Care Management Association, the national organization that represents PBMs, says the mission of PBMs is to lower prescription drug pricing and therefore increase patient access to prescription medicine.

The main way these companies save money for the insurer is by securing rebates from drug manufacturers to get their drugs listed on formularies. Rebates are widely used by pharmaceutical manufacturers to drive demand for those medicines and incentivize PBMs to include their products on formularies. PBMs often retain

a portion of the rebates they negotiate and pass some of these discounts to health insurers. Those savings, however, are hardly ever passed down to patients at the pharmacy counter, leaving patients covering the cost for expensive medication until they are able to meet their deductible, according to 2017 report from the Pharmaceutical Research and Manufacturers of America (PhRMA).

Further compounding the problem is that many pharmacists are contractually prevented by "gag clauses" from telling patients they could save money if they were to pay out-of-pocket or whether their co-payment might exceed the actual of cost of the drug.

Louisiana was one of 18 states to pass legislation this year prohibiting these "gag clauses." The legislation sponsored by Sen. Fred Mills also requires the Louisiana Dept. of Insurance to publish information about PBMs operating in the state, including the list of drugs they manage and any changes to that list. By June 1, 2020, these companies will be required to disclose the percentage of any rebates they receive from drug manufacturers for drugs listed on their formularies.

Additionally, health insurance companies will be required to let their enrollees know when they are being charged more for a prescription drug than the insurer itself pays.

The role PBMs play in negotiating prices makes it difficult for consumers to know where rebates are going and how drug prices are negotiated, Mills explained.

"This is about providing more transparency for the consumer and having more oversight on how these companies work," he said.

Today, the top three PBMs in the U.S.--Express Scripts, CVSHealth and OptumRx-- manage the drug benefits of approximately 78 percent of Americans- more than 180 million people, according to the National Community Pharmacists Association.

As drugs get more expensive, employers and health plans are looking at ways to manage those costs, said Jennifer Luddy, a spokesperson for Express Scripts.

In a 2016 report, the company said that on average 0.3 percent of their members had annual prescription medication costs of $50,000 or more, a jump of 35 percent from 2014.

More than 25 percent of those costs were for specialty cancer drugs.

"More and more payers are trying to understand, 'Is this the best drug. If we are spending $5,000 on it, will it work?'" she said.

Citing patient confidentiality and privacy laws, Luddy was unable to discuss the details of Raborn's case on the record. She did confirm that an appeal on Raborn's case was completed and communicated within a timeframe of two to three weeks to both Raborn and her physician.

"When a physician appeals a prior authorization decision on behalf of a member, the process begins when we receive necessary documentation for the appeal,

including a Letter of Medical Necessity and consent. Appeals are usually completed with 2-3 weeks, but can sometimes take longer," she said in a written statement.

However, patient advocacy groups argue that the growing role of PBMs in cancer care has resulted in delays, denials and price increases on specialty drugs that directly impact consumers.

PBMs are often dictating what medications a doctor can prescribe and whether or not patients can access it, said Ted Okon, the executive director of the Community Oncology Alliance.

"On the surface PBMs profess to manage drug costs, but reality is that their concern often lies more on saving the payer (health insurer) money," he said. "When you restrict the number of drugs going out the door you are saving them money."

When Raborn was diagnosed with bone cancer in May, her doctor prescribed Ibrance, which when taken in combination with certain hormonal therapies can slow down cancer cell growth in patients with metastatic breast cancer.

The drug costs approximately $10,000 a month without insurance, according to her oncologist Dr. Oubre, the managing physician at the Pontchartrain Cancer Center which has locations in Covington and Hammond.

He explained that when medication becomes more expensive and is more specialized, as is the case with cancer drugs, the more likely there will be a delay in

getting a prescription filled.

This class of prescription drugs require prior authorization from the doctor to show why it is needed for treated. This means that delays are common, but a denial like in Raborn's case is egregious, he said.

"When you have cancer, you don't start treatment at two months from now. You start as soon as is reasonably possible," he said.

This story has been updated with a statement from Express Scripts.

Correction: The Pontchartrain Cancer Center has locations in both Hammond and Covington and Dr. David Oubre is the managing physician.

Maria Clark writes about immigration, health, doctors, patients and health care in Louisiana for NOLA.com | The Times Picayune and NOLA Mundo. Reach her at mclark@nola.com or 504.258.5306. Or follow her on Twitter at @MariaPClark1 .

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April 7, 2021

The Honorable Carolyn Maloney
Chairwoman, House Committee on Oversight and Reform
2308 Rayburn House Office Building
Washington, D.C. 20515

The Honorable James Comer
Ranking Member, House Committee on Oversight and Reform
1017 Longworth House Office Building
Washington, D.C. 20515

Re: *Direct and Indirect Remuneration Fees (DIR Fees)*

Dear Chairwoman Maloney and Ranking Member Comer:

We are writing this letter on behalf of the Board of Directors of the Community Oncology Alliance (COA) **respectfully requesting that the Oversight & Reform 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*

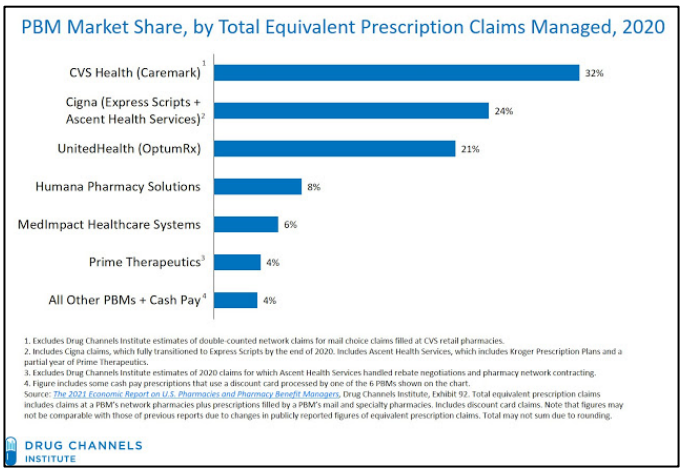
[1] 83 Fed. Reg. 62,152, 62,176 (Nov. 30, 2018).
[2] Senderra Rx Partners, LLC, D/B/A Senderra Specialty Pharmacy v. CVS Health Corporation, F/K/A CVS Caremark Corp., Caremark, LLC, Caremark PCS, LLC, and SilverScript Insurance Company, AAA Case no. 01-18-0000-7001 at *3 (American Arbitration Association July 23, 2019) (Final Award).

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.[3] 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. 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[4], 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 Oversight & Reform 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, threating 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

[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

CVS CAREMARK Part D Services

March 2021

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	① Medication Adherence				Other Categories			④
	Performance Criteria	RAS Antagonists[1]	Statins[2]	Diabetes[3]	Overall Adherence Score	Gap Therapy (Statin)[4]	② CMR Completion Rate (MTM)[5]	③ Formulary Compliance[6]	Final Overall Performance Score
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%**	**78.19%**

†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%	81.09%

†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.

CVS CAREMARK Part D Services

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
National Performance Plans							
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
Regional Performance Plans							
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)							
Premera BlueCross (WA)							
Tufts Health Plan (CT, MA)							

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

CVS CAREMARK Part D Services

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%**

CVS CAREMARK Part D Services

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%**

CVS CAREMARK Part D Services

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
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										

CVS CAREMARK Part D Services

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
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%**

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

FRIER LEVITT
ATTORNEYS AT LAW

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March 1, 2021

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[1] and increased out-of-pocket costs to patients.[2] 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."[3] 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[4], 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

[1] https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir
[2] https://www.amplicare.com/articles/the-dangerous-link-between-dir-fees-and-catastrophic-coverage-and-how-its-hurting-patients-and-pharmacies
[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.[5]

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.[6] 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.[7] 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.[8] 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

[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.
[7] U.S. Department of Health and Human Services. Common Terminology Criteria for Adverse Events. *CTEP*. 2017;5:88-90. https://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_5x7.pdf. Accessed September 24, 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."[9] 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,[10] noting

[9] 83 Fed. Reg. 16591 (Apr. 16, 2018).
[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.

[11] 83 Fed. Reg. 62,152, 62,176 (Nov. 30, 2018).
[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

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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 ESI'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[1] and increased out-of-pocket costs to patients.[2] 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.[3] 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[4], 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

[1] https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir
[2] https://www.amplicare.com/articles/the-dangerous-link-between-dir-fees-and-catastrophic-coverage-and-how-its-hurting-patients-and-pharmacies
[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.
[4] https://www.pharmacytimes.com/news/generic-specialty-medications-the-paradigm-shift. Accessed November 5, 2020.

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.[5] 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.[6] 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.[7] 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 multitiered 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

[5] IMBRUVICA (ibrutinib) [package insert]. Sunnyvale, CA; Pharmacyclics LLC; Revised April, 2020.
[6] U.S. Department of Health and Human Services. Common Terminology Criteria for Adverse Events. *CTEP*. 2017;5:88-90. https://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_5x7.pdf. Accessed September 24, 2020.
[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."[8] 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 423.5050(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,[9] 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."[10] 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.**"[11] 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

[8] 83 Fed. Reg. 16591 (Apr. 16, 2018).
[9] 74 Fed. Reg. 1,494, 1,505 (Jan. 12, 2009) (emphasis added)
[10] 83 Fed. Reg. 62,152, 62,176 (Nov. 30, 2018).
[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

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cc: Norris Cochran, Acting Secretary of Health and Human Services
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Hon. Ron Wyden, Chair Senate Committee on Finance
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