Written Testimony on Hearing:

Stifling Innovation: Examining the Impacts of Regulatory Burdens on Small Businesses in Healthcare

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Committee on Small Business

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Chairman Williams, Ranking Member Velazquez, and members of the House Committee on Small Business thank you for the opportunity to submit this written testimony and participate as a witness for this critically important hearing on regulatory and related burdens on small businesses in healthcare.

I am a practicing medical oncologist for New York Cancer & Blood Specialists (NYCBS) and serve as chair of legislative affairs and patient advocacy. Our medical practice has 54 locations across the greater Metropolitan New York area providing medical, radiation, and surgical treatment for patients with cancer and blood disorders, and diagnostic imaging services. I am also a Board member of the Community Oncology Alliance (COA), a non-profit group advocating for independent (non-hospital owned) community cancer care and am a Past President.

Although NYCBS may not now fit the traditional definition of a "small business," we started as a very small business with seven oncologists and two locations. Our story is one of survival, and even now, we have to fight daily with the mega health systems in New York, which make us a small business compared to their growing dominance. Furthermore, we are faced with the growing power of the consolidated middlemen of insurers and pharmacy benefit managers (PBMs), state regulations, and the Centers for Medicare & Medicaid Services (CMS), which is driving independent physicians to retire or become hospital employees. In this testimony, I will briefly touch upon all these forces threatening the very existence of small businesses in healthcare, but first, let me tell you about my own story as a physician starting out in a very small medical practice.

My career began in a small, three-physician independent community oncology practice in Mooresville, North Carolina, where I practiced until over two years ago. I have been privileged to care for patients in an era of immense scientific progress in overcoming a disease that threatens to take our closest loved ones from us. My physician partners and I worked closely with our nurses, nurse practitioners, medical assistants, and ancillary staff caring for patients battling cancer and blood disorders. We were a family. We lived with our patients on the front lines of an increasingly broken medical system. We often acted as their last line of defense not only for their medical illness but also for the confusing and overwhelming medical system in which they and we, as their providers, increasingly were fighting. Barriers to care, both large and small, sometimes incidental, other times intentional, popped up all over the place and almost always were far too much to bear for patients facing a battle for their lives. Over the years, these barriers have gotten far worse and more numerous.

Over time, our small practice, operating as a small business, encountered significant pressures from large, well-funded hospital oligopolies in the Charlotte area and beyond in North Carolina. These rapidly consolidating large health systems were increasingly employing internal medicine and related physicians who referred patients to us. As such, these health systems effectively controlled our patient base, with the power to direct patients away from our practice.

In 2017, one large health system in our region gave us an ultimatum – be acquired by us or we will hire physicians to compete against you. One of the prime motivators for this aggressive move by the health system was the federal 340B Drug Discount Program, which provides hospitals with very large discounts on drugs, often exceeding 50 percent. And without any mandate that the hospital pass those discounts on to patients in need, the 340B Program has become a huge profit center for so-called "nonprofit" health systems. As such, the acquisition of our practice would generate substantial immediate profits for the health system, allowing it to further expand.

My partners and I had already witnessed other similar small, independent oncology practices in our immediate area, and North Carolina in general, that lost their battle with these health systems. Unfortunately, large health systems have all the power to shut off patient referrals to a practice, referrals that we depended on to stay in business Furthermore, we were faced with declining Medicare payment, as well as from consolidating commercial insurers. Those payment issues contributed to a general hostile healthcare environment that stacked the deck against us small healthcare practices like ours.

In 2018, my two partners and I had little choice but to join the large hospital system as employees. Our small, independent practice that had served the community for over 19 years was gone. Hospital clinics operate under stifling bureaucracies and, as a result, almost immediately I was unable to see the same number of patients I was able to see daily in my own independent practice. As devastating, the hospital switched over to its billing system and was able to charge significantly more for the same services – for example, chemotherapy administration – meaning my patients were paying more for the same treatment that had been receiving in my practice. They came to the same building, were treated by me, their same physician, and received the same drugs but paid more. Patients who I had treated and followed for years simply left.

After three years, I left the health system. I simply could not practice in an environment where hospital bureaucracy ruled, impacting my ability to provide the best treatment for my patients but who were paying more for that treatment – much more than when our small practice operated independently of the hospital.

Due to the consolidation of hospitals into large health systems in North Carolina, I joined NYCBS in New York, even though it meant commuting from my still home in Charlotte, North Carolina. As I related, my current practice of almost 300 predominantly oncologists serving all of New York City and Long Island is independent. Unlike the large health systems, we are the only major cancer treatment provider in our region that accepts all insurance plans while also being the only major cancer treatment provider that does not receive state funding or other subsidies. We have opened clinics in underserved communities, are the lowest-cost cancer provider in all of our markets, and were recently named the number one physician practice in New York by Castle Connolly, a rating system based on physician peer reviews.

As I stated previously, every day, our practice is fighting to survive and thrive, especially as federal regulations have created an unduly burdensome environment threatening small provider-based businesses in healthcare. This is an unfolding crisis as the costs of healthcare, especially medical treatment, are escalating out of control, and the increasing demand for physicians is outstripping a decreasing supply. Do you know that during COVID alone roughly145,000 burned-out practitioners, half of which were physicians, walked away from medicine?[1]

Small independent medical practices are vanishing, especially as hospitals in North Carolina and across the country are combining, acquiring physician practices in the process, to become mega health systems. When you couple an almost total lack of regulation from allowing these mega systems to develop[2] with misguided regulation throwing up more barriers to small, independent practices, “small business” in healthcare is going the way of the dinosaurs. You have to grow

[1] https://www.phillymag.com/be-well-philly/2024/04/22/doctors-appointment-scheduling/
[2] https://www.northcarolinahealthnews.org/2024/04/22/the-rise-of-mega-hospitals/

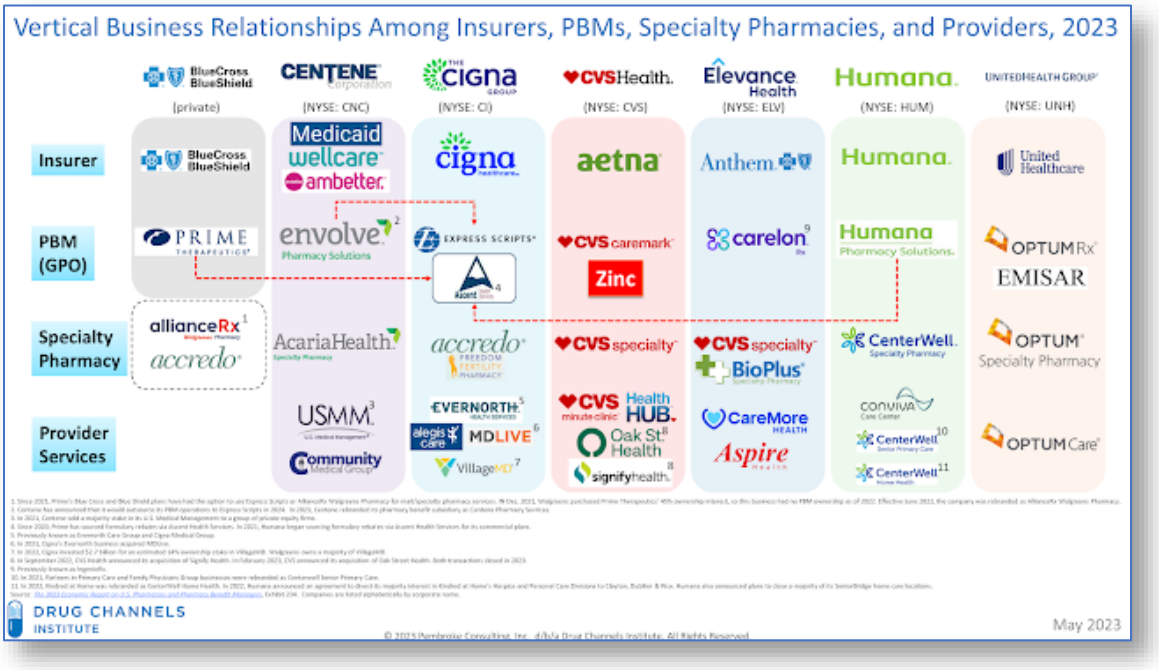
bigger, be more innovative, and fight for misguided regulations to be stripped away to survive. Make no mistake, who suffers in all of this are Americans who are paying more for drugs and medical services, and increasingly having a harder time finding a physician. This is a sobering reality.

Cancer research, drug development, and care delivery are in a renaissance. I am privileged to practice in this era of breakthrough scientific progress. However, patients often do not get the treatment that they need or in the best manner possible. We face a fundamental choice in this country – who is in charge of patient medical care? Is it the physicians and patients making the best treatment decisions together in the exam room? Or is it insurance companies, massive, consolidated health systems, and government regulators like CMS controlling personal healthcare decisions from afar? Over my career, the shift absolutely has been towards the latter.

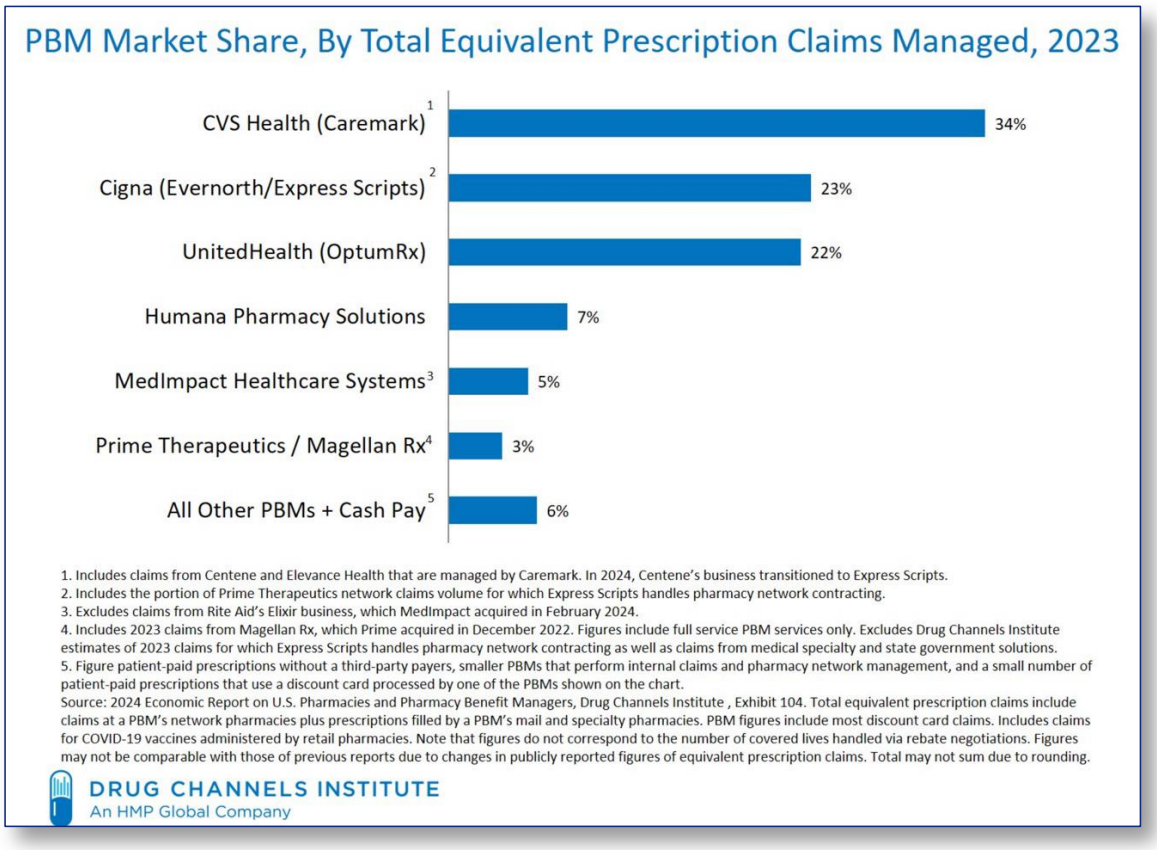
I applaud the House Committee on Small Business for exploring barriers to innovation and the impacts of regulation on small businesses in healthcare. Not to get in the weeds too much, let me touch on some of the misguided regulations that get in my way every day as a practicing oncologist from providing the highest quality, most affordable cancer care to my patients. Hopefully, this will give you a better understanding of what physicians practicing in small healthcare businesses face daily.

Utilization Management by Insurers and PBMs

Let me first explain that there has been tremendous consolidation among insurers, among PBMs, and among the combination of insurers and PBMs. This chart shows the horizontal and vertical integration of insurers, PBMs, and affiliated healthcare delivery entities.



To give further understanding of this consolidation, the largest PBMs control 80 percent of the prescription drug market and the top 6 control 94 percent of all prescription drugs.



What this means is that insurers and their PBMs are increasingly dictating the treatment that my patients receive, as well as how and where they are to receive it. Dictating treatment is done through a number of methods referred to as "utilization management" and include:

- **Prior Authorization** where the insurer/PBM demands that treatment be authorized prior to my administering. Not only do staff and I have to argue with insurance staff, who are often not oncologists, but this is most often unduly time-consuming. There are even increasing reports of how insurers are using AI in prior authorizations.[3]
- **Fail-First Step Therapy** where the insurer/PBM requires the patient to fail first on a sub-optimal therapy before I can administer the best treatment for the patient.
- **Formulary Control** where certain drugs are excluded from the insurer's formulary of their approved medications.

What is important to understand with utilization management is that the insurer and their PBMs are motivated to use the most profitable drugs for them, not the most effective medications for my patients. That is because due to misguided regulations that provide safe harbor protection allowing insurers/PBMs to extract rebates from pharmaceutical manufacturers, these corporate entities are legally allowed to bypass any anti-kickback laws.

Our practice dispenses oral cancer medications to patients through *medically integrated dispensing*. This means that our pharmacy team is closely connected to our team of physicians both through the electronic medical records and the physical locations of our offices. It is common for oral

[3] https://www.propublica.org/article/cigna-pxdx-medical-health-insurance-rejection-claims

cancer therapies to cause side effects necessitating treatment interruption or dose changes. This information is available in real time to our integrated pharmacies. Our integrated pharmacy care reduces waste, improves compliance, and improves outcomes. However, PBMs now often dictate that patients receive their drugs via their mail order pharmacies. This not only takes treatment choices and monitoring out of my hands but also increases costs.

With the consolidation of insurers and PBMs alone, the deck is stacked against the medical practice that is a small business. You are forced to consolidate your practice or simply give up the fight.

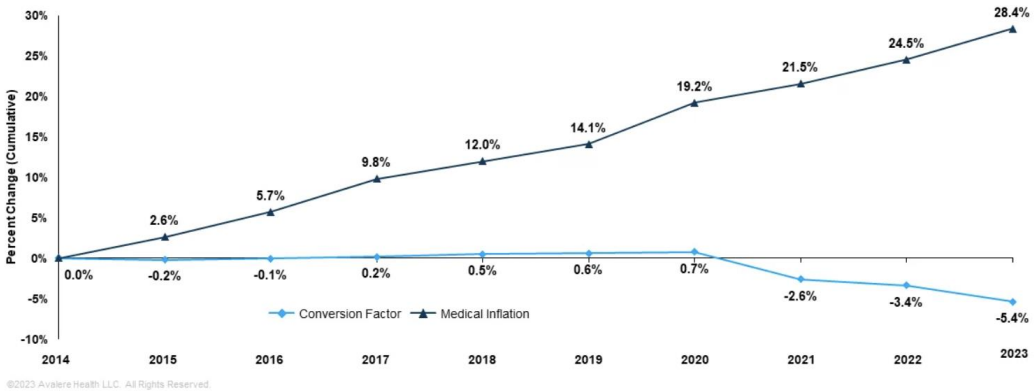
CMS & Medicare Regulations

Hospital Pressures and the 340B Program

I previously touched on pressures from large consolidating health systems, which have been allowed to grow due to a lack of regulation and oversight. Let me just touch on the difference in payment structures and the 340B Program.

There have been more studies and analyses of how hospitals charge more than independent physician-run medical practices, including charging what is called a hospital "facility fee." Simply put, patients pay more in hospitals. That is in large part because Medicare, which is typically the single largest payer in cancer treatment, pays hospitals more for identical procedures than independent community oncology practices like ours. Additionally, Medicare annually provides inflation adjustments to hospitals but does not to physician-run practices. In fact, as this graph shows, as the cumulative inflation rate has increased over the past 10 years, Medicare payments to physicians have been flat and recently declining.

Figure 1. Cumulative Change in Conversion Factor and Medical Inflation Since 2014, by Year



Source: US Bureau of Labor Statistics, "Consumer Price Index Historical Tables for US City Average, 2023"; US Bureau of Labor Statistics, "BLS Data Viewer, 2023"; American Medical Association, "History of Medicare Conversion Factors, 2023."

It is increasingly impossible for independent practices, especially those operating as small businesses, to survive given how CMS implements Medicare payments.

Additionally, CMS has fueled hospital consolidation and acquisition of medical practices, especially in oncology, by grossly over-paying hospitals for deeply discounted 340B drugs. Hospitals with 340B drug discounts not only put independent practices at a disadvantage but are also a prime motivating factor to acquire those practices.

Barriers to Patients Getting Their Drugs Delivered & the Stark Law

What is further harming independent medical practices, especially those like ours treating sick cancer patients, is a relatively new CMS regulation that popped up during the COVID public health emergency (PHE). CMS has ruled that when the PHE expired, it is a Stark Law violation for practices like ours to deliver an oral cancer drug to a patient or even to have a patient's family member or caregiver pick up the drug at our practice for the patient. This presents serious treatment obstacles for patients who are too sick, without regular transportation, and simply unable to appear in person for their oral drugs. The Stark Law was put in place close to 35 years ago to make it a crime for physicians to refer "designated health services" payable by Medicare (and Medicaid) to entities that the physician (or family member) has a financial interest in, with certain exceptions. The current CMS regulation is simply wrong because delivering a drug to a patient, or allowing a patient representative to pick it up, involves no referral to anything I have a financial interest in, yet it puts a real barrier to my patients getting their drugs.

I add that the Stark Law in this day and age is not only archaic but places physician-run practices at a serious disadvantage to hospitals, which can refer to themselves in any manner, regardless of whether it is a clinical or financial detriment to the patient.

Barriers to Patient Efficient Care

Certain CMS regulations compel practices to operate in highly inefficient manners, often lacking discernable logic for physicians and patients alike. For example, a Medicare regulation – referred to as modifier-25 because of the Medicare coding involved – deems it unreasonable for a physician to administer both a cancer drug infusion (such as chemotherapy) or injection and also conduct a professional visit with the patient <u>on the same day</u>. Consider the scenario of a patient with anemia stemming from chronic kidney disease, whose condition typically responds favorably to erythroid stimulating agents administered via subcutaneous injection every two to three weeks. Concurrently, physicians must monitor this therapy, ensuring proper response, adjusting dosage as necessary, and observing for adverse effects such as exacerbation of high blood pressure. While it would be advantageous for patients to receive both the physician visit and the injection <u>on the same day</u>, Medicare does not reimburse for both services concurrently.

As a result of this non-sensical CMS regulation, patient caregivers often need to take additional time off work to accommodate separate appointments for their elderly parents, compounding the burden on families. This issue extends to other treatment areas, including those aimed at enhancing the immune system to combat cancer. The outcome is that sick cancer patients are compelled to make multiple unnecessary visits to their physician's office, adding strain and inconvenience to an already challenging situation.

Previously, Medicare and commercial insurers, following CMS' lead, would accept a "modifier-25" adjustment to billing codes, allowing for treatments and medical evaluations on

the same day. However, recent CMS regulations have become significantly more stringent. As a result, our office had to educate physicians, nursing staff, and clerical personnel to adjust appointments to circumvent this conflict, leading to understandable confusion among staff and patients alike. This situation epitomizes the deleterious impact of misguided regulations, needlessly complicating treatment for cancer patients.

Conclusion

In all of this, physicians are increasingly burdened by onerous paperwork, reporting, and computer data reporting. This takes time away from what we are not only trained to do but take an oath to do – put our patients first in providing them with the highest quality medical treatment. Rather than having regulations and laws to help us do that, it is the other way around. Small healthcare "businesses "are going extinct because the regulatory environment is stacked against them. I could go on and on with additional examples but will be happy to answer any questions, or elaborate on what testimony I have provided, from the committee.

I appreciate the opportunity to testify today.

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