FRIER LEVITT

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Via Regular Mail and Electronic Delivery (<u>Michelle.Buchanan@CVSHealth.com</u>)

CVS Caremark Corporation Attn: Michele W. Buchanan, Esq. 9501 E. Shea Boulevard Scottsdale, AZ 85260

Re: Illegal "Slow Rolling" and "Pretextual Denials" of Applications by Dispensing Physicians Seeking Admission into CVS Caremark's Pharmacy Networks

Dear Ms. Buchanan:

As you are aware, Frier Levitt is counsel to the Community Oncology Alliance ("COA"). We trust you are familiar with the COA organization as a non-profit dedicated to advocating for dispensing physicians and the patients they serve (including predominantly Medicare beneficiaries). For close to 20 years, COA, and its affiliate, the Community Oncology Pharmacy Association ("COPA"), have built a national grassroots network of community oncology and urology practitioners to enhance the effectiveness and efficiency of patient care, as well as to advocate for public policies that benefit patients. We are now writing on behalf of COA and the community oncology and urology providers it represents nationwide in an attempt to reiterate our goal of having CVS Health Corporation and its Pharmacy Benefit Manager ("PBM") subsidiary, CVS Caremark, actually admit physician dispensers into CVS Caremark's networks in good faith.

As of this date, in addition to COA and COPA, Frier Levitt represents thirty-five (35) dispensing physician oncology and urology practices specifically listed in <u>Exhibit A</u> (hereinafter, the "Practices"). These Practices have been directly and negatively impacted by CV Caremark's pattern of abuse and bad faith in "slow rolling" applications into CVS Caremark's pharmacy networks. To that end, these Practices have authorized Frier Levitt to initiate a legal action on their behalf.

This letter serves as a final demand for immediate network access, or a framework for the timely, reasonable and transparent admission into CVS Caremark's pharmacy networks, for each of the specifically enumerated dispensing physician oncology and urology practices. If these requests are not timely honored, these Practices are prepared to file a multiparty lawsuit in Federal Court challenging CVS Caremark's improper conduct and have engaged Frier Levitt to that end.

I. THE ISSUE

As detailed further herein, the Practices constitute a broad cross-section of dispensing oncology and urology physician practices that have applied to CVS Caremark's networks, and have either been "slow-rolled" (i.e. had an application pending without decision for months or years), or have been denied participation on a purely pretextual

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(i.e., non-good faith) basis. The Practices are located across the country and represent some of the largest, most progressive oncology and urology practices in the industry, that have taken on establishing in-office dispensing to elevate the level of care to their patients. The Practices range in size from just two physicians, to over 40 physicians.

For each of the Practices listed in <u>Exhibit A</u>, we affirm that the Practices adequately and properly submitted their applications, that they did not knowingly omit requested material information, and that they are otherwise in-fact generally qualified to participate on reasonable and relevant good faith terms and conditions. Some of these Practices, in addition to being state-licensed and regulated, are also accredited by one of more independent third parties, such as the Accreditation Commission for Health Care ("ACHC") or the Joint Commission. As such, CVS Caremark continues to deny admission to duly qualified and credentialed dispensing physician practices seeking admission to its networks.

II. BACKGROUND

Beginning in early 2016, CVS Caremark espoused a self-serving stance that dispensing physician practices were now to be deemed "out of network" and no longer able to participate in Medicare Part D networks. CVS Caremark then backtracked on this position and began allowing "grandfathered" physician dispensing practices to remain innetwork, but delayed the processing of any new, "non-grandfathered" dispensing physician practices. After several additional efforts, as well as communications with CMS, CVS Caremark decided to open its network to all dispensing physician practices. While on its face a positive step, CVS Caremark shifted tactics to essentially "slow roll" credentialing applications by dispensing physician practices or deny dispensing physician practices on pretextual bases. CVS Caremark's actions show a pattern of intentional delay and denial on the part of CVS Caremark, and an intent to prevent or significantly limit dispensing physician practices from actually entering its networks.

Unfortunately, as set forth in greater detail below, it appears that this murky construct is by design. These physician dispensing practices have no ability individually to control or curb this rigged system and its opaque and abusive practices designed to exclude them from network participation. However, collectively these stakeholders and COA/COPA have chosen to assert their rights and challenge CVS Caremark from continuing to circumvent the overwhelming body of Federal authority, including Any Willing Provider laws, that were enacted to protect the Medicare Part D program and its recipients. Briefly, the Federal Any Willing Provider Law indicates that a provider that otherwise meets the reasonable terms and conditions of a network should be allowed admission. Without immediate action, patients, taxpayers and the Medicare Part D program will suffer.

III. CVS CAREMARK'S CONDUCT UNDER THE GUISE OF APPLICATION REVIEW AND CREDENTIALING

All of the enumerated Practices have submitted one or more applications to CVS Caremark seeking network participation and remitted at least one \$1,500 application fee. However, none of these 36 Practices have been approved for participation in CVS Caremark's networks. In the time that has elapsed since these Practices began applying, several clear and unmistakable trends have emerged. Most of the credentialing applications have been pending for 7-10 *months* (or longer), even though CVS Caremark promises processing in 4-12 *weeks*. Many of the individual practices in fact reached out to CVS Caremark many times seeking status updates, which were wholly ignored. Frustratingly, as a result of this "slow rolling," and the months of time CVS Caremark continues to take in "reviewing" these applications, certain information that is submitted becomes expired or out-of-date. As part of its "slow rolling" *modus operandi*, CVS Caremark will then typically send the Practice a notification that certain items are out of date and need to be updated. At any given point of time, there will constantly be renewals and updates to an application (e.g. medical license renewals, DEA numbers, NPI numbers, etc.). CVS Caremark provides no opportunity for the Practices to proactively update their applications with updated information, and each time it makes these supplemental requests, it not only causes the Practice to incur an additional fee, but effectively "bumps" their application back to the bottom of the pile. Moreover,

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the chances of this occurring with applications that take many months for CVS Caremark to review are much higher. Many Practices have experienced such long delays by CVS Caremark reviewing their application, that they have to provide the same "updated" information multiple times, with CVS Caremark sitting on the application, then rerequesting the same information, then placing the practice back at the beginning of the queue, thus restarting the perpetual cycle all over again. Given the grossly, unreasonable timeline involved, and CVS Caremark's history on the issue of physician dispensing, there is a clear *indicia* of intentional stalling and delay to admit these Practices to its networks, resulting in a *de facto* rejection.

For the few Practices that have endured these unreasonably long waits long enough to receive a response, it is not a proverbial "light at the end of the tunnel." Rather, after these frustratingly long waits, CVS Caremark's usual practice is to issue from "CVS Caremark-Network Operations", unsigned denials indicating vaguely:

"We reviewed your dispensary's credentialing and qualifications, and we have concluded that your dispensary does not meet the terms and conditions of a "Dispensing practitioner." We are unable to admit you into the pharmacy network at this time because you have not submitted all of the items required in the credentialing packet for dispensing practitioners."

What is most troubling is that these Practices were initially provided an acknowledgement that CVS Caremark has received their application and that they would be informed if additional documentation was required. In fact, sections of CVS Caremark's Provider Manual addressing the submission of credentialing applications explicitly state:

"Once the Applicant submits the online enrollment application, the applicant will be notified via email by Caremark if any required documentation or information is missing or incomplete. The review of an application will not begin until a complete application is received."

These Practices were never advised of missing documents and, in fact, were denied any update on their applications. Thus, CVS Caremark is in violation of its own Provider Manual.

The Practices that have received an unsigned denial letter are provided with no recourse for reconsideration other than to wait six months to reapply and pay an additional \$1,500 application fee. This cycle then repeats itself for these unfortunate Practices. Oddly, the denials are unsigned and there is no CVS Caremark phone number or email for the practice to contact. Practices are simply left to figure out what was missing and wait the 6 months. This "Where's Waldo" puzzle is particularly egregious coming from a large integrated PBM and plan sponsor.

A review of the credentialing applications for these Practices yield an undeniable trend on CVS Caremark's part, and clear-cut desire to keep out dispensing physician practices. Where the denials were not based on allegedly missing information, additional common pretextual bases included that Standard Operating Procedures were "not specific to practice." Contrary to CVS Caremark's broad allegations, the Practices' SOPs have been carefully developed, assembled and implemented by the staff at the practice. CVS Caremark never afforded any Practice the ability to challenge such a sweeping and inaccurate statement.

Finally, in a number of instances, CVS Caremark provided no reasons for the denial at all, thereby making it impossible for the Practice to figure out what the alleged deficiency was and to reapply. In these cases, CVS Caremark states "Credentials have not successfully established you as a qualified applicant". Five potential reasons are listed but ultimately state "When the application has been denied, specific reason(s) for the denial will not be disclosed." Practices are left to guess at the reason for denial.

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Moreover, we are prepared to fully demonstrate CVS Caremark's abusive and discriminatory practice. Briefly highlighted below are just some of the many egregious examples of CVS Caremark's intentional slow rolling or pretextual denial of practices:

- One application was submitted in May 2019. After many weeks of waiting, more information was requested by CVS Caremark (despite the fact that the practice had already supplied the very information in its original application); the practice re-applied in August 2019 and a full five months later CVS Caremark requested proof of HIPAA training of employees (even though the training was current at the time of the application submission). The practice supplied proof of the training and was informed that the application review would take an additional 10-12 weeks for an answer. Many months later, the practice has yet to receive a response from CVS Caremark.
- One application was submitted in August 2019. The Practice, which is ACHC accredited, has heard nothing back (substantive or otherwise) from CVS Caremark in over 11 months, despite repeated documented emails which have been ignored.
- Another Practice applied in December 2019. CVS Caremark acknowledged receipt of the application, but the Practice has heard nothing back (substantive or otherwise) from CVS Caremark in over 8 months. Emails to CVS Caremark from the practice regarding the application status have been ignored.
- Another practice applied in July 2018. The application was denied as "incomplete" in September 2018. The application was re-submitted, and again denied in July 2019. There were no communications from CVS Caremark to the practice to submit additional documents. No reason was provided for the denial. The practice has not reapplied a third time as it has been unable to identify what the basis for the denial was.

Again, these are just a few examples of the improper pattern on the part of CVS Caremark to effectively exclude an entire class of providers that are otherwise entitled to participate in CVS Caremark's pharmacy networks.

IV. FEDERAL AND STATE LAW COMPELS CAREMARK TO PERMIT THE PRACTICES TO PARTICIPATE IN ITS PHARMACY NETWORKS

CVS Caremark's conduct and exclusionary efforts are wholly improper and violate an array of Federal and State Laws, including CMS requirements and State Any Willing Provider Laws, as detailed below. Far beyond the financial implications to these physician practices, these actions affect patient access and choice. As a multitiered healthcare conglomerate, CVS Health is a direct competitor to the Practices, and stands to benefit directly by unduly narrowing the networks and excluding an entire class of trade from gaining admission to CVS Caremark's networks. In this vein, the narrowing of dispensing networks 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 any intentional delay – which essentially constitutes exclusion – from Medicare networks. Further, CVS Caremark's exclusion of the 35 practices below from its pharmacy networks is a blatant violation of the federal Any Willing Provider Law ("AWPL") and the Medicare Patient Freedom of Choice Law ("MPFC"). Pursuant to 42 U.S.C. §1395w-104(b)(1)(A), the AWPL requires CVS Caremark to permit the participation of any provider that meets the terms and conditions under the plan. CVS Caremark's refusal to admit the 35 practices into its pharmacy networks despite their willingness to comply with CVS Caremark's terms and conditions plainly violates the AWPL. CMS has explicitly commented on the ability of dispensing physician practices to duly participate in Medicare Part D networks and has dispelled any supposed reinterpretation of requirements by CVS Caremark. Further, the MPFC guarantees Medicare beneficiaries the right to obtain health services from any provider qualified to participate in Medicare. *See*, 42 U.S.C. § 1395a. CVS Caremark's refusal similarly constitutes a clear-cut violation of the MPFC.

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In addition to violating the AWPL and the MPCF, CVS Caremark's policy of wrongfully excluding dispensing physician is impermissible under the Administrative Procedures Act ("APA") as codified in 5 U.S.C. § 706, et seq. As set forth in the APA, a reviewing court shall hold unlawful and set aside agency action that is conducted without the observance of procedure required by law. 5 U.S.C. §706. Caremark's policy of excluding physician dispensers from its Medicare Part D pharmacy networks constitutes "agency action" under the APA; however, such agency action was conducted without observance of the procedures required by law, i.e. notice and comment rulemaking pursuant to 5 U.S.C. § 553. As a result, CVS Caremark's policy also constitutes a violation of the APA, and a reviewing court will undoubtedly hold the policy unlawful and enjoin CVS Caremark from further enforcement of the policy.

Further, CVS Caremark's failure to admit these Practices is evidence of a systematic denial of providers that otherwise satisfy required network terms and conditions in an attempt to acquire, enhance, and maintain its monopoly power in the market, in violation of Section 2 of the Sherman Act. 15 U.S.C. § 2.

Even further, CVS Caremark's actions are a clear-cut breach of each and every contract CVS 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 CVS Caremark must contain language obligating CVS Caremark to abide by all applicable federal laws and regulations, including the AWPL. As a result, these 36 Practices have inherent rights against CVS Caremark as third party beneficiaries under such agreements.

V. CONCLUSION

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 CVS Caremark to forge a workable solution for each of the 36 affected Practices. 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 antitrust violations, violations of state law, and common law claims such as tortious interference with prospective economic advantage, violation of any willing provider laws and violation of unfair trade and competition laws. The Practices are prepared to seek any all other legal and equitable relief to which they are entitled, including attorneys' fees.

The power of PBMs to restrict the classes of "in network" providers clearly alters patient care and the healthcare landscape. Despite these overarching legal principles, CVS Caremark continues to block network access to dulyqualified practices, and benefits financially from this restricted network. Only three PBMs control network access for more than 76% of the covered lives in the United States. CVS Caremark controls 30% of all prescription claims and is one of the largest Part D payors.¹ Network access is critical.

In light of the serious issues set forth in this letter, we would expect and appreciate a prompt response from CVS Caremark. If we do not hear a response from CVS Caremark by September 30, 2020, the Practices will assume that CVS Caremark 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.

¹ 2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. Drug Channels Institute. Available at http://drugch.nl/pharmacy



Very truly yours,

FRIER & LEVITT, LLC

/s/ Jonathan Levitt

Jonathan E. Levitt, Esq.

cc: Hon. Alex Azar, Secretary of Health and Human Services
Seema Verma, Administrator, Centers for Medicare & Medicaid Services
Hon. Richard Neal, Chair, House Committee on Ways and Means
Hon. Frank Pallone, Chairman, Committee on Energy and Commerce
Hon. Chuck Grassley, Chairman, U.S. Senate Committee on Finance
Hon. Kevin Brady, Ranking Member, House Committee on Ways and Means
Hon. Greg Walden, Ranking Member, House Committee on Energy and Commerce
Hon. Ronald Wyden, Ranking Member, U.S. Senate Committee on Finance
Ted Okon, Executive Director, Community Oncology Alliance



Exhibit A

List of Represented Practices

- 1. Advanced Urology (NCPDP 0624355)
- 2. Advanced Urology of the Pee Dee (NCPDP 4235479)
- 3. Urology Associates of the Central Coast (NCPDP 5656395)
- 4. Rockford Urologic Associates (NCPDP 1492305)
- 5. Associated Urologists of North Carolina (NCPDP 3471389)
- 6. Urology Health Center, PC (NCPDP 5656395)
- 7. First Urology (NCPDP 1565792)
- 8. North Georgia Urology Clinic (NCPDP 1167572)
- 9. The Urology Group (NCPDP 2592271)
- 10. Urological Associates of Savannah (NCPDP 1169285)
- 11. Urology Associates of Mobile PA (NCPDP 0143507)
- 12. San Bernardino Urology Associates (NCPDP 5664657)
- 13. Urology Associates of Nashville (NCPDP 4447238)
- 14. Kansas City Urology (NCPDP 1722087)
- 15. Urologic- Urology Professional Association (NCPDP 2592358)
- 16. Spokane Urology (NCPDP 4938633)
- 17. The Urology Center (NCPDP 2819730)
- 18. North West Georgia Urology Associates (NCPDP 1166722)
- 19. Carolina Urology Partners (NCPDP 3465110
- 20. Wisconsin Institute of Urology (NCPDP 5137129)
- 21. Urology Specialists of the Carolinas (NCPDP 3465095)
- 22. MidLantic Urology (NCPDP 6007632)
- 23. Cape Girardeau Urology Associates (NCPDP 2645806)
- 24. Urology Nevada (NCPDP 2994982)
- 25. Adult Pediatric Urology & UroGyn (NCPDP 2818992)
- 26. Golden Gate Urology (NCPDP 5662425)
- 27. NEO Urology (NCPDP 3683895)
- 28. Advanced Urologic Institute of Georgia (NCPDP 1172496)
- 29. Advanced Prostate Cancer Institute- Mclver Clinic (NCPDP 5738969)
- 30. Potomac Urology Clinic (NCPDP 4847868)
- 31. Urology of St. Louis (NCPDP 2643117)
- 32. Siouxland Urology Associates (NCPDP 4354914)
- 33. Freemont Urology Health (NCPDP 2819881)
- 34. Urology & Oncology Specialists, PC (NCPDP 0141591)
- 35. Urology Centers of Alabama (NCPDP 0140070)