



*Division of Vascular Surgery*

September 1, 2021

Ms. Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1751-P  
P.O. Box 8016  
7500 Security Boulevard  
Baltimore, MD 21244-8016

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

Re: File Code CMS-1751-P; Medicare Program; CY 2022 Payment Policies under the Physician Payment Schedule and Other Changes to Part B Payment Policies; (July 23, 2021)

Dear Administrator Brooks-LaSure:

My name is Mark Iafrati, MD. I am a Board-Certified Vascular Surgeon who works in Nashville TN, taking care of patients with venous disease.

I am writing regarding the Centers for Medicare and Medicaid Services (CMS) 2022 Physician Fee Schedule (PFS) proposed rule, released on July 13, 2021, which in its present form will result in cuts as high as 20% to critical services I perform in my non-facility office-based vein clinic. If these cuts are implemented on January 1, 2022, I will find it difficult to keep my non-facility office-based vein clinic open.

Venous disease is believed to be present in about 1/3 of US adults. A typical case in my practice is a 70 year old man who is active and generally healthy. He notes that he has had varicose veins on both legs for many years. He has used compression stockings which have allowed him to remain active though the skin in his lower legs has darkened and a few months ago he developed and ulceration. He has been seeing a wound specialist who has been doing weekly wound scraping(debridement) and providing various wound care products in addition to compression wraps but the wound has not improved. He has had to cut back on his walking to elevate his feet and he needs to take over the counter pain medications every day for pain relief. His sleep is impacted, and he has just finished a course of antibiotics for a leg infection (cellulitis).

Data reveals that early intervention (ie. Scheduled within 2 weeks) results in faster healing than delayed surgery. Office procedures are uniformly easier to schedule. In many practices scheduling time for hospital based surgery can be up to 2 months whereas office based procedures are commonly accomplished within 1-2 weeks of approval.

In 2019 in the US, these procedures were performed 170,260 times in Medicare patients. Among these “Vein Ablation” procedures >90% were performed in the office setting. While excellent outcomes can be achieved in any approved site of service the overwhelming predominance of office based procedures for vein ablations is a testament to the excellent patient experience and effective resource utilization of this system.

Unfortunately, many of the offices where these procedures are currently performed are at risk of closing if the proposed PFS is enacted as written. If that were to occur and the patients were to seek care in hospital outpatient facilities, access to hospital based surgeons and operating rooms which is already delayed would certainly become much worse. In addition, the costs to CMS and to our patients (co-Pays) would increase dramatically. Using the 2021 rates and looking at Radiofrequency ablation the Office (non-facility) CMS global rate is \$1,317 whereas the Hospital outpatient fee for the facility + physician = \$3,145. With many patients responsible for 20% of Medicare charges we would have nearly triple the cost to Medicare and to the patient for a service that is generally less convenient and less accessible. This all assumes that our patient was able to eventually access this important, if more expensive, care at their local hospital. The reality is that a significant though undefined portion of patients would Not get the care they need and would suffer unnecessarily.

Understanding the many advantages of office based procedures, many “non facility” offices have made the investment in this equipment, infrastructure, and specialized staffing to be able to offer this advanced care in an office setting. Controlling all aspects of the managing of the non facility office allows for more timely access to care with shorter waiting times. More timely access to care in the case of venous leg ulcers reduces the time for the ulcers to heal and thus reduces pain and suffering.

While reflux in the leg veins is the most common venous disease, the patient noted above could also have had blockage of the iliac vein which drains the affected limb. Catheter based treatments with intravascular ultrasound (IVUS) and stenting are effective and increasingly performed in office based labs. Again implementation of the proposed cuts would may make it impossible for me to continue to offer these vitally important procedures in my non-facility site. Again this has the potential for a marked increase in per case expenditures if cases move from the non-facility site to hospital outpatient. In this case for IVUS (37252) plus Venous stenting (37238) the CMS payment schedule in 2021 is \$4,289 vs \$10,133, Again more than higher cost for CMS, higher co-pays for patients, less convenience, and less access to care.

The upcoming 20% cuts in Medicare reimbursement for vein procedures performed in non-facility office based vein centers will result in a shift of vein care from the office based setting to the hospital setting increasing cost and decreasing access. PLEASE DO NOT IMPLEMENT the proposed Medicare cuts.

Sincerely,



Mark Iafrati MD  
Board Certified Vascular Surgeon