September 13, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
ATTN: CMS-1751-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: **[CMS-1751-P] Medicare Program: CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; et al.**

Dear Administrator Brooks-LaSure:

The American Venous Forum (AVF) greatly appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the Physician Fee Schedule (PFS) Proposed Rule for Calendar Year (CY) 2022 (CMS-1751-P).[1] Our comments focus on the proposed update to the wage data used to determine clinical labor costs under the PFS. We understand and support CMS' determination that the wage information needs to be updated. However, we are extremely concerned that the unintended downstream consequences of the proposed update will have a devastating impact on the ability of vein specialists to care for Medicare beneficiaries with vein disease in the office setting. Below we describe that impact and recommend that CMS delay the wage update.

I. Background on the AVF, Vein Disease and Patients Affected

The AVF was established in 1987 with the mission to advance science, education, and advocacy in venous and lymphatic disease. We currently represent approximately 800 members who are primarily vascular surgeons although our membership also includes a variety of other specialties such as interventional radiologists, general and cardiac surgeons, and family practitioners Our members work in academic and private practice and deliver care in hospital and non-facility sites of service.

Vein disease is believed to be present in about 1 out of every 3 adults in the United States with the disease affecting approximately 15 million Medicare beneficiaries. The most advanced manifestation of vein disease is skin ulceration, which

[1] 86 Fed. Reg. 39104 (July 23, 2021).

occurs in about 2 million Americans over the age of 65. Patients with venous leg ulcers require daily home wound care (there is often a need for a visiting nurse) and weekly visits to a wound specialist which may include painful debridement of the ulcer. Complications include significant wound drainage, local infections and systemic infection which may require hospital admission. Once healed, these patients have a high risk of ulcer recurrence (60%).

In addition, older patients with vein disease who do not have ulcers suffer from quality-of-life issues that affect their ability to care for themselves and their loved ones. Patients experience symptoms of: pain, throbbing, swelling and aching on a daily basis. They need to elevate their legs during the day, take pain medication and don support stockings. Many cannot do this due to co-morbid conditions such as arthritis or lower back issues. They cannot ambulate as far or as long and need to curtail their daily activities.

Studies have shown that racial disparities play an important role in the care of patients with venous disease with outcomes affected by race.[2] African American patients are noted to present with more advanced disease at younger age and more frequently present with skin changes and active ulcers compared with white patients. African American patients also have been found to have an increased incidence of blood clots, slower ulcer healing, higher ulcer recurrence rates, as well as the need for repeated ulcer debridement and hospitalization with the consequent increase in cost of care. All the data indicate that racial disparities impact initial presentation and diagnosis, cost of care, and long-term outcomes as related to venous disease. Lower socioeconomic status with attendant poor nutrition has also been shown to affect presentation, severity, increased rates of recurrent ulceration, delayed time to healing, and high cost of care have been shown in these disadvantaged groups.

While non-operative care, including dressing care and compression wraps, show clear benefit in patients with vein disease, it is often necessary to treat the underlying venous pathology with minimally invasive surgical procedures in order prevent recurrent disease. Most venous disease can be divided into problems related to venous reflux resulting from poorly functional or absent vein valves (resulting in pooling of blood in the veins of the leg) or from obstruction to venous flow from venous compression or prior clots. In either case the result is increased venous pressure, stagnant flow, with the sequelae mentioned above. Chronic vein disease has a significant burden to society.

Common treatments for these debilitating diseases address one or both vein pathologies – reflux or obstruction. When first developed in the late 1990's, these treatments were primarily done in the hospital-setting. In the last 10 – 15 years, care in over 95% of cases has migrated to the office setting with local anesthesia. Advances in technology have allowed shift of care for these patients into the office setting, allowing easier access to care.

[2] Kim Y, Png CYM, Sumpio BJ, DeCarlo CS, Dua A. Defining the human and health care costs of chronic venous insufficiency. Semin Vasc Surg. 2021 Mar;34(1):59-64.

II. Proposal to Update Clinical Wages and Impact on Vascular Procedures

Clinical labor is one of the three direct inputs (along with supplies and equipment) that CMS uses as the basis for PFS rates. The clinical labor costs are estimated using an estimate of the average per hour wage for the clinical staff type that typically performs the task. The data currently used to estimate per hour wages was last updated in 2002. In this rule, CMS proposed to use wage data from 2019 to update the clinical labor direct inputs. The AVF concurs with CMS that an update is long overdue.

However, because the wage update significantly increases labor costs relative to the cost of the other direct inputs, budget neutrality requirements of the proposal cause major changes to the practice expense (PE) RVUs throughout the PFS. Some specialties are impacted more than others. AVF members include physicians in two of the specialties affected the most by this proposal: vascular surgery will see an overall 4 percent decrease in payments from 2021 to 2022 and interventional radiology will see an overall decrease of 5 percent. We note that this estimate is specific to the impact of the proposed clinical labor update and does not take into account the planned 3.75 percent reduction in the conversion factor or the last year of the market pricing adjustments to supply and equipment costs that began in 2019. The total estimated impact of the proposed rule provisions is a reduction in overall allowed charges of 8 percent for vascular surgeons and 9 percent for interventional radiologists who perform a mix of arterial and venous interventions.

More importantly, the specialty level impacts mask the impact of the proposal on many individual physicians. Physicians who perform technology intense procedures in the office setting are disproportionately impacted by the proposed update because it significantly reduces the non-facility payment rates for services that require high-cost equipment or supplies. The table on the following page shows examples of procedures commonly used by our members to treat patients with venous disease, frequently presenting with severe and disabling sequelae up to and including ulceration. These procedures will see cuts of at least 15 percent with most CPT codes greater than 20 percent in 2022, if the proposed changes are enacted.

Table 1
Examples of Venous Services with Significant Cuts for 2022

CPT Code	Descriptor	2020 Allowed Services[3]	% Non-Facility[2]	Non-Facility Rate		% Chg
				2022	2021	
36465	Njx noncmpnd sclrsnt 1 vein	35,418	99%	$1,205	$1,545	**-22.0%**
36466	Njx noncmpnd sclrsnt mlt vn	13,964	98%	$1,344	$1,724	**-22.0%**
36473	Endovenous mchnchem 1st vein	6,151	98%	$1,120	$1,441	**-22.3%**
36475	Endovenous rf 1st vein	79,702	92%	$1,016	$1,318	**-22.9%**
36478	Endovenous laser 1st vein	36,226	93%	$933	$1,108	**-15.8%**
36482	Endoven ther chem adhes 1st	40,699	95%	$1,517	$1,941	**-21.8%**
37238	Open/perq place stent same	9,273	52%	$3,129	$3,977	**-21.3%**
37241	Vasc embolize/occlude venous	1,655	23%	$4,268	$5,159	**-17.3%**

The services in **Table 1** account for more than 80 percent of the typical work performed by a vein specialist in the office setting.

The negative impact on services for which the majority of the direct input costs are supplies or equipment is because the financial pool of direct inputs is fixed. Increasing the cost of clinical labor decreases the share of the pool attributed to supplies and equipment and requires a more significant scaling adjustment to maintain budget neutrality. The wages used to determine the labor costs increased for almost all labor categories and for most categories the increase was more than 60 percent. As the AMA-RUC noted in their comments on the proposed rule, the increase in labor costs requires a more significant scaling adjustment to keep practice expense budget neutral. This scaler reduces the adjusted cost for equipment and supplies, which unlike labor costs are not generally higher under the proposed rule than in 2021. Under CY2022 proposed rule non-physician labor is 53 percent of total direct costs across all specialties; for vascular surgery it is only 18 percent. Therefore, more than 80 percent of vascular surgery direct costs are negatively impacted in the direct PE scaling adjustment. We agree with the AMA -RUC that this puts an unfair burden on specialties, such as vein specialists, who require higher cost equipment, supplies and skill level of office staff to treat their patients.

In addition to accounting for a larger share of the direct inputs, clinical labor also has greater impact on indirect PE allocation than other direct inputs because clinical labor is used as a separate allocator for non-physician work services.

[3] Allowed Services and non-facility percentage calculated from 2020 utilization data used to develop the 2022 MPFS proposed rule.

This adjustment dramatically increases the number of services with highly anomalous PE rates. In 2021, there were fewer than 10 codes with PE rates that exceeded the price of supply direct inputs for the service. Under the proposed rule, there would be more than 100 such codes (a 1,000 percent increase), including a number of important venous/vascular procedures (**see Table 2**).

Table 2
Examples of Vascular Codes with Proposed PE Rates Less than Supply Costs

CPT Code	Descriptor	Total Supply Input Costs	Proposed Non-Facility PE Rate	% Supply Costs Exceed PE Rate
36465	Njx noncmpnd sclrsnt 1 vein	$1,252	$1,111	**-12.7%**
36466	Njx noncmpnd sclrsnt mlt vn	$1,277	$1,225	**-4.3%**
36473	Endovenous mchnchem 1st vein	$1,132	$980	**-15.5%**
36482	Endoven ther chem adhes 1st	$1,652	$1,376	**-20.1%**
37238	Open/perq place stent same	$3,463	$2,886	**-20.0%**
37241	Vasc embolize/occlude venous	$4,153	$3,931	**-5.6%**

The PE rate is so inadequate that after paying for supplies a practice would essentially be unable to cover clinic labor, equipment, or indirect costs required for these services.

The proposed rates will threaten the continued viability of the approximately 700 non-facility vein/vascular practices in the United States. In some instances, those services may shift to facility settings such as the hospital outpatient department or ambulatory surgical centers (ASCs). Unfortunately, COVID has limited access to hospital and ASC care in many areas, especially for non-emergent procedures. Therefore, the lack of access to office-based procedures may result in some Medicare beneficiaries being unable to receive needed care because hospitals and ASCs can simply not meet the higher demand. To the extent services are shifted to hospitals and ASCs, the result could be higher spending by Medicare since many of these services have facility rates that are two to three times the PFS rates.

We also note that the non-facility site of service provides Medicare beneficiaries with several advantages. Office-based vein centers provide a source of care in the local community that allow earlier access to care and are easier to navigate than hospital complexes. In-office care typically is more efficient (90 minutes of total service time vs 4 hours in the hospital setting), involves less anesthesia and fewer pre-op labs, and probably lower cost. The populations that will be at greatest risk from reduced access to physician office care are minority, underserved, and rural populations that are most at risk for vascular disease as these communities often include Native American, African American, and Latino populations. It is clear from the literature that these groups of patients present with advanced disease, have higher recurrence rates and utilize more health care resources.[2] Any reduction in the access to venous care will negatively impact this group of patients the most.

III. AVF Recommends CMS Delay the Proposed Update to Clinical Labor Costs

Due to the extreme negative impact of the update on some services and the impact on many patients especially underserved communities, AVF recommends that CMS delay the proposed update. We note that CMS is considering potential improvements to the allocation of indirect PE to individual services. As presented in a town hall meeting earlier this spring, RAND Corporation is evaluating significant changes in this methodology. These changes include new approaches to allocating indirect costs, updates to indirect cost data, and updates to the specialty level practice expense data used in the PE calculation. We note that the current specialty level data is from roughly the same time period as the wage data that CMS is proposing to update. For this reason alone, CMS should delay incorporation of the more recent wage data until it has contemporaneous data on overall specialty specific practice expenses. Furthermore, when CMS does update the specialty specific PE data, it should ensure that a representative sample of physicians who perform venous procedures in the office setting are included. This would result in using contemporaneous data sets for wages and overall practice expenses which would be more reliable when used to revise the indirect PE allocation methodology.

In conclusion, while we agree the wage data needs to be updated, we recommend that the update occur as part of a more global and inclusive update to the indirect PE methodology. The broader update should include changes that could offset some of the drastic cuts predicted at the individual service level if clinical labor were to be updated alone. This would lead to greater stability in rates overall and reduce the potential for whipsawing rates. Delaying the update will best maintain the ability for physicians and CMS to offer vascular services to our (CMS and AVF) most vulnerable patients and avoid further reducing access to care during the COVID-19 PHE.

Thank you for the opportunity to submit these comments. We would be pleased to answer any questions you may have.

Sincerely,

Antonios Gasparis, MD

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