September 6, 2022

Submitted electronically via: http://www.regulations.gov

The Honorable Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services
Attention: CMS–1770–P
7500 Security Boulevard
P.O. Box 8016
Baltimore, MD 21244-8016

Re: CY 2023 Physician Fee Schedule Proposed Rule

Dear Administrator Brooks-LaSure:

The Outpatient Endovascular and Interventional Society (OEIS) appreciates the opportunity to offer its comments to the Centers for Medicare and Medicaid Services (CMS) on the proposed rule for the CY 2022 Physician Fee Schedule (CMS-1770-P).[1] OEIS is a society of over 700 vascular surgeons, interventional cardiologists and interventional radiologists, all dedicated to promoting safe, appropriate, effective, and accessible outpatient care. OEIS is the voice for outpatient and office interventional suites, working to enhance the safety, quality and patient satisfaction of outpatient endovascular procedures. OEIS also develops standards of practice for the operation of outpatient endovascular and interventional cases.[2]

OEIS appreciates this opportunity to comment on the proposed regulations. As discussed in further detail below, OEIS states at the outset that ongoing cuts to office-based specialists under the Physician Fee Schedule are contributing to office-based center closures, health system consolidation and, as a result, undermining this Administration's efforts on addressing health equity issues.

This letter will comment on the following issues:

- Ongoing Cuts to Office-Based Specialists Cause Center Closures
- 2023 PFS Proposed Rule Continues Historical Cuts to Office-Based Specialists
- Principles and Options for PFS Reform
- Developing a Limb Salvage MVP

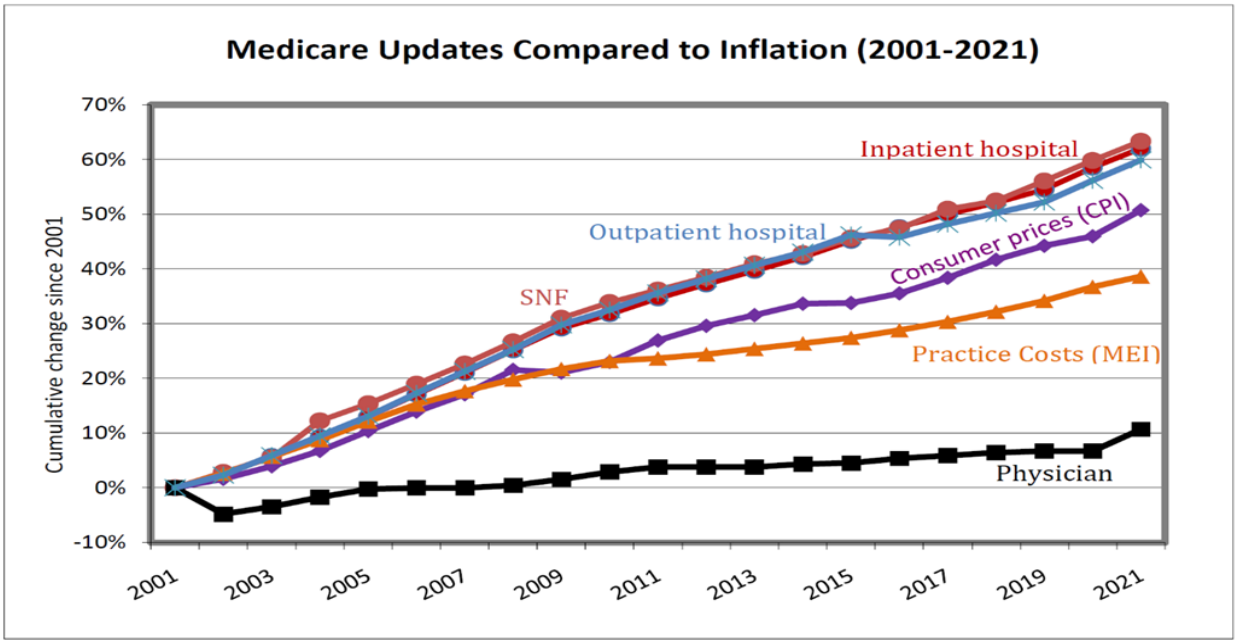
[1] Federal Register, 87 FR 45860 (July 29, 2022)
[2] For more information about OEIS, please see https://oeisociety.com/

I. ONGOING CUTS TO OFFICE-BASED SPECIALISTS CAUSE CENTER CLOSURES

While "budget-neutrality" sounds like good policy, when it operates within a Physician Fee Schedule that has not kept up with inflation, it results in massive swings in reimbursement and punishes providers irrespective of the value they add to the healthcare system. This is because, while reimbursement under the overall Physician Fee Schedule has increased 11 percent over the last two decades, the cost of running a medical practice has increased 39 percent over that same period (see AMA's "Medicare Updates Compared to Inflation" chart below).

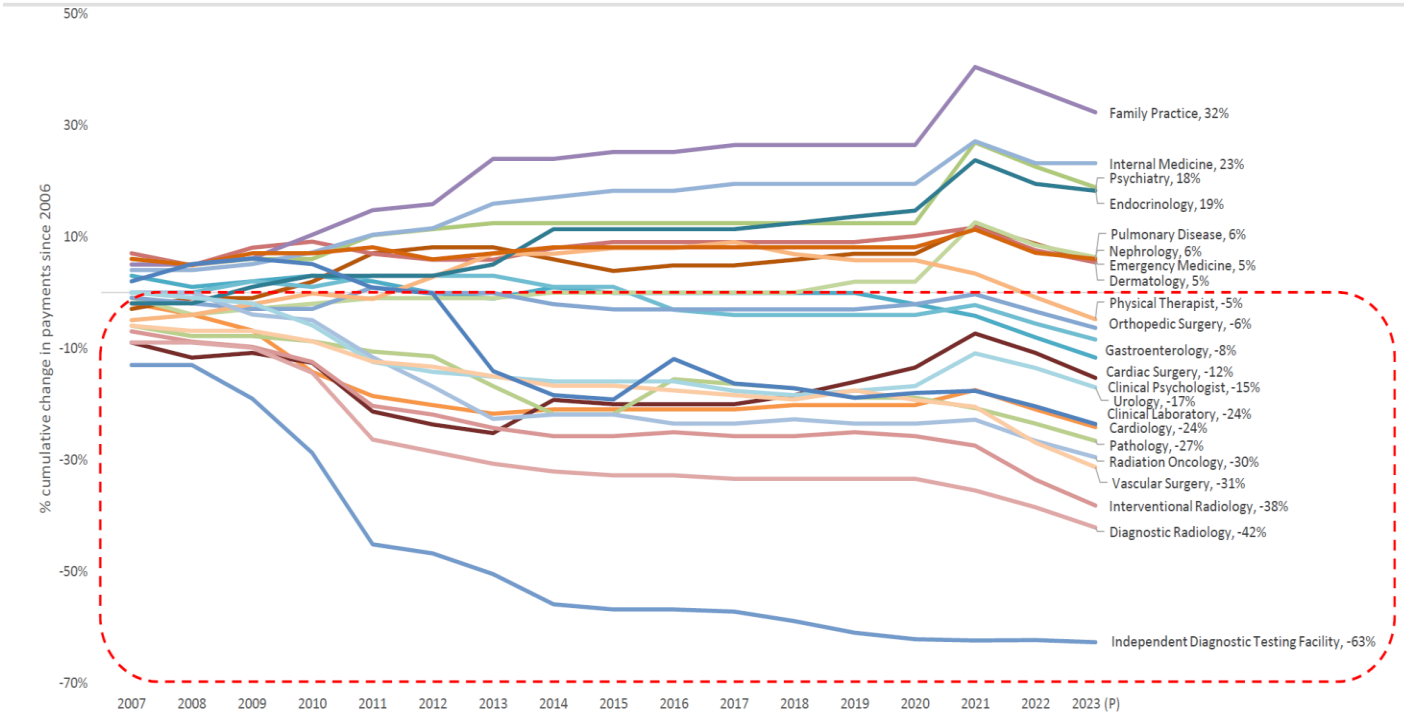
As a result of budget-neutralizing an underfunded system, the 2021 Physician Fee Schedule (PFS) Rule cut the conversion factor by 10% after an update to E/M data, which had a disproportionate impact on non-primary care providers. For example, physical therapists, who make on average roughly $89,000 per year, were cut 9% while primary care providers, who make $241,000 per year, saw a historic increase in reimbursement.[3] Indeed, 2021 PFS cuts were so significant Congress phased them in with the first tranche occurring in 2021, the second tranche occurring in 2022 and the next tranches now set to occur in 2023 (3%) and 2024 (3%).[4]

The 2022 PFS cut office-based specialists still further due to a 24% cut to the PFS direct adjustment factor, again due to so-called "budget-neutrality" provisions relating to an update to clinical labor data. As a result of the 2022 PFS, office-based specialists providing care to patients with cancer, end-stage renal disease, fibroids, as well as limb salvage and venous ulcer needs, will see their reimbursement decreased in some cases by more than 20% through 2025 on top of other aforementioned cuts to the conversion factor. Moreover, it is critical to understand that for many office-based specialists, these cuts also come on top of still further cumulative cuts of up to 60% since 2006 (see HMA's "Significant Specialty Variation" chart below).



Sources: Federal Register, Medicare Trustees' Reports and U.S. Bureau of Labor Statistics

[3] Primary care has kept up with practice costs (e.g. family practice has seen cumulative PFS increases of 36% since 2006). It is non-primary care providers, particularly those utilizing innovative technologies, which have been most impacted by the underfunding of practice costs in the PFS..
[4] Cuts were phased-in through H.R. 133 in 2020 and S. 610 in 2021.

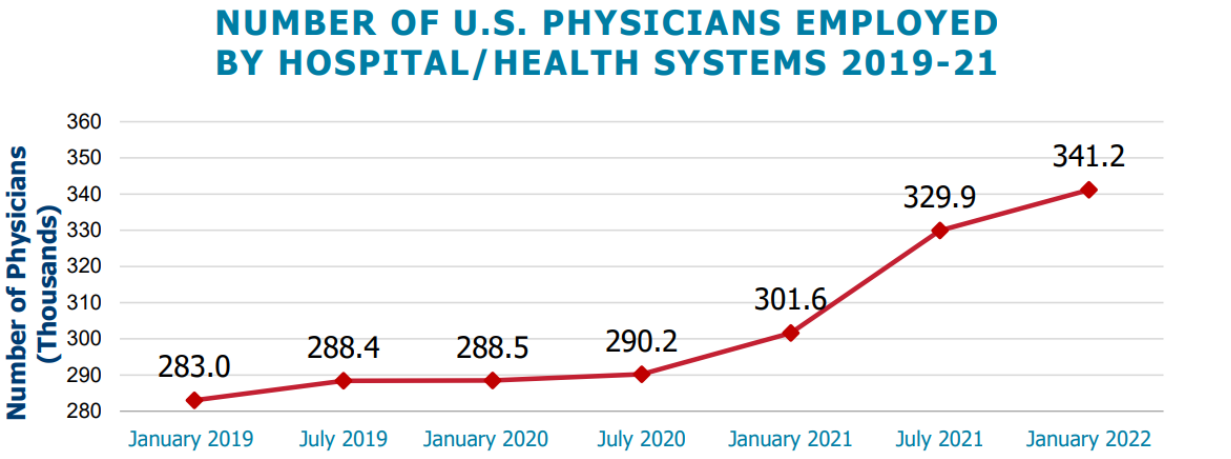


Ongoing Cuts to Office-Based Specialists as a Driver of Health System Consolidation

While President Biden's *Executive Order on Promoting Competition in the American Economy* makes it clear that this Administration is concerned with health system consolidation, the 2023 PFS Proposed Rule serves to undercut this initiative. **According to the American Medical Association, the share of physicians working for a hospital increased from 29.0 percent in 2012 to 39.8 percent in 2020.**[5] The ongoing pandemic also has accelerated these trends with hospitals and acquiring 58,200 additional physicians over the last three years (see chart on next page).[6] Given that the reimbursement for medical specialties is, on average, $178,000 more in a vertically integrated health system, the incentive is clear for beleaguered **PFS providers who may no longer be able to sustain further cuts in the 2023 PFS Proposed Rule to simply close their centers and continue the migration to large health systems.**[7] As noted by the Medicare Payment Advisory Commission (MedPAC), "the preponderance of evidence suggests that hospital consolidation leads to higher prices."[8]

[5] American Medical Association, *Recent Changes in Physician Practice Arrangements: Private Practice Dropped to Less Than 50 Percent of Physicians in 2020*, Carol K. Kane, PhD, June 2021
[6] Physicians Advocacy Institute, *Covid-19's Impact on Acquisitions of Physician Practices and Physician Employment*, April 2022 [Prepared by Avalere]
[7] Post, Brady PhD et al., *Hospital physician integration and Medicare's site-based outpatient payments*, Health Serv Res. 2021;56:7 15
[8] Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy*, March 2022

National Trends: Sharp Uptick in Physician Hospital Employment in Months Following Onset of Pandemic



- **58,200** additional physicians were employed by hospitals over the three-year study period – **51,000** of that shift occurred after the onset of COVID-19
- Physician employment grew in each of the six 6-month periods analyzed
- There was a **9.7% increase** in the growth rate of hospital-employed physicians following the onset of COVID-19

Avalere analysis of IQVIA OneKey database that contains physician and practice location information on hospital/health system ownership

Due to ongoing cuts under the Physician Fee Schedule, office-based providers are left with a limited set of options: (1) close their office, (2) join a hospital or (3) convert to an ASC. However, due to up-front costs, CON laws, business licensure, etc., setting up an ASC is impossible in many areas. For example, 35 states have certificate-of-need requirements for ASCs which often means a physician office alternative is the only possible non-hospital vascular access option in many states. As a result, (1) service migration to a hospital or (2) office-based center closure actually are the only true options and office-based center closures are indeed ongoing.

A 2022 joint study by the Outpatient Endovascular and Interventional Society / American Vein & Lymphatic Society to examine the effects of the COVID-19 pandemic and decreased Medicare physician payments found that 27% of respondents were likely or very likely to close their interventional practice within the next two years. **Reducing the availability of office-based revascularization access services through ongoing cumulative cuts of more than 20% to key revascularization codes (e.g. 3722x – 3723x codes) will almost certainly result in**

further office-based center closures and increased amputation rates. Given that the reimbursement for medical specialties is, on average, $178,000 more in a vertically integrated health system, the incentive is clear for beleaguered **PFS providers who may no longer be able to sustain further cuts in the 2023 PFS Proposed Rule to simply close their centers and continue the migration to large health systems.**[9] As noted by the Medicare Payment Advisory Commission (MedPAC), "the preponderance of evidence suggests that hospital consolidation leads to higher prices."[10]

Ongoing Cuts to Office-Based Specialists as a Driver of Health Inequities

The proposed cuts in the 2023 PFS Proposed Rule will have profoundly negative effects on health equity. While the Administration has launched a number of initiatives aimed at addressing health inequity through the elimination of disparities in health care, the 2023 PFS Proposed Rule actually threatens to undermine these initiatives in areas throughout the PFS by continuing to phase in the 2022 PFS clinical labor cuts. The table below highlights code reductions contained in the 2022 PFS Proposed Rule. While CMS decided to phase-in these cuts over four years, this just delays the ultimate impact to these services until 2025.

Disease/Service	**Health Inequity**	**2022 PFS**
Venous Ulcer / Endovenous radiofrequency ablation	Black patients present with more advanced venous insufficiency than White patients[11]	Key Code (36475) Cut by 23%
ERSD / Dialysis Vascular Access	Black and Latino patients start dialysis with a fistula less frequently despite being younger[12]	Key Code (36902) Cut by18%
Cancer / Radiation oncology	Black men are 111 percent more likely to die of prostate cancer; Black women are 39 percent more likely to die of breast cancer[13]	Key Code (G6015) Cut by 15%
Peripheral Artery Disease / Revascularization	Black Medicare beneficiaries are three times more likely to receive an amputation[14] Latinos are twice as likely[15]	Key Codes (37225-37221) Cut by 22%
Fibroid / Uterine Fibroid Embolization	Uterine fibroids are diagnosed roughly three times more frequently in Black women[16]	Key Code (37243) Cut by 21%

Ongoing Cuts to Office-Based Specialists Weaken Our Nation's Pandemic Response

Ongoing cuts to office-based specialists under the PFS also are weakening our healthcare system's ability to deal with the ongoing COVID-19 pandemic. A key lesson from the pandemic is that it is critical that hospitals have sufficient resources to care for their sickest patients. Yet

[9] Post, Brady PhD et al., *Hospital physician integration and Medicare's site-based outpatient payments*, Health Serv Res. 2021;56:7 15
[10] Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy*, March 2022
[11] Vascular and Endovascular Surgery, *Advanced Chronic Venous Insufficiency: Does Race Matter?*, 26 December 2016
[12] *Racial/Ethnic Disparities Associated With Initial Hemodialysis Access*. JAMA Surg.2015 Jun;150(6):529-36. doi: 10.1001/jamasurg.2015.0287
[13] Cure, *Cancer Sees Color: Investigating Racial Disparities in Cancer Care*, Katherine Malmo, 16 February 2021
[14] Dartmouth Atlas, *Variation in the Care of Surgical Conditions: Diabetes and Peripheral Arterial Disease*, 2014
[15] J. A.Mustapha, *Explaining Racial Disparities in Amputation Rates for the Treatment of Peripheral Artery Disease (PAD) Using Decomposition Methods*, J. Racial and Ethnic Health Disparities (2017) 4:784–795
[16] University of Michigan, *Understanding Racial Disparities for Women with Uterine Fibroids*, Beata Mostafavi, 12 August 2020

other patients dealing with cancer, end-stage renal disease, coronary disease, and other post-acute issues cannot wait for the cancer care, dialysis vascular access repair, imaging, physical therapy, etc. that is critical to keeping them alive or out of the hospital.[17][18] Office-based care under the PFS provides a critical site-of-service outside of the hospital to deal with non-COVID cases so hospitals can focus on a resurging pandemic; ongoing cuts to PFS providers threaten the viability of the critical office-based setting during the COVID-19 pandemic.

II. 2023 PFS PROPOSED RULE CONTINUES HISTORICAL CUTS TO OFFICE-BASED SPECIALISTS

The 2023 PFS Proposed Rule continues these historical cuts to office-based specialists by reducing the 2023 Medicare conversion factor by about 4.5% from $34.6062 to $33.0775. This is largely a result of:

- The expiration of the 3% increase to the conversion factor at the end of calendar year 2022 pursuant to S. 610.
- Yet another round of budget neutrality related cuts from revaluations of EM codes families, including hospital, emergency medicine, nursing facility and home visits. These changes are estimated to require an additional reduction of about 1.5% to the 2023 Medicare conversion factor due to statutory budget neutrality requirements.

In addition, CMS is continuing with the second year of the 2022 clinical labor policy which adds additional cuts to revascularization providers of another 4.5% so that these particular office-based specialists will be subject to cuts of up to 9% in 2023 alone.

[17] See, for example, the March 2020 CMS "Adult Elective Surgery and Procedures Recommendations," which listed several "do not postpone" procedures such as most cancers, cardiac patients with symptoms, limb threatening vascular surgery, etc.
[18] See also August 2020 CMS "Key Components for Continued COVID-19 Management for Dialysis Facilities," which effectively lists dialysis vascular access as a "do not postpone" procedure.

		2022 Final PFS (post S. 610)		2023 Proposed PFS		2023 Proposed RVU Difference	2023 Proposed Payment Difference
CF			34.61		33.08		
Revascularization							
CPT	Procedure Description	2022 Non-Facility Total RVU/Unit **(Final)**	2022 Non-Facility Total Payments **(Final)**	2023 Non-Facility Total RVU/Unit **(Proposed)**	2023 Non-Facility Total Payments **(Proposed)**	2023 Proposed vs 2022 Final	2023 Proposed vs 2022 Final
37220	Iliac revasc	78.27	$2,709	75.57	$2,500	-3%	-8%
37221	Iliac revasc w/stent	96.58	$3,342	92.98	$3,076	-4%	-8%
37222	Iliac revasc add-on	18.92	$655	18.46	$611	-2%	-7%
37223	Iliac revasc w/stent add-on	39.91	$1,381	38.39	$1,270	-4%	-8%
37224	Fem/popl revas w/tla	91.57	$3,169	88.16	$2,916	-4%	-8%
37225	Fem/popl revas w/ather	276.03	$9,552	264.61	$8,753	-4%	-8%
37226	Fem/popl revasc w/stent	257.50	$8,911	246.34	$8,148	-4%	-9%
37227	Fem/popl revasc stnt & ather	353.69	$12,240	338.99	$11,213	-4%	-8%
37228	Tib/per revasc w/tla	130.22	$4,506	125.22	$4,142	-4%	-8%
37229	Tib/per revasc w/ather	279.39	$9,669	268.97	$8,897	-4%	-8%
37230	Tib/per revasc w/stent	281.17	$9,730	269.28	$8,907	-4%	-8%
37231	Tib/per revasc stent & ather	366.87	$12,696	355.82	$11,770	-3%	-7%
37232	Tib/per revasc add-on	25.40	$879	24.68	$816	-3%	-7%
37233	Tibper revasc w/ather add-on	31.83	$1,102	31.30	$1,035	-2%	-6%
37234	Revsc opn/prq tib/pero stent	113.28	$3,920	109.61	$3,626	-3%	-8%
37235	Tib/per revasc stnt & ather	121.24	$4,196	119.55	$3,954	-1%	-6%
37236	Open/perq place stent 1st	85.82	$2,970	82.62	$2,733	-4%	-8%
37237	Open/perq place stent ea add	40.18	$1,390	38.75	$1,282	-4%	-8%
37238	Open/perq place stent same	107.53	$3,721	104.03	$3,441	-3%	-8%
37239	Open/perq place stent ea add	53.15	$1,839	51.64	$1,708	-3%	-7%
37252	Intrvasc us noncoronary 1st	29.65	$1,026	28.69	$949	-3%	-8%
37253	Intrvasc us noncoronary addl	5.07	$175	5.05	$167	0%	-5%

We are pleased to note that CMS has begun to acknowledge the need to track the viability of office-based specialists. CMS stated in the 2023 PFS Proposed Rule:

- *We have received requests from interested parties for CMS to provide more granular information that separates the specialty-specific impacts by site of service. These interested parties have presented high-level information to CMS suggesting that Medicare payment policies are directly responsible for the consolidation of privately owned physician practices and free-standing supplier facilities into larger health systems. Their concerns highlight a need to update the information under the PFS to account for current trends in the delivery of health care, especially concerning independent versus facility-based practices. In response to interested party feedback, we have recently improved our current suite of public use files (PUFs) by including a new file that shows estimated specialty payment impacts at a more granular level, specifically by showing ranges of impact for practitioners within a specialty.*

While an important first step, we note that there also are many shortcomings with the way the office-based (or "nonfacility") data has been presented, including 1) a lack of historical context and 2) missing data in Tables 139 and 148.

- **Lack of Historical Context.** As shown in the above chart, "Significant Specialty Variation in Estimated Payment Changes," some specialties could experience double digit reductions in payments under the PFS and still be well above the historical average while other specialties already have experienced cuts of 20 to 40% or more. It's important to note that the specialty variation shown in the chart is by specialty and not by site-of-service (as CMS has not historically presented such data). It is likely if CMS had

presented such data historically, it would have shown even worse impacts to office-based specialists.

- **Missing Data in Tables 139 and 148.** While Table 139 appears to show a fairly benign cut of -1% to nonfacility providers and increase of +2% to facility providers, in fact, the table leaves out the 3% cut to the conversion factor that occurs in 2023 due to the expiration of provisions in S. 610. As a result, cuts to office-based providers are closer to -4% overall and facility providers also will be subject to a -2% cut. Similarly, Table 148 appears to show a +2% increase to nonfacility providers and a -4% increase to facility providers but does not include the third tranche of the 3% cuts to the conversion factor to occur in 2024 due to the implementation of G2211 or ongoing clinical labor cuts through 2025. Together these policies likely would result in still further cuts to office-based providers even with the inclusion of considered MEI rebasing and revising by CMS.

In the 2023 PFS Proposed Rule, CMS notes "In light of feedback from interested parties, CMS has prioritized stability and predictability over ongoing updates." However, the historical data and the experiences of the 2021 EM policy resulting in a 10% cut to the conversion factor and the 2022 clinical labor policy resulting in a 24% cut to the direct adjustment factor show that ongoing updates indeed are causing huge unrelated and undeserved cuts to office-based specialists.

REQUEST: We believe it would be best for CMS to truly "prioritize stability and predictability over ongoing updates" and temporarily freeze the implementation of further policy updates – including the clinical labor policy in 2023 through 2025, EM revisions in 2023 and the implementation of G2211 in 2024 – that will result in further significant redistributions to the Physician Fee Schedule and focus on fundamental PFS reform.

III. PRINCIPLES AND OPTIONS FOR PFS REFORM

Given significant funding gaps between practice costs and PFS reimbursement, CMS PFS reform concepts have focused on *practice expense* (PE) RVUs. In June 2021, CMS held a Town Hall on "Improving Practice Expense Data & Methods"[19] where the agency explained:

- PFS Reimbursement = (work RVUs + PE RVUs + MP RVUs) * conversion factor.
- PE RVUs = direct PE RVUs (supplies, equipment and labor) + indirect PE RVUs (administrative, overhead, nonclinical labor, rent, information technology).[20]

We believe PFS reform principles should promote stability, alignment and transparency as it relates to contemplated reforms of direct and indirect practice expenses as follows:

- **Stability.** Medicare providers should have stable reimbursement so they can focus their time on treating patients. Unfortunately, Medicare reimbursement has been particularly unstable in the Physician Fee Schedule for many years. Any new system should promote stability.

[19] https://www.cms.gov/medicare/physician-fee-schedule/practice-expense-data-methods
[20] https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/Test.pdf

- **Alignment Across Ambulatory Settings.**[21] Medicare should reimburse for *direct* practice expenses equally, regardless of setting (HOPD, ASC, or office): a stent used in an office is the same stent used in a hospital; a CT machine used in an ASC is the same machine used in a hospital; a nurse working in an office on Monday and a hospital on Thursday is the same nurse. For *indirect* practice expense, CMS should recognize differential overhead needs by setting (e.g. a typical hospital has more overhead than a typical primary care office).
- **Transparency.** The PFS PE methodology is a 19-step algorithm that is exceedingly complex and opaque and much of the data used in the methodology derives from an AMA RUC process which is not publicly accessible. CMS should promote transparency in any new PFS system.

Applying PFS Reform Principles to Two Distinct Options for PFS Reform

In the 2023 PFS Proposed Rule, CMS notes that it believes, "Of the various PE data inputs, we believe that indirect PE data inputs, which reflect costs such as office rent, IT costs, and other non-clinical expenses, present the opportunity to build consistency, transparency, and predictability into our methodology to update PE data inputs" and notes that the primary source for indirect PE information – the Physician Practice Information Survey (PPIS) – reflects 2006 data. **We disagree and note that the last time the PPIS survey was conducted in 2007/2008, it resulted in yet another huge redistribution in the Physician Fee Schedule.**[22] **Moreover, we believe the *direct* PE portion of the Physician Fee Schedule presents the best opportunity for consistency, transparency, and predictability.**

Two distinct, mutually exclusive, PE related PFS reform options have been proposed in recent years: (1) using new HOPPS data for PERVUs or (2) removing PERVUs from the PFS:

- **Using HOPPS Data for PFS PERVUs.** In a 2021 report, Rand describes using data from the Hospital Outpatient Prospective Payment System (HOPPS) for PFS PERVUs.[23] Due to OPPS "ancillary services," however, CMS either would overstate costs in the PFS if APC values are used or understate cost if CPT values are used. In order to promote reimbursement stability, alignment across ambulatory settings, and transparency, CMS should (1) derive direct costs from HOPPS data in a transparent manner for inclusion in the PFS on an equivalent basis through a new methodology which promotes alignment across settings and (2) exempt this new data from underlying budget-neutrality and other provisions in the PFS. Given that direct costs should be equivalent across settings, we believe the use of HOPPS data should require using HOPPS data at 100% of its HOPPS value (likely requiring a new methodological process).
- **Removing PERVUs from the PFS.** At a 2020 RUC meeting, the AMA RUC recommended CMS separately identify and pay for high-cost disposable supplies.[24] Since 2019, CMS has been using a contractor (StrategyGen) to provide equipment and

[21] MedPAC explored this issue in an April 2022 briefing, "Aligning fee-for-service payment rates across ambulatory settings"

[22] The previous 2007 / 2008 AMA survey resulted in significant cuts to office-based specialties (e.g. cardiology [-13%], interventional radiology [-10%], radiation oncology [-5%]) when incorporated in the 2009 Physician Fee Schedule.

[23] https://www.rand.org/pubs/research_reports/RRA1181-1.html

[24] https://www.ama-assn.org/system/files/oct-2020-ruc-recommendations.pdf

supply pricing data for PFS direct costs. Removing PERVUs from the PFS could necessitate a new, technical fee schedule for all ambulatory settings and promote stability and alignment across settings, but CMS should strengthen transparency of the StrategyGen process through public comment on how exactly how CMS arrives at pricing data (GPO discounts, setting, etc.) for specific equipment and supplies.

It's important to note that while the HOPPS and ASC Fee Schedules include only technical payments (e.g., the high-technology equipment, supplies and other interventions that have been a hallmark of the U.S. healthcare system) for HOPDs and ASCS, the PFS includes technical payments for office-based providers *plus* professional payments for physicians in all settings (e.g. HOPD, ASC and office). As a result, PFS technical payments currently "budget-neutralize" office-based supplies and equipment to *dissimilar* items such as professional payments for physician work in the hospital. This dynamic is a significant contributor to the payment volatility within the PFS.

Included in PFS Budget Neutrality:

- Office Technical Component
- Office Professional Component
- Hospital Professional Component
- ASC Professional Component

Not Included in PFS Budget Neutrality:

- Hospital Technical Component
- ASC Technical Component

REQUEST: We agree with CMS' focus on practice expenses as the main source of volatility in the PFS, but urge CMS and Congress to focus on direct practice expenses in the Physician Fee Schedule as the best opportunity for PFS payment stability.

IV. DEVELOPING A LIMB SALVAGE MVP

In the proposed rule, CMS notes that diabetes affects 34 million people in the United States and that a "serious potential complication of diabetes is lower extremity amputation (LEA), resulting from peripheral neuropathy (nerve damage), peripheral artery disease (PAD, reduced blood flow to the extremities), or both." CMS further explains that patients with PAD are vulnerable to amputation which occur at a rate of 5.6% per 1,000 persons with diabetes and amputation rates are on the rise with substantially higher rates of amputations in Black, Native American, and Hispanic patients. CMS cites evidence that Black patients are less likely to undergo potentially limb-saving interventions, such as revascularization or wound debridement, prior to having an amputation, as compared to White patients.

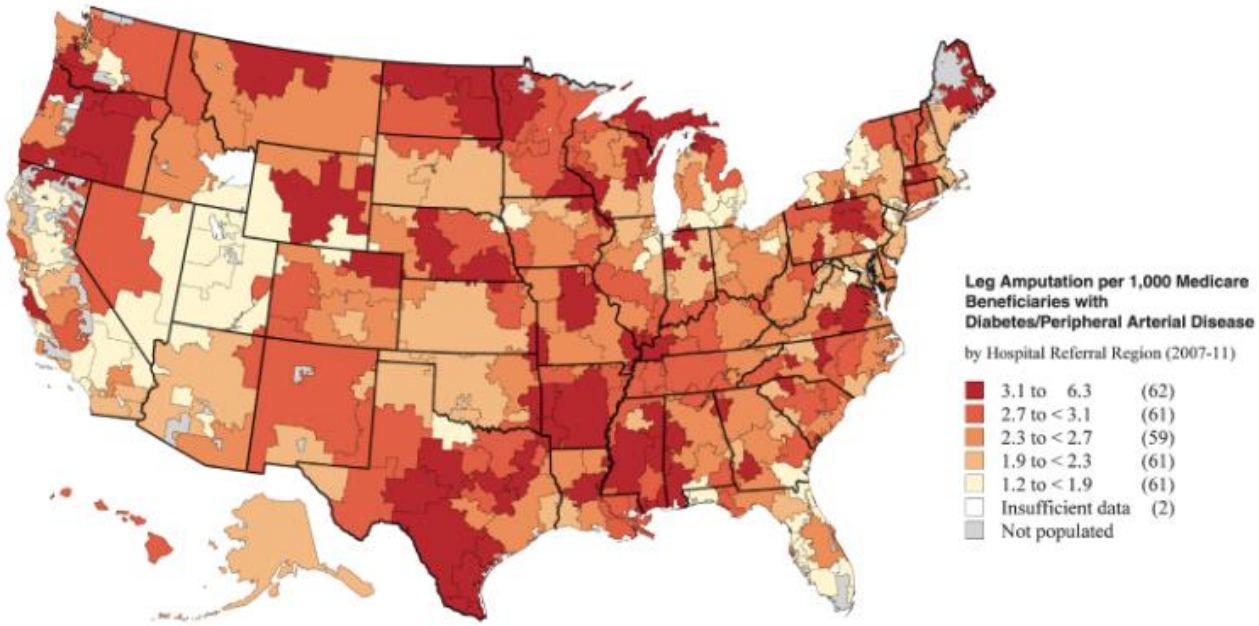
OEIS agrees with these CMS findings. Notwithstanding advances in technology for PAD patients downstream in their disease progression (i.e. revascularization) or upstream in their disease progression (e.g. medical therapy, supervised exercise therapy), there are several barriers to the achievement of non-traumatic, non-emergent amputation as a "never event" when it comes

to PAD. These barriers include racial and ethnic disparities in care and the underutilization of arterial testing.

Racial and Ethnic Variation in Care

Unfortunately, significant variation still exists in the provision of vascular care to patients in the year before major amputation.[25] As a result, racial and ethnic disparities in amputation rates for patients with PAD are substantial. Native Americans in the West are more than twice as likely to be amputated as Caucasians and Hispanics are 50% - 75% more likely to be amputated than Caucasians.[26] African-Americans living with diabetes appear to be subject to the worst disparities in care: African-Americans living with diabetes have amputation risks as much as four times higher the national average.[27] Data from a 2014 Dartmouth Atlas study outlines the scope of the problem.

NATIONWIDE

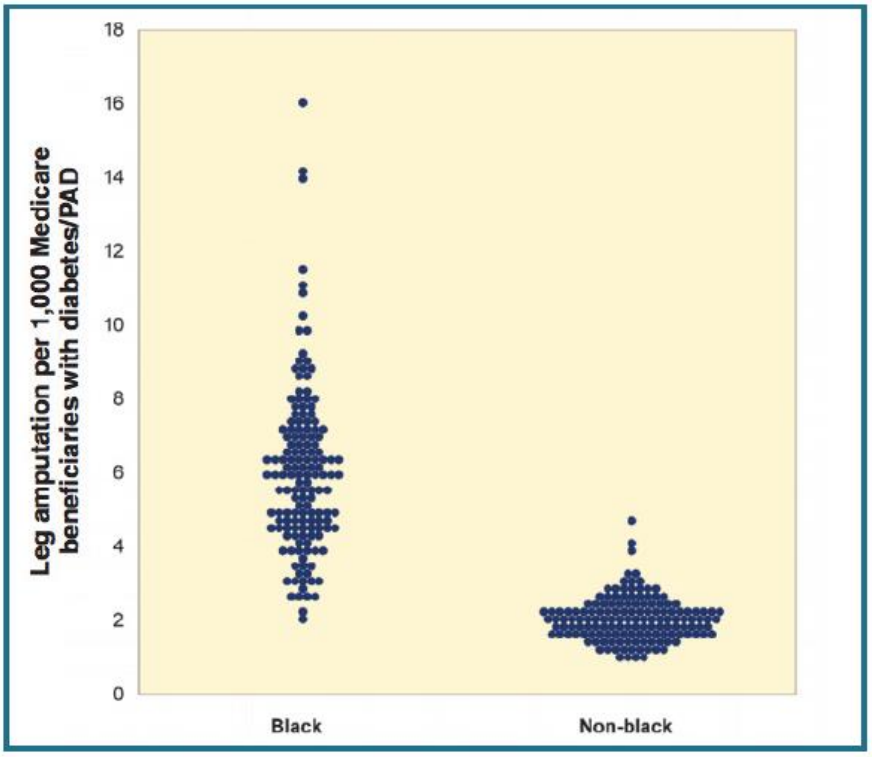


DISTRUBITION BASED ON HOSPITAL REFERRAL REGION

[25] Goodney, P. P., L. L. Travis, B. K. Nallamothu, K. Holman, B. Suckow, P. K. Henke, F. Lee Lucas, D. C. Goodman, J. D. Birkmeyer, and E. S. Fisher. "Variation in the Use of Lower Extremity Vascular Procedures for Critical Limb Ischemia." Circulation: Cardiovascular Quality and Outcomes 5.1 (2011): 94-102. Web.

[26] Industry analysis of the Healthcare Cost and Utilization Project (HCUP) database

[27] *Variation in the Care of Surgical Conditions: Diabetes and Peripheral Arterial Disease*, A Dartmouth Atlas of Health Care Series, 2014



Underutilization of Arterial Testing

Studies show vascular diagnostics are underutilized notwithstanding "the proven benefit of revascularization in amputation-free survival and quality of life."[28] Vemulapalli et al. found overall arterial testing rate of 68.4% prior to amputation, including a rate of preamputation testing with ankle brachial indices (ABI) of only 47.5% (notwithstanding PAD guidelines recommend ABI as part of initial management of patients undergoing amputation), and angiography rates of only 38.7% (invasive angiography), 5.6% (MR angiography), and 6.7% (CT angiography).[29] Furthermore, Henry et al state that "patients evaluated with an angiogram were at 90% lower odds of having amputation" than those not receiving an angiogram.[20]

Perhaps as a result of underutilization of arterial testing, the OEIS notes there are almost 43,000 Medicare patients per year receiving non-traumatic amputations. Medicare spending on CLI patients with major amputations averages $90,000, while Medicare spending on CLI patients who undergo revascularization and subsequently do not require an amputation is almost 40% less. According to Avalere Health, policies that encourage revascularization rather than major amputation could reduce Medicare spending by up to $2 billion over 10 years.[21]

[28] Vemulapalli et al., Circ Cardiovasc Qual Outcomes. 2014; 7:142-150

[29] Ibid

[20] Henry AJ, Hevelone ND, Belkin M, Nguyen LL. Socioeconomic and hospital-related predictors of amputation for critical limb ischemia. J Vasc Surg. 2011 Feb;53(2):330-9.e1. doi: 10.1016/j.jvs.2010.08.077. Epub 2010 Dec 15. PMID: 21163610; PMCID: PMC3282120

[21] Avalere Health, May 2015 analysis of CY2011 – 2013 Medicare claims

Developing a Limb Salvage MVP

As a result of concerns relating to avoidable amputations, CMS is exploring the development of both a process quality measure and a composite measure for amputation avoidance for the Merit-based Incentive Payment System (MIPS) program. However, CMS also notes in the proposed rule that "MVPs will be available for voluntary reporting beginning with the CY 2023 MIPS performance period, and we intend for MVPs to become the only method to participate in MIPS in future years, although we have not yet finalized the timing for the sunset of traditional MIPS."

Although OEIS is supportive of new MIPS amputation measures in principle, given the sunset of traditional MIPS, OEIS questions whether CMS instead should focus on a multidisciplinary MVP "area of practice" for clinicians treating patients in virtual or physical "centers of excellence" focused on limb salvage. OEIS believes such an MVP structure should be available for clinicians treating patients in virtual or physical locations with teams of skilled experts with access to advanced diagnostics and technologies to intervene rapidly to prevent limb loss. Limb Salvage MVPs should focus on 1) increasing awareness related to PAD, 2) screening for at-risk patients, 3) increasing the use of arterial testing, and 4) encouraging multi-disciplinary care. Outcomes could include limb salvage rate, high-low amputation ratio, days to heal for foot wounds, healing percentage of foot wounds, and quality of life measures.

We believe if these broad policy parameters were adopted as a comprehensive amputation reduction initiative across CMS and other federal health programs, we could substantially advance the goal of making non-traumatic, non-emergent PAD related amputations a never-event. We note that comprehensive approaches such as the Veterans Health Administration's Preventing Amputations in Veterans Everywhere (PAVE) program have resulted in significant reductions in amputations for at-risk patients.

Conclusion

We look forward to continuing to work with CMS to reform the Physician Fee Schedule to ensure the viability of office-based specialists. If you have additional questions regarding these matters and the views of the OEIS, please contact Jason McKitrick at (202) 465-8711 or by email at jmckitrick@libertypartnersgroup.com.

Sincerely,

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