Congress of the United States
House of Representatives
Washington, DC 20515

October 30, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Baltimore, Maryland 21244

Dear Administrator Brooks-LaSure:

We write to you regarding this year's Physician Fee Schedule (PFS), in which the Centers for Medicare and Medicaid Services (CMS) requested input on how to improve the practice expense (PE) methodology. We are encouraged that CMS recognizes that its existing PE methodology creates significant barriers to the uptake of digital health innovations through the classification of most software as a medical device (SaMD) as indirect practice expense.[1]

While the existing PE methodology is meant to account for a physician practice's costs, both direct and indirect, the ongoing choice of CMS to categorize SaMD as an indirect practice expense discourages the uptake and use of SaMD, remains one of the largest barriers to meaningful Medicare payment reforms, and is long overdue for a change. CMS' indirect methodology leverages cost bases and uses physician work relative value units (RVUs) but does not account for other factors like device maintenance.

While CMS began considering SaMD an indirect cost in 2019,[2] CMS has more recently indicated an interest in revising its approach to SaMD. CMS has been cross-walking payment rates for SaMD-inclusive codes to what CMS would have paid if the SaMD product had been included as a direct input. CMS has an obligation to steward Medicare beneficiary access to leading SaMD solutions and should seize this opportunity to advance meaningful PE methodology reform. We ask CMS to engage in the following recommendations to make these valuable SaMDs more accessible to Medicare beneficiaries.

We urge CMS to evolve its PE methodology to reflect the value that software provides by incorporating the value of software into CPT codes to address PE and/or work intensity for RVUs.

Specifically, the value of services delivered by a physician to interpret or act on new digital health technology information should be included in work RVUs, and the value of the software used to address improvements and efficiency in patient care should be factored into practice expense RVUs.

As CMS allows for SaMD reimbursement as direct supply inputs, CMS should obtain the most accurate estimate of the per-service cost of the input as possible, particularly by relying on invoices.

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[1] E.g., Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; et al, 85 Fed. Reg. 84472, 84629 (Dec. 28, 2022) ("While we agree that the costs for AI applications should be accounted for in payment, AI applications are not well accounted for in our PE methodology.").

[2] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; et al, 83 Fed. Reg. 59452, 59557 (Nov. 23, 2018).

CMS' equipment amortization formula should only apply in the case of locally installed computer programs with an upfront payment where a useful life can be estimated and where that SaMD is only used in one service at one time.

CMS should bring eligible digital health innovations into Medicare beneficiaries' care continuum by clarifying whether digital medical devices, such as SaMD, are included in existing benefit categories.

Consistent with CMS' clear authority and its obligation to improve Medicare beneficiary outcomes, we call on CMS to act in its Calendar Year 2025 Physician Fee Schedule rulemaking to effect overdue changes to its PE methodology to accurately categorize and support the use of SaMD in Medicare; and (2) to then launch a standalone consultation to inform broader reforms to its PE methodology. We appreciate your attention to this important issue and look forward to working with you to broaden beneficiary access to SaMD.

Sincerely,

Vern Buchanan
Member of Congress

David Schweikert
Member of Congress

Michelle Steel
Member of Congress