DIGESTIVE HEALTH
PHYSICIANS ASSOCIATION®

DHPAssociation.org

10770 COLUMBIA PIKE | SUITE 400 | SILVER SPRING, MD 20901

September 9, 2023

BY E-MAIL

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments to CMS-1784-P

Dear Administrator Brooks-LaSure:

On behalf of the Digestive Health Physicians Association ("DHPA"), we thank you for the opportunity to comment on the Medicare Physician Fee Schedule ("MPFS") Proposed Rule for Calendar Year 2024.[1] DHPA® is the only national medical association that exclusively represents the voices of gastroenterologists who have chosen to care for patients in the independent practice setting. DHPA includes over 100 member gastroenterology practices from 39 states in every region of the country. Our more than 2,500 physicians provide care to approximately three million patients annually and diagnose more than 25,000 new cases of colon cancer each year. Physicians in DHPA member practices are on the front lines of providing innovative treatments for serious diseases and chronic conditions such as colorectal cancer, Crohn's disease, and Ulcerative Colitis.

Our comments on the Proposed Rule focus on four issues impacting Medicare beneficiaries' access to high-quality, affordable care for gastrointestinal conditions and diseases. First, we ask CMS to consider the risks, resources, and complexity involved in administering a particular drug when assigning drug administration CPT codes and related reimbursement amounts for non-chemotherapeutic drugs, rather than just the disease being treated. Second, we ask CMS to make permanent CMS's definition of "substantive portion" for split (shared) visits in the facility setting that is in effect for CY 2022 and CY 2023 or, at the very least, redefine "substantive portion" to include *either* more than 50 percent of the medical decision-making by the physician or non-physician practitioners ("NPPs") or more than 50 percent of the time spent by the physician or NPP. Third, we ask CMS to finalize its proposal to not only

[1] 88 Fed. Reg. 52262 (Aug. 7, 2023).

extend "Direct Supervision via Use of Two-Way Audio/Video Communications Technology" until December 31, 2024, but to make this flexibility permanent. Fourth, we ask CMS to support Congressional efforts to provide the physician community with relief from the impending payment cuts set to take effect on January 1, 2024.

I. When Assigning Drug Administration CPT Codes and Related Reimbursement Rates to Non-Chemotherapeutic Drugs, CMS Should Base its Decisions on the Risks, Resources, and Complexity Involved in Administering a Particular Drug Rather than the Disease Being Treated.

On a daily basis, the more than 2,500 gastroenterologists in DHPA's member practices are caring for patients suffering from Crohn's disease and ulcerative colitis, and we know how critical certain complex biologic drugs administered in our medical offices have become in improving those patients' lives. It is with the benefit of this perspective that we implore CMS to intercede and remedy the reimbursement rate for non-chemotherapeutic complex drug administration, which stakeholders across the health care community have informed CMS "has become increasingly inadequate due to existing coding and Medicare billing guidelines that do not accurately reflect the resources used to furnish these infusion services."[2]

As noted in our comments last year, certain MACs had downgraded the classification and payment codes for administration of approximately 20 complex biologic drugs, including drugs such as Entyvio® (J3380), Stelara® (J3358), Tysabri® (J2356), and Cimzia® (J0717) that are vitally important to our treatment of patients with Crohn's disease and ulcerative colitis. These drugs had been classified properly under the "Chemotherapy and Other Highly Complex Drug or Highly Complex Biological Agent Administration Current Procedural Terminology (CPT) Codes" (CPT 96401-96549), but, without stakeholder input, the administration CPT codes for these drugs were shifted to the less complex "Therapeutic Prophylactic, and Diagnostic Injections and Infusion Codes" (CPT 96360-96379).

The amount of payments for the administration of drugs should be driven by an assessment of nursing time, specialized training needed to administer the drug, patient acuity, the severity of potential side effects, and physician supervision requirements, rather than what disease the drug is being used manage. As noted last year, it is the clear view of the gastroenterology, rheumatology and infusion communities that certain biologics that were down-coded via Local Coverage Articles ("LCAs")

[2] Id. at 52387.

> "are comparable in risk and complexity and require the same intense level of clinical care, specialized training, and monitoring regardless of the particular disease state or chronic condition for which the biologic is being used. Disease states should not prejudice reimbursement when the risks, preparation, specialized training requirements, physician supervision requirements, and toxicity management of products are equivalent whether the biologic is being used to treat a patient with cancer or a patient with multiple sclerosis, rheumatoid arthritis, or Crohn's disease."[3]

Monoclonal antibodies, and other biologic medicines, sometimes use the same mechanism of action as products used in oncology practices. Thus, use of such biologics can require the same pre-medication and pre-administration protocols and monitoring requirements. Biologics used to treat chronic and complex diseases can have serious side effects, including, but not limited to, (i) immediate risk of anaphylaxis or other allergic reaction, which requires close monitoring; and (ii) development of antibodies to drugs such as ustekinumab (e.g., Stelara®) that require close clinical monitoring and/or intervention.[4]

Additionally, drugs such as Tysabri®, require intense Risk Evaluation and Mitigation Strategy (REMS) programs. Drugs subject to REMS can require time-consuming supplemental documentation and monitoring, which is a factor that CMS should consider when setting reimbursement.

If CMS's reimbursement for drug administration does not align with the risks, resources and complexity involved, it will jeopardize the ability of independent medical practices and community-based infusion centers to furnish these services. And that, in turn, will shift care into the higher-cost hospital setting for the administration of drugs that can be furnished at a lower cost, with the same quality and greater convenience, in the independent medical practice setting.

As CMS seeks to "promote coding and payment consistency and patient access to infusion services,"[5] we believe CMS should consider the risks, resources, and complexity involved for administration of drugs when determining the appropriate coding and reimbursement. In particular, from the perspective of independent gastroenterology practices, it is critically important that CMS increase reimbursement for the administration of Entyvio® (J3380),

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[4] See Letter of American Gastroenterological Association, Coalition of State Rheumatology Organizations, Florida Society of Rheumatology, Digestive Health Physicians Association, Infusion Providers Alliance, National Infusion Center Association, National Organization of Rheumatology Management to CMS Administrator Brooks-LaSure, p. 2 (August 30, 2022).
[4] See Id. at p. 1
[5] 88 Fed. Reg. at 52387.

Stelara® (J3358), Tysabri® (J2356), and Cimzia® (J0717) to be consistent with the reimbursement provided under the "Chemotherapy and Other Highly Complex Drug or Highly Complex Biological Agent Administration Current Procedural Terminology (CPT) Codes" (CPT 96401-96549).

II. CMS Should Not Merely Delay Implementation of its Definition of "Substantive Portion" of Split (or Shared) Visits Until January 1, 2025, But Rescind the Policy and Adopt a More Flexible Approach that Is More Consistent with Coordinated, Team-Based Care.

As discussed in our comments last year, DHPA continues to believe that CMS's decision in the CY 2022 MPFS Final Rule to define the substantive portion of a split (or shared) visit furnished in the facility setting as more than half of the total time spent with the patient undermines effective co-management and clinical alignment among physicians and NPPs, sews confusion across the provider community, and imposes unnecessary administrative burdens on clinicians.

Although we appreciate CMS's proposal to delay implementation until January 1, 2025,[6] **we believe the more appropriate action would be for CMS to make permanent its approach to the definition of "substantive portion" that has been in effect since CY 2022[7], or, at the very least, redefine "substantive portion" to include *either* more than 50% of the medical decision-making by the physician or NPP or more than 50% of the time spent by the physician or NPP**. We urge CMS to announce in the Final Rule for CY 2024 that it will maintain a more flexible approach to defining "substantive portion" not only for CY 2024, but on a permanent basis.

We believe that it is ill-advised to limit the definition of "substantive portion" to more than half the total time spent by the physician or NPP. We cannot overstate the administrative burden and practical challenges of tracking time individually, which is made even more complicated when the physician and NPP are with a patient together. Even more problematic is that this time-based approach shifts the focus away from coordinated care to a counting of time that, at its core, is placing the physician and NPP in silos as they deliver care to patients.

Proper diagnosis and medical decision making, rather than time, are the critical elements to providing quality patient care. NPPs are usually involved in tasks that require significant time,

[6] Id. at 52351-52.
[7] Under current policy, clinicians who furnish split (shared) visits are permitted to define "substantive portion" based on taking a patient history, performing a physical exam, medical-decision making, or more than half of the total practitioner time spent.

such as obtaining the medical history from a patient, obtaining diagnostic test results, seeking consultations, preparing the medical record and more. By having NPPs perform such time-consuming tasks, physicians are able to analyze the information gathered by their NPPs and more efficiently use the information to conduct the physical exam, take a patient's history, and/or make the medical decision. Under the current flexibility, physicians are incentivized to continue to be efficient and remain involved in medical decision- making, which in turn allows for more timely care being provided to more patients.

Accordingly, CMS should provide physicians and NPPs with the flexibility to use medical decision-making as the basis for determining the "substantive portion" of a clinical visit, rather than time alone. We continue to join our colleagues across the physician community in urging CMS to include medical decision-making as a permanent option for determining the substantive portion of the shared visit starting January 1, 2024.[8]

III. The Flexibility to Meet the Immediate Availability Requirement of Direct Supervision via Use of Two-Way Audio/Video Communications Technology Should Be Made Permanent After January 1, 2024.

The action CMS took in the March 31, 2020, COVID-19 Interim Final Rule with comment period to change the definition of "direct supervision" as it pertains to supervision of diagnostic tests and physician services to allow immediate availability for direction supervision through virtual presence has—for the last three-and-a-half years—"facilitate[d] the provision of telehealth services by clinical staff of physicians and other practitioners incident to their own professional services."[9] We share CMS's concern that abruptly ending this flexibility on December 31, 2023, would present a barrier to patients' access to many services. We believe maintaining this flexibility will continue to be valuable in promoting access to high-quality care beyond the end of the year, especially in underserved communities of color and rural communities.

We do not believe that there are any significant patient safety concerns in allowing immediate availability through real-time audio and visual interactive communications for many of the types of services gastroenterologists provide in their offices, because when there is direct patient contact involved, there are appropriately trained personnel providing the services. For example, services incident to a physician, especially those involving NPPs, could be provided

[8] See, e.g., For further explanation of DHPA's concerns with defining the substantive portion of E/M visits only as more than 50% of total time spent, see the letter that DHPA and 18 other national medical associations submitted to CMS earlier this year. Letter from American Academy of Neurology et al. to CMS Administrator Brooks-LaSure (March 22, 2022).

[9] 88 Fed. Reg. at 52301.

by an NPP independently without a physician being onsite. Many of the services provided by nurses and auxiliary personnel incident to an NPP or a physician, are generally also safe, and would not require onsite supervision. There are already safeguards for patient safety built-in with regards to scope of practice and appropriate treatment protocols for most services. If CMS identifies any significant patient safety risks, CMS could require personal supervision or require direct supervision on site.

Therefore, **we believe that CMS should, on a permanent basis, take the default position that a virtual presence is a permissible method to provide "immediate availability," unless CMS finds that for a specific service there is a patient safety or over-utilization concern that requires on-site supervision.**

At a minimum, this flexibility should be extended until December 31, 2024. As noted by CMS, such an extension would align with many of the PHE-related telehealth flexibilities that were extended under provisions of the Consolidated Appropriations Act, 2023.[10] By aligning the virtual presence flexibility with the other PHE-related telehealth flexibilities, CMS is taking a responsible step that helps reduce avoid confusion amongst the provider community.

IV. DHPA Urges CMS—and the Administration More Broadly—to Support Congressional Efforts to Provide the Physician Community with Relief from the Impending Payment Cuts Set to Take Effect on January 1, 2024.

The physician community is caught in a vicious cycle in which we are again facing significant payment cuts under the MPFS due to statutorily-required reductions to the MPFS conversion factor ("MPFS CF").[11] Although we know that relief from the impending 3.36% cut to the MPFS CF will require Congressional action, we urge CMS—and the Administration as a whole—to weigh in with Congressional leadership on both sides of the aisle to emphasize the need for relief. CMS is well-positioned to communicate to Congress the seriousness of these impending cuts to the provider community at a time of persistently high inflation, providers continuing to struggle with staffing shortages and staffing costs, and COVID-19 cases rising again which could create additional challenges across the provider community, despite the PHE having ended earlier this year. Although CAA 2023 provided a 1.25% positive adjustment for CY 2024, we note that Congress provided a larger positive adjustment for previous years (e.g., 2.5% positive adjustment in CY 2023, and 3% positive adjustment in CY 2022).

[10] See id. at 52302.
[11] Id. at 52679. The 2024 proposed conversion factor is $32.7476, which is a 3.36% cut from the 2023 CF of $33.8872. The proposed cuts are caused primarily by the required budget neutrality adjustment to account for changes in RVUs.

DHPA is asking for CMS's support in obtaining, through Congressional action, payment reduction relief to further offset the scheduled reduction, at least to be in-line with previous positive adjustments that Congress has enacted.

IV. Request for Action.

We thank CMS for the opportunity to comment on the Proposed Rule. We urge the Agency to take the following actions as it finalizes the MPFS for CY 2024:

- Analyze the risks, resources, and complexity of administration of particular drugs when assigning codes and reimbursement to such drug's administration, rather than merely looking at whether the drug treats cancer or not. From the perspective of independent gastroenterology practices that care for patients with Crohn's disease and ulcerative colitis, it is particularly important that CMS set reimbursement for the administration of Entyvio® (J3380), Stelara® (J3358), Tysabri® (J2356), and Cimzia® (J0717) consistent with the reimbursement provided under the "Chemotherapy and Other Highly Complex Drug or Highly Complex Biological Agent Administration Current Procedural Terminology (CPT) Codes" (CPT 96401-96549).

- Make permanent CMS's definition of "substantive portion" for split (shared) visits in the facility setting that was in effect for CY 2022 and remains in effect for CY 2023 or, at the very least, redefine "substantive portion" to include *either* more than 50% of the medical decision-making by the physician or NPP or more than 50% of the time spent by the physician or NPP.

- Make permanent the flexibility to meet the "immediate availability" requirement for direct supervision via use of two-way audio/video communications technology, unless CMS finds that for a specific service there is a patient safety or over-utilization concern that requires on-site supervision. At a minimum, CMS should extend the flexibility through December 31, 2024, so that this flexibility aligns with other telehealth flexibilities.

- Support Congressional efforts to provide the physician community with relief from impending payment cuts set to take effect on January 1, 2024.

DHPA looks forward to serving as a resource to CMS as it works to finalize the MPFS for CY 2024. Please reach out to me directly with any questions or requests for additional information (scott.ketover@mngi.com, 612-870-5408).

Sincerely,

Scott R. Ketover, M.D.
DHPA President & Chair of Health Policy