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September 6, 2022

**BY E-MAIL**

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

Re: Comments to CMS-1770-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 2023.<sup>1</sup> 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 2,400 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 such as colorectal cancer, Crohn’s disease, and ulcerative colitis.

Our comments on the MPFS Proposed Rule focus on five issues impacting Medicare beneficiaries’ access to high quality, affordable care for gastrointestinal conditions and diseases. First, we ask that CMS finalize its proposals to expand Medicare coverage of CRC screening tests, while making clear in the Final Rule that colonoscopy is a critical first-line screening test, particularly in Medicare-age patients. Second, we urge CMS to compel Medicare Administrative Contractors to discontinue the inappropriate use of Local Coverage Articles (LCAs) to down-code certain complex biologic drugs, including drugs used to treat patients with serious gastrointestinal diseases such as Crohn’s disease or ulcerative colitis, and

<sup>1</sup> 87 Fed. Reg. 45860 (July 29, 2022).

to insure that any such LCAs currently in effect are invalidated. Third, 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 or, at the very least, redefine “substantive portion” to include *either* more than 50 percent of the medical decision-making by the physician or nonphysician practitioner (NPP) or more than 50 percent of the time spent by the physician or NPP. Fourth, starting with the year following the end of the COVID-19 Public Health Emergency (PHE), we ask that CMS make permanent the flexibility to meet the “immediate availability” requirement for direct supervision through virtual presence using real-time, audio/video technology. Fifth, 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, 2023.

**I. DHPA Strongly Supports CMS’s Proposals with Respect to CRC Screening And Urges the Agency to Clarify the Importance of Colonoscopy as a First-Line Screening Test for Medicare Beneficiaries.**

DHPA applauds CMS for its proposals aimed at expanding coverage for colorectal cancer (“CRC”) screening and removing barriers to such screening.<sup>2</sup> These proposals, when finalized, will significantly advance our country’s efforts to screen for this deadly disease, especially in underserved communities of color and rural communities.

The more than 2,400 gastroenterologists in DHPA’s member practices are on the front lines diagnosing and treating patients with colorectal cancer. They know, first-hand, that colonoscopies save lives as the only CRC tests that screen, detect, treat, cure, and prevent colorectal cancer. For these reasons, DHPA has been advocating for policy changes to expand coverage of—and remove barriers to—CRC screening tests, generally, and colonoscopy, in particular, since DHPA’s inception nearly a decade ago.

This work is critical. Colorectal cancer continues to be the third most common cancer diagnosed in men and women in the United States, excluding skin cancers.<sup>3</sup> Colorectal cancer is the second most common cause of cancer deaths for men and women combined, with the disease expected to cause more than 52,000 deaths this year.<sup>4</sup> With early detection, the five-year survival for a localized colorectal cancer is 91 percent.<sup>5</sup>

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<sup>2</sup> Id. at 46081-86.

<sup>3</sup> American Cancer Society – Key Statistics for Colorectal Cancer, available at <https://www.cancer.org/cancer/colorectal-cancer/about/key-statistics.html> (last accessed Aug. 3, 2022).

<sup>4</sup> Id.

<sup>5</sup> American Cancer Society – Survival Rates for Colorectal Cancer, available at <https://www.cancer.org/cancer/colorectal-cancer/detection-diagnosis-staging/survival-rates.html> (last accessed Aug. 3, 2022).

We strongly support both of CMS’s proposals. We agree with the proposal to expand Medicare coverage of certain CRC screening tests by reducing the minimum age payment limitation from 50 years to 45 years. As CMS recognized in the Proposed Rule, this expansion of coverage would align Medicare coverage policy with the recently revised recommendation by the United States Preventive Services Task Force for certain CRC screening tests.<sup>6</sup> We also agree with the proposal to expand the regulatory definition of CRC screening tests to include a follow-on colonoscopy after a Medicare-covered, stool-based CRC screening test returns a positive result.

We submit these comments to thank CMS for making these proposals and to ask CMS to make three clarifications as it finalizes these proposals for implementation for CY 2023.

**A. CMS’s Proposal to Expand Coverage of CRC Screening Tests to Include a Follow-On Colonoscopy after a Medicare-covered, Non-Invasive Stool-Based CRC Screening Test Returns a Positive Result Will Remove Barriers to Cancer Detection and Prevention and Will Accelerate Efforts to Eliminate Health Disparities in CRC Screening.**

Coinsurance obligations have a significant chilling effect on Medicare patients obtaining colonoscopies. In a survey of the National Colorectal Cancer Screening Network, which includes public health and health care professionals who provide screening services, 70% of the survey respondents said that they thought the potential of unexpected costs could deter individuals from being screened.<sup>7</sup> A study published on the Centers for Disease Control website, reporting on the results of a survey of people’s attitudes on CRC screening by colonoscopy, found that “[r]espondents with low income were significantly more likely to select cost as a barrier than respondents with an annual income of \$50,000 or more.”<sup>8</sup>

The elimination of cost-sharing obligations for follow-on colonoscopies is critically important to eliminating health disparities in CRC screening. We agree with CMS’s assessment that removing

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<sup>6</sup> 87 Fed. Reg. at 46081, 46083-84. Importantly, as CMS noted, screening colonoscopy does not have a minimum age requirement under Medicare coverage; thus, the proposal to reduce the minimum age from 50 to 45 applies only to other CRC screening tools such as stool-based tests and the direct visualization test of flexible sigmoidoscopy.

<sup>7</sup> Pollitz, K., Lucia K., Keith, K. et. al, Coverage of Colonoscopies Under the Affordable Care Act's Prevention Benefit, Henry J. Kaiser Family Foundation, published Aug. 31, 2012, available at [https://www.kff.org/report-section/coverage-of-colonosopies-under-the-affordable-care-acts-prevention-benefit-report/#endnote\\_link\\_120591-17](https://www.kff.org/report-section/coverage-of-colonosopies-under-the-affordable-care-acts-prevention-benefit-report/#endnote_link_120591-17) (last accessed Aug. 3, 2022) (referencing McAbee K, Martinez E and Wolf H., Mining the Colorectal Cancer Screening Network to explore practices, policies, and challenges in colorectal cancer screening. Technical report submitted to National Colorectal Roundtable, funded by American Cancer Society and CDC (Cooperative Agreement Number U50/DP001863) (October 2012)).

<sup>8</sup> Redmond Knight J, Kanotra S, Siameh S, Jones J, Thompson B, Thomas-Cox S. Understanding Barriers to Colorectal Cancer Screening in Kentucky. *Prev Chronic Dis* 2015;12:140586, available at [https://www.cdc.gov/pcd/issues/2015/14\\_0586.htm](https://www.cdc.gov/pcd/issues/2015/14_0586.htm) (last accessed Aug. 3, 2022).

the cost-sharing obligation for follow-on colonoscopies will “directly advance health equity by promoting access and removing barriers for much needed cancer prevention and early detection within rural communities and communities of color.”<sup>9</sup> A recent study published in *The New England Journal of Medicine* confirmed that providing greater choice of CRC screening options to communities of color promotes “equitable delivery of effective interventions across the care continuum [and] can decrease, or even eliminate, related health disparities over time.”<sup>10</sup>

The additional expense to the Medicare program of eliminating the cost-sharing obligation for colonoscopies following a positive stool-based test will be more than outweighed by the overall cost savings to Medicare. It is well-established that increases in CRC screenings ultimately drive down cost to the Medicare program and beneficiaries. A 2017 study from Health Affairs, found that “[w]aiving coinsurance was estimated to initially increase costs, but led to cost savings after a decade due to averted [colorectal cancer] cases.”<sup>11</sup>

### **B. We Ask that CMS Clarify in the Final Rule the Importance of Colonoscopy as a First-Line Screening Test for Medicare Beneficiaries.**

We fully support the proposal to remove cost-sharing obligations for colonoscopies that follow stool-based tests that return positive results, but we are concerned that certain statements in the Proposed Rule inappropriately favor stool-based tests over colonoscopies and could discourage the use of colonoscopy as a first-line CRC screening test in the Medicare population. We believe this does a disservice to Medicare beneficiaries, the physicians and other health care professionals who advise patients on screening options, and the Medicare program as a whole.

Our concerns arise out of the following statement in the Proposed Rule:

“It has been reported that a large proportion (46 percent) of screening colonoscopies<sup>[FN]</sup> found no polyps so optimizing use of a non-invasive stool-based screening test as a first step (when determined appropriate by the patient and their healthcare professional) would benefit the patient and also the Medicare program.

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<sup>9</sup> 87 Fed. Reg. at 46082.

<sup>10</sup> Doubeni, Chyke A., Corley, Douglas A., Zhao, Wei, Association between Improved Colorectal Cancer Screening and Racial Disparities, *N Engl J Med* 386;8 (Feb. 24, 2022), available at <https://www.nejm.org/doi/pdf/10.1056/NEJMc2112409?articleTools=true> (last accessed Aug. 11, 2022) (reporting on study of members of Kaiser Permanente Northern California health plan that showed percentage of Black persons who were up to date with screening having increased from 42% in 2000 to 79 to 80% during period from 2015 through 2019 following initiation of screening program providing option of proactive mailed fecal immunochemical testing annually and on-request colonoscopy).

<sup>11</sup> Petrese, E.F.P., Meester, R.G.S, Gini, A., et al., Value of Waiving Coinsurance of Colorectal Cancer Screening in Medicare Beneficiaries, *Health Affairs* (Millwood). 2017 December; 36(12): 2151–2159, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6067012/pdf/nihms-978754.pdf> (last accessed Aug. 3, 2022).

In many instances, a colonoscopy is not the most appropriate first step in colorectal cancer screening and would represent an unnecessary burden and over-servicing for both the patient and healthcare system.”<sup>12</sup>

We have three principal concerns. First, the 22-year-old study CMS cited in support of “optimizing use of a non-invasive stool-based screening test as a first step” was not a study of screening colonoscopy in the *Medicare population*.<sup>13</sup> Second, CMS does not mention that the study was limited to *asymptomatic* adults (and, within that cohort, almost exclusively men (96%)).<sup>14</sup> It is well-established that screening colonoscopy is the recommended test for anyone with above-average risk for cancer, including but not limited to a personal or family history of colorectal cancer or history of cancers that share genetic risks with colorectal cancer. Third, in focusing on the “optimization” of using stool-based tests, CMS makes no mention of the fact that colonoscopy is often the most appropriate first-line CRC screening test, particularly in the Medicare population.

As CMS notes, there are instances in which “a colonoscopy is not the most appropriate first step in colorectal cancer screening,” but it is equally true—and critical for Medicare beneficiaries, primary care physicians, and the medical community more broadly to understand—that screening colonoscopy is the right first-line screening option for a significant portion of Medicare-age patients and is the only CRC screening test option that screens, detects, treats, cures, and prevents colorectal cancer.

As CMS recognized in the Proposed Rule, “[s]ince the overall goal of programmatic cancer screening using any CRC screening test is to prevent cancer, allow for early detection and treatment and reduce cancer mortality,”<sup>15</sup> we ask that the Agency avoid making statements that could have the unintended consequence of dissuading Medicare beneficiaries (or any patients) from receiving colonoscopies as first-line screening tests. **We urge CMS to make clear in the Final Rule that colonoscopy remains a critical first-line screening test for colorectal cancer especially in the Medicare population and that patients, in consultation with their physicians and other healthcare professionals, are in the best position to make the most appropriate choice of CRC screening option for them.**

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<sup>12</sup> 87 Fed. Reg. at 46085.

<sup>13</sup> Lieberman, David A., Weiss, David G., Bond, John H. et al., Use of Colonoscopy to Screen Asymptomatic Adults for Colorectal Cancer, *N Engl J Med* 2000; 343:162-168 (July 20, 2000), available at <https://www.nejm.org/doi/full/10.1056/nejm200007203430301#:~:text=We%20believe%20that%20the%20use,distal%20to%20the%20splenic%20flexure> (last accessed Aug. 11, 2022) (reporting that the mean age of the patients was 62.9 years).

<sup>14</sup> Id.

<sup>15</sup> 87 Fed. Reg. at 46081.

**C. We Ask that CMS Confirm in the Final Rule that, beginning January 1, 2023, Screening Colonoscopy Following a Positive Result on a Stool-Based Test Should Be Coded and Billed in the Same Manner as Screening Colonoscopies Are Coded and Billed for in CY 2022.**

As CMS noted in the Proposed Rule, “the follow-up colonoscopy is integral to non-invasive stool-based screening” and “government bodies and professional societies now consider CRC screening incomplete for individuals with a positive result on a stool-based test until a follow-on screening colonoscopy is also completed.”<sup>16</sup> We agree and, as such, **we believe that the coding and billing for screening colonoscopies that follow a positive result on a stool-based test should be identical to the process for coding and billing screening colonoscopies that do not follow such a positive stool-based test.** We ask CMS to confirm this understanding in the Final Rule or provide guidance on how, if at all, coding and billing procedures are to be modified for such follow-on colonoscopies for CY 2023.

**D. We Ask that CMS Clarify that the Expansion of Coverage of CRC Screening Tests Includes a Follow-On Screening Colonoscopy After Any Medicare-Covered, Non-Invasive CRC Screening Test and Not Only Stool-Based CRC Screening Tests.**

We agree with the fundamental premise underlying CMS’s proposal—an understanding that a CRC screening is not “complete” following a positive result from a non-invasive, stool-based test and that the follow-on screening colonoscopy is “part of a continuum of a complete CRC screening and not a separate diagnostic, therapeutic or other procedure.”<sup>17</sup> For those Medicare beneficiaries who determine, in consultation with their physician, that a non-invasive CRC screening test is an appropriate first-line screening, they will now have the peace of mind of knowing that a follow-on colonoscopy, if needed because of a positive result from the non-invasive screening test, will be fully covered.

We do not believe this expansion of coverage through elimination of cost-sharing obligations should be limited to colonoscopies following positive results from non-invasive CRC screenings that are *stool-based* tests. The key is not that the initial test is stool-based, but rather that a CRC screening is only complete when a non-invasive screening test that returns a positive result is followed by a screening colonoscopy. With other non-invasive (and non-stool based) screening tests in development, **we believe that CMS should modify its proposal to eliminate cost-sharing obligations associated with screening colonoscopies that follow a positive result from**

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<sup>16</sup> Id. at 46081-82.

<sup>17</sup> Id. at 46084-85.



**any non-invasive CRC screening test covered under the Medicare program and not only those that are stool-based.**

## **II. We Urge CMS to Compel the MACs to Discontinue the Inappropriate Use of Local Coverage Articles to Down-code Certain Complex Biologic Drugs and to Invalidate Any Such LCAs Currently in Effect.**

On a daily basis, the more than 2,400 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 a significant error in judgment that certain MACs have made by using LCAs to make substantive policy changes to drug reimbursement for life-saving and life-changing biologics across a series of disease states.**

MACs have downgraded the classification and payment codes for administration of approximately 20 complex biologic drugs, including drugs such as Entyvio<sup>®</sup> (J3380), Stelara<sup>®</sup> (J3358) and Cimzia<sup>®</sup> (0717) 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) and, yet, without stakeholder input that would be obtained through Local Coverage Determination (LCD) or National Coverage Determination (NCD) processes, certain MACs have shifted these drugs to the less complex “Therapeutic Prophylactic, and Diagnostic Injections and Infusion Codes” (CPT 96360-96379).

These are not mere “billing instructions” as the MACs contend. Such wholesale reclassifications of drugs used to treat patients with complex diseases and chronic conditions should not be made without stakeholder input. And such reclassifications, if any are to be made, should be driven by an assessment of specialized training needed to administer the drug, patient acuity, the severity of potential side effects, and physician supervision requirements. Reclassifications should not be made—as the MACs have done—by determining whether the infused or subcutaneously-administered drug is used to treat one disease or another. To this very point, it is the clear view of the gastroenterology, rheumatology and infusion communities that the biologics that have been down-coded via LCAs

“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.”<sup>18</sup>

These policy decisions via LCAs also fail to account for how the dramatic cuts in reimbursement will impact access to these drug treatments in physician offices. Simply put, the wholesale downcoding of these biologic drugs 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.

At the very least, such a profound change to coding policy for biologic drugs should be made through LCD or NCD processes, not through ad hoc LCAs. The consequences for patients being able to access care in the independent medical practice setting—and for the overall cost to the Medicare program—are too profound to permit such a sea change via LCAs.

Gastroenterologists are not alone in voicing these concerns. Our colleagues across medical specialties have made clear that the MACs’ unilateral downcoding of biologic drugs through LCAs is leading to inappropriate reimbursement for critical therapies that “threatens beneficiaries’ access which may lead to disease progression and higher overall healthcare cost.”<sup>19</sup> **We stand with the broader physician community in urging CMS to compel the MACs to discontinue the inappropriate use of LCAs to down-code certain complex biologic drugs and to ensure that any such LCAs currently in effect are invalidated.**

### **III. CMS Should Not Merely Delay Implementation of its Definition of “Substantive Portion” of Split (or Shared) Visits Until January 1, 2024, But Rescind the Policy and Adopt a More Flexible Approach that Is More Consistent with Coordinated, Team-Based Care.**

DHPA believes 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

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<sup>18</sup> 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).

<sup>19</sup> See Letter of American Academy of Allergy, Asthma & Immunology, American Academy of Dermatology Association, American Academy of Ophthalmology, American Association of Orthopaedic Surgeons, American College of Radiology, American College of Rheumatology, American College of Surgeons, American Gastroenterological Association, American Orthopaedic Foot & Ankle Society, Coalition of State Rheumatology Organizations to CMS Administrator Brooks-LaSure (June 14, 2022).



administrative burdens on clinicians. And although we appreciate CMS’s proposal to delay implementation until January 1, 2024,<sup>20</sup> **we believe the more appropriate action would be for CMS to make permanent its approach to the definition of “substantive portion” that is in effect for CY 2022<sup>21</sup> or, at the very least, redefine “substantive portion” to include *either* more than 50 percent of the medical decision-making by the physician or NPP or more than 50 percent of the time spent by the physician or NPP.** We urge CMS to announce in the Final Rule for CY 2023 that it will maintain a more flexible approach to defining “substantive portion” not only for CY 2023, 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.

At a minimum, 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. Accordingly, we join our colleagues across the gastroenterology community and the physician community more broadly, 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.<sup>22</sup>

#### **IV. The Flexibility to Meet the “Immediate Availability” Requirement for Direct Supervision Through Virtual Presence Using Real-Time, Audio/Video Technology Should Be Made Permanent in the Calendar Year Following the End of the COVID-19 Public Health Emergency.**

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 two-and-a-half years—“facilitate[d] the provision of telehealth services

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<sup>20</sup> 87 Fed. Reg. at 46002-03.

<sup>21</sup> 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.

<sup>22</sup> See, e.g., Comment Letter from AGA, ACG and ASGE to CMS Administrator Brooks-LaSure re: MPFS Proposed Rule for CY 2022 (Sept. 13, 2021). 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).

by clinical staff of physicians and other practitioners incident to their own professional services.”<sup>23</sup> Although this change was made on a temporary basis only through December 31 of the year in which the COVID-19 PHE ends, we are convinced that this flexibility will prove equally valuable in promoting access to high quality care beyond the end of the PHE, especially in underserved communities of color and rural communities. We ask CMS to work with the medical community to explore potential guardrails that can be established to address concerns about potential over-utilization of the virtual presence option for direct supervision, but to make that option permanent.

At a minimum, while CMS continues to work with the medical community in assessing the appropriateness of making permanent the virtual presence option, we ask that CMS extend the “virtual presence” flexibility at least through the end of 2023. The PHE is currently in effect through at least October 13, 2022.<sup>24</sup> In light of the Biden Administration’s commitment to provide a minimum of 60-days’ notice before any expiration or termination of the PHE,<sup>25</sup> we note that the only way in which the PHE would not extend into 2023 would be if the Administration announces prior to November 2, 2022, that the PHE will not be extended. Given current incidence and mortality levels associated with COVID-19, we expect that we will remain under the PHE through at least year end, but even if that were not to be the case, **we believe it is critical that the “virtual presence” supervision flexibility be extended until at least the end of CY 2023**, given how important that flexibility has been in ensuring adequate access to care delivery since March 2020.

#### **V. 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, 2023.**

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”).<sup>26</sup> Although we know that relief from the impending 4.5% cut to the MPFS CF and the threat of the 4% pay-as-you-go (“PAYGO”) reduction 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 when the country remains under the COVID-19 PHE most recently extended by HHS Secretary Becerra on

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<sup>23</sup> 87 Fed. Reg. at 45900.

<sup>24</sup> See HHS Secretary Xavier Becerra “Renewal of Determination that a Public Health Emergency Exists,” available at <https://aspr.hhs.gov/legal/PHE/Pages/covid19-15jul2022.aspx> (last accessed Aug. 12, 2022).

<sup>25</sup> Letter from HHS Secretary Xavier Becerra to Governors (May 10, 2022).

<sup>26</sup> 87 Fed Reg at 46385-86. The 2023 proposed conversion factor is \$33.0775, which is a 4.42% cut from the 2022 CF of \$34.6062. The proposed cuts are caused primarily by the expiration of the 3.75% temporary payment increase provided by the Consolidated Appropriations Act for 2021. The remainder of the cut is attributed to the required budget neutrality adjustment to account for changes in RVUs.

July 15, 2022. The need for this relief is made all the more acute in light of the termination in July 2022 of the 2% sequestration moratorium.

**DHPA is asking for CMS’s support in obtaining, through Congressional action, payment reduction relief along the lines of the provisions in last year’s “Protecting Medicare and American Farmers from Sequester Cuts Act” that provided a three percent positive adjustment to the MPFS CF for CY 2022 to partially offset a scheduled reduction and averted an additional four percent Medicare payment reduction due to PAYGO requirements.**

## **VI. 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 2023:

- Finalize the proposal to expand Medicare coverage of certain CRC screening tests by reducing the minimum age payment limitation from 50 years to 45 years;
- Finalize the proposal to expand coverage of CRC screening tests to include a follow-on screening colonoscopy after a Medicare-covered, non-invasive stool-based CRC screening test returns a positive result and take the following additional steps in support of that policy:
  - Clarify the importance of colonoscopy as a first-line screening test for Medicare beneficiaries;
  - Confirm that, beginning January 1, 2023, screening colonoscopy following a positive result on a stool-based test should be coded and billed in the same manner as screening colonoscopies are coded and billed in CY 2022;
  - Clarify that the elimination of cost-sharing obligations for CRC screening tests extends to screening colonoscopy after *any* Medicare-covered, non-invasive CRC screening test and not only stool-based CRC screening tests;
- We urge CMS to compel MACs to discontinue the inappropriate use of LCAs to down-code certain complex biologic drugs, including drugs used to treat patients with serious gastrointestinal diseases such as Crohn’s

disease and ulcerative colitis, and to insure that any such LCAs currently in effect are invalidated.

- Make permanent CMS’s definition of “substantive portion” for split (shared) visits in the facility setting that is in effect for CY 2022 or, at the very least, redefine “substantive portion” to include *either* more than 50 percent of the medical decision-making by the physician or NPP or more than 50 percent of the time spent by the physician or NPP.
- Starting with the year following the end of the COVID-19 PHE, make permanent the flexibility to meet the “immediate availability” requirement for direct supervision through virtual presence using real-time, audio/video technology. At a minimum, while CMS works with the medical community in assessing the appropriateness of making permanent the virtual presence option, CMS should extend the “virtual presence” flexibility at least through the end of 2023 even if the COVID-19 PHE ends on or before December 31, 2022.
- Support Congressional efforts to provide the physician community with relief from impending payment cuts set to take effect on January 1, 2023.

DHPA looks forward to serving as a resource to CMS as it works to finalize the MPFS for CY 2023. Please reach out with any questions or requests for additional information to DHPA’s Chair of Health Policy, Dr. Scott Ketover ([scott.ketover@mngi.com](mailto:scott.ketover@mngi.com), 612-870-5408), or to DHPA’s legal counsel, Howard Rubin ([Howard.Rubin@katten.com](mailto:Howard.Rubin@katten.com), 202-625-3534).

Sincerely,



Latha Alaparthi, M.D.  
President



Scott R. Ketover, M.D.  
Chair, Health Policy

cc: Kevin Harlen, DHPA Executive Director  
Howard Rubin, Esq., Katten Muchin Rosenman LLP