DIGESTIVE HEALTH
PHYSICIANS ASSOCIATION®

August 21, 2017

BY ELECTRONIC SUBMISSION

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Comments to CMS-5522-P

Dear Administrator Verma:

The Digestive Health Physicians Association ("DHPA") appreciates the opportunity to comment on the CY 2018 Updates to the Quality Payment Program ("QPP") Proposed Rule (the "Proposed Rule").[1] As the voice of the nation's leading independent gastroenterology practices, DHPA is committed to working with CMS as it continues its work implementing the Medicare Access and CHIP Reauthorization Act ("MACRA").

The proposals set forth in the Proposed Rule are a critical component of the broader, "national conversation" on which CMS is embarking to "improve[e] the healthcare delivery system."[2] As part of that effort, the Agency is asking important questions that should be top of mind for the Agency as it works to finalize the QPP rules for CY 2018: "how Medicare can contribute to making the delivery system less bureaucratic and complex; and how we can reduce burden for clinicians, providers, and patients in a way that increases quality of care and decreases costs, thereby making the healthcare system more effective, simple, and accessible while maintaining program integrity and preventing fraud."[3] We reviewed the Proposed Rule with those questions in mind, while also asking ourselves whether the QPP, as the implementation mechanism for MACRA, is working to ensure that independent gastroenterology (and other specialty) practices are being given the tools to succeed under the Merit-based Incentive Payment System ("MIPS") and Advanced Alternative Payment Models ("APMs") for the benefit of our patients.

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[1] 82 Fed. Reg. 30010 (June 30, 2017).

[2] See Proposed Policy, Payment, and Quality Provisions Changes to the Medicare Physician Fee Schedule for Calendar Year 2018, available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-07-13-2.html (last accessed Aug. 17, 2017).

[3] Id.

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In this comment letter, we provide three specific suggestions for CMS to consider incorporating into the Final Rule to ensure Medicare beneficiaries' continued access to critically important drug treatments and to facilitate greater participation by independent gastroenterology practices in the payment systems mandated by MACRA: (i) CMS should protect patient access to Part B drugs administered in the physician office by delaying its plan to apply MIPS payment adjustments to the actual cost of Part B drugs until reevaluating as part of the notice-and-comment rulemaking process for the CY 2019 QPP; (ii) CMS should modify the process for review and approval of Physician-Focused Payment Models ("PFPMs") in order to provide the Physician-Focused Payment Model Technical Advisory Committee ("PTAC") with greater authority to implement PFPMs and, relatedly, approve proposed APMs, including those submitted to PTAC and CMMI, in a more timely manner; and (iii) in its ongoing dialogue with Congress with respect to MACRA implementation, CMS should seek additional statutory authority to permit the use of "virtual groups" as a mechanism for encouraging specialty practices, including those with more than 10 physicians, to participate in the MIPS.

Digestive Health Physicians Association

DHPA formed in early 2014 to promote and protect the high quality, cost-effective and coordinated care furnished in independent gastroenterology practices. DHPA is the only national medical association that exclusively represents the voices of those gastroenterologists who have chosen to care for patients in the independent practice setting. DHPA has grown to include 75 member gastroenterology practices from 36 states in every region of the country. Our more than 1,700 physicians provide care to approximately 2.5 million patients annually in more than four million distinct patient encounters. Our physician members 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.

I. CMS Should Not Apply MIPS Payment Adjustments to the Cost of Part B Drugs Without Subjecting this "Clarification" to Notice-and-Comment Rulemaking for the CY 2019 Quality Payment Program.

Gastroenterologists regularly provide high-quality care for Medicare beneficiaries with autoimmune disorders such as Crohn's disease and Ulcerative Colitis. We believe that preserving access to care for these patients—who often depend on office-administered, Part B medications such as Remicade (infliximab) as their only treatment option—should be one of the Agency's highest priorities.

We were, therefore, very concerned by the "clarification" that CMS included in its discussion of the definition of a "MIPS eligible clinician" at the front-end of the Proposed Rule:

> "For Part B items and services furnished by a MIPS eligible clinician such as purchasing and administering Part B drugs that are billed by the MIPS eligible clinician, such items and services may be subject to MIPS adjustment based on the MIPS eligible clinician's performance during the applicable performance period or included for eligibility determinations. For those billed Medicare Part B allowable charges relating to the purchasing and administration of Part B drugs that we are able to associate with a MIPS eligible clinician at an NPI level, such

> items and services furnished by the MIPS eligible clinician would be included for purposes of applying the MIPS payment adjustment or making eligibility determinations."[4]

This is the only statement CMS made in the Proposed Rule with respect to Part B drugs. The Agency did not make a formal proposal or solicit comments on the wisdom of applying MIPS adjustments based on clinicians' performance to the cost of Part B drugs. Respectfully, we believe this is too significant an issue—with consequences too great for Medicare beneficiaries—to be addressed in two sentences in the Proposed Rule without subjecting the pronouncement to notice-and-comment rulemaking. That process should happen in conjunction with the updates to the QPP for CY 2019 a year from now, given that the Agency did not solicit comments on the issue in the CY 2018 QPP Proposed Rule.

Applying MIPS adjustments to the cost of Part B drugs is inconsistent with the purpose of the MIPS. Congress created the MIPS program as a means of affecting payment for physician services. This is clear based on where Congress placed the MIPS statutory provisions—in section 1848 of the Social Security Act entitled "Payment for Physician Services."[5] In the two sentences devoted to this issue in the Proposed Rule, CMS does not address the tension between a legislatively-created MIPS reporting and payment structure applicable to physician services rendered during performance periods and application of MIPS adjustments not merely to payments for physician services, including the administration of Part B drugs, but to the cost of the actual drugs.[6]

What makes this even more troubling—and worthy of further consideration in future notice-and-comment rulemaking—is that CMS's "clarification" is at odds with how the Agency treated payment adjustments under predecessor programs. The Agency made no reference to this prior history in the Proposed Rule, even though it has previously noted that under the PQRS, the EHR Incentive Program, and Value-Based Payment Modifier,[7] "the payment adjustments were only made to the services paid under the Medicare PFS, which included administration of Part B drugs, but not the cost of the actual drugs."[8] CMS should not adopt such a fundamentally different approach to application of payment adjustments without studying the implications that such a change will have on patients' access to life-saving and life-changing Medicare Part B covered drugs.

There can be no doubt that application of MIPS payment adjustments to the cost of Part B drugs will adversely affect the care and treatment of Medicare patients with certain diseases and complex conditions such as cancer, Crohn's disease, Ulcerative Colitis, and primary

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[4] 82 Fed. Reg. at 30019 (emphasis added).

[5] 42 U.S.C. § 1395w-4 (emphasis added).

[6] See 82 Fed. Reg. at 30019.

[7] See 42 U.S.C. § 1395w-4(a), (k), (m), (o), (p).

[8] 81 Fed. Reg. 77008, 77340 (Nov. 4, 2016) (emphasis added).

immunodeficiency diseases. These adjustments could upend the current Part B drugs payment system, which the Medicare Payment Advisory Commission ("MedPAC") has recognized as being cost effective and successful in ensuring patient access to appropriate treatment.[9] Congress—not CMS—created the current drug payment methodology of Average Sales Prices ("ASP") + 6% (which has been reduced to ASP + 4.3% as a result of sequester cuts).[10]

With the sequester and MIPS downward adjustments factored together, Part B drug payment rates would effectively be reimbursed at ASP + 1% in 2019 decreasing to ASP – 3.2% in 2022 and beyond. Physicians subjected to downward adjustments would risk administering Part B drugs at a loss, especially when larger negative payment adjustments are applied in later years. This would pose a direct threat to patient care and should not be implemented without CMS issuing a formal proposal and soliciting comment from stakeholders.

II. CMS Should Expand PTAC's Authority to Approve PFPMs.

Implementation of Physician-Focused Payment Models ("PFPMs") is absolutely critical to the overall success of MACRA. In order to ensure that success, the Physician-Focused Payment Model Technical Advisory Committee ("PTAC") needs to be given greater authority to design, develop and implement PFPMs in a more timely fashion.

Independent gastroenterology practices have been at the forefront of developing PFPMs for the benefit of Medicare beneficiaries. The first of those proposals, Project Sonar, is "a care management program developed by community-based physicians in partnership with a major payer to improve the management of patients with chronic disease."[11] The second proposal (which will be resubmitted to PTAC, in revised form, this Fall), the Comprehensive Colonoscopy Advanced Alternative Payment Model for Colorectal Screening, Diagnosis and Surveillance ("Colonoscopy Advanced APM"), is "a comprehensive prospective bundled payment advanced alternative payment model [designed] to more effectively manage patients who require colonoscopy for colorectal cancer screening and surveillance, for evaluation of a positive finding of on other CRC screening modalities as recommended by the US Preventive Services Task Force, and for other diagnostic purposes."[12] DHPA supports both proposals, because we believe that Project Sonar and the Colonoscopy Advanced APM are the types of innovative care models that will ensure high quality, cost-efficient care for Medicare beneficiaries.[13]

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[9] See Letter to Leader McConnell, Leader Reid, Speaker Ryan and Leader Pelosi from 316 Organizations regarding CMS Medicare Part B Drug Model (Mar. 17, 2016) p. 2 n.2.

[10] 42 U.S.C. § 1395w-3a(b)(1).

[11] See Project Sonar submitted by the Illinois Gastroenterology Group and SonarMD, LLC (Dec. 21, 2016), available at https://aspe.hhs.gov/system/files/pdf/253406/ProjectSonarSonarMD.pdf p. iv (last accessed Aug. 18, 2017).

[12] See Colonoscopy Advanced APM submitted by the Digestive Health Network, Inc. (Dec. 28, 2016), available at https://aspe.hhs.gov/system/files/pdf/253406/PFPM.pdf (last accessed Aug. 18, 2017).

Unfortunately, CMS has refused to set deadlines on its obligation to review PTAC recommendations in a timely manner.[14] And, with the PTAC having reviewed only three of the 13 proposals submitted to date (one of the three being Project Sonar),[15] clinicians are left to wonder whether CMS will prioritize the conversion of models developed by the PTAC into MIPS APMs or Advanced APMs. The concern is even greater when factoring in the additional 17 Letters of Intent filed with PTAC,[16] which can be expected to result in more formal proposals being submitted with the reasonable expectation that they should be acted upon in a timely fashion. This backlog creates a missed opportunity, as the briefest of summaries of Project Sonar and the Colonoscopy Advanced APM demonstrate.

Project Sonar is a critically important Advanced APM for our physicians who are on the front lines diagnosing and caring for thousands of patients with Inflammatory Bowel Disease (IBD). The two variants of IBD—Crohn's Disease and Ulcerative Colitis—are among the most significant, chronic gastrointestinal conditions, affecting upwards of 1.5 million Americans.[17] The key to Project Sonar, which has been deployed, to date, with great success for patients with Crohn's disease, is the combined use of evidence-based medicine coordinated with proactive patient engagement. A Project Sonar Advanced APM will have great value on two levels—not only will it have a profound impact in care delivery for thousands of patients with Crohn's disease, but it can serve as a model for the expansion of Project Sonar and other chronic care

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[13] Public Comment from Digestive Health Physicians Association to Physician-Focused Payment Model Technical Advisory Committee (Jan. 20, 2017) re: Project Sonar Advanced APM ("DHPA Comment on Project Sonar"), available at https://aspe.hhs.gov/system/files/pdf/255731/ProjectSonarPublicComments.pdf (last accessed Aug. 18, 2017); Public Comment from Digestive Health Physicians Association to Physician-Focused Payment Model Technical Advisory Committee (Jan. 5, 2017) re: Colonoscopy Advanced APM, available at https://aspe.hhs.gov/system/files/pdf/255731/ComprehensiveColonoscopyAAPMPublicCommentsUpdated.pdf (last accessed Aug. 18, 2017) ("DHPA Comment on Colonoscopy Advanced APM").

[14] 81 Fed. Reg. 77008, 77492 (Nov. 4, 2016) ("We do not believe it would be reasonable to require that we adhere to a deadline in deciding whether to test a particular proposed PFPM. It is important for us to retain the flexibility to test APMs when we believe that it is the right time to do so, taking into account the other APMs we are currently testing, any potential design changes to the proposed PFPM, interactions with our other policies, and resource allocation.").

[15] See "Reports to the Secretary," (voting to recommend Project Sonar submitted by the Illinois Gastroenterology Group and SonarMD, LLC and the ACS-Brandeis Advanced APM submitted by the American College of Surgeons for limited-scale testing and voting not to recommend the COPD and Asthma Monitoring project), available at https://aspe.hhs.gov/proposal-submissions-physician-focused-payment-model-technical-advisory-committee (last accessed Aug. 18, 2017).

[16] See "Proposal Submissions: Physician-Focused Payment Model Technical Advisory Committee," available at https://aspe.hhs.gov/proposal-submissions-physician-focused-payment-model-technical-advisory-committee (last reviewed Aug. 21, 2017).

[17] An analysis in the peer-reviewed literature estimates that annual, IBD-associated treatment costs in the United States are $6.3 billion ($3.6 billion for Crohn's disease, $2.7 billion for ulcerative colitis). See Kappelman, MD, et al., "Direct Health Care Costs of Crohn's Disease and Ulcerative Colitis in United States Children and Adults," Gastroenterology 2008 Dec; 135(6): 1907-1913, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2613430/, (last accessed Aug. 18, 2017).

management programs that physician specialists can employ for the benefit of their patients.[18] In its Report to the Secretary, PTAC recognized that "Project Sonar holds promise" and that "the potential benefits of the model justify moving forward with [limited-scale] testing."[19]

For its part, the Colonoscopy Advanced APM is a comprehensive, prospective bundled payment with retrospective reconciliation that will encourage practitioners from multiple specialties to collaborate and coordinate care across settings to more effectively manage patients who require colonoscopy for colorectal cancer (CRC) screening, diagnosis, and surveillance, and for other diagnostic purposes. As we noted in our public comments in support, given the critical nature of early CRC screening as a tool in fighting colon cancer, and the serious deficiencies in screening rates that continue to exist in eligible U.S. adults age 50 to 75, the Colonoscopy Advanced APM presents a perfect opportunity to close the gaps in CRC screening, improving detection of CRC at early stages, decreasing the rate of CRC, and improving survival for this disease.[20] Importantly, the Colonoscopy Advanced APM will also address a substantial problem with Medicare's current reimbursement scheme, which unnecessarily pays hospitals twice as much as independent ambulatory surgery centers for the facility fee in connection with identical colonoscopy procedures.

Despite the innovative delivery and payment models being developed and submitted for consideration to PTAC, to date, PTAC's recommendations are accorded no priority for review by CMS and the Agency has explicitly refused to place any deadline whatsoever on when it will review those PTAC-approved proposals. CMS can—and should—rectify this flaw in the PFPM approval process through a limited number of actions that would result in a more meaningful role for the PTAC in design and implementation of APMs:

- Commit (i) to a 90-day period from date of submission for the PTAC to review and decide whether to approve a PFPM as an Advanced APM or MIPS APM, and (ii) to approve a certain number of PTAC-proposed PFPMs as Advanced APMs each year;

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[18] As we noted in our public comments supporting Project Sonar, there are four aspects of Project Sonar that make it a PFPM particularly worthy of implementation: (i) Project Sonar enables us to decrease the cost of care for our patients with Crohn's disease by decreasing the complication rate through better medical management; (ii) Project Sonar enables us to identify the high-risk patient with Crohn's disease before complications ensue; (iii) Project Sonar enables us to channel care of patients to those healthcare professionals in our practices who have the most knowledge, experience and expertise to address the specific patient's needs; and (iv) Project Sonar enables us to better engage our patients so that early warning signs can routinely be assessed even before the patients realize they need intervention. DHPA Comment on Project Sonar p. 2.

[19] See PTAC Comments and Recommendations to The Honorable Thomas E. Price, Secretary, U.S. Department of Health and Human Services, re: Project Sonar (May 31, 2017), available at https://aspe.hhs.gov/system/files/pdf/255906/SonarReportSecretary.pdf (last accessed Aug. 18, 2017).

[20] DHPA Comment on Colonoscopy Advanced APM p. 2.

- Provide clinicians with clearer guidance in their development of PFPM proposals by publishing relevant, objective benchmarks that will be used by PTAC and CMMI to approve submitted models;

- Apply a rebuttable presumption that, at a minimum, CMS will adopt any PFPMs approved by PTAC as MIPS APMs.

We believe that the success of MACRA—particularly for gastroenterologists and other physician specialists in independent practice—depends on CMS taking these steps to bolster the process for development and implementation of PFPMs. There is a substantial backlog of APM proposals at PTAC and CMS. Without expeditious review and an increased urgency on moving these proposals through the process, CMS will not achieve the goals of MACRA—substantially greater numbers of physicians providing more coordinated care which will improve outcomes and constrain costs.

III. Virtual Groups Will Play a Critical Role in the Ability of Independent Practices to Participate in the MIPS.

We commend CMS for the proposals it has made establishing requirements for MIPS reporting at the virtual group level.[21] As the Agency notes, Congress granted the Secretary "discretion to establish appropriate classifications regarding the composition of virtual groups such as by geographic area or specialty."[22] In exercising that discretion, CMS stated:

> "[W]e believe it is important for virtual groups to have the flexibility to determine their own composition at this time, and, as a result, we are not proposing to establish any such classifications regarding virtual group composition."[23]

Accordingly, CMS proposed not to limit the number of TINs that may form a virtual group and also proposed not to limit virtual group size.[24] Of equal importance, CMS chose not to create classifications that would constrain specialists from participating in virtual groups either with other physicians in their own specialty, a different specialty, or other clinicians (e.g., primary care physicians or non-physician providers).[25] These proposals are fully consistent with the Agency's broader goal of "reduc[ing] burden for clinicians, providers, and patients in a way that

[21] See 82 Fed. Reg. at 30016; id. at 30027-30034.

[22] Id. at 30028.

[23] Id.

[24] Id.

[25] See id. at 30027-34.

increases quality of care and decreases costs, thereby making the healthcare system more effective, simple, and accessible while maintaining program integrity and preventing fraud."[26]

There is a disconnect, however, between the Agency's objective of implementing policies designed to provide flexibility in the establishment and operation of virtual groups and the arbitrary cut-off that prohibits groups with more than 10 physicians from electing to participate in a virtual group.[27] We recognize that the 10-physician cut off is a creature of statute, specifically section 1848(q)(5)(I)(ii) of the Social Security Act,[28] and, therefore, will need to be modified through legislative action. But, as the agency tasked with implementing MACRA, we believe it is important for CMS to seek from Congress additional statutory authority that would permit CMS to make virtual group participation available to group practices, regardless of size. Such added flexibility will enable CMS to implement the MIPS more effectively and for a broader cross-section of clinicians.

DHPA's members—75 independent gastroenterology practices with more than 1,700 physicians furnishing care to millions of patients in 36 states across the country—are among the medical group practices that would benefit from having the option of electing to participate, for MIPS reporting purposes, in virtual groups with other clinicians and group practices. Although the virtual group structure is available to the 23 DHPA member practices consisting of 10 or fewer physicians, the majority of DHPA's member practices (38 of 75) have between 11 and 30 physicians in their groups. It is unreasonable—and serves no clinical or health policy objective—to permit two group practices consisting of seven physicians each to participate in a virtual group with one another, yet one of those seven-physician practices cannot similarly elect to participate in a virtual group with an 11-physician practice. The cutoff at 10 physicians makes even less sense when one considers that CMS, appropriately, is not proposing limits on the number of TINs that may form a virtual group or on virtual group size. Therefore, seven medical practices with 10 physicians each (70 physicians in total) can form a virtual group for MIPS reporting purposes, yet three medical practices with 11 physicians each (33 physicians) are not

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[26] See Proposed Policy, Payment, and Quality Provisions Changes to the Medicare Physician Fee Schedule for Calendar Year 2018, available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-07-13-2.html (last accessed Aug. 17, 2017). CMS noted—and we do not dispute—that "qualifications as a virtual group for purposes of MIPS do not change the application of the physician self-referral law to a financial relationship between a physician and an entity furnishing designated health services, nor does it change the need for such a financial relationship to comply with the physician self-referral law." 82 Fed. Reg. at 30028. With that said, we believe Congress's shift to new value-based payment structures through the MIPS and Advanced APMs, along with new reporting vehicles such as virtual groups, underscores the need to modernize the physician self-referral ("Stark") law—a law created more than a generation ago in a strictly fee-for-service payment environment.

[27] See 82 Fed. Reg. at 30027 (citing 42 U.S.C. § 1848(q)(5)(I)(ii) for proposition that an individual MIPS eligible clinician or a group consisting of not more than 10 MIPS eligible clinicians can elect, for a given performance period, to be a virtual group with at least one other such individual MIPS eligible clinician or group) (emphasis added).

[28] 42 U.S.C. § 1395w-4(q)(5)(I)(ii).

permitted to do so. There can be no doubt that the challenges of complying with the MIPS are equally burdensome for a 10-physician practice (permitted to participate in a virtual group) and an 11-physician practice (prohibited from participating).

To be clear, the burdens of MIPS reporting are not limited to "smaller" medical practices. The largest of DHPA's member medical practices (with anywhere from 31 to 100+ physicians) confront just as many challenges and burdens—as measured by time commitment and resource allocation—with MIPS compliance as do our member practices with fewer physicians. And, as policymakers look to enhance, rather than inhibit, opportunities for physicians to collaborate and coordinate care across medical specialties, independent GI practices of all sizes should have the flexibility to elect to participate in the MIPS through virtual groups with solo practitioners, other GI practices, primary care practices and practices devoted to other clinical specialties (e.g., colorectal surgery, pathology, anesthesiology). Clinicians need CMS's support in obtaining greater flexibility for participation in the MIPS through reporting at the virtual-group level.

IV. Request for Action

DHPA looks forward to working with CMS to continue the transition to the delivery and payment systems created by MACRA in a way that promotes and protects the high quality, cost-efficient care that gastroenterologists and other physician specialists furnish to Medicare beneficiaries in the independent practice setting. Consistent with our comments above, we respectfully request that CMS:

- Not apply MIPS payment adjustments to the cost of Part B drugs or, at a minimum, delay doing so until such time that the Agency receives feedback, through the notice-and-comment rulemaking process for the CY 2019 QPP, on the expected impact that such action would have on Medicare beneficiaries' access to Part B drugs;

- Modify the process for review and approval of PFPMs in order to provide the PTAC with greater authority to implement PFPMs and, relatedly, approve proposed APMs, including those submitted to PTAC and CMMI, in a more timely manner; and

- Finalize the proposals with respect to "virtual groups" as a mechanism for encouraging specialty practices to participate in the MIPS and seek additional statutory authority from Congress to permit MIPS reporting at the virtual-group level, including for group practices with more than 10 physicians.

Please reach out with any questions to DHPA's Chair of Health Policy, Dr. Lawrence Kim (lkim@gutfeelings.com, 303-788-8888), or to DHPA's legal counsel, Howard Rubin (Howard.Rubin@kattenlaw.com, 202-625-3534).

Sincerely,

Fred Rosenberg, M.D.
President

Lawrence Kim, M.D.
Chair, Health Policy

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