DIGESTIVE HEALTH PHYSICIANS ASSOCIATION®

EXECUTIVE COMMITTEE:

Fred Rosenberg, MD
President and
Chairman of the Board
Illinois Gastroenterology Group

Michael L. Weinstein, MD
Vice Chairman
Capital Digestive Care, LLC

Michael Dragutsky, MD
Treasurer
Gastro One

David B. Ramsay, MD
Secretary
Digestive Health Specialists, PA

Scott R. Ketover, MD
Past President
Minnesota Gastroenterology, PA

Lawrence S. Kim, MD
Chair, Health Policy
South Denver Gastroenterology, PC

Arif Aziz, MD
Chair, Data Analytics
GI Specialists of Georgia

Marc Sonenshine, MD
Chair, Communications
Atlanta Gastroenterology
Associates, LLC

Charles Accurso, MD
At-Large Member
Digestive Healthcare Center

Pradeep Bekal, MD
At-Large Member
Ohio Gastroenterology and
Liver Institute

John J. Hong, MD
At-Large Member
United Gastroenterologists

Kevin Harlen
Executive Director
Capital Digestive Care, LLC

June 27, 2016

BY ELECTRONIC SUBMISSION

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Comments to CMS-5517-P

Dear Acting Administrator Slavitt:

The Digestive Health Physicians Association ("DHPA") appreciates the opportunity to comment on CMS's Proposed Rule Implementing the Merit-Based Incentive Payment System ("MIPS") and the Alternative Payment Model ("APM") Incentive Under the Physician Fee Schedule, and Establishing Criteria for Physician-Focused Payment Models ("PFPMs") (collectively, the "Proposed Rule").[1] As the voice of the nation's leading independent gastroenterology practices, DHPA is committed to working with CMS as it implements the Medicare Access and CHIP Reauthorization Act ("MACRA").

The Agency has provided an excellent roadmap for the transition to a new, value-based payment system; however, the Proposed Rule does not do enough to ensure that independent gastroenterology (and other specialty) practices will be able to participate fully in this new payment system. In this comment letter, we provide three specific suggestions for CMS to incorporate in the Final Rule in order to facilitate greater participation by independent gastroenterology practices in the payment system mandated by MACRA: (i) CMS should use its existing authority to modify certain Stark law regulations so that physicians in independent gastroenterology practices can effectively manage and coordinate patients' resource use and quality outcomes across multiple sites of care; (ii) CMS should revise the rules governing resource use so that they are not so heavily weighted to inpatient services and in order to ensure that high quality, cost-efficient services provided in ambulatory surgical centers, including colonoscopies and other endoscopic procedures, can be evaluated properly; and (iii) CMS should provide adequate options for gastroenterologists and other specialists to report cross-cutting measures and Clinical Practice Improvement Activities.

[1] 81 Fed. Reg. 28162.

12510 PROSPERITY DRIVE | SUITE 200 | SILVER SPRING, MD 20904

I. 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. In its first two years of existence, DHPA has grown to include 61 member gastroenterology practices from 31 states in every region of the country. Our more than 1,400 physicians provide care to approximately 2.5 million patients annually in more than 3.5 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.

II. Overview of MIPS and APM Incentives Relevant to Independent GI Practices

MACRA calls on CMS to implement two significant new programs. Under the MIPS, the fee-for-service system will combine existing CMS reporting programs into a single composite score through which physicians will be rated on the basis of quality, resource use, use of certified electronic health records, and Clinical Practice Improvement Activities ("CPIAs").[2] CMS proposes that, under the **quality** component, physician groups will be required to report on at least six quality metrics, one of which must be a "cross-cutting" measure.[3] CMS proposes that, under the **resource use** measure, group practices will be evaluated on the basis of three measures: 1) the total Medicare spending for all beneficiaries attributed to the group; 2) Medicare Spending Per Beneficiary (an inpatient-specific quality metric); and 3) a set of "care episode groups" designed by CMS to track spending on specific clinical categories.[4] Under the **CPIAs**, physician groups will be rewarded for engaging in a certain number of CMS-defined activities that are deemed to be clinically beneficial.[5]

The other option created by MACRA is payment under an Alternative Payment Model (or "APM").[6] A clinician will receive a bonus under MACRA if he or she is deemed a Qualifying Participant ("QP") in an "Advanced APM".[7] CMS proposes that in order to achieve QP status, a clinician would be required to demonstrate that a certain percentage of his or her patients are seen, or reimbursement is received, through an "Advanced APM."[8] CMS proposes that an APM will only be an "Advanced APM" if it requires the use of a certified EHR, bases at least some payments on quality metrics equivalent to those used in the MIPS, and accepts "financial risk beyond a nominal amount."[9] This last standard is particularly difficult for Advanced APMs to

---

[2] 42 U.S.C. §§ 1395w-4(q)-(s).

[3] 81 Fed. Reg. at 28186.

[4] Id. at 28198.

[5] Id. at 28261.

[6] 42 U.S.C. § 1395L.

[7] 81 Fed. Reg. at 28234-5.

[8] Id.

[9] Id.

meet because CMS has chosen a standard for the "nominal amount" that is extremely high.[10] The practical effect for independent gastroenterology practices is that, under current CMS proposals, they would only be able to qualify as Advanced APMs under three programs: the Medicare Shared Savings Program ("MSSP") Track Two and Three, and the Next Generation ACO program.[11] In addition to the affirmative bonus payment, QPs are insulated from negative payment adjustments under the MIPS.[12] Clinicians who receive a significant portion of payments through an Advanced APM (but who do not qualify as QPs), are treated as Partial QPs and may choose to be graded under the MIPS.[13] Finally, clinicians who participate in an APM at *any* level receive advantageous treatment by reporting under the "MIPS APM" rules.[14]

III. CMS Regulations Must Promote Integrated Care To Achieve the Goals of MACRA.

It will be very difficult for physicians in independent gastroenterology practices to achieve MACRA's policy objectives in the face of Stark Law provisions that, in many instances, have the effect of inhibiting coordination between providers in a fee-for-service system. In order for MACRA to succeed, CMS must develop new flexibilities within the Stark Law to allow physicians to better coordinate care, work as teams (often across specialties such as gastroenterology and pathology) and participate in a broad range of APMs. At the same time, the success of independent specialty practices under MACRA depends in part on the use of existing provisions of the Stark Law, including the in-office ancillary services exception, that ensure the delivery of comprehensive, integrated care demanded by MACRA.

The Stark Law prohibits a physician from making a referral to any entity with which he or she has a financial relationship, unless an exception applies.[15] This prohibition is interpreted broadly, such that it even restricts a physician from ordering services provided in her own physician office unless certain stringent conditions are met.[16] This is why the Stark Law poses such a significant barrier to MACRA's goals. And, yet, we believe the success of the existing Medicare Shared Savings Program and Center for Medicare & Medicaid Innovation models in the last six years (supported by broad CMS waivers of the Stark Law) demonstrates that CMS can use its existing authority to design a new Stark Law exception to support APM models under MACRA. CMS needs to provide that same flexibility to physician-led specialty care.

MACRA makes physician group practices much more accountable for the overall healthcare status and resource use of their patients—whether or not these measures are driven by services provided by the group itself. As but one example, the MIPS resource use metric, and the measures of spending used by each of CMS's approved Advanced APMs, are largely based on

---

[10] Id. at 28306.

[11] Id. at 28312-3. Gastroenterology practices may be able to qualify for additional Advanced APMs in the future if CMMI approves relevant models that meet the high standards CMS proposes in this Proposed Rule.

[12] QPs are not treated as MIPS "Eligible Clinicians." See 42 U.S.C. § 1395w-4(q)(1)(C)(ii).

[13] 42 U.S.C. § 1395w-4(q)(1)(C)(iii).

[14] 81 Fed. Reg. at 28234-5.

[15] 42 U.S.C. § 1395nn.

[16] See 42 C.F.R. § 411.351, "Referral" and "Entity."

the *total cost* of each attributed patient's care under Medicare Part A and Part B.[17] The total cost of care will necessarily capture spending for services outside the domain of the independent practice itself, such as hospitalization, prescription drugs and post-acute care.

Under MACRA, physicians will be required to share responsibility for the quality and cost of care provided to patients, whether or not providers across sites of service have any formal relationship. As such, physicians in independent practice need options to structure relationships with hospitals and other community providers to ensure patients are receiving care from high-quality, cost-efficient providers on a coordinated basis. Moreover, physicians need assurance that they may move to formal APMs to redesign the model of care offered to patients without violating the strict liability terms of the Stark Law.

The Proposed Rule does not create the structures needed to support this transition to APMs and the gainsharing methodology at the heart of most APM models. CMS should utilize its existing authority to create new exceptions, which create "no risk for program or patient abuse."[18] The Agency has exercised this authority in the past to protect a number of essential commercial relationships.[19] CMS last attempted to use this authority to protect gainsharing arrangements prior to enactment of the Affordable Care Act.[20] The result was an extremely limited, technical proposal that CMS chose not to finalize after it failed to attract significant support.[21]

The landscape of risk-based arrangements has changed dramatically since CMS's gainsharing proposal. Notably, the Affordable Care Act created the MSSP and CMMI and provided CMS with the ability to develop waivers to support these programs.[22] Since then, the Agency has established a broad waiver of the Stark Law for MSSP ACOs, and has issued many tailored waivers for CMMI demonstrations.[23] The waivers have now been in place for many years without creating fraud and abuse risks and have encouraged more coordinated care that improves patient outcomes and often times lowers costs.

However, those limited waivers are generally not relevant to independent gastroenterology practices that seek to participate meaningfully in APMs. The existing waivers are limited to ACOs operating under the MSSP, or models under the CMMI demonstration authority.[24] The waivers cannot extend to APMs operating under Medicaid or commercial payer arrangements, including those that qualify as "Other Payer Advanced APMs" under the Proposed Rule.[25] CMS should address this deficiency since MACRA provides an avenue to becoming a QP through

---

[17] 81 Fed. Reg. at 28198.

[18] 42 U.S.C. § 1395nn(b)(4).

[19] See e.g., 42 C.F.R. § 411.357(l) (exception for fair market value relationships).

[20] See 73 Fed. Reg. 38502, 38548.

[21] Id.

[22] 42 U.S.C. §§ 1395jjj(f) and 1315a(d)(1).

[23]See the list of CMS and HHS-OIG fraud and abuse waivers for these programs at: https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html.

[24] 42 U.S.C. §§ 1395jjj(f) and 1315a(d)(1).

[25] See 81 Fed. Reg. at 28327-330.

participation in Advanced APM models with commercial payers under the all-payer metric.[26] Without CMS protection, gainsharing payments or other distributions in an Other Payer APM would create "financial relationships" between participants in the APM,[27] and all *Medicare* referrals between these participants could be prohibited.

Independent gastroenterology practices need a new Stark Law exception protecting our members' participation in any type of *bona fide* APM – whether it is operated by Medicare or another payer. We do not believe that Congress or CMS intended to create an artificial distinction between how physicians who participate in the MSSP or CMMI models treat Medicare patients as contrasted with patients who are covered by other payers. For now, though, waivers apply *only* to arrangements with MSSP ACOs and entities participating in CMMI programs, but **no waivers or other Stark Law exceptions apply** to the equivalent entities in a non-Medicare context. Existing Stark Law exceptions for compensation relationships frequently do not protect non-Medicare value-based arrangements because these exceptions prohibit payments that vary with the volume or value of "other business generated."[28] Thus, financial relationships between a physician and a DHS entity created as a result of participation in a **Medicare** program are protected from Stark liability, but the same financial relationships created under a **non-Medicare** program could violate the Stark Law. As a result, current Stark Law exceptions arguably force a physician and DHS entity to establish entirely different care models for treating non-Medicare patients. This will become increasingly unworkable as MACRA transforms the entire payment system—public and private.

We ask CMS to use its current authority to create a new regulatory exception under the Stark Law for participation in Medicare *and* non-Medicare APMs. This exception should be consistent with the structure of the waivers issued by CMS for existing MSSP and CMMI ACO models. Such a new exception—coupled with the Stark Law's existing in-office ancillary services exception that fosters care models that deliver integrated, comprehensive care—is needed to ensure that independent gastroenterology (and other specialty) practices can participate in a full complement of APMs. This will go a long way toward promoting better, more integrated care—a key goal of MACRA.

IV. Independent Specialists Need More Options to Comply With MIPS.

We are concerned that a number of required reporting categories under the MIPS are heavily focused on the role of primary care providers. In particular, we are concerned that the mandate to report "cross-cutting" quality measures and Clinical Practice Improvement Activities ("CPIAs") will be difficult to achieve for independent gastroenterology practices.

---

[26] 42 U.S.C. § 1395L(z)(2)(B).

[27] Note that this would be true for any non-Medicare model that is operating as an APM, whether or not it meets the criteria for an "Advanced" APM.

[28] See *e.g.*, 42 C.F.R. § 411.357(l)(3) (the exception for fair market value arrangements). Although this exception might protect the financial relationship created between an entity and a physician as a result of non-Medicare shared savings earned collectively by both entities, the fact that such savings would potentially reflect the referral patterns of the physician to the entity could arguably "take into account the volume or value of . . . other business generated by the referring physician."

To its credit, CMS has defined a set of seven gastroenterology specialty measures, recognizing that specialty groups have unique practice patterns.[29] However, the Agency has included a requirement to report at least one "cross-cutting" measure.[30] The list of cross-cutting measures is much shorter, and generally includes activities associated with coordination between providers. Although we support the goal of greater coordination, we are concerned that this list is generally weighted towards primary care providers. Of the 10 proposed cross-cutting measures, six relate to management of tobacco use, alcohol abuse, high blood pressure, and high body mass index; one requires physicians to inquire into whether patients older than 65 have an advanced care plan or surrogate decision maker (which may be duplicative and may not be appropriate for all patients seeking gastroenterology care).[31] The only cross-cutting measures likely to be relevant to gastroenterologists are (i) receipt of a report from a specialist in the very few cases in which a gastroenterologist refers to another specialist (for example, a surgeon); (ii) use of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey; and (iii) attestation that the physician has received a complete list of all medications taken by the patient.[32]

This leaves independent gastroenterology practices with few options to demonstrate compliance with the cross-cutting requirement and creates significant risk for practices in the event that they are unable to collect and report this information in a given performance year (for example, a malfunction or data error in a reporting system). Given that quality is initially the largest part of the MIPS composite score, and the composite score itself translates to payment adjustments by comparing the performance of various physicians and/or groups, the inability to report a cross-cutting measure could be enough, standing alone, to cause a negative payment adjustment.[33]

CPIAs have a similar problem. CMS proposes to provide each physician group reporting under MIPS with a CPIA Inventory (a list of all CMS-designated CPIAs).[34] The physician group would then select all CPIAs that apply. However, the CPIAs also lean heavily toward primary care. As a result, independent gastroenterology (and other specialty) practices are inherently disadvantaged and could find it more difficult to identify enough CPIAs to meet performance standards.

We respectfully ask CMS to work with DHPA and other gastroenterology professional societies to refine the existing set of cross-cutting measures and CPIAs. CMS should not implement a reporting system applicable to all physicians without providing meaningful avenues for independent gastroenterology and other specialty group practices to comply.

---

[29] 81 Fed. Reg. at 28469-70.

[30] Id. at 28186.

[31] Id. at 28447-8.

[32] Id.

[33] Id. at 28269.

[34] Id. at 28215.

V. Measures of Value Should Be Based on Services Furnished In All Sites of Service, Including Independent Practices and Ambulatory Surgery Centers.

Under MACRA, the resource use component of the MIPS will slowly rise in importance until it is worth as much as the quality component.[35] As this occurs, we are concerned that the measures of resource use that CMS has proposed will make it difficult for independent specialty practices to demonstrate their value. The Agency proposes that resource use will be measured through three measures:[36]

- The total cost of care across Medicare Part A and Part B incurred by patients attributed to the group practice (note that this is the same metric currently used by ACO programs);
- Medicare Spending Per Beneficiary, a metric that reflects the average cost of care for services before and after certain "index" hospital-based procedures, as attributed to the practice (identified by Tax Identification Number) responsible for these procedures.
- Care episode groups, developed by CMS to group certain sets of clinically associated procedures in order to evaluate the Medicare Part A and Part B spending for these services.

Care episode groups are the most meaningful measure of resource use for specialty physicians because they represent focused analysis that is limited to services that are genuinely connected to one another. Unlike the total cost of care, which reflects spending on services wholly unrelated to any particular specialty's spending, care episode groups represent a tightly defined set of services that may reflect a given specialty group's relative efficiency as compared to its competitors. As such, it is important that these care episode groups consider services provided in all potentially applicable settings, particularly when the same service is provided at very different cost levels depending on the site of service.

Unfortunately, CMS has not taken this approach. Rather, the Agency has designed care episode groups to be "triggered" by services performed in a hospital. As one problematic example, it appears that CMS will only assess the costs associated with a colonoscopy and biopsy if the procedure was conducted in the hospital setting.[37] This places those gastroenterologists who perform colonoscopies in ambulatory surgical centers at an extreme disadvantage. This is short-sighted and ignores the reality that the physician controls where a patient receives GI care. Medicare commonly pays ASCs about half of what the identical services are paid in the hospital outpatient department ("HOPD") setting. For example, Medicare pays hospitals $793 for a lesion removal colonoscopy and diagnostic colonoscopy, but pays ASCs just $429 for exactly the same procedures. Hospitals receive $747 for an upper GI endoscopy biopsy, yet ASCs receive just $404 from Medicare for that procedure. In short, the same procedure, same equipment, same physician, and same medical outcome result in nearly twice the cost in the hospital setting.

---

[35] Id. at 28269.

[36] Id. at 28198.

[37] Id. at 28207, "Colonoscopy and Biopsy." ("Episodes are triggered by the presence of a trigger CPT/HCPCS code on [a] claim when the code is the highest code service for a patient on a given day. Medical condition episodes are triggered by [inpatient] stays with specified MS-DRGs.")

The Agency's lack of attention paid to the role of ASCs in controlling resource use is disappointing given the substantial evidence that ASCs provide care that is clinically equivalent to hospitals at a dramatically lower price. An April 2014 Health and Human Services Office of Inspector General (OIG) report found that ASCs saved Medicare $7 billion from 2007 to 2011. In that same report, the OIG also estimated that reducing hospital outpatient department (HOPD) payments to the ASC rate for low-risk and no-risk procedures could save Medicare an additional $15 billion and beneficiaries $4 billion in reduced copays.[38] In addition, a recent study by Healthcare Bluebook found that total U.S. healthcare costs are reduced by nearly $40 billion due to the availability of ASCs, and an additional $55 billion could be saved if more services migrate from hospital outpatient departments to ASCs.[39] The study also suggests that ASCs are more consistent with patient-centered care, noting that: "ASCs tend to be more convenient and cost effective than HOPDs while still providing excellent care."[40] Finally, the study found that nearly half (48%) of common surgical procedures are performed at ASCs.[41] In light of these enormous quality and cost advantages, CMS should ensure that physicians are rewarded for delivering care in the efficient ASC setting.

VI. Request for Action.

DHPA looks forward to working with CMS to transition to the payment system created by MACRA. We believe that CMS can take simple steps to ensure that the new payment system works well for all physicians, including those of us who care for patients in the independent practice setting. To that end, we respectfully request that CMS:

- Create a new exception to the Stark Law that is consistent with the structure of existing MSSP and CMMI waivers for ACO models, and maintain other existing protections for integrated care, so that independent gastroenterology practices can participate in a full complement of APMs.

- Provide more options for cross-cutting quality measures and CPIAs that are relevant to independent gastroenterology practices.

- Allow care episode groups to be triggered by services such as colonoscopies that are furnished in ambulatory surgery centers.

---

[38] Office of Inspector General, "Medicare and Beneficiaries Could Save Billions if CMS Reduces Hospital Outpatient Department Payment Rates for Ambulatory Surgical Center-Approved Procedures to Ambulatory Surgical Center Payment Rates," Report A-05-12-00020 (April 2014), http://oig.hhs.gov/oas/reports/region5/51200020.pdf.

[39] Healthcare Bluebook, Ambulatory Surgery Center Association, and HealthSmart, Commercial Insurance Cost Savings in Ambulatory Surgery Centers, p. 1, http://www.ascassociation.org/viewdocument/?DocumentKey=61197e80-d852-4004-860a-2424968b005b.

[40] Id. at 3.

[41] Id. at 7.

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.	Lawrence Kim, M.D.
President	Chair, Health Policy

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