DIGESTIVE HEALTH PHYSICIANS ASSOCIATION®

November 17, 2015

BY ELECTRONIC SUBMISSION

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Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
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RE: Comments on CMS-3321-NC

Dear Acting Administrator Slavitt:

On behalf of the more than 1,300 gastroenterologists and other physician specialists whose independent medical practices are members of the Digestive Health Physicians Association (DHPA), we want to thank you for the opportunity to comment on the Request for Information Regarding Implementation of the Merit-Based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payment for Participation in Eligible Alternative Payment Models (CMS-3321-NC).[1] DHPA appreciates CMS's request for stakeholder input as it implements the new payment system created by the Medicare Access and CHIP Reauthorization Act ("MACRA").

Beginning in 2019, MACRA requires all Medicare Physician Fee Schedule payments to be paid either through a fee-for-service Merit-Based Incentive Payment System ("MIPS") or risk-based Alternative Payment Models ("APMs"). In addition, MACRA authorizes new Physician-Focused Payment Models ("PFPMs"). DHPA focuses its comments primarily on the MIPS and PFPMs. Although APMs are also extremely important, they are largely based on existing Medicare value-based payment programs. By contrast, the MIPS calls for far-reaching changes in the basic structure of fee-for-service payments to all physicians. DHPA believes that CMS must handle carefully the project of incorporating value-based elements into the Physician Fee Schedule, with serious consideration given to physician feedback. Given the degree of change and the number of fundamental questions that CMS has raised in the RFI, we have chosen to focus this comment letter on the following topics of particular importance to independent gastroenterology practices:

[1] 80 Fed. Reg. 59102 (October 1, 2015).

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- CMS should offer a broader set of acceptable quality metrics, condition-focused measures of resource use, and clinical practice improvement activities than those currently available under existing value-based payment programs and proposals, in order to ensure that all specialties can meaningfully participate.

- CMS should align requirements under the Qualified Registry and Qualified Clinical Data Registry reporting system for reporting under the MIPS.

- CMS should incorporate measures of patient satisfaction into quality metrics under the MIPS.

- CMS should analyze resource use based on overall costs of care for enrollees attributed to physicians, whether provided by a single entity or by multiple "downstream" entities. CMS should also provide reporting to independent entities to assist their management of this care.

- CMS should design PFPMs that allow independent specialty practices to participate in their own right, without integration or consolidation with hospitals or other providers.

- CMS should provide numerous opportunities for stakeholders to provide feedback as it designs and implements the MACRA payment reforms—both at the initial planning stage and through notice-and-comment rulemaking on specific proposals.

I. The 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. It 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 less than two years, DHPA has grown to include 59 member GI practices from 29 states in every region of the country. Our more than 1,300 physicians provide care to more than 2.5 million patients annually in approximately 3.5 to 4 million distinct patient encounters.

II. The MIPS Fundamentally Changes The Calculation of Fee-For-Service Payments By Incorporating New Measures of Value.

Beginning in 2019, MACRA will transition fee-for-service payments to the MIPS. Eligible professionals (including physicians) will receive upward or downward adjustments to their Physician Fee Schedule payments on the basis of a composite performance score developed through four performance categories: **quality**, **resource use**, **clinical practice improvement activities**, and **meaningful use of EHR technology**.[2] Each eligible professional will be scored

[2] 42 U.S.C. § 1395-w4(q)(2)(A). Note that qualifying and partially qualifying APM participants and practices with low volume are not MIPS-eligible professionals. *Id*. at (q)(1)(C)(ii).

on a scale of 0-100 each year, although the precise methodology for the MIPS composite score is delegated to the Agency.[3] CMS solicits comments on each of these MIPS performance categories. Our comments focus on elements with specific relevance to our unique perspective as independent GI specialists, particularly the development of the MIPS **quality**, **resource use**, and **clinical practice improvement** performance categories.

III. DHPA Supports the Use of PQRS Quality Metrics in the MIPS

A. CMS Should Phase In Implementation of the MIPS Quality Metrics.

CMS requests comment on the methods of incorporating quality measures and reporting obligations under the Physician Quality Reporting System ("PQRS") into MIPS. DHPA generally supports the use of existing quality measures and reporting processes wherever possible. However, we note that the MIPS reporting obligations are built upon PQRS reporting systems that are still quite new. **As a result CMS should create a process to incorporate feedback from stakeholders as providers and the Agency learn about strengths and weaknesses of the existing quality reporting system**.

Reporting under PQRS only began in 2013 for groups of more than 100 physicians, with the associated payment adjustments taking effect in 2015.[4] PQRS has been phased in for progressively smaller groups, with payment adjustments for the smallest groups due in 2017.[5] In addition, the "quality-tiering" process that is the model for MIPS has previously been only a *voluntary* process, in which a small minority of groups have chosen to participate.[6] Although quality-tiering became mandatory beginning in 2015, this information will not be used to adjust payments until 2017.[7] This means that CMS and providers have extremely limited experience with reporting systems and quality assessment under this approach.

Because physicians and groups have invested significant time and resources in implementing PQRS reporting, DHPA believes that existing reporting rules and processes should be incorporated into MIPS as much as possible. At the same time, the physician community is still actively learning from the experience of PQRS. Quality performance data reported through MIPS will be a significant basis for future payment increases for *all* physicians. This represents a significant departure from the pure reporting obligations in effect thus far; CMS and providers have very little data on this process. The sample size of providers electing quality-tiering is

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[3] 42 U.S.C. § 1395-w(q)(5)(A). The Secretary is also required to develop a system to evaluate the quality scores of group practices consistent with the Physician-Quality Reporting System, and has the discretion to incorporate these concepts into evaluation of the other MIPS components. *See* 42 U.S.C. § 1395w-4(q)(1)(D), *citing* 42 U.S.C. § 1395w-4(m)(3)(C).

[4] *Value-Based Payment Modifier*, Centers for Medicare and Medicaid Services, available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/ValueBasedPaymentModifier.html.

[5] Id.

[6] *Changes for the Physician Value-based Payment Modifier in the CY 2015, Centers for Medicare and Medicaid Services*, available at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2014-Fact-sheets-items/2014-10-31-5.html?DLPage=2&DLSort=0&DLSortDir=descending.

[7] Id.

extremely small, leaving CMS and providers with very little information on the likely impact of this system. Of the more than 1,000 groups that were required to report in 2013, only 127 elected quality-tiering, and only 25 received an upward or downward payment adjustment in 2015.[8] Moreover, CMS's current PQRS enrollee attribution policy is based entirely on primary care services, and specifies that an enrollee will not be attributed to a specialist if he or she has obtained *any* services from a primary care provider.[9]

By contrast, the MIPS quality component will apply the principles of the quality-tiering program to virtually all physicians, including specialists. It is nearly inevitable that CMS and providers will refine this process, and identify additional problems or areas for improvement, as they gain more experience. **As such, CMS should establish an extended timeframe to allow providers to adjust to the MIPS quality obligations, including additional reporting to assist providers in understanding their performance under this system *before* payments are adjusted.**

B. CMS Should Retain Existing Gastroenterology PQRS Measures and Reporting Methods, but CMS Should Allow More Flexible Reporting Across Domains.

We believe that existing CMS PQRS measures accurately capture certain important aspects of independent gastroenterology practice. In particular, we believe that adenoma detection rate for colonoscopies for people over 50 and proper interval between colonoscopies are meaningful.

However, current reporting minimums call for all providers to report on at least nine measures across at least three National Quality Strategy domains.[10] Failure to do so triggers a Measure Applicability Validation process, which may still yield a negative payment adjustment.[11] This minimum reporting requirement can be difficult for specialist providers to meet because the vast majority of PQRS quality measures are more suited to primary care providers. In addition, many of the existing measures are limited to individuals diagnosed with a given disease (for example, most of the gastroenterology codes relate to patients with hepatitis). Overall, CMS has only identified seven measures generally applicable to gastroenterologists, covering only four domains.[12] Although gastroenterologists may report non-PQRS measures through a Qualified

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[8] 2015 Value-Based Payment Modifier Program Experience Report, Centers for Medicare and Medicaid Services, June 16, 2015, available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/2015-VM-Program-Experience-Rpt.pdf.

[9] *Fact Sheet: Two-Step Attribution for Measures Included in the Value Modifier*, Centers for Medicare and Medicaid Services, August, 2015, available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/Attribution-Fact-Sheet.pdf.

[10] *Payment Adjustment Information*, Centers for Medicare and Medicaid Services, available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Payment-Adjustment-Information.html.

[11] Id.

[12] *Potential Gastroenterology Preferred Specialty Measure Set*, Centers for Medicare and Medicaid Services, available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/Potential_Gastroenterology_Preferred_Specialty_Measure_Set_06_30_2014_508.pdf. Note however that "cross-cutting" measures related to disease management and disease-specific measures may also apply to certain patients.

Clinical Data Registry, these reporting systems can be costly, and are subject to more burdensome reporting standards.

In order to ensure that independent practices are able to adequately report data without resorting to duplication of primary care services, **CMS should reduce the number of domains required for independent specialty practices and streamline the Measure Applicability Validation review process as it transitions to MIPS**.

C. The Results of the Consumer Assessment of Healthcare Providers and Systems ("CAHPS") Survey or Similar Measures of Patient Satisfaction Should be Retained as Quality Measures.

CMS requests comment on whether CAHPS and similar patient satisfaction surveys should continue to be incorporated into quality metrics.[13] DHPA feels strongly that the experience of patients is an extremely important aspect of quality care, and an integral component of the triple aim. Independent practices provide high-quality care while also placing an unparalleled focus on the patient experience. We are able to provide significant benefits in patient access, convenience, amenities, and cost. DHPA strongly believes that the improved patient experience provided by our practices is appropriately treated as a quality metric.[14]

D. Quality Reporting Through a Qualified Clinical Data Registry ("QCDR") Should be Treated as the Equivalent of Reporting Through a Qualified Registry ("QR") .

Reporting data under existing PQRS rules is complex. Reporting options vary depending on whether a professional reports data as an individual practitioner or through a group. One resource published by CMS details these options as follows:[15]

[13] 80 Fed. Reg. 59102, 59105.

[14] We note, however, that patient experience may be captured by surveys other than CAHPS. Therefore, we endorse the proposal by the American Gastroenterological Association that CMS approve a set of patient satisfaction questions that may be incorporated in a range of surveys. *See* Letter from John I. Allen, MD, MBA, American Gastroenterological Association, to Andrew Slavitt Regarding CMS-3321-NC, dated November 17, 2015 ("AGA Comment Letter").

[15] Centers for Medicare and Medicaid Services, *PQRS: How to Get Started*, https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/How_To_Get_Started.html.

Individual Eligible Practitioners may choose to report information on individual PQRS quality measures or measure groups using the following mechanisms: (1) Medicare Part B claims (2) Qualified PQRS registry (3) Direct electronic health record (EHR) using certified EHR technology (CEHRT) (4) CEHRT via data submission vendor (5) Qualified clinical data registry (QCDR)	**Group Practices** may choose to report information on PQRS quality measures using the following mechanisms: (1) Qualified PQRS registry (2) Web Interface (for groups of 25+ only) (3) Direct EHR using CEHRT (4) CEHRT via data submission vendor (5) CAHPS for PQRS via CMS-certified survey vendor (for group practices of 2+) to supplement PQRS group practice reporting

Even this summary neglects some of the most important and complicated distinctions facing a physician with reporting obligations under the PQRS. Perhaps most importantly, it does not reflect the significant differences between Qualified Registry ("QR") reporting and Qualified Clinical Data Registry ("QCDR") reporting.

On their faces, QRs and QCDRs are similar. CMS defines a QR as "a medical registry or a maintenance of certification program operated by a specialty body of the American Board of Medical Specialties that, with respect to a particular program year, has self-nominated and successfully completed a vetting process (as specified by CMS) to demonstrate its compliance with the PQRS qualification requirements specified by CMS for that program year."[16] By contrast, a QCDR is defined as "a CMS-approved entity that has self-nominated and successfully completed a qualification process that collects medical and/or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients."[17]

The true distinction is that a QR is *purely* used to report quality metrics approved by CMS for PQRS reporting, while a QCDR may be used to report a wide range of other, clinically valid metrics.[18] As a result, QCDRs are a powerful tool to disseminate the clinical metrics developed by specialty societies and other stewards of high-quality care. In the case of DHPA's member practices, the applicable QCDR is GIQuIC, which reports thirteen separate quality metrics tailored to assessing and improving the quality of colonoscopy services.[19] GIQuIC has become widespread through our profession, with over two million colonoscopies now tracked.[20]

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[16] 42 C.F.R. § 414.90(b), "Qualified Registry".

[17] *Id*. at "Qualified clinical data registry."

[18] *Cf.* 42 C.F.R. §§ 414.90(j)(2)(ii) (individual eligible professional reporting requirements through QR require "reporting of PQRS quality measures or PQRS measures groups to CMS") *and* 414.90(k)(2) (individual eligible professional reporting requirements through QCDR require use of QCDR to report information on quality measures identified by QCDR).

[19] Qualified Clinical Data Registry Measures, GIQuIC, http://giquic.gi.org/docs/GIQuIC_Measure_Submission.pdf.

[20] GIQuIC Colonoscopy Colonoscopy Registry Reaches 2 Million Colonoscopy Cases – Clinical Benchmarking Tool Doubles its Dataset in Less Than a Year , GIQuIC, http://giquic.gi.org/docs/GIQuICTwoMillionColonoscopiesFinalOctober2015.pdf.

As a result, this QCDR has created a wealth of information on the safety and efficacy of colonoscopy practices that CMS may use to drive powerful changes in healthcare.

Unfortunately, the power of QCDRs is limited because of certain complexities and limitations associated with their use. CMS rules require a practice using a QCDR to report on 50% of all patients (whether or not Medicare), while practices using a QR may show compliance through three different approaches – including reporting on only 20 patients.[21] In addition, prior to 2016, QCDR reporting was only available to eligible professionals – *not* a group practice.[22] A QCDR may also only be used to report individual measures rather than a measure group.[23] Finally, a QCDR is limited to reporting thirty non-PQRS measures.[24] And, a specialty QCDR cannot easily transition to a QR because this would require more intensive reporting of PQRS quality metrics that are significantly more common in the primary care setting.

CMS has recently taken important steps to align QRs and QCDRs. For example, beginning in 2016, group practices will be allowed to engage in QCDR reporting.[25] MACRA also directs CMS to "encourage the use" of QCDRs in carrying out the MIPS.[26] **As a result, CMS should adopt a single set of rules aligning the operations of QR and QCDR reporting systems in the MIPS.** Most importantly, the Agency should allow a consistent pathway for specialty societies to propose non-PQRS measures that could fulfill reporting obligations and serve as the basis for the MIPS quality subcategory. This option should be available even for specialty physicians who do not currently provide large numbers of primary care services, as required under the existing PQRS quality measures. QCDRs present an enormous opportunity for CMS to translate the learned experience of thousands of providers into actionable quality improvement data; CMS should reduce barriers to their use wherever possible.

IV. MIPS Resource Use Analysis Should Support and Recognize Efficient Care Management by Independent Specialists.

MACRA bases the MIPS "resource use" performance category on the existing value-based payment modifier ("VM") program. Under the current methodology (as adopted by MACRA) "resource use" is determined through three metrics: **Total Per Capita Medicare Expenditures for All Attributed Beneficiaries**; **Medicare Spending per Beneficiary**; **and Total Per Capita Medicare Expenditures for Beneficiaries With Specific Conditions**.[27] The VM is currently

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[21] Cf. 42 C.F.R. §§ 414.90(k)(2) (2016 reporting requirements for eligible professionals reporting through QCDRs) and 414.90(j)(3)(ii)(A)(1) (2016 reporting requirements for eligible professionals reporting through QRs).

[22] 78 Fed. Reg. 74230, 74465 (December 10, 2013).

[23] Id. at 74475-76.

[24] 79 Fed. Reg. 675548, 67779-67780 (November 13, 2014).

[25] Physician Quality Reporting System (PQRS): 2016 Qualified Clinical Data Registry (QCDR) Criteria, Centers for Medicare and Medicaid Services, http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2016QCDR_Criteria_Toolkit.zip.

[26] 42 U.S.C. § 1395w-4(q)(1)(E).

[27] 80 Fed. Reg. 59102, 59106. See also Value-Based Payment Modifier, Centers for Medicare and Medicaid Services, available at: https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeedbackprogram/valuebasedpaymentmodifier.html.

based on resource use for beneficiaries attributed to providers under the PQRS, using a methodology exclusively based on expenditures for primary care services. MACRA requires CMS to expand this methodology by creating new categories of "care episodes" and "patient condition groups."

Although the resource use calculation currently used by the VM is a reasonable framework for the MIPS process, we are concerned that it does not adequately reflect important realities of independent specialty practice. In particular, CMS could improve on this process as follows:

- CMS should evaluate the use of all resources devoted to the patient, including the use of imaging, lab, or other services provided by separate "downstream" entities;
- CMS should provide independent specialists with reporting on these downstream entities to assist practices in effective and efficient clinical decision-making;
- CMS should implement a flexible system of attribution for specialty practices to reflect the wide variety of roles played by specialist physicians;
- CMS should expand the set of condition-focused resource use categories to allow independent specialists additional opportunities to demonstrate relative savings; and
- CMS should allow stakeholders to review and comment on proposed "care episode" and "patient condition" groupings well in advance of finalizing these.

A. Measures of Resource Use Should Include "Downstream" Utilization by and Provide Reporting to Track This Metric.

In establishing "care episode groups," the Secretary must take into account the patient's **clinical problems** at the time items and services are furnished during an episode of care, such as the clinical conditions or diagnoses, whether or not inpatient hospitalization occurs, and the principal procedures or services furnished.[28] In establishing "patient condition groups," the Secretary must take into account the patient's **clinical history** at the time of a medical visit, such as the patient's combination of chronic conditions, current health status, and recent significant history (such as hospitalization and major surgery during a previous period).[29] **In other words, we understand "care episode groups" to represent an effort to group services involved in a clinical episode while "patient condition groups" represent an attempt to track the risk and health status of a patient**.

DHPA believes that gastroenterologists could be evaluated several different ways based on these definitions. For example, services provided by independent gastroenterologists could be part of a "care episode group" covering colorectal cancer screening and/or adenoma removal using colonoscopy, irritable bowel syndrome ("IBS"), or certain other discrete GI diseases. DHPA believes that these disease states present a significant opportunity for Medicare savings due to their high prevalence and costs of treatment. Note that, although IBS is generally a disease

[28] 42 U.S.C. § 1395w-4(r)(2)(D)(ii).

[29] 42 U.S.C. § 1395w-4(r)(2)(D)(iii).

presenting in younger people, our members expect that its incidence and prevalence in the Medicare population will rise as the current cohort ages. In addition, independent specialists provide care to patients who might be placed in a "patient condition group" defined around high-acuity colorectal cancer or IBS.

However, in order to be truly successful participants in this kind of resource use evaluation, independent specialist practices will require significantly more information about their partners. Specifically, independent specialist practices must effectively manage "downstream" imaging, lab, and other services provided to patients as a result of specialists' referrals. Unfortunately, independent practices are often unable to track and manage the effectiveness of these services because they are frequently provided by separate entities. Independent practices are more limited than hospitals in the types of services they may integrate under Medicare rules. In some cases state regulations or other requirements wholly prohibit integration of these services into independent group practices.

CMS can assist independent practices in managing resource use by providing specialists with reports on the performance of local providers of imaging, lab, and other "downstream" services. Specialists could use this data to evaluate which of their partners are more effective and efficient, in order to better manage their referrals for these services. **Moreover, the "resource use" calculation for specialists should incorporate and acknowledge this type of decision-making.** In other words, resource use calculations for specialists should acknowledge and promote those specialists who do an effective job managing the *overall* cost of care provided by themselves and providers of other services.

B. Attribution Categories Should be Flexible to Reflect Practice Realities.

MACRA also requires CMS to develop new methods to attribute patients based on the physician's relationship to the patient.[30] This is an extremely important move away from the previous model of attribution based solely on primary care services. Under the new model, a patient's experience may be attributed to a physician or other practitioner under one or more of the following categories:[31]

> (i) The provider considers him or herself to have the primary responsibility for the general and ongoing care for the patient over extended periods of time;
>
> (ii) The provider considers him or herself to be the lead physician or practitioner and who furnishes items and services and coordinates care furnished by other physicians or practitioners for the patient during an acute episode;
>
> (iii) The provider furnishes items and services to the patient on a continuing basis during an acute episode of care, but in a supportive rather than a lead role;
>
> (iv) The provider furnishes items and services to the patient on an occasional basis, usually at the request of another physician or practitioner; or

[30] 42 U.S.C. § 1395w-4(r)(3)(A).

[31] 42 U.S.C. § 1395w-4(r)(3)(B).

(v) The provider furnishes items and services only as ordered by another physician or practitioner.

We support this change in definition, which will allow more effective tracking of specialists' contribution to a patient's care. However, we are concerned that this set of definitions may not fully capture the realities of specialties such as gastroenterology, in which a referral for what is expected to be a purely screening procedure may unexpectedly require acute care. For example, a screening colonoscopy might be considered a "service furnished to a patient on an occasional basis . . . at the request of another physician or practitioner." However, if an adenoma is discovered and removed, this becomes a therapeutic procedure that might fall under a different category. This distinction will be particularly important if CMS calculates, risk adjusts, or otherwise treats resource use differently depending on the category. **CMS should therefore ensure that providers have flexibility to classify themselves under multiple categories based on the clinical nature of each claim.**

C. We Encourage CMS to Develop Condition-Specific Resource Use Measures for Other Specialties.

MACRA requires CMS to track resource use for all attributed enrollees based on total allowed charges under Medicare Parts A and B, stratified by care episode codes and patient condition codes.[32] MACRA also gives the Secretary discretion to expand this category to other metrics of resource use.[33] In the RFI, CMS states that its experience under the VM will "help shape this performance category" and requests comment on cost or resource measures "other than the ones [used in the VM]."[34] **This language suggests that CMS plans to incorporate the three resource use categories currently measured under the VM: Total Per Capita Medicare Expenditures for All Attributed Beneficiaries; Medicare Spending per Beneficiary; and Total Per Capita Medicare Expenditures for Beneficiaries With Specific Conditions.**

DHPA is concerned that the specific conditions currently tracked by the VM do not provide opportunities for gastroenterologists to demonstrate savings. The conditions currently tracked are: Diabetes, Coronary artery disease, Chronic obstructive pulmonary disease, and Heart failure. This list is missing important gastrointestinal diseases that represent a major disease burden, and major source of Medicare expenditures. For example, colorectal cancer is the third most commonly diagnosed cancer and the third leading cause of cancer death in both men and women, with an estimated 136,000 new cases and over 50,000 new cases in 2014 alone.[35]

It is well-understood that independent specialty practices like those represented by DHPA provide important screening and treatment services for colorectal cancer much more efficiently than in other settings. DHPA believes that the efficiency of our providers should be incorporated into this assessment of relative costs.

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[32] 42 U.S.C. § 1395w-4(r)(5)(C).

[33] 42 U.S.C. § 1395w-4(r)(5)(C)(ii).

[34] 80 Fed. Reg. 59102, 59106.

[35] American Cancer Society, *Colorectal Cancer Facts & Figures 2014-2016*, p. 1.

D. CMS Should Allow Providers and Societies to Study Data Before Finalizing Patient Condition and Care Episode Groups.

Resource use analysis based on patient condition codes and episode codes will be a significant departure from existing Medicare payment processes. Therefore, we request that CMS work closely with DHPA and other professional societies to develop these, and give providers ample time and opportunity to comment on the development and refinement of these codes. **In particular, CMS should publish a set of proposed patient condition codes and episode codes and provide a detailed explanation of its rationale for these groupings in a formal proposed rule that is subject to stakeholder comment.** And, as we requested with regard to the MIPS quality performance category, CMS should establish a process for continued review and refinement of these codes as providers learn to implement these changes.

V. CMS Should Create Clinical Practice Improvement Categories That Recognize Variation Between Clinical Settings.

The newest MIPS performance category is "clinical practice improvement activities." MACRA defines a clinical practice improvement activity as "an activity that relevant eligible professional organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes."[36] The statute specifies four required sub-categories, and empowers the Secretary to create additional sub-categories. The sub-categories created by statute include the following:[37]

- The subcategory of expanded practice access, such as same day appointments for urgent needs and after-hours access to clinician advice.

- The subcategory of population management, such as monitoring health conditions of individuals to provide timely health care interventions or participation in a qualified clinical data registry.

- The subcategory of care coordination, such as timely communication of test results, timely exchange of clinical information to patients and other providers, and use of remote monitoring or telehealth.

- The subcategory of beneficiary engagement, such as the establishment of care plans for individuals with complex care needs, beneficiary self-management assessment and training, and using shared decision-making mechanisms.

- The subcategory of patient safety and practice assessment, such as through use of clinical or surgical checklists and practice assessments related to maintaining certification.

[36] 42 U.S.C. § 1395w-4(q)(2)(C)(v)(III).

[37] 42 U.S.C. § 1395w-4(q)(2)(B)(iii).

- The subcategory of participation in an alternative payment model (as defined in section 1395l(z)(3)(C) of title 42).

CMS further proposes a set of additional sub-categories in the RFI:[38]

- Promoting Health Equity and Continuity (demonstrated by accepting Medicaid and dual-eligible beneficiaries, participating in Marketplace and state exchange plans, and promoting access to care for individuals with disabilities).

- Social and Community Involvement (demonstrated by referrals, partnerships, and collaboration with community and social services).

- Achieving Health Equity (demonstrated by high quality care for underserved populations, including people with behavioral health conditions, racial and ethnic minorities, sexual and gender minorities, people with disabilities, and people living in underserved areas).

- Emergency Preparedness and Response (demonstrated by professional participation in the Emergency System for Advance Registration of Volunteer Health Professionals, relevant reserve and active duty military volunteer activities, and volunteer participation in medical relief work).

- Integration of Primary Care and Behavioral Health (demonstrated by co-location of behavioral health and primary care services; shared/integrated behavioral health and primary care records; and cross-training of professionals).

CMS requests comment on these categories, as well as the proper method of reporting achievement of clinical practice improvement (e.g., attestation vs. transmission of relevant metrics to CMS). CMS also requests comment on the processes for identifying and validating that "improvement" has occurred, and how various categories should be weighted.

Although DHPA believes the public health issues identified by CMS are important, we are concerned that these elements are not well-tailored to *clinical* improvements. In particular, these sub-categories have limited applicability to specialist physicians; instead, they are focused on primary care improvements. We urge CMS to work closely with medical professionals, including specialty societies such as DHPA, to identify focused, actionable steps that specialty physicians could take to improve the clinical care provided to patients. These improvements should align closely with the metrics in the "quality" performance category. For example, in the case of gastroenterology, one of the most important indicators of high-quality care is adenoma detection rate.[39] A study published in the New England Journal of Medicine found that the removal of precancerous polyps was highly beneficial, and significantly reduced new cases of,

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[38] 80 Fed. Reg. 59102, 59106 – 59107.

[39] Ann G. Zauber, Sidney J. Winawer, et al., Colonoscopic Polypectomy and Long-Term Prevention of Colorectal-Cancer Deaths, 366 New Eng. J. Med. 687 (February 23, 2012).

and mortality from, colorectal cancer.[40] As such, *improvement* in this core clinical metric should be rewarded independently of a given practice or professional's quality ranking.

Moreover, the sub-categories proposed by CMS will require additional investment that is not covered under existing payment structures. Additional investments such as these will naturally be more burdensome for independent practices than for large, institutional providers. DHPA is extremely concerned about any change in policy that would exacerbate the current payment disparity in favor of institutional providers as compared to independent practices.

VI. Physician-Focused Payment Models Require Regulatory Flexibility

MACRA requires CMS to create Physician-Focused Payment Models, but delegates virtually all of the policymaking authority for these models to CMS and an independent advisory board. Under MACRA, a Physician-Focused Payment Model Technical Advisory Committee must review and provide comments and recommendations to the Secretary on proposed PFPMs submitted by stakeholders.[41] This independent panel is responsible for evaluating PFPMs consistent with criteria developed by CMS. Importantly, a PFPM is *not* required to involve a traditional APM entity such as an ACO or medical home.[42]

Accordingly, MACRA provides enormous latitude to CMS to define, structure, and create PFPMs.[43] As a result, CMS requests comment on many of the fundamental aspects of this model including:[44]

- The best definition of a "physician focused payment model".
- Criteria for assessing a PFPM.
- Whether additional or different criteria are required for specialist models.
- Opinions on criteria used by existing insurance plans to test or approve established models.

DHPA's member practices are deeply committed to participating in efforts to improve patient care. In recent years, our members have engaged in a number of promising initiatives with private payors to manage bundled payment for various gastroenterological conditions. Our members are ready to use this experience to engage in additional efforts to improve care for Medicare beneficiaries. MACRA has now given CMS an important tool to greatly accelerate this process by designing PFPM models that can expand these interventions without sacrificing the precise focus provided by our specialist physicians. **In particular, we join the American Gastroenterological Association in urging CMS to use the wide latitude provided by**

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[40] *Id*.

[41] 42 U.S.C. § 1395ee(c).

[42] Id.

[43] 42 U.S.C. § 1395ee(c).

[44] 80 Fed. Reg. 59102, 59112.

MACRA to design models that are uniquely physician-focused and distinct from existing APMs that encourage integration and consolidation with hospitals.[45]

For example, we ask CMS to explore models that focus on coordination of care in the management of specific types of diseases and/or conditions. Current innovative models like Accountable Care Organizations have been inaccessible for many specialist groups because of the large number of required enrollees and the requirement to furnish the full range of care.[46] CMS should use this opportunity to design care models that focus on effective management of one or more physician practices, and that *do not* necessarily require the involvement of a hospital. This could take the form of gainsharing or shared savings payments focused on specialists, bundled payments to manage a given episode of care, advance payments to fund care coordination nurses or other personnel, or testing integration models for electronic health systems. The AGA has developed a bundled payment and episode payment models that could serve as a template for such specialty-focused PFPMs.[47] As the AGA recognized, "[m]ost gastroenterologists have not had opportunities to participate in APMs due to the specialty's lack of inclusion in CMS alternative payment model pilot programs."[48]

Finally, DHPA is concerned that innovative models under the PFPM program will encounter many of the same regulatory hurdles faced by participants in APM models. We note that HHS has exercised its authority under the Medicare Shared Savings ACO program to allow the creation of financial relationships between multiple independent entities, even when such payments might otherwise implicate the Stark law and Anti-Kickback Statute.[49] For PFPMs to be successful, physician practices will require similar flexibility. **Therefore, we request CMS to create flexibility for entities participating in a PFPM to enter into arrangements that might otherwise be prohibited by the Stark Law, Anti-Kickback Statute, or other laws designed to prevent fraud and abuse in the legacy fee-for-service payment system.** This could potentially be accomplished through alignment of PFPMs with Innovation Center programs, given that the Innovation Center has authority to waive the application of payment rules such as these.[50] Alternatively, CMS should move aggressively to implement a regulatory gainsharing exception to the Stark law.[51]

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[45] AGA Comment Letter at p. 3.

[46] *See e.g.*, 42 C.F.R. § 425.110(a)(1), establishing eligibility criteria for the Medicare Shared Savings Program including primary care ACO professionals that are sufficient to provide care for a minimum of 5,000 assigned beneficiaries.

[47] For example, the AGA has developed a colonoscopy bundled payment program, an episode payment framework for gastroesophageal reflux disease (GERD), and a similar framework for obesity management. See AGA Comment Letter at p. 1.

[48] Id. at p. 3.

[49] 80 Fed. Reg. 66726 (October 29, 2015).

[50] 42 U.S.C. § 1315a(d)(1), providing waiver authority to the Secretary as necessary to test models under the Innovation Center.

[51] CMS recently solicited comments on the need for additional regulatory flexibility for such arrangements in the 2016 Proposed Medicare Physician Fee Schedule rule. See 80 Fed. Reg. 41686, 41928 (July 15, 2015).

VII. Conclusion

MACRA creates a number of new challenges and opportunities for CMS and the providers who participate in Medicare. DHPA looks forward to working with CMS as it implements this profound change to our nation's healthcare reimbursement system. However, we also urge CMS to move deliberately and maintain avenues for provider involvement and comment as it enacts these new programs. Beyond notice-and-comment rulemaking, CMS should consider engaging in listening sessions, webinars, or other opportunities to engage with the provider community prior to finalizing these enormous changes.[52] DHPA would welcome the opportunity to participate in such dialogue with the Agency. The physicians in our member practices are specialists who are devoted to delivering high-quality, cost-efficient and accesible digestive health care. Uncertainty in the physician reimbursement system – particularly as it relates to independent physician specialty practices– creates significant instability and concern that distracts from our members' focus on providing the best possible care to their patients.

Specifically, we request that CMS:

- Create quality metrics, resource use policy, and clinical practice improvement categories that acknowledge the unique circumstances of specialists such as gastroenterologists furnishing acre in the independent practice setting.
- Incentivize independent practices to exercise more effective and efficient control over a patient's care, even when this care is provided "downstream" of the provider, and provide better reporting to support this management.
- Align the requirements of QR and QCDRs to provide maximum flexibility to reporting MIPS eligible professionals.
- Define and implement PFPMs broadly to allow independent specialty practices to participate in their own right, without consolidation with hospitals.
- Allow substantial opportunities for independent specialists to comment and provide feedback as CMS implements the massive changes required by the MIPS and PFPMs.

DHPA – with its more than 1,300 gastroenterologists who prevent, detect and treat serious gastrointestinal disease on a daily basis – looks forward to serving as a resource to CMS as it moves forward with its efforts to implement MACRA. In particular, we look forward to working with CMS to ensure that the transition from the traditional fee-for-service system to a MIPS

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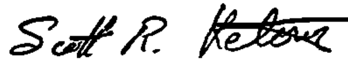
[52] CMS has traditionally convened numerous listening sessions as it implements major policy shifts. See e.g., *Medicare Program; Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty (CMP) Laws*, 75 Fed. Reg. 57039 (September 17, 2010). See also *Transcript of Listening Session Regarding: Physician Feedback Program and Implementation of the Value-Based Payment Modifier for Fee-for-Service Medicare,* (September 24, 2010), available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/downloads/092410_Listening_Session_Feedback_Program_Transcript.pdf.

system based on quality metrics is smooth, predictable, and appropriately accounts for physician specialists caring for patients in the independent practice setting.

Please reach out with any questions to DHPA's Chair of Health Policy, Dr. Michael Weinstein (Michael.Weinstein@capitaldigestivecare.com, 202-296-3449,), or to DHPA's legal counsel, Howard Rubin (Howard.Rubin@kattenlaw.com, 202-625-3534).

Sincerely,



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