DIGESTIVE HEALTH
PHYSICIANS ASSOCIATION®

May 9, 2016

BY ELECTRONIC SUBMISSION

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

RE: Comments to CMS-1670-P

Dear Acting Administrator Slavitt:

On behalf of the Digestive Health Physicians Association ("DHPA"), we thank you for the opportunity to comment on the Proposed Part B Drug Payment Model ("the Proposed Rule") to be operated by the Center for Medicare and Medicaid Innovation ("CMMI").[1] As the voice of the nation's leading independent gastroenterology practices, DHPA is committed to partnering with CMMI to develop value-based payment models that maintain high quality GI care for Medicare beneficiaries while achieving cost efficiencies for our health care system. The Proposed Part B Drug Payment Model, however, creates a significant risk to our being able to achieve these goals. The proposal contains serious deficiencies that will undermine a system carefully designed by Congress, while undermining access to essential treatment for important conditions like Crohn's disease and ulcerative colitis. Although DHPA stands willing to assist the Centers for Medicare and Medicaid Services ("CMS" or "the Agency") in its bold goals to transition to a new payment system, we urge the Agency to move judiciously in a manner that is mindful of the consequences of its proposals. CMS should not sacrifice beneficiary access to necessary medication in order to achieve its cost reduction goals, nor should it undercut the clear and effective payment regime for Part B medications devised by Congress.

In choosing to undertake a nationwide experiment affecting three-quarters of physicians and beneficiaries without their consent, CMS is not following the statute that authorized CMMI, which requires CMMI to undertake demonstrations on "defined populations where there are deficits

[1] 81 Fed. Reg. 13230.

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

of care."[2] CMS has provided no evidence to indicate that care provided to Medicare beneficiaries is compromised under the current Average Sales Price ("ASP") + 6% reimbursement methodology. Nor is the demonstration properly focused. Instead, CMS appears to rewrite explicit statutory dictates and long-standing policy under the guise of a "model" to be tested by CMMI. No demonstration in the 50-year history of the Medicare program has ever been undertaken of such size and scope and, most troubling, without the involvement of the people's elected officials in Congress.

In attempting to address perceived, misaligned incentives in the existing ASP methodology created by Congress, CMS threatens to implement a policy whose incentives directly contradict clinical realities. The proposed model would cut reimbursement for uniquely effective therapeutic medications, while arbitrarily creating enormous windfalls for less-vital supportive drugs, purely to achieve budget neutrality.

The Medicare Payment Advisory Commission ("MedPAC") has already examined this issue thoroughly and concluded that there was little evidence to support the notion that physicians select drugs based on the current ASP + 6% methodology. CMS did not provide any evidence in the Proposed Rule that reimbursement levels drive physician drug choice, nor has evidence been presented by government agencies or in the peer-reviewed literature that the current system has led to deficiencies in care or abuse. CMS can easily test whether payment cuts to Part B drugs drive physician prescribing behavior by evaluating the impact of the existing two percent sequester, which has already reduced payments from ASP + 6% to ASP + 4.48%. No further demonstration is necessary to study this issue. And yet, the Agency proposes a demonstration that will be layered on top of that payment cut, such that actual reimbursement will be less than 101% of ASP. This enormous reduction in reimbursement will make it extremely difficult for many physicians to continue administering certain clinically important, but expensive drugs.

As we explain in more detail below, we have the following serious concerns about the implementation of this model:

- The proposed policy prescribes significant shifts in reimbursement with no consideration for the clinical utility or the available alternatives to any Part B medication. Of particular concern to our patients, it will become significantly more difficult for physician practices to afford Remicade, an important drug that gastroenterologists use to treat autoimmune disorders that cause inflammatory bowel disease. This drug, which is a last-resort medication with no clinical alternatives for physicians to administer for certain inflammatory bowel diseases, will experience a major reimbursement cut. This raises an important question: ***what is the purpose of this payment cut if patients and physicians have no ability to choose a cheaper alternative?***

- At the same time, less clinically useful drugs will be reimbursed at far greater rates—apparently for the sole purpose of ensuring budget neutrality. Thus, CMS's proposed pricing structure runs counter to the clinical utility of the particular drugs at issue.

[2] 42 U.S.C. § 1315a(b)(2)(A).

- We are concerned that the demonstration includes no metrics to measure or evaluate patients' clinical outcomes, a legal requirement for CMMI's experiment.[3]

- CMS has not addressed how the model will impact implementation of MACRA, which proposes to compare the resource use of physicians across the country on a national scale.

- The geographic distribution model is designed around primary care, but will cause significant hardship for specialty physicians who are more widely dispersed through most geographic areas.

- CMS has not established that this major change in policy falls under CMMI's authority to test models addressing a "defined population experiencing deficits of care."[4] Such a limitation is not only mandated by statute, but it is critical to ensuring that CMS not exceed its already broad waiver authority.

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 60 member GI practices from 31 states in every region of the country. Our more than 1,300 physicians provide care to approximately 2.5 million patients annually in more than 3.5 million distinct patient encounters. And, of particular relevance to this Proposed Rule, our physician members are on the front lines of providing innovative treatments for serious, chronic conditions and diseases such as Crohn's disease and ulcerative colitis.

Improved use and management of physician-administered medications is not just a theoretical interest for DHPA. Our members have been at the forefront of exploring innovative value-based models to achieve the triple aim in gastroenterology. For example, a value-based collaboration between a DHPA member practice in Illinois and Blue Cross Blue Shield of Illinois used a specially-developed clinical decision support tool to improve management of Crohn's disease patients.[5] The joint project revealed that better management of Crohn's disease reduced the total cost of care for a small cohort of patients by over 11%, or over $200,000.[6] This was driven by a reduction in emergency department costs of more than 50%, and inpatient admission costs of

[3] 42 U.S.C. § 1315A(b)(4)(A)(i) requires an evaluation of each CMMI model including an analysis of "the quality of care furnished under the model, including the measurement of patient-level outcomes and patient-centeredness criteria determined appropriate by the Secretary."

[4] 42 U.S.C. § 1315a(b)(2)(A).

[5] Lawrence Kosinski, Joel V. Brill, Michael Sorensen, et al., Project Sonar: Reduction in Cost of Care in an Attributed Cohort of Patients With Crohn's Disease, Abstract to be presented at Digestive Disease Week 2016, https://ep70.eventpilot.us/web/page.php?page=Inthtml&project=DDW16&id=2442763.

[6] Id.

nearly 60 percent.[7] Critically, these enormously positive findings were associated with a small *increase* in spending on physician-administered infusible biologics (such as Remicade).[8]

II. The Part B Drug Payment Model Jeopardizes Access to Therapeutic Medications.

The Medicare Part B Drug Payment Model, if finalized, will specifically change reimbursement for those medications that are directly administered by physicians (or by staff under a physician's direct supervision).[9] The vast majority of costs to the Medicare program for these drugs are concentrated in cancer care, yet treatment of other diseases will also be substantially impacted and should not be overlooked.[10] Gastroenterology is not generally considered a major driver of Part B drug costs.[11] However, our patients will be adversely affected by CMS's Proposed Rule when they have medical conditions that require the use of expensive therapeutic medications. We are particularly concerned about the impact of the proposal's severe reduction for reimbursement of Remicade (infliximab), a therapy used to treat GI autoimmune disorders such as Crohn's disease and ulcerative colitis.[12]

Crohn's disease and ulcerative colitis are both major categories of Inflammatory Bowel Diseases (IBD). IBD affects an estimated 1.6 million Americans.[13] Crohn's disease affects an estimated 700,000 Americans, many of whom are now entering the Medicare population.[14] Inflammatory bowel disease can lead to years of debilitating pain and discomfort and, in some cases, life-threatening complications.[15] These chronic diseases tend to run in families and they affect males and females equally. Disparities exist in diagnosis and treatment; although Caucasians are more likely than other ethnic groups to have IBD (with especially high prevalence in Jews of European descent (Ashkenazi Jews)), African Americans and Hispanics in the United States are increasingly affected.[16]

Crohn's disease is a chronic inflammatory condition of the gastrointestinal tract and may affect any body part from the mouth to the anus.[17] Ulcerative colitis is a chronic inflammatory

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[7] Id.

[8] Id.

[9] 81 Fed. Reg. at 13233.

[10] MedPAC June 2015 Report to the Congress ("MedPAC 2015 Report"), p. 66.

[11] See 81 Fed. Reg. at 13255.

[12] Food and Drug Administration, "Prescribing Information: Remicade (infliximab)", http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/103772s5281lbl.pdf.

[13] Crohn's & Colitis Foundation of America, http://www.ccfa.org/what-are-crohns-and-colitis/what-is-crohns-disease/.

[14] Id.

[15] Id.

[16] Id.

[17] Id.

condition limited to the colon, otherwise known as the large intestine.[18] Medical treatment for Crohn's disease and ulcerative colitis has two main goals: achieving remission (control or resolution of inflammation leading to symptom resolution) and maintaining remission.[19]

Biologics like Remicade represented a major step forward for treatment of IBD. Biologic therapies offer a distinct advantage in IBD treatment because their mechanisms of action are more precisely targeted to the factors responsible for IBD.[20] For example, unlike corticosteroids, which affect the whole body and may produce major side effects, biologic agents act more selectively. These therapies are targeted to particular proteins in people with IBD.[21]

The cut in reimbursement is particularly disturbing in the case of Remicade because it is a therapy of last resort. The FDA has approved its use for Crohn's disease and ulcerative colitis for patients "who have not responded well to other medications."[22] Before a patient receives Remicade, however, the physician must document that a conventional oral agent (including mesalamine, corticosteroids, 6-mercaptopurine, or azathioprine) has been used for at least three months and failed to control symptoms of these conditions.[23] Respectfully, we fail to see the justification for reducing reimbursement for this medication with no generic option or clinical alternative for physicians to administer for certain inflammatory bowel diseases, whether in terms of cost reduction or research benefit.

As MedPAC observed, the ASP + 6% methodology can only create an incentive to shift utilization where "there are alternative drugs with different prices available to treat a particular patient's condition."[24] That is not—and cannot be—the case with a medication such as Remicade, which is used only *after* alternative therapies have failed. At the same time, there is no competing medication on the market. Although the FDA approved an infliximab biosimilar under the brand name "Inflectra" in April 2016, [25] this product is not yet sold in the United States and no pricing information is available.[26] The vast majority of the clinical data regarding this biosimilar has been collected from rheumatology patients; gastroenterologists have less

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[18] Id.

[19] Id.

[20] Id.

[21] Id.

[22] "Medication Guide: Remicade," Food and Drug Administration, http://www.fda.gov/downloads/Drugs/DrugSafety/ucm089023.pdf.

[23] See e.g., "Remicade (infliximab) Medical Necessity Criteria", Magellan Pharmacy Solutions, https://specialtydrug.magellanprovider.com/mhs/sdrug/content/pdfs/MCCFLMNC/Remicade.pdf.

[24] MedPAC 2015 Report at pp. 69, 92.

[25] See http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm494227.htm.

[26] "Press Release: FDA Approves INFLECTRA™ (Biosimilar Infliximab), The First U.S. Biosimilar Monoclonal Antibody, For All Eligible Indications," http://www.pfizer.com/news/press-release/press-release-detail/fda_approves_inflectra_biosimilar_infliximab_the_first_u_s_biosimilar_monoclonal_antibody_for_all_eligible_indications.

assurance that Inflectra will be an effective substitute for Remicade in caring for our patients.[27] Moreover, legal disputes between pharmaceutical manufacturers could delay its launch for several years.[28] Until that time, the only option available to patients is Remicade.

Congress has set clear rules for the payment of Part B medications. Most commonly, physicians are paid a modifier based upon the ASP of the medication.[29] However, the ASP is *not* the price at which many providers or suppliers acquire the product. ASP, by definition, incorporates all discounting, rebates and other price concessions made by manufacturers to drug purchasers. Entities that command significant market power, such as large hospital systems and multi-state corporate medical entities, can negotiate steep discounts. At the same time, smaller customers with less market power, including many independent, and often rural, physician practices, often pay **above** the ASP. As a result, a payment policy reflecting a real reimbursement rate of 101% of ASP will result in many physician practices taking a loss on every unit of certain medications.

CMS now proposes a "demonstration model" to test two "phases" of payment reform. The demonstration would involve waiving—through agency action—nearly the entirety of a ***statutory*** payment system and replacing it with a variety of new payment systems. The Agency has unilaterally chosen to implement this experiment in two phases. Phase I would replace the Congressionally-enacted payment model with a new "percentage plus flat fee" model of ASP + 2.5% + $16.80 (reduced further by the sequester).[30] Phase II, which would be implemented as soon as five months after Phase I is initiated and before it could even be evaluated in any serious way, would require the use of various value-based payment methodologies associated with specific drug codes.[31] CMS will allow roughly one-quarter of the country (including CMS's home state of Maryland because CMS asserts that the state's all-payer system may introduce "unobservable bias") to continue to be paid as a "control" group under the model designed by Congress, while the Agency will assign the rest of the country to: 1) a "Phase I"-only track; 2) a "Phase II"-only track; or 3) a "combined" track incorporating both Phase I and Phase II.

We are particularly concerned that the models which incorporate "Phase I" methodologies will have a significant negative impact on patient access to Remicade and other drugs that are critical to the care of our patients.

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[27] Nicole Gray, "Why Inflectra may face greater challenges than Zarxio in winning over US docs," BioPharmaDive, http://www.biopharmadive.com/news/why-inflectra-may-face-greater-challenges-than-zarxio-in-winning-over-us-do/418206/.

[28] Nancy Walsh, "A Rocky Start for Biosimilar Inflectra," MedPage Today, http://www.medpagetoday.com/Rheumatology/Arthritis/57239.

[29] 42 U.S.C. § 1395w-3a.

[30] 81 Fed. Reg. at 13239.

[31] Id. at 13242.

III. Phase I Contradicts Congressional Intent and Does Not Properly Value Important Therapeutic Services.

The methodology implemented by Congress in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 was an explicit attempt to move towards a "market based price" approach in which Part B reimbursement for a specific drug would be pegged to that medication's actual sale price across the entire country.[32] ASP replaced the average wholesale price reimbursement (AWP), which reflected manufacturers' list prices but, in reality, far exceeded the acquisition cost of physician practices and hospitals. Reform of AWP was a subject of controversy, requiring substantial deliberation and carefully negotiated, bi-partisan legislation that established the current ASP + 6% methodology.[33] Congress also acknowledged that drug payments were *designed* to account for physician practice expense associated with administering the medications. In response to worries that the shift to a "market-based" ASP model could threaten access to care, Congress substantially increased the practice expense relative value units ("RVUs") for certain drug administration codes under the Medicare Physician Fee Schedule and also provided the 6% add-on.[34] Now, with no input from Congress and in apparent contravention of the statute creating CMMI, which requires the agency to "consult with clinical and analytical experts in medicine and health care management" and "use open door forums or other mechanisms to seek input from interested parties,"[35] CMS proposes to undertake on a unilateral basis a radical experiment that threatens patient access to therapeutic medications.

CMS's proposed pricing methodology—purely in the name of achieving budget neutrality—favors less expensive but also less critical drugs over those drugs that are primary modes of treatment for serious diseases.[36] In other words, as we noted above, **the pricing structure designed by CMS runs counter to the clinical utility of the particular drugs at issue**. Physician reimbursement associated with more expensive medications would effectively be reduced, while reimbursement for administering less expensive medications would substantially increase. We are perplexed by this proposed policy that would cut physician payments for critical drugs while creating windfalls for administering more elective drugs.

CMS has an obligation to consider how its policy will impact patient care. But, the Agency proposes to force millions of patients into a cost-control experiment that contains no metrics that will enable CMS to study or evaluate patient health outcomes. Respectfully, we do not see how CMS can fully and accurately evaluate the success of the demonstration if patient clinical outcomes are not tracked, analyzed and compared. We are left to wonder: how does CMMI define what constitutes success **for the patient** in this demonstration? Are guardrails in place to protect patients, equivalent to those that physicians must demonstrate to institutional review boards before treating patients enrolled in clinical trials? We find nothing in the Proposed Rule

[32] H.R. Rep. No. 108-391, at 582 (Nov. 21, 2003) (Conf. Rep.).

[33] Id. at 590.

[34] See 42 U.S.C. § 1395w-4(c)(2)(H)-(J).

[35] Id. § 1315A(a)(3).

[36] 81 Fed. Reg. at 13256.

that establishes metrics to track patient outcomes and quality of care—let alone provide protections to ensure that quality does not diminish.

IV. CMS Has Failed to Address Essential Policy Implementation Considerations, Including Those Identified by MedPAC.

Even beyond the fundamental design issues that put the Proposed Rule in conflict with current law, there are serious flaws in how CMS intends to implement the Part B Drug Model. We have three particular concerns: 1) by reducing payment for expensive medications without addressing hospital purchasing supports, CMS will exacerbate the growing shift of care into the more expensive hospital setting; 2) the unit of analysis selected by CMS is far too geographically limited and will create unjustified differences in patient access to certain medications paid under Part B; and 3) CMS has not properly adjusted national payment reform models to account for the differences in utilization and cost that the model will introduce over these new geographic units.

A. The Proposed Rule, If Finalized, Will Drive Care Into the More Expensive Hospital Setting.

Policymakers are increasingly concerned about incentives created by Medicare that shift services away from the lower-cost physician office setting to the higher-cost hospital setting.[37] In its analysis of a similar "percentage plus flat fee" approach, MedPAC identified exactly this risk, noting that "variation in drug acquisition prices across providers **would likely mean** that some providers, especially small providers, would not be able to purchase some expensive drugs at prices within the Medicare reimbursement amount."[38] MedPAC goes on to warn that these providers will be forced to send patients to other entities that are better able to absorb the cost (including hospital outpatient departments), observing that "[i]f these types of shifts in site of care occurred, the effect on beneficiaries (e.g., in terms of travel time to a provider) is unknown."[39]

Hospital outpatient departments are better able to withstand price variation in drugs they purchase because of the significant purchasing incentives they enjoy over their counterparts in the independent medical practice setting. Although the Part B Drug Payment Model formally treats hospitals and physician offices equivalently, CMS ignores the effect of the 340B drug purchasing program, which provides large discounts on pharmaceuticals to the 50 percent of hospitals that benefit from that program.[40] ***MedPAC estimates that 340B hospitals are able to purchase outpatient drugs at a price that is, on average, at least 22.5% below ASP.***[41] Because of this, hospitals eligible for the 340B program enjoy a much larger profit margin on drugs. As one national study estimated, the blended profit margin for Part B drugs (accounting for both

[37] See MedPAC, March 2014 Report to the Congress, pp. 51-54.

[38] MedPAC 2015 Report, p. 70 (emphasis added).

[39] Id.

[40] MedPAC 2015 Report, p. 71. Note that although eligibility for the 340B program is based on Medicaid population, Medicare will pay its normal reimbursement rates for these drugs.

[41] Id., p. 63.

Medicare and commercial business) is only about 16% for physicians, but 210% for 340B hospitals.[42] In response, MedPAC suggested that CMS should reduce Medicare Part B drug payments to 340B hospitals, or reduce beneficiary cost-sharing for drugs provided by 340B hospitals[43]—a suggestion that CMS did not adopt in the Proposed Rule. Failing to reform 340B while substantially cutting payments to physicians will only result in more provider consolidation and a migration of care into the more expensive site of service.

If finalized, the demonstration will have the exact opposite effect of its stated goal. Rather than reducing overall health care costs, the demonstration will result in even more care shifting into the higher-cost hospital setting—a phenomenon that will only worsen as independent GI (and other specialty) practices find themselves unable to afford to provide expensive, but critically important medications. As MedPAC explained, "Medicare pays the same rates (ASP + 6 percent) for Part B drugs to 340B hospitals and non-340B hospitals, even though 340B hospitals are able to purchase outpatient drugs at **steep discounts**." The discounts average more than 50% for the most expensive drugs.[44] The same logic applies to independent physician practices that compete with these hospitals. And, the 340B program has been growing rapidly, with an ever-greater number of hospitals enjoying these "steep discounts."[45] For example, between 2004 and 2013, Medicare spending for Part B drugs provided in 340B hospitals grew "from $0.5 billion to $3.5 billion, or 543%."[46] As a result, a policy that leaves the 340B program untouched while effectively cutting reimbursement for the most expensive drugs will naturally advantage hospitals as a site of service. If CMS moves forward with any policy to reduce reimbursement for high-cost medications, it should also modify the 340B program to ensure a level playing field is available across all sites of care.

B. CMS Has Designed Inappropriately Small Geographic Attribution Regions.

Under the Proposed Rule, geographic regions will be randomly assigned to a model on the basis of Primary Care Service Areas ("PCSAs").[47] PCSAs are purely academic tools currently used by the Health Resource Services Administration to study primary care workforce issues.[48] They reflect the distance that patients are willing to travel to access *primary care* only.[49] In practice, this means that each PCSA is extremely small—the median land area of a PCSA is only 158

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[42] Raina H. Jain, Stephen M. Schleicher, Coral L. Atoria, Peter B. Bach, Part B payment for drugs in Medicare: Phase 1 of CMS's proposed pilot and its impact on oncology care, Memorial Sloan Kettering Cancer Center Evidence Driven Drug Pricing Project, http://www.drugabacus.org/wp-content/uploads/2016/04/Part-B-Payment-Phase-1-Report.pdf, p. 5.

[43] MedPAC 2015 Report, p. 63.

[44] Id., p. xiii. Emphasis added.

[45] Id., p. 71.

[46] Id.

[47] 81 Fed. Reg. at 13238.

[48] Health Resources and Services Administration, http://bhpr.hrsa.gov/healthworkforce/data/primarycareserviceareas/index.html.

[49] Health Resource and Services Administration, "PCSA Version 3.1 Methods", available at: http://datawarehouse.hrsa.gov/data/datadownload/pcsa2010download.aspx.

square miles (or a radius of just over 7 miles),[50] and 4,000 of the roughly 7,000 PCSAs have a radius of less than ten miles.[51]

The small size of these regions effectively guarantees that several areas within the same geographic region will feature dramatically different compensation structures for the same medications. This is a particularly serious problem for specialty providers such as gastroenterologists, who generally draw patients from a wider geographic region than the primary care providers who formed the basis for this attribution system.

Unfortunately, this random assortment of payment methodologies in a region may have serious consequences. CMS is taking the position that its "model" payment is the sole method of payment for most drugs in any given PCSA. As a result, patients located in a PCSA assigned to a model using the "Phase I" methodology may find it more difficult to access certain therapies than patients in other parts of the same region. Over the long term, providers may experience a substantial incentive to concentrate infusion centers or relevant hospital outpatient departments in regions assigned to "control" models. This is not an abstract risk—under the current PCSA system, many large cities are split among a dozen or more PCSAs, creating the real possibility that certain providers will relocate, acquire competitors, or consolidate services, all based on the arbitrary assignment of a PCSA into a more or less advantageous model.

Administering this complex geographic project will be extremely burdensome to our physician practices, many of which serve multi-county or metropolitan areas through a single billing office. This experiment will place a significant administrative burden on DHPA's member practices as they seek to understand reimbursement for each drug administered depending on the PCSA in which a particular physician in the practice administers that drug. It will be particularly challenging for groups with multiple locations to create meaningful revenue projections, given that reimbursement will randomly vary based on location. Moreover, PCSAs are not widely used by providers, so it will be difficult for many practices to identify the model applicable to each location. In fact, to our knowledge there is no widely available tool for a provider to enter a street address and identify the applicable PCSA. We also anticipate that practices assigned to "Phase II" models will need to invest significant time and expense to implement the applicable value-based payment regimes that may apply (although CMS has provided little-to-no detail about the implementation of these regimes). Respectfully, we cannot understand why CMS would unilaterally impose such complexity and burden on our member gastroenterology practices and other independent physician specialty practices, particularly in service of a demonstration that does not appear to be focused on improving patient outcomes.

C. CMS Is Silent on the Implications the Proposed Rule, If Finalized, Would Have on Implementation of MACRA.

Less than a year ago, Congress enacted—on a bi-partisan basis—the Medicare Access and CHIP Reauthorization Act ("MACRA") as a new framework for value-based payment.[52] MACRA

[50] Id. at p. 9.

[51] Id.

[52] Public Law 114-10.

calls for *all* physician payments made under Medicare Part B to be shifted to either the Merit-Based Incentive Payment System ("MIPS") or an Alternative Payment Model ("APM").[53] Providers have begun significant (and often costly) efforts to prepare for this enormous shift towards value-based payment. However, the Part B Drug Model raises important questions about how physicians who administer expensive, but critical drugs to patients will be evaluated.

Of particular note, the MIPS will rate providers, in part, on the basis of "resource use," which roughly translates to the Medicare-wide expense of treating a physician's patient.[54] CMS has proposed to use a "payment standardization" methodology to allow nationwide comparison of physicians' resource use.[55] Providers are already investing resources to understand the implications of this complicated methodology, which CMS released late last year. This methodology presumes that payment for Part B drugs will not require any adjustment because "the Medicare allowed amount on the claim is already free of geographic adjustments and special program payments."[56] Of course, this assumption would be false if CMS now mandates PCSA-level differences in reimbursement that—by definition—result in geographic adjustments to program payments. Unless CMS now further complicates this policy to account for PCSA-level differences, this mismatch will cause physicians paid under the MIPS to receive a penalty or windfall based purely on their random assignment to either a "model" or "control" arm under the demonstration.

V. CMS's Expansive Use of the CMMI Waiver Undermines Payment Reform and Exceeds the Agency's Statutory Authority.

Federal courts have made clear that, as long as CMS determines a Part B drug is medically necessary, it is required to reimburse providers at the statutory rate of ASP + 6 percent.[57] CMS now proposes to use the CMMI waiver authority to sidestep this rule.[58] DHPA appreciates the important role CMMI plays in promoting payment reform. Our member practices are actively exploring methods to participate in Accountable Care Organizations, bundled payment initiatives, and other voluntary models operated by CMMI. We have never opposed a CMMI model to date, nor have we opposed an application of the waiver authority. However, we are concerned that CMS now contemplates a model that is far broader than any prior demonstration and one that does not satisfy the clear statutory standards required to test a model under CMMI.

CMMI's authority allows the Secretary of HHS to waive almost any Medicare statutory rule "solely" for the purpose of testing a model authorized by Section 1115A of the Social Security Act. However, CMMI is empowered to test a model only if "the Secretary determines that there

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[53] See 42 U.S.C. § 1395L(z) and 42 U.S.C. § 1395w-4(q)-(s).

[54] 42 U.S.C. § 1395w-4(r).

[55] "Basics of Payment Standardization," CMS, http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350.

[56] Id at p. 11.

[57] Hays v. Leavitt, 583 F.Supp.2d 62 (2008), *aff'd* Hays v. Sebelius, 589 F.3d 1279 (D.C. Cir. 2009).

[58] 81 Fed. Reg. at 13250.

is evidence that the model addresses a **defined population** for which there are **deficits in care** leading to **poor clinical outcomes** or **potentially avoidable expenditures**."[59] And, CMMI's exercise of that discretion is subject to judicial review.[60]

We are concerned that the proposed demonstration does not meet the statutory standard. CMS does not include any determination that a "defined population" exists that is experiencing "deficits in care," or that such deficits (if any exist) are leading to poor clinical outcomes or potentially avoidable expenditures. The population to be studied under the model is not "defined" in any clinically meaningful way. Rather, the supposedly "defined population" consists of *all* Medicare beneficiaries receiving medications covered under Medicare Part B, without regard to any beneficiary's underlying clinical condition. The Agency has also failed to identify any discrete "deficit in care" associated with this large subset (i.e., three-quarters) of the overall Medicare population. Although the Agency states that the ASP + 6% methodology may lead to "potentially avoidable expenditures," there is no link made to "deficits in care," as required to justify a waiver. Indeed, CMS does not propose to monitor or evaluate any patient health outcomes that may be impacted by changes in access to drugs like Remicade. Without such an evaluation, the proposal cannot fairly be deemed a bona fide "demonstration model."

There is extensive case law concerning HHS's use of its waiver authority. The Agency must act consistent with the statute in waiving elements of the Social Security Act, because it represents an "all-encompassing series of statutory requirements."[61] In waiving laws for purposes of testing a model, the Agency must demonstrate that the test is consistent with statutory authorities.[62] CMS cannot simply use a waiver to facilitate a "simple benefits cut," but instead must design a model that genuinely attempts to "learn something new."[63]

Ultimately, we do not believe that Congress, in establishing the waiver authority, intended to provide CMS with a tool to rewrite national drug payment policy at will. The design of this kind of fundamental national policy is the job of our elected officials, not of an unelected Executive Branch agency.

VI. Request for Action

Gastroenterologists regularly provide high-quality care for Medicare beneficiaries with serious, chronic illnesses such as inflammatory bowel disease. Preserving access to care for these patients—who often depend on Part B medications such as Remicade as their only treatment option—should be the Agency's first and highest priority. Consistent with our comments above and the clear guidance Congress has already provided with respect to the proper method for

[59] 42 U.S.C. § 1315a(b)(2)(A).

[60] See, e.g., Beno v. Shalala, 30 F.3d 1057, 1066 (9th Cir. 1994) (analyzing waivers by the Department of Health and Human Services of certain Medicaid and other social program statutory obligations).

[61] Id. at 1067.

[62] Id.

[63] Id. at 1069; see also Wood v. Betlach, 922 F. Supp.2d 836, 844 (D. Ariz. 2013), citing Beno v. Shalala, 30 F.3d 1057, 1066 (9th Cir. 1994).

paying for Part B drugs and the limited scope of CMMI waiver authority, DHPA respectfully requests that CMS withdraw the Proposed Rule until it addresses, with stakeholder input, the serious legal and policy challenges with the current proposal.

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