DIGESTIVE HEALTH
PHYSICIANS ASSOCIATION®

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July 16, 2018

BY ELECTRONIC SUBMISSION

The Honorable Alex Azar
Secretary of Health and Human Services
200 Independence Ave., SW
Room 600E
Washington DC 20201

RE: Comments to RIN 0991-ZA49

Dear Secretary Azar:

On behalf of the Digestive Health Physicians Association ("DHPA"), we thank you for the opportunity to respond to HHS's Request for Information entitled "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs."[1] As the voice of the nation's leading independent gastroenterology practices, DHPA is committed to working with HHS as it continues the important work of realigning the country's drug payment system to "improve health outcomes and lower both out-of-pocket cost and total cost of care."[2] In this comment letter, we focus on several of the key initiatives highlighted in the RFI:

- DHPA supports site neutrality for physician-administered drugs across the hospital and independent physician practice settings in order to promote competition and reduce the overall cost of care for the Medicare system and beneficiaries.

- DHPA supports reform of the 340B drug discount program to address the program's anti-competitive nature and to ensure that low-income and uninsured patients benefit from the program.

[1] 83 Fed. Reg. 22692 (May 16, 2018).
[2] Id. at 22692.

- Consistent with the President's commitment to "put American patients first,"[3] DHPA cannot support a shift of drugs from Medicare Part B to Medicare Part D. Moving drugs from Part B to Part D would not achieve the Administration's goals of improving health outcomes, lowering out-of-pocket costs, and decreasing total cost of care.

- For similar reasons, DHPA is concerned about the repercussions of HHS relaunching a Competitive Acquisition Program ("CAP") for Part B drugs. If such a program were re-introduced, physician participation should be voluntary and substantial guardrails would need to be put in place to ensure that CAP vendors do not interfere in the physician-patient relationship.

Digestive Health Physicians Association

DHPA formed in early 2014 to promote and protect the high quality, cost-effective and coordinated care furnished in independent gastroenterology practices. DHPA is the only national medical association that exclusively represents the voices of those gastroenterologists who have chosen to care for patients in the independent practice setting. DHPA has grown to include 78 member gastroenterology practices from 36 states in every region of the country. Our more than 1,800 physicians provide care to approximately 2.5 million patients annually in more than four million distinct patient encounters. Physicians in DHPA member practices are on the front lines of providing innovative treatments for serious diseases and chronic conditions such as colorectal cancer, Crohn's disease, and Ulcerative Colitis.

I. Site Neutrality for Physician-Administered Drugs

Developing a site-neutral payment policy between the outpatient hospital and physician practice settings is critical to achieving the Administration's goals of improving health outcomes, lowering out-of-pocket costs, and reducing the total cost of care.[4] Neither the Medicare program nor beneficiaries (who are responsible for out-of-pocket, cost-sharing payments) receive greater value to justify the higher costs for identical health care services furnished in the outpatient hospital setting. And yet, the payment disparity between hospital outpatient departments ("HOPDs") and independent physician practices continues, fueling provider consolidation and undermining competition in many communities, which has implications far beyond the Medicare program.

[3] Id.
[4] See id. at 22697.

It is well-established that Medicare pays HOPDs considerably more for drug administration than it pays independent physician practices. A 2015 study by the U.S. Government Accountability Office determined that Medicare pays hospitals twice as much for administering drugs than freestanding physician practices.[5] Consistent with that finding, a 2017 study by the Berkeley Research Group found that the share of Medicare Part B chemotherapy drug administration in HOPDs increased from 23 percent in 2008 to almost 50 percent in 2016.[6] The shift of care into the hospital setting also results in higher costs for Medicare beneficiaries. An analysis by Avalere found that patients spent $411 million more in out-of-pocket costs over a three-year period when receiving drug transfusions in the hospital setting rather than in physician offices.[7]

DHPA supports the Administration's efforts to drive greater payment equity across sites of service. A site neutral payment policy for administration of Part B drugs will result in greater efficiencies for the Medicare program and cost savings for patients. Gastroenterologists are particularly concerned about these heightened costs. The shift of care into the more expensive hospital setting—whether it be for physician-administered drugs such as Remicade (infliximab) for treatment of Crohn's disease or colonoscopies to screen for colon cancer—results in higher beneficiary out-of-pocket costs that, over time, impacts patient access to care. Reforming the drug payment system to stop driving care into the more expensive hospital setting will not only create cost savings for the Medicare program and Medicare beneficiaries, but it will also help address the troubling trend of increased physician employment by hospitals, which grew by 49% between 2012 and 2015.

II. The Need to Improve 340B Program Integrity

As part of its commitment to achieving site-neutral payment policies, generally, and with respect to physician-administered drugs, in particular, the Administration is appropriately looking for ways to further reform the anti-competitive 340B drug discount program.[8] In the CY 2018 Outpatient Prospective Payment System ("OPPS") Final Rule, CMS reduced the payment rate under the 340B program from ASP + 6% to ASP minus 22.5 percent.[9] This

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[5]GAO-15-442, "Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals," U.S. Government Accountability Office (June 2015).
[6]"Oncology Drug Marketplace: Treads in Discounting and Site of Care," Berkeley Research Group (Dec. 2017), https://www.communityoncology.org/wp-content/uploads/2017/12/BRG_COA-340B-Study_NOT_EMBARGOED.pdf (last accessed July 6, 2018).
[7]"Implications of Hospital Employment of Physicians on Medicare & Beneficiaries," Avalere Health, LLC (Nov. 2017), http://www.physiciansadvocacyinstitute.org/Portals/0/assets/docs/PAI_Medicare%20Cost%20Analysis%20--%20FINAL%2011_9_17.pdf (last accessed July 6, 2018).
[8]83 Fed. Reg. at 22698-99.
[9]See generally, CY 2018 OPPS Final Rule.

was an important step—but only a first step—in what will need to be further adjustments to the 340B program in order to achieve the Administration's goals of lowering patients' out-of-pocket costs and the total cost of care.

Although the statutory intent of the 340B program was "to maximize scarce Federal resources as much as possible, reaching more eligible patients, and providing care that is more comprehensive,"[10] the price discounts have become so steep and hospitals' profits so vast that a change in approach is clearly needed.[11] HHS reported that the number of hospitals participating in the 340B program nearly quadrupled between 2005 and 2014—not a surprising statistic given that covered entities saved $3.8 billion on outpatient drugs purchased through the 340B program in 2013[12] and approximately $6 billion in 2015.[13] In an October 2017 study, the Berkeley Research Group found that sales to 340B covered entities doubled between 2010 and 2015 and the 340B program expanded by 66 percent between 2012 and 2015.[14]

HHS asked for comment on the "unintended consequences" of the 340B program.[15] The practical effect of the program—whether intended or unintended—has been to drive services, including drug treatment for patients with cancer, into the more-expensive outpatient hospital setting. As one national study estimated, the blended profit margin for Part B drugs (accounting for both Medicare and commercial business) is only about 16% for physicians, but 210% for 340B hospitals.[16] This has encouraged hospital-physician consolidation because hospitals can expand their profit margins on drugs provided by the acquired practices.[17]

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[10]82 Fed. Reg. at 33632 n.15 (citing H.R. Rep. No. 102-384(II), at 12 (1992)).
[11]See id. at 33632 (citing MedPAC Report to the Congress (March 2015) p. 79; OIG Report cited in MedPAC Report to the Congress: Medicare Payment Policy (March 2016)).
[12]Id. at 33633 & n.21 (citing U.S. Department of Health and Human Services, HRSA FY 2015 Budget Justification, p. 342).
[13]83 Fed. Reg. at 22699 (citing 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1227 (Jan. 5, 2017)).
[14]Site of Care Shift for Physician-Administered Drug Therapies, Berkeley Research Group, LLC (Oct. 2017).
[15]83 Fed. Reg. at 22699.
[16]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 (last accessed July 9, 2018).
[17]Desai and McWilliams, "Consequences of the 340B Drug Pricing Program," New England Journal of Medicine, Feb. 8, 2018 available at https://www.nejm.org/doi/full/10.1056/NEJMsa1706475?query=recirc_curatedRelated_article (last accessed July 9, 2018).

Although the 340B program has been a boon for participating hospitals, it has been profoundly unfair to Medicare beneficiaries who routinely see no relief from their 20% co-payment obligations even while 340B covered entities generate massive profits. In a November 2015 Report, OIG offered the disturbing example that in at least one quarter of 2013, beneficiary coinsurance alone "was greater than the amount a covered entity spent to acquire the drug."[18]

DHPA supports the Administration's continued efforts to reign in the excesses of the 340B program. It is an anti-competitive program that has not lowered drug prices for patients. Revising the definition of "patient" in the 340B program to encompass only low-income and uninsured patients and requiring 340B discounts to be passed through to patients would further the Administration's goals of improving competition, reducing out-of-pocket spending for patients, and lowering the total cost of care.

III. Implications of Shifting Critical Drug Therapies from Medicare Part B to Part D

DHPA supports reform of our drug payment system in ways that align with "President Trump's bold plan to put American patients first."[19] We are concerned, however, that moving Medicare Part B drugs to Medicare Part D could jeopardize the affordability of—and access to—critical drug treatments for millions of Medicare beneficiaries in direct contravention of the Administration's articulated goals.

Gastroenterologists regularly provide high-quality care for Medicare beneficiaries with autoimmune disorders such as Crohn's disease and Ulcerative Colitis—two categories of Inflammatory Bowel Diseases ("IBD"). IBD affects an estimated 1.6 million Americans.[20] Crohn's disease affects an estimated 700,000 Americans, many of whom are now entering the Medicare population.[21] IBD can lead to years of debilitating pain and discomfort and, in some cases, life-threatening complications.[22] We believe that preserving access to care for these patients—who often depend on office-administered, Part B medications such as Remicade (infliximab) as their only treatment option—should be a priority as the Administration evaluates how best to reform the country's drug payment system.

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[18]82 Fed. Reg. at 33633 (citing HHS-OIG Report, "Part B Payments for 340B-Purchased Drugs," p. 9 (OEI-12-14-00030) (Nov. 2015)).
[19]83 Fed. Reg. at 22692.
[20]Crohn's & Colitis Foundation of America, http://www.ccfa.org/what-are-crohns-and-colitis/what-is-crohns-disease/ (last accessed July 9, 2018).
[21]Id.
[22]Id.

DHPA believes that shifting drugs such as Remicade from Medicare Part B to Medicare Part D is at odds with the President's commitment to "put American patients first."[23] Patients who suffer from Crohn's disease rely on highly specialized treatment regimens—developed in close consultation with their doctors—to treat their disease most effectively. The shift of Part B drugs to Part D would insert Pharmacy Benefit Manager middlemen into the physician-patient relationship. Instead of trusting a physician and patient to develop the most effective treatment protocol for the patient's disease, Part D plans would have the authority to decide which drugs are covered for particular indications and to impose restrictions such as step-therapy or other prior authorization protocols that inhibit patient access to drugs treatments.

Shifting drugs such as Remicade from Part B to Part D will also have serious financial implications for Medicare beneficiaries. Under Medicare Part B, more than 80 percent of seniors have supplemental insurance to cover their out-of-pocket costs. Non-low-income seniors—approximately 60 percent of the senior population—can be expected to pay more if expensive drugs are moved into Part D because Part D prohibits Medigap coverage of out-of-pocket expenses. A shift of Part B drugs to Part D will likely come with cost-sharing obligations that can reach as high as 30, 40 or 50 percent. A study by Avalere Health concluded that, in 2016, average out-of-pocket costs for new cancer therapies under Part D were approximately 33% higher than for those covered under Part B ($3,200 vs. $2,400).[24] Even worse, Medicare beneficiaries who are not enrolled in a Part D coverage plan—more than one out of every four Medicare beneficiaries—face the prospect of losing coverage altogether.

We are also concerned that the shift of drugs from Part B to Part D will increase beneficiaries' out-of-pocket costs without any countervailing cost savings to the health care system. In its analysis of the President's budget, the Congressional Budget Office was unable to identify savings that would be associated with the shift of drugs from Part B to Part D.[25] Given the Administration's commitment to a "patient first" drug payment policy, we believe it is critical to protect patient access to affordable drug treatments under Medicare

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[23]83 Fed. Reg at 22692.

[24]Brow & Kane, "Avalere Analysis Highlights Complexities of Transitioning Medicare Part B Drugs into Part D," May 21, 2018. http:/avalere.com/expertise/life-sciences/insights/Avalere-analysis-highlights-complexities-of-transitioning-medicare-part-b-d?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=top (last accessed July 6, 2018).

[25]"Proposals Affecting Medicare–CBO's Estimate of the President's Fiscal Year 2019 Budget," https://www.cbo.gov/system/files/115th-congress-2017-2018/dataandtechnicalinformation/53906-medicare.pdf (last accessed July 6, 2018).

Part B and not create added complexities to a drug payment system for uncertain savings.

IV. Competitive Acquisition Program

DHPA does not oppose the relaunching of a Competitive Acquisition Program (CAP), although physician participation should be voluntary and sufficient guardrails would need to be put in place to ensure that CAP vendors are not given the authority to determine which drugs are covered for particular indications or to impose restrictions such as step-therapy or other prior authorization protocols that inhibit patient access to drugs treatments. With that said, DHPA appreciates that introduction of some form of a market competition model could lead to cost savings for the Medicare program and its beneficiaries while maintaining full access to Part B drugs. We would favor exploration of such a market competition model over a shift of Medicare Part B drugs into Part D.

V. Request for Action

DHPA looks forward to working with HHS as it continues the important work of realigning our drug payment system to promote the development of affordable innovations that improve health outcomes and lower both out-of-pocket cost and the total cost of care. We believe that the Administration's blueprint for transforming the system must include policies that promote and protect the high quality, cost-efficient care that gastroenterologists and other physician specialists furnish to Medicare beneficiaries in the independent practice setting. Consistent with our comments above, we respectfully request that HHS:

- Implement site neutrality for physician-administered drugs across the hospital and independent physician practice settings in order to promote competition and reduce the overall cost of care for the Medicare system and beneficiaries;

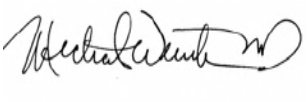
- Reform the 340B drug discount program to address the program's anti-competitive nature and to ensure that low-income and uninsured patients benefit from the program;

- Protect patient access to physician-administered drugs such as Remicade for treatment of Crohn's disease under Medicare Part B and not shift such drugs to Medicare Part D; and

- Only consider relaunching a Competitive Acquisition Program for Part B drugs if physician participation is voluntary and substantial guardrails are put in place to ensure that CAP vendors do not interfere in the physician-patient relationship.

Please reach out with any questions to DHPA's Chair of Health Policy, Dr. Naresh Gunaratnam (gunaratnamn@hurongastro.com, 734-714-0455), or to DHPA's legal counsel, Howard Rubin (Howard.Rubin@kattenlaw.com, 202-625-3534).

Sincerely,



Michael Weinstein, M.D.
President

Naresh Gunaratnam, M.D.
Chair, Health Policy

cc: Kevin Harlen, DHPA Executive Director
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