Drug Pricing Lab
Memorial Sloan Kettering

September 11, 2017

SUBMITTED ELECTRONICALLY VIA WWW.REGULATIONS.GOV

Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: File Code CMS-1678-P – Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, Proposed Rule (82 Fed. Reg. 33558 (July 20, 2017)

Dear Ms. Verma:

The Drug Pricing Lab of the Memorial Sloan Kettering Cancer Center is pleased to submit these comments on the above-entitled proposed regulation. The Drug Pricing Lab focuses on the development of rational approaches to drug pricing and health insurance coverage that encourage innovation while ensuring patient access and affordability.

We respond specifically to the proposed changes to OPPS policy regarding payment for drugs and biologicals ("drugs") purchased with a 340B program discount (Section V.B.7 of the preamble, 82 Fed. Reg. at 33632-35). Paying separately for non pass-through drugs purchased with the 340B discount, at a rate of ASP minus 22.5%, has significant potential to alleviate the burden that high-priced medical benefit drugs place on patients, and would be a welcome move to reduce the financial incentives created by the current reimbursement system, particularly for 340B hospitals.

Changing the reimbursement amount for medical benefit drugs in the OPPS for hospitals in the 340B program will directly reduce the patient share (set at 20%) for those drugs. While the majority of patients with Part B coverage have additional help to pay their 20% coinsurance, significant numbers do not have this additional protection. For a drug that is reimbursed at $10,000 per month (a plausible price point for many specialty

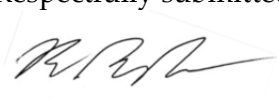
drugs), the change to ASP minus 22.5% will save beneficiaries around $500 per month. This is a sizable sum for many, one that may mean the difference between obtaining necessary treatment or foregoing it for financial reasons.

To some extent, this move may also mitigate the strong incentives for 340B hospitals to acquire smaller clinics and provider groups. While practice consolidation into hospitals does not meaningfully affect Medicare reimbursement rates,[1] it drives up prices for commercial insurance, often to a very large degree.[2]

We also note that having a proportional profit that rises as a drug becomes more expensive is problematic. 340B hospitals currently capture a mark-up that exceeds 30% in many cases. The change in reimbursement to a lower level could therefore decrease the incentive for these hospitals to use more expensive drugs, as a recent GAO report suggested they do.[3] The change to an ASP-based payment methodology in 2005 was originally intended to prevent health care providers from receiving payments far exceeding their acquisition costs.[4] This problem persists with respect to 340B hospitals, and CMS's proposed adjustment is necessary to correct it.

Thank you for the opportunity to provide our comments on this matter. Should you have any questions, please feel free to contact me or the Drug Pricing Lab program director, Anna Kaltenboeck.

Respectfully submitted,



Peter B. Bach, M.D., M.A.P.P.
Director, Drug Pricing Lab

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1 Drug Pricing Lab Report, Hospital outpatient versus physician office cost for physician administered cancer drugs, (Jan 2017).

2 Conti RM, Bach PB. Cost Consequences of the 340B Drug Discount Program. JAMA : the journal of the American Medical Association. 2013;309(19):1995-1996. doi:10.1001/jama.2013.4156.

3 See GAO, Rep. No. GAO-15-442, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, 20 (June 2015).

4 H.R. Rep. No. 108-391, at 582-83 (Nov. 2003).