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September 11, 2017

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1678-P
7500 Security Boulevard
Baltimore MD 21244-1850

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Program for CY 2018 (CMS-1678-P)

Dear Ms. Verma:

The Association of American Medical College (AAMC) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services (CMS's) proposed rule entitled *Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Program for Calendar Year (CY) 2018*, 82 Fed. Reg. 33558 (July 20, 2017).

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members comprise all 147 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their nearly 167,000 full-time faculty members, 88,000 medical students, and 124,000 resident physicians.

Summary of Major Issues on Which AAMC Provides Comments

CMS should rescind the proposal to cut the reimbursement for non-pass-through drugs for 340B hospitals. The AAMC strongly opposes CMS's proposal to cut Medicare Part B drug payments to hospitals that participate in the 340B Drug Pricing Program (340B Program) and recommends that CMS rescind this proposal. The 340B Program was designed to allow safety-net hospitals, many of which are teaching hospitals, to support programs to help low-income, vulnerable patients at no cost to taxpayers. The proposal represents a significant payment reduction that will undermine the purpose and benefits of the 340B Program, while crippling the ability of 340B hospitals to provide support and programs to serve vulnerable and low-income patients.

Among the other issues on which AAMC comments are the following:

- CMS should not finalize the proposal to remove Total Knee Arthroplasty from the Inpatient Only List until it makes revisions to bundled payment programs to avoid a significant negative impact on hospitals participating in those programs
- CMS should not package low-cost drug administration services of unrelated lab tests until further analysis occurs; and,
- CMS should account for sociodemographic factors in hospital quality provisions.

CMS Must Rescind the Proposed Cuts to Reimbursement for Part B Drugs Purchased Under the 340B Drug Pricing Program

In the calendar year (CY) 2018 Outpatient Prospective Payment System (OPPS) proposed rule, CMS has targeted safety net hospitals for Medicare reductions by proposing to dramatically cut the reimbursement rate for Medicare Part B drugs purchased under the 340B Drug Pricing Program. Currently, Medicare pays for separately payable, non pass-through drugs for all hospitals at the average sales price (ASP) **plus 6 percent** (ASP +6%). CMS proposes to pay ASP **minus 22.5 percent** (ASP -22.5%) for these drugs for only 340B hospitals beginning January 2018. **In actuality, the devastating cut to 340B hospital drug payments is 28.5%.**

At the August 21, 2017 meeting, the CMS Advisory Panel on Hospital Outpatient Payment, voted overwhelmingly that CMS not finalize the proposed cut to drugs furnished by 340B hospitals for CY 2018. The panel also recommended that CMS collect data to understand the impact of the proposal and assess the regulatory burden associated with the proposed modifier to identify drugs not purchased under the 340B program.

The AAMC strongly opposes the CMS proposal, which is a cut squarely aimed at hospitals that treat the most vulnerable and underserved patients and communities, and urges CMS to rescind the proposal. Those teaching hospitals that participate in the 340B Program do so to expand services and provide medications and treatments to patients who may not otherwise have access. Cutting Medicare payments for 340B drugs undermines the laudable purpose of the 340B Program and reduces critical drug reimbursements needed by teaching hospitals and other safety net providers to furnish services to uninsured and indigent patients. Such dramatic cuts to drug reimbursements will require hospitals to reduce or eliminate services elsewhere, including the programs to assist low-income patients that 340B was designed to support.

Proposed cuts undermine the intent of the 340B Program

Congress created the 340B Program in 1992 to allow certain safety net hospitals and other covered entities to purchase outpatient drugs at a discount from drug manufacturers in order to expand services that benefit vulnerable populations. Savings are generated from the 340B Program because pharmaceutical companies are required to sell the drugs to hospitals at a reduced price. At no cost to taxpayers, the 340B Program has been a success, allowing hospitals that treat large numbers of uninsured and underinsured patients to generate savings from the

discounts that are then used to expand health care services and provide access to needed drugs for these vulnerable populations.

Other than modest appropriations to administer the program, the 340B Program is self-sustaining; the financial support hospitals receive is derived from drug manufacturer discounts, rather than federal investments. Under the Program, drug manufacturers offer lower prices on covered outpatient drugs to eligible hospitals and other settings, enabling these eligible entities to reinvest the difference in health care services for underserved and uninsured patients.

The expansion of the 340B Program to include critical access hospitals and rural hospitals is an acknowledgement of its success and the desire to expand program eligibility to reach more patients.

Major teaching hospitals operate a variety of programs and provide services that otherwise may not be financially viable without support from the 340B Program, including:

- Free or substantially discounted prescriptions to uninsured or low-income patients,
- Mobile units to bring care to communities that have no local primary care or pharmacy,
- Multidisciplinary clinics offering substance abuse and mental health needs, and,
- Transportation support to patients who frequent the emergency room.

In the preamble to the proposed rule, CMS states that its goal “is to make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs while recognizing the intent of the 340B program to allow covered entities, including eligible hospitals, to stretch scarce resources while continuing to provide access to care.”

Unfortunately, the proposal does the opposite—undercutting the ability of 340B hospitals to provide access to care by reducing critical Medicare payments. These cuts will likely result in Medicare and other patients losing access to important services that preserve the health of their communities and could result in higher hospital use of emergency rooms and increased hospital admissions, with resultant higher costs and poorer health outcomes for vulnerable populations.

The CMS proposal uses faulty assumptions and is unsupported by a CMS data analysis

In the preamble to the proposed rule, CMS discusses several reports, including a Medicare Payment Advisory Commission (MedPAC) examination of Part B spending for 340B and non-340B hospitals from 2008-2012¹, noting that the spending increase has been greater in 340B hospitals, and suggests that such increase is inappropriate. However, the MedPAC report fails to account for the fact that 340B hospitals are significantly different from non-340B hospitals, and many compounding factors may contribute to differences in Part B spending. Over the period of time studied, many new types of hospitals joined the 340B Program and 340B hospitals serve a very different patient population and offer a wider range of services than those hospitals that are outside the program. Also, CMS did not provide its own independent analysis to reach the conclusion that 340B hospitals should receive a 22.5% payment cut for Part B drugs.

¹ MedPAC Report to Congress: Medicare and the Health Care Delivery System, June 2017; accessed at http://medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf?sfvrsn=0

- ***340B hospitals are significantly larger, serve a different patient population, and are financially more fragile than non-340B hospitals***

In the proposed rule, CMS highlights findings from a Government Accountability Office (GAO) report² that compared financial and other characteristics between hospitals that participate in the 340B program and hospitals that do not. GAO found that “on average, beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at other non-340B hospitals. The differences did not appear to be explained by the hospital characteristics GAO examined or by patients’ health status.” (82 *Fed Reg* 33633) Prior to the publication of the report, the U.S. Department of Health and Human Services (HHS) was given an opportunity to respond to GAO’s findings. HHS’s response stated that “we are concerned that the report characterizing spending on Part B in 340B DSH hospitals as ‘excess,’ ‘potentially inappropriate,’ and ‘more than necessary to treat Medicare Part B beneficiaries’ is not supported by the study methodology. GAO’s study, which only examined average differences in per-beneficiary spending by hospital type, did not examine any patient differences in terms of quality or outcome.”³

- ***CMS did no independent data analysis to support the cut***

CMS did no independent data analysis to justify its payment cut of 28.5% (ASP-22.5%). Rather, the Agency relied on a MedPAC analysis to support this proposal. The 22.5% is derived from a May 2015 MedPAC estimate of the “lower bound of the average discount received by 340B hospitals for drugs paid under” OPSS. (Appendix A, page 25). MedPAC estimated the difference between drug ceiling prices and average sales prices based on 2013 data. CMS has provided no justification for the use of this data.

Part of the reason why CMS did not do its own analysis may be because the Agency did not know which data to rely upon. CMS acknowledges this fact by writing in the proposed rule preamble that “current data limitations inhibit identification of which drugs were acquired under the 340B program in the Medicare OPSS claims data.” (82 *Fed Reg*. 33633). To remedy this lack of data, CMS will establish a modifier, to be effective as of January 1, 2018. (The AAMC discusses the difficulty of adding this modifier later in our comments.)

CMS cannot implement a payment cut of the magnitude proposed without providing a sufficient and replicable methodology that supports the proposal for payment rate of ASP minus 22.5 percent. Relying on a MedPAC analysis does not suffice for this important fiduciary, and legal, requirement.

The 340B Drug Pricing Program is NOT causing unnecessary utilization or overutilization of separately payable drugs

The 340B Program is being unjustly targeted as “unnecessary utilization and potential overutilization of separately payable drugs.” According to the Health Resources and Services

² Action Needed to Reduce Financial Incentives to prescribe 340B Drugs at Participating Hospitals, GAO-15-442, June 2015; accessed at <https://www.gao.gov/products/GAO-15-442>

³ GAO Study, 340B Drug Pricing Program, page 38

Administration (HRSA), which administers the 340B Program, 340B sales are less than three percent of the total U.S. drug market.⁴ Reducing how Medicare reimburses hospitals that participate in the 340B Program for these drugs will not address drug use; rather, it will have the detrimental effect of impeding hospitals' ability to maintain programs that provide services to vulnerable populations, including Medicare beneficiaries.

Outpatient drug spending growth is the result of volume, type of service, and price. Outpatient volume can increase for multiple reasons, but two predominant factors are the shift of providing services from the inpatient to outpatient setting. In recent years, hospital outpatient departments have seen dramatic increases in volume as more services are moving from the inpatient to the outpatient setting. MedPAC's analysis⁵ shows that outpatient visits per beneficiary have increased by 44.2% between 2006 and 2014, while inpatient discharges per beneficiary decreased by nearly 20% during the same time period. This shift reflects efforts to increase the value of many services and overall represents a savings for the Medicare program. As part of this shift, more complex treatments are able to be performed safely in the outpatient setting. For example, more advanced medication regimens for cancer and immunologic disorders are now often treated in outpatient infusion centers, with a concomitant growth in the volume and related overall costs for the drug regimen.

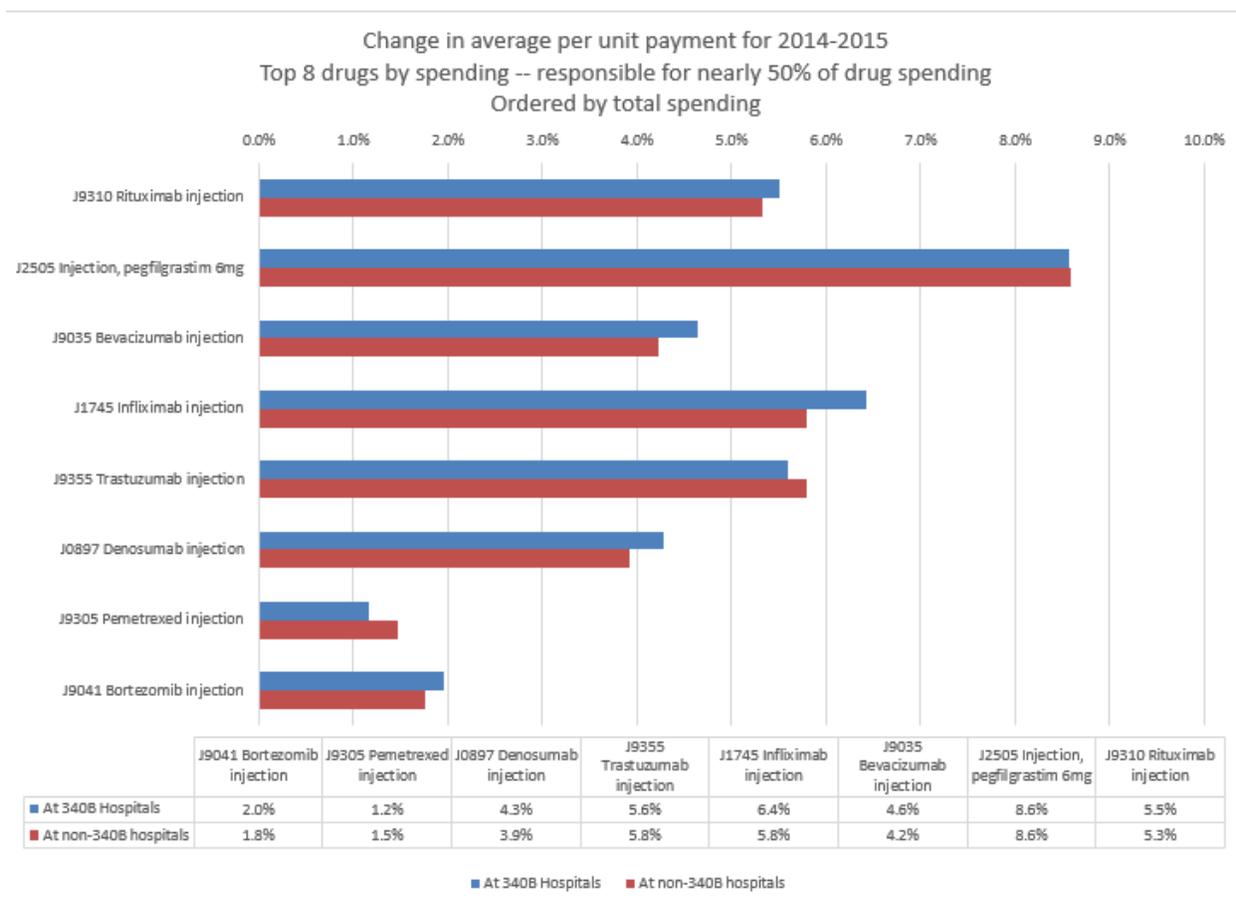
In 2016, almost 1.7 million new cases of cancer were diagnosed.⁶ The median age at cancer diagnosis is 65 years – the age most Americans are eligible for Medicare implying that half of these new cases occur in the Medicare population. Much of this care occurs in the outpatient setting. As a result, more patients with cancer will logically mean more outpatient cancer drug costs.

In addition to volume, drug pricing (as reflected by the average sales price, or ASP) affects overall drug costs. While medications allow patients to live healthier lives, some medications often come with a hefty price tag. There are more expensive drugs on the market than ever before. As MedPAC reports, 8 of the top 10 drugs paid under the ASP system in Medicare are biologics, many of which have limited to no competition. For some chronic conditions, a year of treatment with a specialty drug can easily exceed \$100,000. The price of a drug upon entry into the market continues to rise. It is estimated that prices for new drugs entering the market have doubled since 2012. AAMC-member teaching hospitals report dramatic price increases for oncology medications, particularly new medications. There is no question that drugs have become unaffordable for millions of Americans and impose uncompensated care costs on the providers that care for them.

An analysis by Watson Policy Analysis (WPA) showed a similar growth in the unit payment for the top eight outpatient drugs, which account for almost 50% of drugs used in the outpatient setting, for both 340B and non-340B hospitals.

⁵ MedPAC June 2016 Report to the Congress.

⁶ <https://www.cancer.gov/about-cancer/understanding/statistics>



It is illogical to suggest that the solution to rising drug costs is to gut a program that represents less than 3% of the total U.S. drug market⁷. Moreover, it is equally illogical to believe that reducing Medicare payments to 340B hospitals will in any way address the fundamental drivers of the increase in Part B drug expenditures: volume and price. If CMS wants to address rising drug costs, the Agency should do so directly, not by cutting critical Medicare payments to safety net hospitals or undermining the 340B Program.

- **The 340B Program does not incentivize overutilization of drugs**

The AAMC disagrees with the statement in the proposed rule that practitioners in 340B hospitals are prescribing more drugs and more expensive drugs. Relying on findings from MedPAC, GAO, and the HHS Office of Inspector General (OIG), CMS asserts that the current reimbursement structure (ASP + 6%) incentivizes 340B participating hospitals to over-utilize medications and to prescribe more expensive medications. This makes no clinical sense. Clinicians provide the care that patients need. This is particularly true with cancer patients. As a result of new and emerging drug therapies, clinicians often prescribe drug treatments that are more expensive because of the prices set by pharmaceutical companies. Moreover, for these

⁷ Department of Health and Human Services Fiscal Year 2018 Health Resources and Services Administration, *Justification of Estimates for Appropriations Committees*, page 244

patients, often the first regimen doesn't work and multiple drug regimens are needed to find the one that will be successful, which can also drive up total costs.

As major referral centers with highly specialized expertise, academic medical centers serve a sicker, more complex, and more vulnerable patient population – patients who often are unable to seek the necessary care elsewhere. These hospitals, many of which participate in the 340B Program, provide a wide variety of services to a diverse patient population. More complex patients often require more medications. Commenters to the GAO report noted that GAO did not adequately take into account case complexity when looking at drug utilization at 340B hospitals. So-called “overutilization” could actually be due to treating a more complex patient population. GAO did note that the average risk scores were higher at 340B DSH hospitals but stated that “the differences we found were likely not explained by the health status of the outpatients served.” HHS took exception to this conclusion, stating that “this claim is not supported by the analysis.”

CMS Does Not Have the Statutory Authority to Implement the Proposed Cut to 340B DSH Hospitals

As the attached memorandum from Mark D. Polston and Justin A Torres, King & Spalding, LLP clearly demonstrates, the Secretary's attempt to cut payments to 340B DSH hospitals is contrary to law and in excess of his statutory authority. The proposal runs counter to Congress's intent when it designed the 340B Program which was to stretch federal resources and allow covered entities to retain the difference between their drug acquisition costs and payment rates to provide services for vulnerable populations. The proposal also is in excess of the Secretary's authority under §1833(t)(14) of the Social Security Act which requires that any survey data used to set payment rates must be derived from statistically rigorous surveys; impermissibly employs aggregate rather than drug-specific data, contrary to the plain text of the statute; and impermissibly uses 340B status as a “relevant characteristic,” to vary payment rates, although doing so fails to take into account Congress's separate treatment of 340B covered entities in the Public Health Service Act.

The CMS estimate of the financial impact of the payment decrease is unsupported by data

In the proposed rule, CMS estimates Medicare payments for the affected Part B drugs would decrease by at least \$900 million. An analysis by WPA estimated that the savings are more likely to be in the range of \$1.2 to \$1.6 billion. In other words, the real financial impact on 340B hospitals will be far greater than CMS projected in the proposed rule, lending support to the notion that the proposal is unsupported by adequate analysis. Should this proposal be finalized, it will have very real and harmful consequences on vulnerable populations. Therefore, it is imperative that CMS be precise in the impact methodology it uses and that the Agency share that methodology with stakeholders to allow them to engage in their own modelling.

The best way to achieve “Budget Neutrality” is to maintain the current system

CMS proposes to implement the cut to 340B hospitals in a “budget neutral” manner by increasing non-drug OPPS payment rates for all hospitals by approximately 1.4 percent in CY 2018. Among other issues, CMS asks for comment on “whether and how the offsetting increase

should be targeted to hospitals that treat a large share of indigent patients, especially those patients who are uninsured.”

We appreciate that CMS recognizes the role of safety net hospitals and the need for these hospitals to receive these payments. We believe the best way to achieve this goal is by rescinding the proposal and maintaining the current payment rates for 340B hospitals. Not only will this ensure that all hospitals receive the same Medicare payment for outpatient drugs, but it will eliminate the need to impose an unfair two-tiered payment system, add bureaucracy to an already overly-complex payment system, and place vulnerable populations at risk.

The proposed 340B claims modifier for non-340B drugs is administratively burdensome, may unfairly penalize hospitals, and cannot be implemented by January 1, 2018

CMS acknowledges current data limitations that prevent the Agency from identifying which drugs were acquired under the 340B Program in the Medicare OPPS claims data, but nonetheless uses the assumption that all drugs used in hospitals outpatient departments are purchased under the 340B Program. To remedy this lack of data, CMS states that it will “establish a modifier, to be effective, January 1, 2018, for hospitals to report with separately payable drugs that were not acquired under the 340B program.”

CMS is proposing to include a claims modifier to identify drugs not purchased under the 340B Program to allow analysis of acquisition costs. The Agency further proposes unless a modifier is appended to the OPPS claim, the payment will be made as though the drug had been purchased under the 340B program. This is not currently possible, however, as many hospitals report that they are not able to determine whether a patient meets HRSA’s 340B eligibility requirement at the time of billing, but do so retrospectively.

It also will be impossible for hospitals to comply with the proposed implementation date of January 1, 2018. All hospitals, both 340B hospitals and non-340B hospitals, need additional time to adapt billing systems to accommodate the claims modifier, allow for testing to ensure the modifier is working correctly before using, and educate staff who must append the modifier. This process could take up to 12 months to test and implement. If the modifier does not appear on the claim automatically, it would have to be added manually by hospitals’ billing staff, a time and labor intensive task. This proposed requirement is administratively burdensome and will unfairly penalize any hospital that fails to append the modifier. **CMS should not finalize this proposal because it does not have a reasonable methodology for obtaining this information.**

Based on the aforementioned reasons, the AAMC strongly urges CMS to rescind the proposed Medicare cut to hospitals that participate in the 340B Drug Pricing Program.

This unconscionable cut to major safety net providers would undermine the intent of the 340B Program, which is to provide life-saving services to underserved patients. Under this proposal, participating hospitals would be forced to reduce or eliminate critical programs that support low-income communities. The AAMC looks forward to working with CMS and the Administration to address rising drug costs, but reducing Medicare payments to 340B hospitals is not a solution to this problem.

CHANGES TO THE INPATIENT ONLY LIST

CMS Cannot Remove Total Knee Arthroplasty from the Inpatient Only List until Significant Revisions to Bundled Payment Program Target Price Methodologies are Made in order to avoid a Significant Negative Impact on Participant Hospitals

In the CY 2017 proposed OPSS rule, CMS requested comments on the removal of total knee arthroplasty (TKA) (CPT code 27447) from the Inpatient Only (IPO) list. Among the criteria for removal from the list are: most outpatient departments are equipped to provide the services to the Medicare population; the simplest procedure described by the code may be performed in most outpatient departments; the procedure is related to codes that have already been removed from the IPO list; a determination is made that the procedure is being performed in numerous hospitals on an outpatient basis; and, a determination is made that the procedure can be appropriately and safely performed in an ASC, and is on the list of approved ASC procedures or has been proposed by CMS for addition to the ASC list. After consideration of the comments, CMS has proposed in the CY 2018 proposed rule that TKA be removed from the IPO list. In making this proposal, CMS has not addressed the ways in which it will adversely impact hospitals participating in Medicare bundled payment models including TKA patients. **Prior to finalizing the proposal, CMS must establish a methodology to adequately risk-adjust target prices for the shift in patient populations between surgery settings through notice and comment rule-making.**

The AAMC agrees that there may be instances in which physicians deem that a TKA can be safely performed as an outpatient procedure on certain Medicare patients, particularly those who are younger and healthier, just as that procedure commonly is performed in that setting for many non-Medicare patients. However, outpatient TKA may not be reasonable for many Medicare patients who would be older and more complex. The decision as to whether to perform TKA on an inpatient or outpatient basis should rest complete with the physician in consultation with their patient solely based on the patient's clinical circumstances. In addition, the AAMC is concerned that removing TKA from the IPO list will create undue significant negative financial implications for hospitals participating in the Bundled Payments for Care Improvement (BPCI), Comprehensive Care for Joint Replacement (CJR), and future major joint replacement of the lower extremity (MJRLE) bundled payment programs. To avoid unfairly penalizing participants in BPCI Model 2 and CJR, CMS should not finalize its proposal until it makes timely changes to both of these programs through notice and comment rulemaking.

The AAMC supports CMS's proposal to prohibit Recovery Audit Contractors (RACs) from denying inpatient TKA claims for patient status for two years, since this will discourage hospitals from inappropriately shifting TKA procedures to outpatient settings to ensure payment. **CMS should also clarify that its current two-midnight rule policy will apply to the TKA if it were to be removed from the IPO as it does for other inpatient admissions.** That is, if a patient is expected to need two midnights of hospital care, the patient is correctly admitted to the hospital as an inpatient. If the patient is expected to need fewer than two midnights of hospital care, the patient may still be admitted and the hospital paid under the IPPS if the physician's judgement with supporting documentation justifies the need for an inpatient stay. Under CMS'

policy, Quality Improvement Organizations (QIOs) rather than RACs are the first line of review for patient status. Patient status cases are only referred to a RAC if the hospital has repeated problems with two-midnight rule compliance after working with the QIO. **AAMC would not expect TKA to be an area of concern for medical review as we would expect most Medicare patients would be reasonable and necessary for an inpatient admission and we would strongly urge medical reviewers to defer to the judgment of the physician on where to perform TKA.**

Current BPCI Model 2 and CJR Payment Methodology

Both the BPCI and CJR models include 90-day episodes triggered by an inpatient hospitalization for MS-DRGs 469 and 470, and include all related services covered under Medicare Parts A and B during the 90 days following discharge. Aggregate Medicare payments for care provided during episodes are retrospectively compared to a target price to determine the participant's financial results. The target price is based on average episode payments during a baseline period. Under BPCI, this average is based entirely on a hospital's own historical performance. Under CJR, this historical average is a blend of hospital-specific and regional data. This historical average is trended to the performance period and discounted by a certain percentage. If actual payments fall below the target, the hospital is eligible to receive payments from the Medicare program. Conversely, if actual payments exceed the target, the hospital is required to reimburse Medicare for the difference (up to a limit).

Impact of Proposal to Remove TKA from IP List on BPCI and CJR Target Prices

The BPCI and CJR baseline periods include a subset of Medicare FFS TKA cases that could have been performed as outpatient procedures, if outpatient procedures were allowed during that period. CMS' proposal to permit TKA procedures to be reimbursed under OPSS as well as IPPS may significantly alter the composition of BPCI and CJR participant hospitals' patient populations, and thus unfairly hinder hospitals' ability to generate savings under the models. Specifically, younger and healthier patients are more likely to receive outpatient TKAs, meaning a higher proportion of patients receiving inpatient TKAs will be high-risk and/or more likely to require additional post-acute care support. As a result, this change in patient mix could increase the average episode payment of the remaining inpatient TKA BPCI and CJR cases when compared to current payment levels. Because the episode payments for the remaining inpatient TKA episodes are reconciled against the baseline target price calculated using both inpatient and outpatient eligible procedures, the remaining inpatient cases will appear artificially high relative to the target price. Consequently, hospitals will be more likely to sustain losses in the BPCI and CJR models. In the absence of sufficient risk adjustment to modify target prices to reflect CMS' proposed change, some BPCI hospitals may voluntarily leave the program prior to its conclusion in September 2018 in order to mitigate financial losses.

Possible refinements to the BPCI and CJR Models

Without sufficient risk adjustment to account for changes in BPCI and CJR patient populations as a result of CMS's proposal, hospitals will be more likely to sustain financial losses in the

programs that are not due to their own performance. Two primary approaches exist to mitigate financial risk resulting from the removal of TKA from the IPO list:

- 1) Attempt to stratify the baseline to exclude procedures that could have been performed in outpatient departments and recalculate inpatient targets; or,
- 2) Allow BPCI Model 2 and CJR episodes to be triggered by TKA performed in the hospital outpatient department, and calculate target prices stratified by inpatient/outpatient setting.

As is discussed in detail in the attachment, the AAMC recommends that CMS adopt the second approach. These options are further explained in the appendix to this comment letter.

CHANGES TO HOSPITAL OUTPATIENT QUALITY REPORTING (OQR) PROGRAM

AAMC Encourages CMS to Account for Socio-Demographic Risk Factors in the Hospital OQR Program

In the proposed rule, CMS states that it understands that social risk factors play a major role in health and that one of the Agency's main objectives is to ensure all beneficiaries, including those with social risk factors, receive high quality care. The Agency also seeks to ensure that the quality of care furnished by providers is assessed fairly under their programs.

Specifically, CMS seeks public comment on whether OPSS should account for social risk factors, and if so, what method or combination of methods would be most appropriate for accounting for those factors. In addition, CMS requests comment on which social risk factors might be most appropriate for stratifying measure scores and/or potential risk adjustment of a particular measure.

The AAMC is pleased that CMS understands the impact of social risk factors on health and is encouraged that the Agency is requesting comment on how to best incorporate these factors. The Association has long advocated for the inclusion of social risk factors, when appropriate, as that is the only way to level the playing field among providers and to make accurate and useful information about provider quality available to patients and their families. Most outcome measures in the quality performance category and cost measures are affected by sociodemographic status (SDS) factors, which are beyond the control of the provider. Academic medical centers tend to disproportionately treat disadvantaged and vulnerable patient populations and therefore are more likely to be unfairly penalized by performance programs that do not have adequate SDS adjustment.

Over the past several years, a substantial amount of literature has recognized the impact of SDS factors on patient outcomes.^{8,9} Recent reports released by the Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine (NAM) on accounting for social risk factors in the Medicare performance

⁸ Michael Barnett, MD, et al. Patient Characteristics and Differences in Hospital Readmission Rates. JAMA, 2015. Retrieved from: <http://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2434813>

⁹ Jianhui Hu, et al. Socioeconomic status and readmissions: evidence from an urban teaching hospital. Health Affairs, 2014. Retrieved from: <http://content.healthaffairs.org/content/33/5/778.full>

programs have provided evidence-based confirmation that accounting for patients' sociodemographic and other social risk factors is critical in validly assessing the quality of providers. The reports demonstrate that providers caring for large numbers of disadvantaged patients are more likely to receive penalties in the performance programs. Lack of SDS adjustment can worsen health care disparities because the penalties divert resources away from providers treating large proportions of vulnerable patients. The failure to account for SDS variables also is misleading and confusing to patients, payers, and policymakers because it fails to provide them with information about important community factors that contribute to poor health outcomes. Finally, as noted by ASPE, the cumulative effect of the penalties across the Medicare performance and penalty programs could significantly hinder the work of those institutions that disproportionately serve beneficiaries with social risk factors.¹⁰

Both reports clearly show that there are implementable mechanisms by which SDS data elements can be incorporated into quality measurement today. The AAMC urges CMS to incorporate the recommendations below to begin accounting for SDS factors as the first step toward ensuring that all providers are assessed on an even playing field:

- Require measure developers to test a range of national-level sociodemographic data elements, identified in the ASPE4 and NAM5 reports, into the risk adjustment methodology of accountability metrics. Both reports discuss in detail data elements that are publicly available and could be immediately tested to determine whether an empirical relationship exists between SDS and the measure's outcomes. Such elements could include income, education, neighborhood deprivation, and marital status.
- As a first step, consider stratifying certain measures by dual eligible status or other nationally available data elements.
- Implement demonstration projects to encourage eligible clinicians to collect SDS data through their electronic health records (EHR). These elements could be used to supplement the claims data already captured by CMS to greatly improve the measure's risk adjustment methodology. It is essential that CMS include vendors in these discussions.
- Where meaningful and comprehensive neighborhood level SDS-data currently exist, CMS should encourage empirical tests of quality metrics adjusted for those factors to assess the impact of the adjustments on local provider performance metrics. Based on the results of these tests CMS and other agencies will be able to prioritize the national collection of data that are most essential for valid risk adjustment methodologies.

AAMC Supports the Removal of the Six Quality Measures from the Hospital OQR Program quality measures

In the proposed rule, CMS is proposing to remove six measures from the Hospital OQR Program beginning in CY 2020:

¹⁰ "Office of the Assistant Secretary for Planning and Evaluation." Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program. December, 2016. Pg, 92 Retrieved from <https://aspe.hhs.gov/system/files/pdf/253971/ASPESESRTCfull.pdf>

- OP-1: Median Time to Fibrinolysis
- OP-4: Aspirin at Arrival
- OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional
- OP-21: Median Time to Pain Management for Long Bone Fracture
- OP-25: Safe Surgical Checklist
- OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures

The AAMC recognizes the importance of quality measurement to ensure that hospitals and physicians are providing high quality care. However, reporting and transmitting quality measures requires intensive staff training, labor, and resources – and ultimately limits the time clinicians spend with their patients. **AAMC supports removing these measures from reporting.** However, CMS proposes that two of the measures, Median Time to Pain Management for Long Bone Fracture and Hospital Outpatient Volume Data on Selected Outpatient Surgical procedures be removed beginning in CY 2020. The Agency proposes that the other four measures should be removed in 2021. The reason for removing the measures is to alleviate the maintenance costs and administrative burden to hospitals associated with retaining them. **To provide hospitals with more immediate relief related to the costs and burden associated with the measures, the AAMC asks that CMS remove the measures to avoid required reporting after publication of the final CY 2018 rule.**

AAMC supports the delay of inclusion of Outpatient CAHPS Survey Questions

CMS is proposing to delay indefinitely the implementation of the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) measures, currently scheduled for inclusion in the OAR Program measure set beginning with CY 2020 payment. AAMC supports CMS's decision to delay inclusion of the question as it lacks important operation and implementation data and review survey data from 2016 and 2017 to reaffirm the reliability of national OAS CAHPS survey data.

In the past, AAMC has stated its concerns that CMS did not discuss how the questions would be displayed on the Hospital Compare website and noted that this would be discussed in future rulemaking if the measure is finalized. The AAMC is also concerned that the OAS CAHPS survey measures are not NQF-endorsed.

The AAMC supports the use of feedback surveys to assess the overall quality of patient care. However, the Association has serious concerns with the proliferation of these surveys across settings and the potential unintended consequences that may result from an over-surveyed patient population. Currently, there are patient-experience of care surveys for physicians, hospitals, nursing homes, and home health agencies. In addition to the OAS CAHPS, CMS has implemented the Hospital CAHPS for inpatients and is testing an Emergency Department (ED) survey. Patients who receive overlapping care in these settings could receive multiple surveys, leading to confusion for the patient as to which clinicians or facilities are being assessed. The receipt of multiple surveys also may makes it less likely that the patient will choose to respond to

any of them. Compounding this problem is the fact that surveys are distributed long after patients have received care such that the responses may not be accurate due to the time lapse.

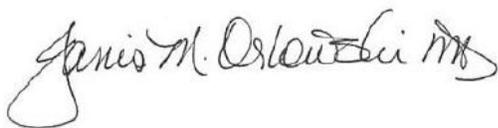
In addition, the AAMC is concerned that mail and telephone surveys, the method by which the CAHPS surveys are currently distributed, are both expensive to administer and are no longer the methodology of choice for certain patient populations. The cost associated with a mailed survey prevents hospitals from sampling a larger population of recent patients, thereby having a negative impact on their ability to respond to concerns at the provider and unit level. CMS should consider allowing patients to opt to receive these surveys electronically, which would allow hospitals to collect feedback from a larger sample and would give patients the flexibility to respond to the survey format that works best for them.

The AAMC does not support the inclusion of another patient experience survey until these issues are resolved. The Association strongly recommends that CMS convene a stakeholder group of providers, patients, vendors, and other relevant parties to discuss the CAHPS survey questions holistically to address how these surveys should be distributed in the future, prioritize the development of these survey tools to a limited subset of provider settings, and determine how to manage the issue of overlapping care. Finally, these survey measures should be NQF-endorsed and approved by the MAP before they are proposed for inclusion in the OQR program.

CONCLUSION

Thank you for the opportunity to present our views. We would be happy to work with CMS on any of the issues discussed above or other topics that involve the academic health center community. If you have questions regarding our comments, please feel free to contact Ivy Baer at 202.828.0499 or ibaer@aamc.org or Mary Mullaney at 202.909.2084 or mmullaney@aamc.org.

Sincerely,

A handwritten signature in cursive script that reads "Janis M. Orlowski".

Janis M. Orlowski, M.D., MACP
Chief, Health Care Affairs, AAMC

Attachments (2):

Memorandum from Mark D. Polston and Justin A. Torres, King & Spalding, LLP
Proposed Transitional Methodology for Bundling Programs

cc: Ivy Baer, J.D., MPH, AAMC
Mary Mullaney, AAMC

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Memorandum

TO: Ivy Baer, J.D., M.P.H.
Senior Director & Regulatory Counsel
Association of
American Medical Colleges
Mark D. Polston
Justin A. Torres

FROM: King & Spalding LLP

DATE: September 8, 2017

RE: Analysis of Statutory Authority for Proposed Changes to 340B Drug Program
Payment Rates

**Privileged and Confidential: Subject
To Attorney-Client Privilege and
Attorney Work Product Doctrine**

You asked us to analyze those portions of the recently proposed rule on Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payments Systems that relate to payments for separately covered outpatient drugs (“SCODs”) under the 340B Drug Pricing Program. *See* 82 Fed. Reg. 33,558, 33,632, *et seq.* (July 20, 2017) (“2018 OPPTS proposal”). Specifically, you asked us to determine whether the proposal of the Secretary of Health & Human Services and the Centers for Medicare & Medicaid Services to reduce payment rates to certain 340B “covered entities” for SCODs from average sales price (“ASP”) plus 6 percent to ASP minus 22.5 percent was a permissible exercise of the Secretary’s authority under the Social Security Act (“SSA”) § 1833(t)(14), *codified at* 42 U.S.C. § 1395l(t)(14). In actuality, the proposal is no mere adjustment but is a cut whose purpose is aimed directly at 340B DSH hospitals.

This memo concludes that the Secretary’s proposal is contrary to law and in excess of his statutory authority, *see* 5 U.S.C. § 706, for two reasons. First, the Secretary’s proposal clearly runs counter to Congress’s intent in designing the 340B Drug Pricing Program (“340B Program” or “program”) in a way that stretches federal resources by permitting covered entities to retain the difference between their drug acquisition costs and payment rates. Second, the 2018 OPPTS proposal is in excess of the Secretary’s authority under SSA § 1833(t)(14), because it (a) impermissibly conflates the two alternative methods for setting payment rates, essentially discarding as too onerous Congress’s requirement that any survey data used in setting payment

rates must be derived from statistically rigorous surveys; (b) impermissibly employs aggregate and not drug-specific data, contrary to the plain text of the statute; and (c) impermissibly uses 340B status as a “relevant characteristic” in varying payment rates by hospital groups, without taking into account Congress’s separate treatment of 340B covered entities in the Public Health Service Act.

I. THE 340B DRUG PROGRAM AND THE 2018 OPPTS PROPOSAL

The 340B Program was created to assist hospitals and other institutions that provide services to disproportionately low-income, uninsured, and underinsured populations and allow those entities to purchase drugs at reduced prices. Under the 340B Program, drug manufacturers agree to “offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.” Public Health Service Act (“PHSA”) § 340B(a)(1), *codified at* 42 U.S.C. § 256b(a)(1). Covered entities are statutorily defined at PHSA § 340B(a)(4), and include qualifying hospitals, Ryan White HIV/AIDS program grantees, black lung clinics, rural referral centers, critical access hospitals, Title X family planning clinics, and other institutions that primarily serve the poor, indigent, or the under- or uninsured. The program is designed to enable covered entities to purchase 340B drugs for all eligible patients, including patients with Medicare or private insurance, and retain the difference if the reimbursements for the drugs exceeds their costs.

Every year, the Secretary of Health and Human Services and the Centers for Medicare & Medicaid Services set a payment rate for SCODs. Since 2013, the payment rate to all hospitals paid under OPPTS, including 340B DSH hospitals, for all separately payable non pass-through drugs, including SCODs, has been ASP + 6 percent. However, in the 2018 OPPTS proposed rule, 82 Fed. Reg. at 33,632, the Secretary has proposed to cut that payment rate to ASP minus 22.5 percent for 340B DSH hospitals only. This figure is based on an estimate of the average 340B discount covered entities receive “for drugs paid under the [OPPTS],” which was produced by the Medicare Payment Advisory Commission (“MedPAC”) in 2015. *Id.* The Secretary did not perform his own independent analysis of 340B discounts. The Secretary estimates that the proposal will reduce payments for 340B drugs by \$900 million annually and will increase non-drug OPPTS payment rates by 1.4 percent. 82 Fed. Reg. at 33,712. In offering this proposal, the Secretary’s purported “goal is to make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs.” *Id.* at 33,633.

II. THE SECRETARY’S PROPOSAL IS INCONSISTENT WITH CONGRESS’S INTENT IN ENACTING THE 340B PROGRAM

The 340B Program was created to assist entities that provide services to disproportionately low-income, uninsured, and underinsured populations and allow those entities to purchase drugs at reduced prices. Under the 340B Program, drug manufacturers agree to charge at or below statutorily defined prices, known as the “340B ceiling prices,” for sales of

certain drugs to “covered entities.” The program is designed to enable covered entities to purchase 340B drugs for all eligible patients, including patients with Medicare or private insurance, and retain the difference if the reimbursements for the drugs exceed their costs. Drug manufacturer participation in the 340B Program is essentially mandatory: Manufacturers must participate as a condition of having their drugs covered by Medicaid, *see* H.R. Rep. 102-384, at 12 (1992), and they cannot discriminate against covered entities in the distribution of drugs by, for example, setting minimum purchase amounts or treating covered entities differently from other purchasers during drug shortages, *see* 59 Fed. Reg. 25,110, 25,111 (May 13, 1994) (“Manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective.”).

By providing manufacturers a strong incentive to participate in the 340B Program and prohibiting them from treating covered entities differently in drug distribution, Congress acted to create a dedicated, ongoing source of funding for institutions that care for vulnerable patient populations at no cost to taxpayers. The 340B Program thus reflects a Congressional purpose to fund services of covered entities that serve indigent and uninsured populations by allowing them to retain the difference between Medicare payments rates and their acquisition costs. “In giving these ‘covered entities’ access to price reductions, [Congress] intend[ed] to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” H.R. Rep. No. 102-384(II), at 12. The fact that CMS pays covered entities more for 340B drugs than it costs covered entities to acquire those drugs—which the Secretary’s 2018 OPPS proposal identified as a flaw in the program justifying the move to ASP minus 22.5 percent, *see* 82 Fed. Reg. at 33,632—is no surprise at all. In fact, far from a bug of the 340B Program, this is a *feature*; simply by normal operation of the 340B Program’s design, covered entities “*should* have lower acquisition costs for many drugs.” Payment for Drugs Under the Hospital Outpatient Prospective Payment System, OEI-03-09-0420, at 4 (Oct. 22, 2010) (emphasis added). *See also id.* at 8 (payment rates that exceed acquisition costs “is an expected result given the purpose of the 340B Program”). The Government Accountability Office has found that access to these reduced price medications enables covered entities “to expand the type and volume of care they provide to the most vulnerable patient populations.” U.S. Dep’t of Health & Human Servs., *Justification of Estimates for Appropriations Committees* at 325 (2017).

Far from limiting the program’s scope to reduce covered entities’ access to this funding stream, Congress has in fact acted to expand the definition of covered entity, allowing a wider range of institutions to participate in the program. *See* Pub. L. 111-148, § 7101 (2010) (expanding “covered entity” to include children’s hospitals, rural referral clinics, critical access hospitals, and other institutions). HRSA estimated that this expansion enabled up to 1,500 new facilities to become “covered entities.” *See* HRSA, 340B Drug Pricing Program Frequently Asked Questions: Affordable Care Act, *available at* <http://www.hrsa.gov/opa/faqs/aca.htm>. With this expansion, HRSA also increased its audit function to ensure program compliance. The

expansion of the program is strong evidence that the results the Secretary now decries are positive and actually reflect Congress's intent. All available evidence thus confirms that allowing covered entities to retain the difference between statutorily prescribed payment rates and acquisition costs is fundamental to the 340B Program's design and is the intended result of the program's operation.

The Secretary's 2018 OPPS proposal is no more than "a novel attempt to reconfigure Congress's statutory scheme," and is thus contrary to law and in excess of statutory authority under the Administrative Procedure Act. *Howard v. Pritzker*, 775 F.3d 430, 432 (D.C. Cir. 2015). The Secretary relies on his authority to adjust payment rates for SCODs "as necessary for purposes of this paragraph" (*i.e.*, Paragraph 14) under Section 1833(t)(14)(A)(iii)(II) of the Social Security Act. But a statutory provision such as this, which provides the Secretary with general authority to do something, cannot be read in isolation from the rest of Title 42 of the U.S. Code. Rather, this "adjustment" provision of Section 1833(t)(14) must be read in light of the entire statutory scheme. *See United States v. Bass*, 404 U.S. 336, 344 (1971) ("[C]ourts should interpret a statute with an eye to the surrounding statutory landscape and an ear for harmonizing potentially discordant provisions[.]"). Where, as in the case of the 340B Program, "Congress has enacted a comprehensive scheme and has deliberately targeted specific problems with specific solutions," an agency has no authority to undo that Congressional scheme by exercise of some general authority found elsewhere in the statute. *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 132 S. Ct. 2065, 2071 (2012) (quoting *Varity Corp. v. Howe*, 516 U.S. 489, 519 (1996) (Thomas, J., dissenting)). *See also Maracich v. Spears*, 133 S. Ct. 2191, 2204 (2013) (when Congress decides to "target [a] problem" with a specific statutory provision, other provisions "should not be construed to interfere with this statutory mechanism unless the text commands it"). In such a case, the "specific governs the general," *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384 (1992), "particularly when the two are interrelated and closely positioned," *HCSC-Laundry v. United States*, 450 U.S. 1, 6 (1981) (per curiam).

These principles govern here. Both the 340B Program and Section 1833(t) of the Social Security Act are codified in Title 42 of the United States Code and are "interrelated," in that they deal generally with the Secretary's authority to regulate outpatient drug payment rates. The Secretary has been given general "adjustment" authority under SSA § 1833(t)(14) relating to SCODs, but that general grant of authority has to be exercised in light of the specific, highly reticulated scheme Congress has enacted under the 340B Program. Congress aimed the 340B Program at a specific problem—increasing resources for care for the indigent and uninsured—and designed the program to generate revenue for covered entities in excess of their acquisition costs, in order to stretch federal resources for these institutions and permit them to expand the scope of their work. It has never acted to limit covered entities' access to funds realized through the normal and expected operation of the 340B Program. In fact, Congress has enlarged the definition of "covered entity" to increase the pool of institutions that have access to this funding. Under these circumstances, the Secretary's general adjustment authority must give way to the

specific scheme enacted in PHSA when the 340B Program was created. *See RadLAX Gateway Hotel*, 132 S. Ct. at 2071; *Maracich*, 133 S. Ct. at 2204.

In fact, the import of these cases is even stronger here than in *RadLAX*, *Maracich*, or *Howard*, where the agency applied some general provision to substantially reduce the scope of a specific statutory provision. At least as to the DSH hospitals affected by these cuts, the Secretary's action fundamentally alters the 340B Program by denying DSH hospitals access to the funds that Congress intended to give them access to, which are the result of retaining the difference between acquisition costs and payment rates. *See* 82 Fed. Reg. at 33,632. If an agency is prohibited from using general authority to substantially reduce the scope of a specifically enacted program, it certainly lacks authority to so fundamentally alter a duly enacted Congressional program, even if only to a certain class of intended beneficiaries. Congress does not invest agencies with such authority through obscure statutory provisions in another law; to do so would be to hide an "elephant in a mousehole," which Congress is never presumed to do. *See Whitman v. Am. Trucking Ass'n*, 531 U.S. 457, 468 (2001) ("Congress . . . does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes."); *see also FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000) ("Congress could not have intended to delegate a decision of such economic and political significance to an agency in so cryptic a fashion."). This presumption is even more warranted in this case where Congress limited the Secretary's authority to adjustments that are "necessary for purposes of" paragraph 1833(t)(14), but the Secretary's true purpose is to rewrite the 340B program.

III. THE SECRETARY'S PROPOSAL IS IN EXCESS OF HIS AUTHORITY UNDER SECTION 1833(T)(14)

Besides being clearly inconsistent with the Congressional purpose in enacting the 340B Program, the 2018 OPSS proposal exceeds the Secretary's authority under Section 1833(t)(14) itself, for three reasons:

- *First*, the Secretary is using a method to determine acquisition costs under subsection (iii)(II) of that paragraph that attempts to approximate the statutorily prescribed method under subsection (iii)(I)—without meeting any of the rigorous requirements imposed by the statute on use of survey data in setting payment rates. This amounts to rewriting the statute to discard onerous provisions.
- *Second*, the Secretary has ignored the statutory directive in Section 1833(t)(14) to set payment rates at the average acquisition cost for specific drugs and not to use averages for all drugs.

- *Third*, the Secretary proposes to use 340B status as a “relevant characteristic” for a hospital group without taking into account Congress’s specific separate treatment of these covered entities in the PHSA.

A. The Secretary’s Impermissible Conflation of the Two Alternative Methods for Setting Payment Rates

The purpose of Section 1833(t)(14) is to give the Secretary specific directions on how to determine the “amount of payment . . . for a specified covered outpatient drug.” SSA § 1833(t)(14)(A). Under the statute, the Secretary was given specific directions on how to set payment rates in 2004 and 2005, but starting in 2006, the Secretary was directed to set payment rates by using one of two alternative processes:

- 1) Under subsection (iii)(I), the Secretary may set the payment rate to be equal to the average hospital acquisition cost for the drug for that year (to vary, at the discretion of the Secretary, by “hospital group” as defined by “relevant characteristics”), “as determined by the Secretary taking into account . . . hospital acquisition cost survey data”; or
- 2) Under subsection (iii)(II), if “hospital acquisition cost data are not available,” the Secretary may use the average price for the drug “as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.”

The statute also sets certain requirements for the hospital acquisition cost data surveys used to set payment rates for SCODs: Under subsection (iii)(I), such surveys must “have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug,” and the Comptroller General is directed to report to Congress the extent of any “variation in hospital acquisition costs for drugs among hospitals based on the volume of covered OPD services performed by such hospitals or other relevant characteristics of such hospitals (as defined by the Comptroller General).” SSA § 1833(t)(14)(D)(iii)-(iv).

The structure of Paragraph 14 of Section 1833(t) reveals a clear purpose—Congress’s preferred method of setting payment rates was to use statistically sound surveys of acquisition costs. The point of using a survey is obvious: to get beyond the data limitations caused by lack of knowledge about average manufacturing prices, the effect of discounts, and other factors that distort sales prices. The survey format also permits the Secretary to rely on recent and reliable data without having to adjust for inflation and increased drug prices. But if those surveys could not be conducted consistent with the statutory focus on statistical rigor, the Secretary was directed to set payment rates based on average price. The choice presented to the Secretary is binary; use statistically rigorous surveys to estimate acquisition costs “for each . . . drug” or use average price. He cannot use some third method of his own design for setting payment rates.

As a historical matter, the Secretary has repeatedly admitted that he has not been able to meet the requirements of subsection (iii)(I) in fashioning a statistically sound survey. *See* 77 Fed. Reg. 68,210, 68,383 (Nov. 15, 2012); 80 Fed. Reg. 70,298, 70,438 (Nov. 13, 2015).¹ Accordingly, in the past, in order to achieve administrative uniformity and ease of acquisition, the Secretary has settled on an ASP + 6 percent payment rate (in order to account for overhead and administrative costs), which is in effect an exercise of the Secretary's subsection (ii)(II) authority. But here, the Secretary proposes to do something *neither* subsection allows: using a "close-enough" survey of acquisition cost data to "adjust" average sales price in the face of a clear Congressional directive that, if survey data are used to set payment rates, they must be derived from surveys that meet the statutory requirements for statistical rigor.

It cannot be denied that the aggregate estimate of 340B discounts the Secretary has proposed to use to "adjust" average sales price does not meet the requirements of Section 1833(t)(14)(D)(iii). The -22.5 percent adjustment in payment rates in the 2018 OPSS proposal is driven by the May 2015 estimate by MedPAC of "the lower bound of the average discount received by 340B hospitals for drugs paid under the outpatient prospective payment system (OPSS)." MedPAC, Overview of the 340B Drug Pricing Program, at App. A (May 2015) ("MedPAC Report"). MedPAC's method was to estimate the difference between drug ceiling prices and ASPs, based on 2013 data. *See id.* Moreover, it yields an average aggregate discount across all drugs rather than yielding an estimate of acquisition costs for "each . . . drug" as required by Section 1833(t)(14)(D)(iii). But the Secretary has offered no justification for his use of data that is not adjusted for possible changes in ceiling prices and ASPs since 2013. MedPAC was also frank about the numerous data limitations in its estimate, including the lack of information about average manufacturer price, a critical component of the ceiling price.

Here, the Secretary is using MedPAC's estimate of average discounts as a proxy or replacement for the surveys required under subsection (iii)(I). This proposal mimics the process Congress set out in subsection (iii)(I) while being devoid of its substance, *i.e.*, statistical rigor "sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each . . . drug." SSA § 1833(t)(14)(D)(iii). Essentially, the Secretary is rewriting the statute to delete the requirements relating to statistically sound surveys because he has found it impossible to comply with the letter of those requirements. But Congress planned for this possibility and gave the Secretary express direction as to what to do: apply the appropriate statutory formula, which uses the average price for the year established under another provision of the statute. *Id.* at 1833(t)(14)(A)(iii)(II). The Secretary's limited "adjustment" authority under subsection (iii)(II) does not extend so far as to gut this explicit statutory directive. *See, e.g., Pettibone Corp.*

¹ Indeed, in the 2018 OPSS proposal, the Secretary asks for comment about how to undertake subsection (iii)(I) surveys in the future: "Accordingly, in the longer term, we are interested in exploring ways to identify the actual acquisition costs that each hospital incurs rather than using an average minimum discounted rate that would apply uniformly across all 340B hospitals." 82 Fed. Reg. at 33,635.

v. United States, 34 F.3d 536, 541 (7th Cir. 1994) (an agency’s authority to interpret a statute “must not be confused with a power to rewrite”).

B. The Proposal Impermissibly Uses An Average of the Discount on All 340B Drugs, Instead of Drug-Specific Information

Further, even were it permissible to use an estimate of 340B discounts to adjust payment rates under subsection (iii)(II), the plain text of Paragraph 14 does not permit the Secretary to use—as he proposes here—an average discount for all 340B drugs, as opposed to drug-specific information. *See Public Empls. Retirement Sys. v. Betts*, 492 U.S. 158, 171 (1989) (“[N]o deference is due to agency interpretations at odds with the plain language of the statute itself.”)

The whole structure of Section 1833(t)(14) requires the Secretary to rely on an average of drug-specific acquisition cost data and sales prices, not averages for all SCODs. The paragraph is replete with references to “*the drug*” and “*a drug*,” an unmistakable directive to the Secretary to use drug-specific average pricing information in fulfilling the purposes of Paragraph 14, *i.e.*, to set payment rates for SCODs. *See, e.g.*, SSA §§ 1833(t)(14)(A)(i)(I) (amount of payment for “*a sole source drug shall in no case be less than 88 percent, or exceed 95 percent, of the reference average wholesale price for the drug*”); (iii)(i) (“the average acquisition cost for *the drug for that year*”); (ii)(II) (“if hospital acquisition cost data are not available, the average price for *the drug*”); (D)(i)(I) (“The Comptroller General of the United States shall conduct a survey in each of 2004 and 2005 to determine the hospital acquisition cost for *each* specified covered outpatient drug”); (D)(ii) (“The Secretary . . . shall conduct periodic subsequent surveys to determine the hospital acquisition cost for *each* specified covered outpatient drug”).

But, the MedPAC discount estimate on which the Secretary proposes to rely to “adjust” payment rates from average sales price is admittedly an “aggregate discount . . . on OPSS-covered drugs,” rather than a drug-specific discount. MedPAC Report at App. A. Indeed, the Secretary frankly admits that because of “the limitations” of the data, he has “not attempted” to calculate a drug-specific discount estimate. 82 Fed. Reg. at 33,634. This use of an aggregate discount is inconsistent with the statutory requirement under both of the methods described in subsection (iii) that payment rates be set on the basis of drug-specific data—and further removed from the clear purpose of Section 1833(t)(14), which is to require rigor in setting payment rates and not permit reliance on gross-level data. *See United States v. O’Hara*, 301 F.3d 563, 568 (7th Cir. 2002) (interpreting a statute in light of the “repeated references” in the statutory text evidencing “Congress’s intent” in enacting the statute).

C. The Proposal Impermissibly Uses 340B Status as a “Relevant Characteristic” Without Taking Into Account the Purposes and Structure of the 340B Program

Finally, the 2018 OPSS proposal employs 340B status as a “relevant characteristic” by which the Secretary may vary payment rates, without taking into account the fact that 340B DSH hospitals are governed by a separate and highly reticulated Congressional enactment.

In a parenthetical, Section 1833(t)(14)(A)(iii)(I) permits the Secretary to vary payment rates to hospital groups based “on volume of covered OPD services *or other relevant characteristics*.” The 2018 OPSS proposal even describes some potentially relevant characteristics by which the Secretary may, in the future, set payment rates that will vary by hospital group. *See* 82 Fed. Reg. at 33,635 (“In addition, we recognize that the acquisition costs for drugs may vary among hospitals, depending on a number of factors such as size, patient volume, labor market area and case-mix.”).

But in the 2018 OPSS proposal, the Secretary has identified only *one* characteristic on which to vary payment—340B status. This is not within the Secretary’s authority. Section 1833(t)(14) was enacted long after the Section 340B program was established, and is hardly an obscure Federal program. But Congress did not identify “340B status” as a “relevant characteristic” by which the Secretary could vary payments to hospital groups in Section 1833(t)(14). Congress enacts legislation in light of pre-existing enactments dealing with the same topics, and is not presumed to have given agencies authority to substantially alter long-standing regulatory schemes in fleeting or obscure provisions. *See Am. Trucking*, 531 U.S. at 468; *Brown & Williamson*, 529 U.S. at 160. It seems unlikely that, having created a specific, targeted program to provide drugs to hospitals at reduced cost, Congress would then permit the Secretary to undo the mechanisms of that program based on one fleeting parenthetical in a later enactment, absent any specific statutory directive. To do so would run directly counter to Congress’s intent in enacting the 340B program to stretch—not to contract—federal resources directed at the indigent and under- and uninsured.

Accordingly, after reviewing the Secretary’s proposal and governing statutes, cases, and regulations, we believe that the 340 Program proposal is vulnerable to challenge on several independent grounds as in excess of the Secretary’s statutory authority.

APPENDIX: PROPOSED TRANSITIONAL METHODOLOGY FOR BUNDLING PROGRAMS

CHANGES TO THE INPATIENT ONLY LIST

CMS proposed to remove total knee arthroplasty (TKA) from the inpatient only (IPO) list. Without sufficient risk adjustment to account for changes in the Bundled Payments for Care Improvement Initiative (BPCI) and Comprehensive Joint Replacement (CJR) patient populations as a result of CMS's proposal, hospitals will be more likely to sustain financial losses in the programs that are not due to their own performance. Two primary approaches exist to mitigate financial risk resulting from the removal of TKA from the IPO list:

- 1) Attempt to stratify the baseline to exclude procedures that could have been performed in outpatient departments and recalculate inpatient targets; or
- 2) Allow BPCI Model 2 and CJR episodes to be triggered by TKA performed in the hospital outpatient department, and calculate target prices stratified by inpatient/outpatient setting.

The AAMC recommends that CMS adopt the second approach.

- **Revision of BPCI and CJR Baselines to Exclude Outpatient Eligible Procedures**

In the first approach, CMS would develop criteria to identify historical TKA cases that could have been performed in an outpatient setting, remove the outpatient eligible patients from the baseline episodes, and re-compute the targets without the outpatient eligible episodes. Although this proposal would preserve existing episode definitions (in which an episode may only be triggered by an inpatient admission), it would create significant methodological challenges and negatively affect hospital financial performance in the models.

- **Methodological Challenges**

In order to successfully implement this proposal, CMS must develop criteria to differentiate outpatient eligible cases from cases appropriately performed in an inpatient setting, and validate the outpatient identification methodology. However, this proposal is inherently flawed for the following reasons:

- 1) Many of the criteria used to determine whether or not a patient can and should receive a TKA in the outpatient setting are based on factors excluded from claims data; and
- 2) It is not possible to validate selected criteria.

Because CMS only has access to claims data, CMS would only be able to stratify cases by measures found in claims data. This fact poses significant limitations to the efficacy of the methodology, as physicians often consider factors not available in claims data such as body mass index, frailty, socio-economic status and smoking status, when determining the appropriate surgical setting. Consequently, this approach will not fully or accurately capture all of the historical episodes which could have been performed as outpatient procedures. Furthermore, comprehensive clinical criteria would be impossible to validate, since Medicare outpatient TKA procedures were not performed during the baseline.

An additional methodological challenge involves hospital specific variations. Because the determination of surgical setting is sometimes based on nonclinical factors such as physician preference or operating room availability, any adjustments to the targets must incorporate these hospital specific factors, which would be impossible to simulate.

- **Reduced Episode Volume**

Although this proposal would preserve existing episode definitions, it may reduce episode volume, since it would exclude patients who receive outpatient TKA procedures. Because BPCI Model 2 major joint replacement of the lower extremity (MJRLE) and CJR episodes can only be initiated by an inpatient admission, the shift in volume from procedures reimbursed under MS-DRG 469 or 470 to Ambulatory Payment Classification (APC) Code 5115 may reduce the number of episodes eligible for inclusion in BPCI and CJR. Consequently, hospitals' financial performance in the models will be based on fewer episodes compared to baseline and prior performance periods. As the AAMC has learned by aiding hospitals in the implementation of bundled payment models, decreased episode volume negatively impacts financial performance by increasing a hospital's vulnerability to variation in episode cost, as a few expensive cases can turn savings into losses without sufficient volume to compensate for outliers.

AAMC Recommends Refinement to the BPCI and CJR Models

In light of the shortcomings of the first proposal, AAMC recommends that CMS adopt the second proposal under which **BPCI Model 2 and CJR episodes could be triggered by TKA performed in the hospital outpatient department, and target prices would be stratified by inpatient/outpatient setting.**

In this approach, CMS would modify episode definitions to permit episodes to be initiated by TKA procedures performed in hospital outpatient departments. CMS would then assign different targets to outpatient TKA cases, substituting the outpatient prospective payment system (OPPS) payment for the DRG payment, while holding the post discharge portion of the target constant. Assuming that post-acute costs do not change *for the same patient* if the surgery is performed in an outpatient setting, the surplus/deficit per episode will not change and the net financial effect will be zero. That is, this proposal would have no financial impact if the factors that determine surgery setting also impact post-discharge care, but the surgery setting does not directly impact discharge disposition. An example of this calculation is shown below in Tables 1-4.

Under current rules, all patients receive TKAs in an inpatient setting (Table 1). In this example, the target price for all TKA episodes is \$22,000, which includes the \$11,000 DRG payment and the \$11,000 post-acute care component of the target price. The hospital's net loss for all eight TKA patients is \$23,000.

Table 1: Net Savings/(Losses) under Current Methodology

All Episodes Receive Inpatient TKA	Target	Index Admission Cost (DRG Payment)	Post-Acute Care Cost	Total Episode Payments	Savings or (Losses) per Episode
Patient 1	\$22,000	\$11,000	\$15,000	\$26,000	(\$4,000)
Patient 2	\$22,000	\$11,000	\$10,000	\$21,000	\$1,000
Patient 3	\$22,000	\$11,000	\$30,000	\$41,000	(\$19,000)
Patient 4	\$22,000	\$11,000	\$25,000	\$36,000	(\$14,000)
Patient 5	\$22,000	\$11,000	\$15,000	\$26,000	(\$4,000)
Patient 6	\$22,000	\$11,000	\$5,000	\$16,000	\$6,000
Patient 7	\$22,000	\$11,000	\$3,000	\$14,000	\$8,000
Patient 8	\$22,000	\$11,000	\$8,000	\$19,000	\$3,000
Net Payment Reconciliation Amount					(\$23,000)

Tables 2-3 illustrate the net savings or losses (the net payment reconciliation amount) which would result if CMS adopted the AAMC's proposal. In Table 2, the five most expensive patients receive inpatient surgery, resulting in net losses of \$40,000 for all inpatient TKA episodes.

Table 2: Proposed Methodology: Impact on Inpatient Episodes

Remaining Inpatient TKA Episodes	Target	Index Admission Cost (DRG Payment)	Post-Acute Care Cost	Total Episode Payments	Savings or (Losses) per Episode
Patient 1	\$22,000	\$11,000	\$15,000	\$26,000	(\$4,000)
Patient 2	\$22,000	\$11,000	\$10,000	\$21,000	\$1,000
Patient 3	\$22,000	\$11,000	\$30,000	\$41,000	(\$19,000)
Patient 4	\$22,000	\$11,000	\$25,000	\$36,000	(\$14,000)
Patient 5	\$22,000	\$11,000	\$15,000	\$26,000	(\$4,000)
Net Payment Reconciliation Amount					(\$40,000)

However, the three lowest-cost patients receive outpatient surgery (Table 3). Assuming that the OPSS payment for the corresponding CPT code for TKA is \$5,000, the outpatient target is \$16,000 (\$22,000 - \$11,000 DRG payment + \$5,000 OPSS payment). The net savings for the outpatient TKA episodes are \$17,000.

Table 3: Proposed Methodology: Impact on Outpatient Episodes

Outpatient TKA Episodes	Target	Index Admission Cost (DRG Payment)	Post-Acute Care Cost	Total Episode Payments	Savings or (Losses) per Episode
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Patient 6	\$16,000	\$5,000	\$5,000	\$10,000	\$6,000
Patient 7	\$16,000	\$5,000	\$3,000	\$8,000	\$8,000
Patient 8	\$16,000	\$5,000	\$8,000	\$13,000	\$3,000
Net Payment Reconciliation Amount					\$17,000

However, when the losses from the inpatient episodes (-\$40,000) are added to the savings generated from the outpatient episodes (\$17,000), the overall financial results are identical (-\$23,000), as shown in Table 4.

Table 4: Financial Performance Comparison: Current Versus Proposed Methodology

Surgical Setting	Current Methodology	Proposed Methodology
Inpatient	(\$23,000)	(\$40,000)
Outpatient	N/A	\$17,000
Net Payment Reconciliation Amount	(\$23,000)	(\$23,000)

The experience of several AAMC hospitals supports this approach. Because surgery location *itself* does not determine the appropriate post-discharge setting, many AAMC hospitals do not modify post-acute care plans based on surgical setting. If post-discharge costs truly do not change for the same patient regardless of surgical setting, then CMS need only alter the index surgery component of target price while utilizing the same post-discharge payment for both the inpatient and outpatient target prices.

By preserving the current target structure for inpatient episodes, but simply adjusting outpatient targets to reflect surgical setting, this proposal would:

- 1) Maintain current MJRLE episode volume; and
- 2) Free CMS from making assumptions about outpatient eligible patients during the baseline period.

Additional Considerations: Short Stays

If CMS includes outpatient TKA procedures in BPCI Model 2 and CJR, CMS should further consider the impact of the substitution of outpatient TKA for short stays and develop an appropriate adjustment. Short stays discharged to post-acute care are defined as inpatient stays: 1) in which the patient is not discharged home or with self-care, and 2) lasting one day less than the geographic mean length of stay.¹ Short stays for MJRLEs, which had a geographic mean length of stay of 2.6 days for MS-DRG 470 in Federal Fiscal Year 2017, last one day/midnight.²

¹ *CMS Price (Payment) Standardization-Detailed Methods*. Vol. 5.

² FY 2017 IPPS Final Rule, Federal Register, Table 5: List of MS-DRGs, Relative Weighting Factors and Geometric and Arithmetic Mean Length of Stay.

These cases may be the ones most likely to move from an inpatient to an outpatient setting. In these cases, an OPPS payment will replace an IPPS payment and the AAMC's recommended target price adjustment would no longer be financial neutral as in the above example. Consequently, CMS needs to develop a methodology to adjust for the difference in payment in this circumstance. AAMC would welcome the opportunity to discuss this further with CMS and suggest potential options.

The AAMC supports CMS' proposal to prohibit Recovery Audit Contractors (RACs) from denying inpatient TKA claims for patient status for two years, since this will discourage hospitals from inappropriately shifting TKA procedures to outpatient settings to ensure payment. As we note above, TKA, like all other cases where a patient status determination is made, should be subject to the two-midnight rule. Under CMS' policy, Quality Improvement Organizations (QIOs) rather than RACs are the first line of review for patient status. Patient status cases are only referred to a RAC if the hospital has repeated problems with two-midnight rule compliance after working with the QIO.

Conclusion

In order to ensure the continued success of the BPCI and CJR models, the AAMC recommends that CMS adopt the following provisions if it finalizes the removal of TKA from the IPO list:

- 1) Allow BPCI Model 2 and CJR episodes to be triggered by TKA performed in a hospital outpatient department;
- 2) Calculate target prices stratified by inpatient/outpatient setting; and
- 3) Explore appropriate adjustments for the shift of some inpatient short stays to the outpatient setting.