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Submitted electronically via www.regulations.gov

September 24, 2018

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1695-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Payment Systems and Quality Reporting Programs, *CMS-1695-P*

Dear Ms. Verma:

The Association of American Medical Colleges ("the AAMC" or "Association") welcomes this opportunity to comment on the proposed rule entitled "Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Payment Systems and Quality Reporting Programs," 83 *Fed. Reg.* 37046 (July 31, 2018), issued by the Centers for Medicare and Medicaid Services (CMS or the Agency).

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 are all 151 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 more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

As will be discussed below, the AAMC strongly opposes the proposals to cut Medicare reimbursements under the Outpatient Prospective Payment System (OPPS). These proposals are based on a misconception by CMS that increases in outpatient services are "unnecessary," whereas they are the result of policy changes CMS has made to drive health care services to lower-cost outpatient settings. For example, CMS has implemented policy changes that moved services that were traditionally only furnished in the inpatient setting to outpatient departments. Finalizing the proposed cuts to hospitals will threaten access to medically necessary health care items and services for Medicare beneficiaries and will penalize the very hospitals that have done the most to further CMS's goals and ensure beneficiaries' access to those settings that are most appropriate.

Summary of Major Payment Policy Issues on Which AAMC Provides Comments

The following items reflect the AAMC's recommendations to key proposals in the OPPS:

- ***Reducing Clinic Visit Payment.*** CMS has not substantiated the claim that the increase in the volume of hospital-based outpatient services is "unnecessary." The increase in volume of services is driven by a significant array of factors which we discuss including the actions of CMS which have encouraged and directed outpatient treatment for individuals that previously was managed in the inpatient setting. CMS does not have the legal authority to expand site-neutral policies to off-campus excepted provider-based departments (PBDs). Do not finalize the proposed cuts to excepted off-campus PBDs that provide medically necessary care to Medicare beneficiaries.
- ***Expansion of 340B reimbursement cuts***. Do not finalize decreases in reimbursement for 340B drugs administered in excepted off-campus PBDs.
- ***Clinical family of services***. Do not limit items and services paid under the OPPS and furnished in excepted off-campus PBDs.
- ***Cardiac catheterization reimbursement in ambulatory surgical centers (ASCs).*** There may be patients for whom performing this procedure in an ASC is appropriate. However, when there is a medical review, CMS should be clear that decisions about patient site of service should rest with the treating physician and patient.
- ***CAR T-Cell Therapy***. Coordination across relevant CMS departments and engagement with stakeholders is necessary to ensure coding, billing, cost reporting and payment decisions for CAR T therapy are aligned and consistent.
- ***Public Reporting of Standard Charges Request for Information.*** Standard charges do not provide patients with meaningful, actionable information about their cost-sharing responsibility which is the information that is most meaningful to patients.
- ***Quality Measure Removals***: Finalize the proposals to remove measures that are burdensome or otherwise do not meet the goals of CMS's Meaningful Measures framework.
- ***Delay Public Reporting on the HCAHPS "Communications About Pain" Questions***: Rather than remove the questions entirely, CMS should continue to test the questions and delay public reporting until the questions are valid, reliable, and do not pose a risk of unintended consequences.
- ***Conditions of Participation***: CMS should not include a requirement for interoperability in the conditions of participation (CoPs) given the significant consequences if this requirement is not met, particularly since interoperability is still in its early stages.

Background

As more services move to hospital outpatient departments (HOPDs) due to a variety of factors that will be discussed later in this letter, the AAMC is alarmed that CMS continues to propose cuts that will harm the hospitals that provide care to vulnerable patients who often can only find care at teaching hospitals. Hospitals that already struggle to remain open due to low Medicare margins will be forced to cut back services, leaving some Medicare beneficiaries with limited options for care.

According to our analysis of the fiscal year 2015 Medicare cost report data, the aggregate Medicare margins for outpatient services were negative 22.7 percent for major teaching hospitals. The Medicare overall margins are low at negative 8.6 percent in 2016.[1] The Medicare Payment Advisory Commission's (MedPAC's) analysis shows that even "efficient" hospitals were experiencing negative Medicare margins

[1] Medicare Payment Advisory Commission (MedPAC). June 2018 Data Book. Health care spending and the Medicare program. http://www.medpac.gov/docs/default-source/data-book/jun18_databooksec1_sec.pdf?sfvrsn=0

in 2016,[2] suggesting systematic underpayment in Medicare programs. "Rapidly aging U.S. population and low reimbursement rates" were cited by Moody's as one of the reasons to revise the U.S. not-for-profit and public hospitals outlook from stable to negative for 2018.[3] Morgan Stanley's analysis revealed 450 hospitals were at risk of potential closure.[4] According to the fiscal year 2016 Medicare cost report data, Medicare margins for outpatient services were a record low of negative 14.8 percent in 2016.[5] Overall, Medicare margins were a record low of negative 9.6 percent in 2016, with a new record low of negative 11.0 percent projected for 2018.[6]

Additional cuts to off-campus PBDs threaten beneficiary access to these needed outpatient services. The substantial payment reductions proposed in this proposed rule will have a negative impact on hospital operations. Hospitals already suffer negative margins providing outpatient care to Medicare patients and such a substantial payment reduction will exacerbate the problem. Our analysis of FY 2015 Medicare cost report data shows that for AAMC member hospitals the aggregate outpatient margins were -22.5 percent and overall Medicare margins were -10.8 percent. **The AAMC opposes further Medicare reimbursement cuts to items and services provided in off-campus PBDs.**

Lastly, we agree with CMS's Hospital Outpatient Payment Panel's (HOP Panel's) recommendation that CMS "not implement the proposals for reduction in payment for outpatient clinic visits or restrictions to service line expansions" requesting that CMS study the matter to better understand the reasons for increased utilization of outpatient services."[7] **Therefore, CMS should not finalize these reimbursement cuts to HOPDs and off-campus PBDs. Further, work by CMS, including substantial stakeholder engagement, is needed to fully understand the impact of the proposed cuts on the availability of services and the health of the patients who are treated at HOPDs and PBDs.**

"Unnecessary Increases in Volume" of Outpatient Services

Hospital Outpatient Departments Do Not Provide "Unnecessary" Services to Medicare Beneficiaries

CMS states in the proposed rule that there has been an "unnecessary increase" in the volume of services in HOPDs and off-campus PBDs compared to physician offices, claiming this shift in services is due to higher reimbursement rates in HOPDs and off-campus PBDs. CMS states this increase is "unnecessary" if the same service can be performed in a physician's office where the reimbursement rate is lower. CMS goes on to say that higher reimbursement rates incentivize hospitals to purchase off-campus PBDs. **There is no evidence that reimbursement rates alone are causing a shift in services to HOPDs and off-campus PBDs; rather, the shift is caused by a confluence of factors that will be described below.**

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[2] MedPAC. Report to Congress, March 2018. Chapter 3: Hospital inpatient and outpatient services. http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch3_sec.pdf?sfvrsn=0

[3] Moody's Investor Service (December 4, 2017). Moody's US not-for-profit and public healthcare outlook changed to negative with rising operating pressure. https://www.moodys.com/research/Moodys-US-not-for-profit-and-public-healthcare-outlook-changed--PR_376421

[4] Becker's Hospital Review (August 20, 2018). 450 hospitals at risk of potential closure, Morgan Stanley analysis finds. https://www.beckershospitalreview.com/finance/450-hospitals-at-risk-of-potential-closure-morgan-stanley-analysis-finds.html

[5] https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Cost-Reports-by-Fiscal-Year-Items/HOSPITAL10-DL-2016.html?DLPage=7&DLEntries=10&DLSort=0&DLSortDir=ascending

[6] American Hospital Association. https://www.aha.org/news/blog/2018-03-28-medicare-margins-continue-drop

[7] Centers for Medicare and Medicaid Services Advisory Panel on Hospital Outpatient Payment. August 20, 2018 meeting. https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html

Growth of the Medicare Population. Medicare expenditures are increasing due in large part to the growth in the Medicare population more likely to need care in the HOPD than a physician's office. With some 10,000 Americans aging into Medicare every day,[8] the Medicare population is expected to reach almost 60 million beneficiaries in 2018.[9] Moreover, many Medicare beneficiaries also struggle with higher disease burden. According to the Kaiser Family Foundation, approximately one-third of Medicare beneficiaries have five or more chronic conditions,[10] and more than 30 percent of beneficiaries live with a cognitive impairment or experience physical limitations in their activities of daily living.[11] Successfully managing these beneficiaries' complex medical needs requires considerable resources and care coordination; HOPDs and PBDs are best prepared to provide the comprehensive and coordinated care suited to their complex situations. Cutting reimbursements will jeopardize access to care for many of these patients that rely on HOPDs and off-campus PBDs.

Improving post-discharge care. As a recognition of the value of more post-discharge visits, in 2013 CMS began providing distinct payment for two transitional care management codes (99495 and 99496) to incentivize timely follow-up care for recently discharged patients as studies have shown that early follow-up care can reduce the risk of 30-day readmissions.[12,13,14] Since the adoption of these codes, there has been a ten-fold increase in the payment for follow-up care under the OPPS, based on analysis by our data consultant, Watson Policy Analysis (WPA).[15] The total spending on the two codes on follow-up care was close to $6 million in 2017.[16] While providing follow-up care, hospitals also provide lab tests, drug injections, clinic visits, and preventive care that totaled $1.7 million on the same claim where the follow-up codes were billed in 2017.[17] This resulted in total spending with the two follow-up codes (including services up to 30 days) being $7.7 million in 2017.[18]

Increases in Prescription Drug Prices. Drug prices are taking a larger share of the health care dollar. Prescription drug prices have increased faster than inflation over the past 12 years.[19] Launch prices for new cancer drugs can be more than $400,00 for a year of treatment.[20] WPA's analysis of OPPS claims shows that the share of spending on separately payable drugs (status indicator K) as a share of total OPPS

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[8] https://www.forbes.com/sites/dandiamond/2015/07/13/aging-in-america-10000-people-enroll-in-medicare-every-day/#7618d5943657

[9] CMS Fast Facts. July 2018 version. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Fast-Facts/index.html

[10] Kaiser Family Foundation. An Overview of Medicare. Published November 22, 2017. https://www.kff.org/medicare/issue-brief/an-overview-of-medicare/

[11] Kaiser Family Foundation. Medigap enrollment and Consumer Protections Vary Across States. July 11, 2018. https://www.kff.org/medicare/issue-brief/medigap-enrollment-and-consumer-protections-vary-across-states/

[12] Hernandez AF, Greiner MA, Fonarow GC, et al. Relationship between early physician follow-up and 30-day readmission among Medicare beneficiaries hospitalized for heart failure. JAMA. 2010;303(17):1716-1722.

[13] Ryan J, Kang S, Dolacky S, Ingrassia J, Ganeshan R. Change in readmissions and follow-up visits as part of a heart failure readmission quality improvement initiative. Am J Med. 2013; 126(11): 989-994.

[14] Sharma G, Kuo YF, Freeman JL, Zh Growth in spending on Part B drugs reflects both price increases in existing drugs and the introduction of new expensive cancer drugs.[14] ang DD, Goodwin JS. Outpatient follow-up visit and 30-day emergency department visit and readmission in patients hospitalized for chronic obstructive pulmonary disease. Arch Intern Med. 2010; 170(18):1664-1670

[15] Watson Policy Analysis. September 2018.

[16] Ibid.

[17] Ibid.

[18] Ibid.

[19] Rx Price Watch Report. Trends in Retail Prices of Prescription Drugs Widely Used by Older Americans: 2006 to 2015. December 2017. https://www.aarp.org/content/dam/aarp/ppi/2017/11/trends-in-retail-prices-of-prescription-drugs-widely-used-by-older-americans-december.pdf

[20] National Cancer Institute. The Imperative of Addressing Cancer Drug Costs and Value. March 15, 2018. https://www.cancer.gov/news-events/cancer-currents-blog/2018/presidents-cancer-panel-drug-prices

spending has increased from 14 percent in 2014 to 17 percent in 2016.[21] Furthermore, if drug prices were kept constant the savings would reduce the pace of OPPS spending increases by eight percent annually from 2014 to 2016.[22] As MedPAC reports, spending on separately payable drugs increased by 98 percent from 2011 through 2016; two-thirds of these drugs are used to treat cancer.[23] Many of these drugs have limited to no competition which keeps prices high.

Rise in Patient Referrals to HOPDs. HOPDs and off-campus PBDs are seeing a spike in referrals of patients requiring treatment for advanced stages of disease, many of whom have multiple comorbid conditions that require care from a variety of practitioners. For many patients, HOPDs are the sole source of access to care for cancer treatments. According to MedPAC, spending for chemotherapy administration rose in the hospital outpatient setting. From 2011 to 2016, chemotherapy administration increased by 56.1 percent (9.3 percent per year), while at the same time the volume for chemotherapy administration decreased by 13.4 percent in physicians' offices.[24] According to the Community Oncology Alliance (COA), cuts to reimbursement for Part B drugs is driving the closure of oncology practices and community cancer clinics leaving Medicare beneficiaries to seek care in HOPDs. [25]

Changes to the Inpatient Only List (IPO). CMS acknowledges in the proposed rule that some of the increase in services experienced by HOPDs are a result of the "shift of services from the inpatient setting to the outpatient setting over the past decade." (83 *Fed. Reg.* 37152). Driven by medical innovation, procedures that were once only provided in the inpatient setting – for example, total knee replacements – are now being successfully performed in hospital outpatient departments for certain patients, at a lower cost for both Medicare and beneficiaries.

Success of Accountable Care Organizations (ACOs). ACOs promote high-quality, efficient care for Medicare beneficiaries enrolled in fee-for-service (FFS). As previously mentioned, Medicare beneficiaries tend to have multiple chronic conditions that require increased resources to manage, including coordinating care across multiple providers in multiple specialties. ACOs associated with major teaching hospitals successfully manage care for these complex individuals by coordinating care in the outpatient setting. The effort to provide more coordinated care and lower spending may result in an increase in OPPS spending. Although some of these patients may receive more outpatient services, ACOs have produced savings for Medicare. According to CMS, 472 ACOs that care for 9 million beneficiaries accounted for $1.1 billion in gross savings in 2017.[26]

Changes to Hospital Inpatient Requirements ("2 Midnights"). The requirement for hospitals to bill inpatient stays that span less than two midnights as outpatient services contributed to an increase of more than 140,000 observation stays in 2014. According to MedPAC, spending for inpatient hospital services was a smaller share of total Medicare spending in 2016 than it was in 2007, falling from 29 percent to 21

[21] Watson Policy Analysis. September 2018.
[22] Ibid.
[23] Medicare Payment Advisory Commission (MedPAC). Report to Congress, March 2018. Chapter 3: Hospital Inpatient and Outpatient Services. http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch3_sec.pdf?sfvrsn=0
[24] MedPAC. Report to Congress, March 2018. Chapter 3: Hospital Inpatient and Outpatient Services. http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch3_sec.pdf?sfvrsn=0
[25] Nelson, Roxanne. Oncology practices have lost $78 million, many closing. September 4, 2018. https://www.medscape.com/viewarticle/901521
[26] Centers for Medicare and Medicaid Services data set. https://data.cms.gov/Special-Programs-Initiatives-Medicare-Shared-Savin/2017-Shared-Savings-Program-SSP-Accountable-Care-O/gk7c-vejx

percent.[27] The number of hospital outpatient observation hours (both packaged and separately paid) has increased substantially, from about 27 million in 2007 to more than 58 million in 2016.[28]

Packaging Services into APCs. Outpatient expenditures increased when laboratory tests began to be paid under the OPPS. Most outpatient services are assigned to an ambulatory payment classification (APC) for payment under the OPPS. Items and services associated with the primary service are packaged within the APC. CMS has expanded packaging in some APCs over the years. However, while the intent of expanded APCs was to give hospitals more incentive to consider costs, packaging has actually increased expenditures under the OPPS in some instances because services that were once paid under another payment system are now packaged and paid under the OPPS. For example, in 2014, CMS decided to package laboratory tests in outpatient APCs. Previously, these tests were paid separately under the Clinical Laboratory Fee Schedule (CLFS). In 2014, CMS added $2.4 billion to the OPPS system to accommodate the shift of payments from CLFS to OPPS, which added over four percent to OPPS spending in 2014.[29]

Most Medicare Beneficiaries are Not Negatively Impacted by Higher Cost Sharing

CMS is concerned about the increased cost-sharing obligations of Medicare beneficiaries who receive care in HOPDs. However, most Medicare fee-for-service (FFS) beneficiaries have supplemental coverage. Almost two-thirds (60 percent) of FFS beneficiaries have either a Medicare supplemental plan (25 percent) or employer-sponsored retiree benefits (34 percent) and another 18 percent have Medicaid to assist with costs that FFS Medicare does not cover.[30] **Therefore, the majority of FFS Medicare beneficiaries will see no benefit from a reduction in reimbursement to hospitals for outpatient services.**

Site Neutral

Do Not Expand Site-Neutral Policies to Excepted HOPDs

As required by law, CMS introduced the site-neutral payment policy in CY 2017 for nonexcepted off-campus HOPDs, those off-campus PBDs that were not billing under the OPPS prior to November 2, 2015.[31] Under this policy, CMS pays the non-excepted off-campus HOPD at 40 percent of the full OPPS rate. Now, CMS proposes to expand that policy to off-campus HOPDs specifically excepted from that reduction – explained in more detail below – to address what it deems an unnecessary shift of services from the physician office to the HOPD. CMS claimed that growth in outpatient services is caused by the difference in payment between sites.

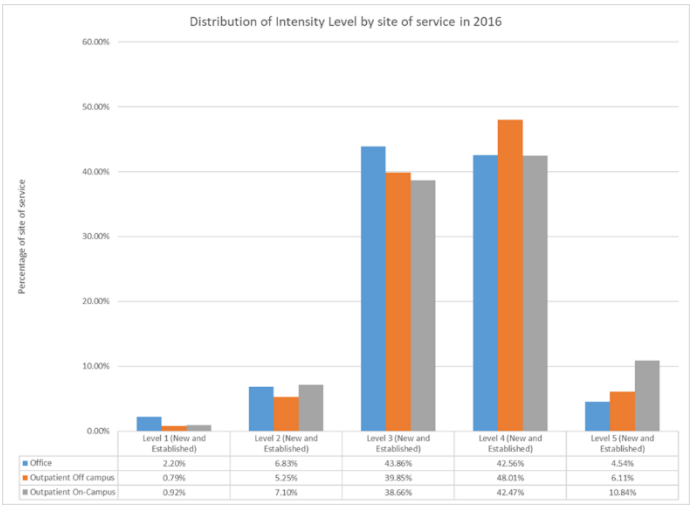
In this proposed rule, CMS cites its authority to control unnecessary increases in volume for outpatient services, proposes to pay a physician fee schedule-equivalent rate for an outpatient clinic visit, HCPCS code G0463. If finalized, this code, the most frequently billed service with the "PO" modifier which is

[27] MedPAC. June 2018 Data Book. Health care spending and the Medicare program. http://www.medpac.gov/docs/default-source/data-book/jun18_databooksec1_sec.pdf?sfvrsn=0
[28] MedPAC. June 2018 Data Book. Ambulatory care. http://www.medpac.gov/docs/default-source/data-book/jun18_databooksec7_sec.pdf?sfvrsn=0
[29] CY 2014 OPPS Final Rule. 78 Fed. Reg. 74826. December 10, 2013. https://www.gpo.gov/fdsys/pkg/FR-2013-12-10/pdf/2013-28737.pdf
[30] Ibid.
[31] CY 2017 OPPS Proposed Rule. 81 Fed. Reg. 45604. July 14, 2016.

used to identify services in excepted off- campus PBDs, would be paid at 40 percent of the full OPPS rate. CMS believes that capping the OPPS payment will control unnecessary volume increases. **The AAMC strongly opposes this proposal as the increase in the volume of services is caused by many appropriate factors. Reducing reimbursement for services received in excepted off-campus PBDs will be detrimental to the important care provided by teaching hospitals to vulnerable Medicare beneficiaries.**

The services provided, and patients seen, in excepted off-campus PBDs continue to be substantially different from physicians' offices. HOPDs and off-campus PBDs treat more medically complex patients than those treated in physicians' offices. Based on WPA's analysis of evaluation and management (E/M) codes, off-campus PBDs are seeing more medically complex patients as compared with physician offices. Table 1 shows that more than half the patients seen at off-campus PBDs require higher level services as compared to physicians' offices (54 percent and 47 percent respectively), confirming that off-campus PBDs treat more medically complex patients.[32] By way of example, certain "non-procedural" specialties, such as oncology, hematology, and nephrology, which see patients with more complex conditions, predominantly bill level 4 and level 5 services.[33] Additionally, off-campus PBDs tend to treat a higher proportion of patients for whom social determinants of health – such as housing, nutrition, literacy, and transportation – provide additional challenges, and add to the complexity of care. The AAMC questions whether CMS has the authority to implement site neutral reimbursement policies to excepted off-campus PBDs. In the CY 2017 OPPS final rule with comment, CMS finalized that excepted off-campus PBDs were not subject to the site neutral policies implemented under section 603 of the Bipartisan Budget Act of 2015 ("section 603"). Section 603 merely directed the Secretary not to pay for services provided in a <u>new</u> off-campus outpatient department. There is no statutory authority to extend the reduced payment rates to excepted off-campus PBDs. **The AAMC believes that section 603 made clear that off-campus PBDs billing OPPS for items and services furnished before November 2, 2015 are exempt from the payment reductions under section 603.**

Table 1: Distribution of intensity level by site of service, 2016



Source: 2016 Medicare Carrier 5 percent Standard Analytic File. Watson Policy Analysis. 2018

Finally, CMS claims that it has authority to implement this proposal in a non-budget neutral manner. CMS notes that under 1833(t)(9)(A) and (B), only *adjustments* are required to be budget neutral, and claims that this rate reduction is not an *adjustment* for the purposes of budget neutrality because it is a *method* for controlling unnecessary increases in services. Yet, CMS arrives at the payment amount to pay for a clinic visit by multiplying the full OPPS payment by the physician fee schedule (PFS) relativity

[32] Watson Policy Analysis. September 2018.
[33] Centers for Medicare and Medicaid Services, CY 2019 Physician Fee Schedule Proposed Rule. July 27, 2018. 83 Fed. Reg 35842.

adjuster.[34] CMS's understanding of this authority rests on the idea that using an *adjuster* in a *methodology* does not equate to making an *adjustment* under 1833(t)(9)(B**)**. The AAMC supports more extensive comments submitted by the American Hospital Association regarding CMS's lack of statutory authority to impose cuts on excepted off-campus PBDs and further questions the Agency's authority to impose cuts that are not budget neutral. **The cuts to the excepted off-campus PBDs should not be finalized. However, if CMS finalizes the cuts it must do so done in a budget neutral manner.**

Use a 2019 PFS Relativity Adjuster of 65 Percent Instead of 40 Percent for Non-Excepted PBDs

In the CY 2019 PFS proposed rule, CMS proposes to continue to use the PFS Relativity Adjuster for non-excepted PBDs until code-specific reductions that represent the technical component of services furnished under the PFS can be established, or until the Agency can implement system changes that would enable hospitals to bill for the services under the PFS directly. In the proposed rule, CMS explains that they made several adjustments to the methodology for calculating the PFS Relativity Adjuster for CY 2019, including use of a full year of claims data for claims submitted with the "PN" modifier. CMS finds that their updated analysis supports maintaining a PFS Relativity Adjuster of 40 percent and therefore proposes to continue the PFS Relativity Adjuster at 40 percent for 2019. Our CY 2019 PFS proposed rule comment letter outlines in detail our concerns about the PFS relativity adjuster. We were unable to replicate CMS's analysis for 2019 because CMS did not provide detailed information needed to replicate the calculation of the PFS relativity adjuster. Therefore, we continue to rely on our analysis from last year, which supports a PFS Relativity Adjuster of 65 percent.

340B Drug Pricing Program

The AAMC supports efforts to reduce drug prices to improve access to medications that improve patients' health and wellbeing. Numerous drugs – new and old – have prices that put them out of reach for many patients. The nation's teaching hospitals struggle firsthand with this challenge, as they strive to ensure access to needed care, including prescription drugs, for their patients and communities to avoid excessive health care spending. **The AAMC continues to oppose Medicare reimbursement cuts for drugs acquired under the 340B Drug Pricing Program. We strongly urge CMS to work to implement drug pricing reforms that address the problem at its source rather than reduce the scope of the 340B Program that provides needed services to underserved communities.**

We continue to believe that the 340B Drug Pricing Program (340B Program) has been unfairly targeted as a driver of high drugs prices, and proposals to undermine this important program are counterproductive in addressing access to affordable medication. As we have noted in our comment letters (CY 2018 OPPS proposed rule[35] and HHS Blueprint to Lower Drug Prices[36]), the 340B Program does not drive high drug prices, but rather, provides vital support and access to vulnerable patients and communities. Consistent with the intent of the program – to help stretch scarce resources as far as possible, reach more eligible patients, and provide more comprehensive services – safety-net hospitals invest their 340B savings in a

[34] CY 2019 OPPS Proposed Rule. 83 Fed. Reg. 3714. July 31, 2018, CMS states "For a discussion of the PFS relativity adjuster that will now also be used to pay for all outpatient clinic visits provided at all off-campus PBDs..."
[35] AAMC CY 2018 OPPS proposed rule comment letter. September 11, 2017.
https://www.aamc.org/download/482774/data/aamccommentlettercy2018opps.pdf
[36] AAMC comment letter. HHS Blueprint to Lower Drug Prices. July 16, 2018.
https://www.aamc.org/download/490210/data/aamccommentsonthehhsblueprinttolowerdrugpricesrfi.pdf

wide variety of programs to meet the needs of their local communities and help vulnerable patients. Since the savings come from drug manufacturer discounts, these services are provided at no cost to taxpayers.

The 340B Program is Not Driving High Drugs Costs

According to data from the Health Resources and Services Administration (HRSA), which administers the Program, 340B sales represent just 3.6 percent of the total $457 billion U.S. drug sales.[37] The net reduction to drug manufacturer revenue is even less - estimated to be approximately 1.4 percent.[38] This is a negligible impact on drug manufacturers, whose worldwide estimated sales revenue increased to $775 billion in 2015 with the largest 25 drug companies reporting annual profit margins between 15 and 20 percent.[39] Such a small percentage of total drug sales is not driving skyrocketing drug prices. The responsibility for high drug costs rests with the high prices set by the manufacturers. CMS should focus on the unsustainable prices of new therapies and identify ways to decrease skyrocketing costs. Shrinking the 340B Program will only harm patients who rely on the services provided by covered entities – it will *not* affect drug prices.

Do Not Finalize the Proposal to Reduce Reimbursement to Nonexcepted Off-Campus PBDs for Drugs Acquired under the 340B Program

CMS is proposing to extend the reductions to separately payable drugs purchased under the 340B program to nonexcepted off-campus PBDs. Beginning January 1, 2019, drugs purchased under the 340B program and furnished and billed by nonexcepted off-campus PBDs would be reimbursed at the average sales price (ASP) ***minus*** 22.5 percent. Currently, drugs furnished in these settings are reimbursed at ASP ***plus*** 6 percent. CMS states in the proposed rule that this differential in reimbursement rates has the potential to shift administration of these drugs to settings with higher reimbursement rates. The AAMC disagrees. Patients receive treatment in the settings that best meet their needs. Hospital outpatient departments and PBDs associated with hospitals tend to care for patients with greater needs – namely, patients that have multiple medical conditions that require specialized care. **The AAMC urges CMS not to finalize this proposal.**

Do Not Implement the Proposal to Decrease Reimbursement for WAC Drugs Purchased Under the 340B Program

Medicare pays for drugs and biologics that do not have a calculated average sales price based on the wholesale acquisition cost (WAC) of those drugs or biologics. Currently these drugs and biologics are paid at WAC plus 6 percent. CMS is proposing to change the reimbursement for WAC-based drugs to WAC plus 3 percent effective January 1, 2019. Additionally, WAC-based drugs that are acquired under the 340B Program would be reimbursed at WAC ***minus*** 22.5 percent. **For the same reasons that CMS should not reduce the payment to 340B hospitals for outpatient drugs to ASP minus 22.5 percent, AAMC urges CMS not to decrease the reimbursement amount for WAC drugs acquired under the 340B Program.**

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[37] Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. Observations on Trends in Prescription Drug Spending. March 8, 2016. https://aspe.hhs.gov/pdf-report/observations-trends-prescription-drug-spending

[38] Dickson, S., Coukell, A., Reynolds, I. The Size of the 340B Program and Its Impact on Manufacturers Revenues. Health Affairs. August 8, 2018. https://www.healthaffairs.org/do/10.1377/hblog20180807.985552/full/

[39] U.S. Government Accountability Office. Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals. https://www.gao.gov/assets/690/688472.pdf

Reassess Payment Reductions to 340B Drugs for CY 2019 Because of Changes to Reimbursement for 340B Drugs to Ensure Budget Neutrality

In the CY 2018 OPPS final rule, CMS adopted a policy that reduced payments for non-pass-through separately payable drugs at 340B hospitals from ASP plus 6 percent to ASP minus 22.5 percent. The estimated savings from the implementation of the policy was $1.6 billion in CY 2018. CMS decided to implement this policy in a budget neutral manner by using an adjustment to the OPPS conversion factor so that the increases in reimbursement for other OPPS items and services for CY 2018 equaled total savings from reduced payment for 340B drugs.

In the CY 2019 proposed rule, CMS states that it will continue the CY 2018 payment policy for drugs purchased under the 340B Program and, therefore, there will be no change to the CY 2019 OPPS conversion factor for this proposal. **The AAMC continues to strongly oppose this policy.** However, if CMS continues the policy then it should be implemented in a truly budget neutral manner for CY 2019. That would require CMS to reassess the impact of the payment reduction to 340B drugs and recompute the payment adjustment on the CY 2019 OPPS conversion factor.

Our analysis shows that CMS's 340B payment policy will result in a total $1.8 billion payment reduction on 340B drugs in CY 2019, $200 million more than last year's estimate. **AAMC urges CMS to recompute the 340B payment adjustment on the CY 2019 conversion factor to ensure that the budget neutrality required by this policy is implemented fairly and accurately.**

Clinical of Family of Services

Do Not Finalize the Proposal to Revise the Definition of "Excepted Items and Services" Furnished in Excepted Off-Campus Provider-Based Departments

In the proposed rule CMS seeks to revise its definition of "excepted items and services" under 42 CFR § 419.48. CMS proposes to remove what it considers to be an incentive for excepted off-campus PBDs to expand items and services furnished in these settings that are paid under the OPPS. Additionally, CMS contends that the current policy incentivizes hospitals to purchase additional physician practices to take advantage of the excepted status. CMS has cited no data to support this view. As stated previously, HOPDs and off-campus PBDs serve a high-acuity patient population with unique care needs. Items and services rendered in these settings are medically necessary based on a patient's needs, not to garner increased reimbursement. As noted earlier in this comment letter, many off-campus PBDs are in underserved areas which allows patients and caregivers access to needed medical care closer to home. As communities and their health care needs change, it is essential that HOPDs and off-campus PBDs be able to add needed services. If a barrier is placed in their ability to do so, the result will likely be a negative impact on patients who may be required to travel longer distances to receive care or who may be unable to access the care at all.

Beginning January 1, 2019, CMS is proposing to limit the scope of the current exception to only those the clinical families of services listed in Table 32 of the proposed rule (p. 37150) that were billed under the OPPS during a baseline period (generally from November 1, 2014 to November 1, 2015). Providers would be able to add items and services under the clinical families that were billed during the baseline, but if they add any new clinical families the payment would be at the PFS rate (40 percent of the OPPS

rate), the same rate paid to nonexcepted PBDs. Any item or service not listed in Table 32 must be reported with modifier "PN,"

These proposals embody the same site-neutral policies that the AAMC has opposed in previous comment letters (CY 2017 OPPS comment letter[40] and CY 2018 OPPS comment letter[41]). The AAMC believes that paying the reduced rate for expanded items and services threatens the flexibility of off-campus PBDs to furnish innovative services and new technologies to expand their clinical offerings to meet the needs of their patient populations. Furthermore, the items and services offered four years ago may have already shifted based on patients' needs and can expect to shift continually. In this circumstance, hospitals will be newly penalized for past actions taken when the hospital had no idea that those actions would result in lower future payments. CMS's proposal has the effect of impermissible retroactive rulemaking. Restricting off-campus PBDs from expanding clinical services through decreased reimbursement rates will jeopardize patients' access to care. **We urge CMS not to finalize this proposal.**

The Determination of the Baseline Services is Burdensome and Confusing; Finalizing This Proposal Will Have A Negative Impact on Beneficiaries

CMS notes that excepted off-campus PBDs would have an affirmative duty to identify the clinical families from which it furnished items and services during the baseline period. **The AAMC believes that this requirement will impose undue administrative burden for excepted off-campus PBDs and is contrary to CMS's ongoing efforts to reduce burden.** For example, the modifier reflecting that an item or service was furnished in a nonexcepted off-campus PBD was implemented after the baseline period upon which the clinical families of services is based. We ask that CMS provide clarification on this and other issues noted below.

CMS should provide clarification on how it will treat items or services that were originally associated with one clinical family but may have been assigned to a different clinical family during or after the baseline period ended. In furtherance of this clarification, CMS should confirm how the clinical families will be defined by the APCs – will the families be defined by the APCs as they are currently mapped, or will they be mapped from the 2014/2015 period. Regardless of how the clinical families are defined, these issues stand to create significant burden for providers tasked with determining which items and services they can furnish under the OPPS rate. As it currently stands, the proposal does not provide enough guidance for providers to determine which clinical families they billed from during the baseline. **CMS should not finalize the proposal until it addresses the operational concerns raised by the AAMC and other commenters.**

If CMS rejects commenters' concerns and implements this proposal, it must provide clarification on the following issues:

- How will CMS treat items and services that have switched APCs or clinical family of services? Will they be grandfathered or considered a new clinical family?
- What happens to an item or service that was in a new technology APC and then is switched to another APC? Is it considered grandfathered?

[40] AAMC CY 2017 OPPS Proposed Rule comment letter. September 6, 2016. https://www.aamc.org/download/469340/data/aamcsubmitsoppscy2017commentletter.pdf
[41] AAMC CY 2018 OPPS Proposed Rule comment letter. September 11, 2017. https://www.aamc.org/download/482774/data/aamccommentlettercy2018opps.pdf

- How will CMS treat a service paid under OPPS but not mapped to one of the clinical families listed?

Comment Solicitation on Clinical Family of Services

As a preliminary matter, AAMC does not believe that CMS has the legal authority to apply a cap of any kind in excepted off-campus HOPDs. As indicated above, the statute explicitly exempts off-campus HOPDs furnishing services paid under the OPPS on or before November 2, 2015 from section 603's provisions. Therefore, CMS has no statutory authority to pay excepted off-campus PBDs under any provisions other than the OPPS. Nevertheless, as CMS has requested comments on the below ideas, AAMC is responding to CMS' comment solicitation on the below ideas despite our belief that CMS does not have the legal authority to apply any kind of payment limit on services furnished in excepted off-campus PBDs under section 603.

Clinical families listed in Table 32 are too narrow. CMS solicits comments on whether the clinical families defined in Table 32 are adequate. **The AAMC does not believe that they are adequate.** It is the AAMC's understanding that the APCs listed in the right-hand column of Table 32 exhaustively define the clinical families listed in its left-hand column. The AAMC contends that limiting the clinical families to the APCs listed on the right column of the table is too restrictive. Using APCs to define the clinical families runs the risk of denying payment to providers who furnished services in those clinical families but were not paid under the limited APCs listed in the table. The AAMC recommends removing the APCs from the table, or instead using a more expansive definition. Ultimately, CMS should ensure that if an entity provided services in a clinical family listed on the left-hand column, they are not denied the higher rate because those services were not paid under one of the APCs in the table.

Baseline period should not be reduced. CMS also requests feedback on whether the baseline period of 12 months is unnecessarily long. **The AAMC urges CMS not to reduce the baseline period to less than 12 months.** Prior to November 1, 2015, off-campus provider-based departments may have furnished several items and services from clinical families that were not furnished throughout the entire year. As noted earlier, the baseline already limits HOPDs to the services they billed four years ago. A shorter baseline period subjects HOPDs to the possibility that they would not be paid the OPPS rate for even the services they did provide prior to November 1, 2015. This would go well beyond CMS' intent to limit HOPDs to the clinical families of services they provided originally, let alone prevent "expansion" of those services.

Caps on OPPS payments should not be considered. CMS asks whether it should adopt a proposal to cap the amount of OPPS payments made to excepted off-campus PBDs in a year based on payment for OPPS services furnished by the PBD during a 12-month baseline period, similar to MedPAC's recommendation.[42] Hospitals would be required to report service volume for each excepted off-campus PBD for the applicable baseline period to establish a baseline service volume cap on excepted services. Once a location reaches the annual cap for excepted services paid under the OPPS, additional services furnished by the off-campus PBD would no longer be considered covered OPD services and would instead be paid under the PFS relativity adjusted OPPS. A volume-based limitation on excepted services would further hamper HOPDs' abilities to meet the needs of their patient populations in addition to being

[42] MedPAC. CY 2018 OPPS Proposed Rule comment letter. September 8, 2018. http://www.medpac.gov/docs/default-source/comment-letters/09082017_opps_asc_2018_medpac_comment_sec.pdf?sfvrsn=0

operationally cumbersome to implement. As previously stated, patient populations tend to change, and a restriction such as this would unjustifiably reduce payment for items and services to a volume set during an arbitrary baseline period. **The AAMC opposes limits on the volume of excepted items and services paid under the OPPS and therefore urges CMS not to finalize such a proposal.**

Addition of Cardiac Catheterization Procedures to the ASC Covered Surgical Procedures

Decisions on Where to Perform a Cardiac Catheterization Should Continue to Rest with the Treating Physician and the Patient

CMS is proposing to update the list of ambulatory surgical center (ASC) covered surgical procedures by adding 12 cardiac catheterization procedures to the list for CY 2019. CMS determined that these 12 procedures, which are separately payable under the OPPS, would not be expected to pose a significant risk to beneficiary patient safety when performed in the ASC, and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. CMS goes on to say that the exclusion of certain cardiac procedures from the list of ASC-covered surgical procedures should not be on the basis of the involvement of major blood vessels when other similar procedures involving major blood vessels have a history of safe performance in ASCs.

The AAMC agrees that there may be instances in which physicians deem that a cardiac catheterization can be safely performed at an ASC on certain Medicare beneficiaries. However, cardiac catheterizations performed in an ASC may pose a danger to older and medically-complex Medicare beneficiaries. Often this procedure may be performed in combination with other evaluations for complex symptoms and care. The decision as to whether to perform a cardiac catheterization in a hospital-based cardiac catheterization lab or at an ASC should rest with the physician in consultation with the patient and be based solely on the patient's clinical circumstances. In the case a medical reviewer questions the site of service, AAMC believes deference should be provided to the physician to make a judgement as to the most appropriate site of service.

Comment Solicitation on Proposals to Address "Unnecessary Increases" in Utilization of Services in Outpatient Departments

Include Severity of Illness and Sociodemographic Status (SDS) of Medicare Beneficiaries When Evaluating Utilization of Outpatient Services

CMS seeks comment on ways to control so-called "unnecessary" increases in the volume of HOPD services if the service could be performed in a lower cost setting, including the inclusion of severity of illness and patient demographics and the use of prior authorization and utilization management. Our responses follow below.

Severity of illness and patient demographics. **The AAMC supports inclusion of patient severity of illness and SDS factors when evaluating utilization of outpatient services.** The nation's teaching hospitals disproportionately treat disadvantaged and vulnerable patient populations in both the inpatient and outpatient settings. Medicare beneficiaries tend to have a higher-level of disease burden with five or

more chronic conditions and half have incomes less than $26,000.[43] Low-SDS patients tend to be sicker and may not have access to preventive care or to the social and other supports services that are necessary for maintaining good health. HOPDs are frequently the sole source of care for low-income and otherwise underserved populations, including Medicare beneficiaries, treating those who otherwise face barriers to being seen in physician offices. Finally, where appropriate, patients' SDS should be included in hospital and physician quality measures and programs to ensure that institutions and providers who treat the nation's sickest and most vulnerable patients are not inappropriately penalized by quality performance programs.

Prior authorization and utilization management. **The AAMC does not support the use of prior authorization, utilization management or other mechanisms that require pre-approval of needed medical services.** Medicare already pays only for those services that are medically necessary. Part of the Patients Over Paperwork effort should be reliance on physician judgment about what is best for a patient. CMS should not implement any of the suggested techniques, each of which will increase provider burden, likely result in delays in care, and can cause emotional and financial stress on patients. Prior authorization and utilization management techniques are used to limit use of services largely based on cost with little regard for a providers' judgement of the medical treatment required by their patients. Prior authorization requirements can slow access to needed medical care which may negatively impact patients. Furthermore, utilization management techniques are often retrospective, resulting in denial of treatments already received.

Finally, we question how CMS would operationalize prior authorization and utilization management techniques in FFS Medicare. Below are a few questions that CMS must consider before moving forward with proposals that involve pre-approval requirements in FFS Medicare.

- How does CMS plan to operationalize prior authorization or utilization management requirements for the 40 million beneficiaries enrolled in fee-for-service Medicare? In other words, who would providers contact to obtain prior approval?
- How will CMS identify items and services that would require prior approval? How often would the list of these items and services be updated? Would volume alone be the deciding factor or would cost also be considered?
- How much time would be allowed for a response? What would be the appeals process for a denied approval of an item or service? Would there be the ability to have an expedited appeal?
- What would be the consequences to the beneficiary and provider if an item or service was retroactively denied?

Chimeric Antigen Receptor T-Cell (CAR T) Therapy

CAR T therapy is a new cell-based gene therapy in which a patient's own T-cells are genetically engineered in a laboratory and administered to the patient by infusion to assist in the patient's treatment to attack certain cancerous cells. As a new technology involving multiple steps across potentially different providers, it is important that appropriate clinical codes be available to report, identify and correctly reimburse the different component services involved in providing CAR T therapy.

[43] Kaiser Family Foundation. An Overview of Medicare. Published November 22, 2017. https://www.kff.org/medicare/issue-brief/an-overview-of-medicare/t

Recently, the American Medical Association approved four CAR T-related category III CPT codes, effective Jan. 1, 2019. These codes capture the harvesting of blood-derived T lymphocytes, preparation of the cells (e.g., cryopreservation, storage), receipt and preparation of CAR T cells for administration, and administration. In addition, the National Uniform Billing Committee (NUBC) approved a new revenue code and value code for reporting cell/gene therapy services, including CAR-T. The new codes, which take effect April 2019, would capture services associated with the acquisition of the cells, storage and infusion/insertion of the manipulated biologic (modified cells). They also would provide CMS and other health plans with an opportunity to examine the associated costs directly related to these therapies.

Given the newness of the CPT, revenue and value codes, there is currently a potential overlap with existing Q codes if they are not revised to exclude the clinical services covered by the new codes. To our knowledge, HCPCS Q or J codes have not been revised. **We urge CMS to coordinate across relevant CMS departments and decision-makers to ensure coding, billing, cost reporting and payment decisions for CAR T therapy are aligned and consistent. Instructions should then be provided to guide the correct reporting of the corresponding component services involved in providing CAR T therapy. Such guidance also should include the proper reporting of dosage for pediatric verses adult indications.**

Request for Information - Public Reporting of Standard Charges

CMS seeks comments on ways to provide patients with consumer-friendly information about hospital and physician charges and the potential cost-sharing obligations patients can expect depending on the services they receive. In the Inpatient Prospective Payment System (IPPS) final rule, CMS finalized its proposal that hospitals are required to make available via the web their standard charges in a machine-readable format beginning January 1, 2019. In this proposed rule, CMS re-states its concern about the lack of adequate price transparency for patients and is considering ways to "improve the accessibility and usability of current charge information." (p. 37212). CMS solicits comments on similar proposals included in the FY 2019 IPPS.

The AAMC supports price transparency but believes that a more comprehensive approach needs to be taken to provide patients and their families with meaningful, actionable price transparency information. We do not think that posting hospitals' standard charges will provide patients with the information that is of most importance or usefulness to them – their financial obligation based on their insurance coverage, including their plan-specific cost-sharing requirements such as whether they have met their deductible and their applicable co-pay amounts, if any. While many hospitals do assist patients to better understand their financial responsibility related to services received, this patient-specific information may not be easily obtained by hospitals.

Ultimately, the cost that is likely to be of most importance to patients is their out-of-pocket expenditures. According to a Kaiser Family Foundation survey, 28 percent of individuals are enrolled in a high-deductible plan – an increase of 9 percentage points since 2012.[44] The Federal Reserve found that 40 percent of Americans would not be able to cover a $400 expense, or would cover it by selling something or borrowing money.[45] The IRS defines a high deductible health plan as any plan with a deductible of at

[44] Kaiser Family Foundation. Employer Health Benefits: 2017 Summary of Findings. Available at: http://files.kff.org/attachment/Summary-of-Findings-Employer-Health-Benefits-2017.
[45] Report on the Economic Well-Being of U.S. Households in 2017, May 2018, https://www.federalreserve.gov/publications/files/2017-report-economic-well-being-us-households-201805.pdf.

least $1,350 for an individual or $2,700 for a family.[46] This suggests that the need for consumers to have information tailored to their specific insurance situation is the way to provide meaningful, actionable information. At a minimum it is imperative that CMS engage insurers, who are likely to be able to provide more details to the out-of-pocket estimate, to move forward with its price transparency efforts. **Therefore, we urge CMS to work with hospitals, insurers, consumers, and other stakeholders to identify information that patients need to better understand the costs they will incur for hospital care.**

Hospital Outpatient Quality Reporting Program

AAMC Supports the Removal of the 10 Quality Measures from the Hospital Outpatient Quality Reporting Program

CMS proposed to remove one measure from the Hospital OQR Program beginning in CY 2020 and nine measures in CY 2021:

- OP-27: Influenza Vaccination Coverage Amount Healthcare Personnel
- OP-5: Median Time to ECG
- OP-9: Mammography Follow-up Rates
- OP-11: Thorax CT – Use of Contrast Material
- OP-12: The Ability of Providers with HIT to Receive Lab Data Electronically Directly into Their Qualified CEHRT as Discrete Searchable Data
- OP-14: Simultaneous Use of Brain CT and Sinus CT
- OP-17: Tracking Clinical Results Between Visits
- OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval in Average Risk Patients
- OP-30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with History of Adenomatous Polyps – Avoidance of Inappropriate Use
- OP-31: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery

The AAMC recognizes the importance of quality measurement to ensure that hospitals and physicians are providing high quality care. As CMS recognizes, reporting and transmitting quality measures requires intensive staff training, labor, and resources – and ultimately limits the time clinicians spend with their patients. We appreciate CMS's efforts to regularly reexamine these measures and **support removing these measures from reporting.**

Consider the Removal of Additional Measures from the Outpatient Hospital Quality Program as Part of its Meaningful Measures Work

The AAMC supports the agency's Meaningful Measures framework and the proposals to remove measures across the hospital quality programs to align programs and to better address quality priorities. We urge CMS to continue to review its portfolio to consider the removal of additional measures from its programs.

The Association believes that measures for CMS consideration for future removal should include OP-8: MRI Lumbar Spine for Low Back Pain and OP-18: Median Time from ED Arrival to ED Departure for

[46] https://www.healthcare.gov/glossary/high-deductible-health-plan.

Discharged ED Patients based upon feedback from the National Quality Forum (NQF) during recent maintenance review of endorsement for each measure. In the case of OP-8, endorsement was removed in May 2017 because the measure did not satisfy the validity sub criterion for scientific acceptability. This was primarily due to concerns with the continued inclusion of "elderly" patients in measurement, even though it is a condition in the Appropriate Use guideline. In addition, the use of administrative claims data to identify use of antecedent conservative therapies (of which, common therapies like NSAIDs, massage therapy, acupuncture, etc.) was inadequate.[47]

The Cost and Efficiency Standing Committee recently did not recommend OP-18 for continued endorsement in its Spring 2018 review cycle, citing a lack of evidence that the measure influences mortality or other patient outcomes.[48] This evaluation of the measure begs the question whether it should be removed from the OQR under removal factor 2 – that the performance or improvement on the measure does not result in better patient outcomes. The Committee's recommendation to remove endorsement will be reviewed by the Consensus Standard Approval Committee in October 2018.

Hospital Inpatient Quality Reporting Program

Retain the HCAHPS "Communications About Pain" Survey Questions but Delay Public Reporting to Address Stakeholder Concerns and Better Test for Potential Unintended Consequences

The AAMC believes that pain management experience measures are an important aspect of patient care. The Association recognizes the steps CMS has taken to develop alternative pain questions for the HCAHPS survey to balance the importance of measurement with the potential unintended consequences related to the opioid prescribing practices and the broader opioid addiction crisis. The AAMC has given tentative support in previous comment letters for the revised "Communication About Pain" questions, while also expressing concern that the revised questions have not been endorsed by the National Quality Forum (pending endorsement maintenance by the Patient Experience and Function Standing Committee in its Fall 2018 review cycle). We appreciate the Agency's agreement with stakeholder feedback that the "Communication About Pain" questions could contribute to the perception of a link to opioid prescribing practices, culminating in the proposal to remove the questions out of an abundance of caution.

The AAMC continues to believe that the consequences of HCAHPS' pain management questions are highly significant for patients and providers, and that the Agency should move cautiously. Until the HCAHPS questions sufficiently address concerns from stakeholders and are properly tested to mitigate against unintended consequences, the AAMC believes that the data should not be publicly reported on the *Hospital Compare* website or included in pay-for-performance quality reporting programs.

Request for Information – Promoting Interoperability

Do Not Create Additional Conditions of Participation (CoPs) as Part of the Agency's Efforts Towards Promoting Interoperability and Electronic Healthcare Information Exchange

[47] "Musculoskeletal Off-Cycle Measure Review 2017: Technical Report," National Quality Forum (July 2017) available at http://www.qualityforum.org/Publications/2017/07/Musculoskeletal_Off-Cycle_Measure_Review_2017.aspx
[48] "Cost and Efficiency, Spring 2018: CDP Report," National Quality Forum (August 2018) available at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=88057

While the agency's goals of interoperability are increasingly important to transforming health care in the digital age, the **AAMC strongly opposes any use of the conditions of participation (CoPs) for interoperability and electronic exchange of health information**. CoPs are not the right vehicle to encourage interoperability given the importance of CoPs and the significant consequences if not met, particularly since interoperability is still in progress. CMS has other policy levers to promote broader interoperability and use of electronic healthcare information exchanges, most notably the Promoting Interoperability Programs. Furthermore, requiring providers to meet interoperability requirements to comply with new CoPs, in addition to the interoperability reporting requirements under the Promoting Interoperability Programs and the Inpatient Quality Reporting Program would be unnecessarily burdensome and duplicative.

The Office of the National Coordinator (ONC) explained that hospitals typically do not have the leverage to solve the obstacles of interoperability in its 2015 report to Congress on issues of information blocking:

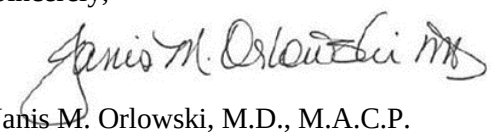
> Having made these investments, providers may be financially and otherwise unable to switch to superior technologies that offer greater interoperability, health information exchange capabilities, and other features. These switching costs make it easier for developers to engage in information blocking without losing existing customers.[49]

Revising CoPs is not likely to have an impact on the significant issue of information blocking. The AAMC suggests that CMS should instead work with stakeholders, including providers and electronic health record vendors, to identify other possible solutions.

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 Mary Mullaney at 202.909.2084 or mmullaney@aamc.org or Andrew Amari at 202.828.0554 or aamari@aamc.org for questions on the payment policy proposals and Phoebe Ramsey at 202.448.6636 or pramsey@aamc.org for questions on the quality proposals.

Sincerely,



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Phoebe Ramsey, AAMC
Andrew Amari, AAMC

[49] "Report on Health Information Blocking," Office of the National Coordinator (April 2015), p. 23, https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf.