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Via e-mail: Seema.Verma@cms.hhs.gov

March 14, 2017
Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-8013

Dear Ms. Verma:

I congratulate you on your confirmation as CMS Administrator. As the Centers for Medicare and Medicaid Services (CMS or the Agency) transitions to new leadership, I am writing to introduce you to the Association of American Medical Colleges (AAMC) and the priorities that we have and which we hope will be shared by CMS. The AAMC is a not-for-profit association representing all 145 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, and 93 academic and professional societies. Through these institutions and organizations, the AAMC represents 160,000 faculty members, 83,000 medical students, and 115,000 resident physicians. Together, these institutions and individuals are the American academic medicine community.

Academic medicine is the combination of medical schools, teaching hospitals, and their faculty members, staff, students, and resident physicians. Medical schools and teaching hospitals sustain an environment where basic, clinical, and health services research can flourish alongside clinical care and training. These organizations and individuals share a commitment to providing education and graduate training to future physicians, biomedical scientists, and other health care professionals; conducting biomedical and clinical research; and advancing medical knowledge, therapies, and technologies to prevent disease, alleviate suffering, and improve quality of life.

Academic Medicine Plays a Pivotal Role in U.S. Health Care

In settings of constant inquiry, medical schools and teaching hospitals integrate the full spectrum of clinical care, training, and research to provide cutting edge health care:

- *Medical Educators:* Through continual renewal and innovation at both the national and institutional levels, America's system of medical education prepares physicians and scientists to meet the nation's evolving health needs.
- *Medical Science Centers:* Our medical schools, teaching hospitals, and faculty pioneer cures and bring them to patients. Over 50 percent of all external research funded by the National Institutes of Health (NIH) is performed by scientists at medical schools and teaching hospitals.
- *Medical Safety Net:* Major teaching hospitals make up only 5 percent of all hospitals, yet they provide 20 percent of all Medicare hospitalizations, 21 percent of all hospital care, 25 percent of all Medicaid inpatient days, and 35 percent of all charity care.

- *Medical Standby Capacity*: Teaching hospitals deliver primary and preventive care we all need every day, but they also provide trauma care, burn units, and intensive care we hope never to need.
- *Community Health and Health Equity*: Academic medical centers partner with local residents through community-based programs to address social determinants of health, such as lack of access to healthful food, safe housing, and transportation.

THE MEDICARE PROGRAM: QUALITY AND OTHER PROVISIONS

The AAMC strongly supports the movement from volume to value. Our members are leaders in the area of providing quality health care, and in creating and implementing innovative care delivery models. However, the Medicare quality programs must take into account the different patient populations that providers treat, incorporating adjustments for the sociodemographic status of patients when appropriate. The metrics used for these quality programs also should not be burdensome to providers; should reflect current standards of care yet be flexible enough to incorporate changes as those standards are revised; be endorsed by the National Quality Forum; and be tested before being adopted. These ideas are discussed in more detail below.

The FY 2018 Proposed Inpatient Prospective Payment (IPPS) Regulation Must Contain Provisions that Will Implement the Risk Adjustment Methodology in the Hospital Readmissions Reduction Program Mandated by the 21st Century Cures Act

The Affordable Care Act (ACA) created the Hospital Readmissions Reduction Program (HRRP) which is intended to reduce payment to IPPS hospitals with excess readmissions, starting with discharges beginning on October 1, 2012. As initially designed, the program lumps all hospitals together, failing to take into account the fact that the patient populations that a hospital treats—for example, patients who are medically complex, and of low sociodemographic status (SDS)—is a key factor in determining whether a readmission is likely.

While only a first step, the 21st Century Cures legislation, signed into law in December 2016, started to correct this situation. The legislation says that for the HRRP the Secretary shall “assign hospitals to groups . . . and apply the applicable provisions of this subsection using a methodology that allows for separate comparison of hospitals within each such group. . . .”¹ The legislation further specifies that the groups are to be “based on their overall proportion, of the inpatients who are entitled to, or enrolled for, benefits under Part A, and who are full-benefit dual eligibles.” The inclusion of dual-eligibles will be used to adjust payment penalties starting FY 2019. Even before CMS begins the rulemaking process, the AAMC encourages the Agency to solicit patient and provider input in developing this methodology. The Association seeks to work with CMS to provide additional guidance regarding approaches to the methodology in the weeks ahead. **To quickly reduce that disadvantage to hospitals that treat a large number of dual eligibles, and to ensure that the FY 2019 start date is met, it is essential that CMS propose the way in which the Agency will implement this provision in the FY 2018 Inpatient Prospective Payment regulation.**

¹ H.R.34 - 21st Century Cures Act: [P.L. 114-255, section 15002](#)

In addition, the AAMC requests that CMS include an addendum in the FY 2018 HRRP hospital specific reports (HSP), which are distributed in the summer of CY 2017, displaying each institution's expected FY 2018 payment adjustment factor utilizing the methodology outlined in the IPPS proposed rule. The AAMC recognizes that the proposed methodology may change following release of the final rule. Nonetheless, it would be helpful for hospitals to have this information as early as possible in order to prepare for future payment adjustments.

CMS Must Reduce Measure Burden for Hospitals and Remove Flawed Measures

By FY 2019, hospitals will be responsible for monitoring and responding to over 50 inpatient measures as a requirement of the Medicare hospital performance and reporting programs. Reporting, monitoring, and transmitting these quality measures requires intensive staff training, labor, and resources. The AAMC recognizes the importance of quality measurement as one way to ensure that hospitals and physicians are providing high quality care, but we are concerned that the increase in quality measurement is a burden for providers.

These same concerns have been cited by members of the hospital Measure Applications Partnership (MAP) Workgroup. In their most recent report, the Workgroup noted that "providers may have limited resources for measurement and that the addition of new measures to the programs should be balanced with the removal of measures that may no longer be needed. The group recommended that measures that are topped out, have unintended consequences, have lost NQF endorsement, or are no longer aligned with the current evidence or the program's goals be removed."² The AAMC agrees with this assessment and urges CMS to take steps to reduce overall measure burden across all programs by creating a streamlined measure set that provides the most value for patients and providers.

As part of this measure overhaul, the AAMC requests that the Agency review flawed measures in the quality programs, in particular the PSI-90 patient safety composite. This measure is currently included in the Hospital Acquired Conditions Reduction Program (HACRP) and in the hospital Value Based Purchasing (VBP) Program. CMS will require a modified version of the measure in the HACRP and Inpatient Quality Reporting (IQR) Program starting FY 2018 payment determination. The AAMC is concerned that both the current and modified PSI-90 composite measure remain susceptible to surveillance bias; may not be preventable through evidence based practices; lack appropriate and necessary exclusions; and, are based on administrative claims data so cannot capture the full scope of patient-level risk factors³⁴. In addition, recent research by the AAMC and the American Hospital Association notes that individual components in the PSI-90 composite unfairly penalize large and small hospitals

² "Hospital MAP Workgroup." Report retrieved from http://www.qualityforum.org/MAP_Hospital_Workgroup.aspx

³ Rajaram, Ravi et al. "Concerns About Using the Patient Safety Indicator-90 Composite in Pay-for-Performance Programs." *JAMA*. Vol 313, No. 9. March 3, 2015. Retrieved from: <http://jama.jamanetwork.com/article.aspx?articleid=2109967>

⁴ "Medicare's Hospital-Acquired Condition Reduction Program. *Health Affairs: Health Policy Briefs*. August 6, 2015. Retrieved from http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=142

depending on the probabilities of the measured complication.⁵ Until these flaws are adequately addressed, the AAMC strongly urges CMS to remove the PSI-90 composite from the Medicare performance and penalty programs.

Modify the Methodology for the Hospital Compare Overall Star Ratings

The overall hospital star ratings were first included on the Hospital Compare website in July 2016, and will be updated bi-annually in 2017. The problem with the ratings as currently determined is that they paint a confusing and conflicting picture of the quality of U.S. hospital care that ignores important differences in the patient populations and the complexity of conditions that different types of hospitals treat. Changes must be made to this methodology to help ensure a more apples-to-apples comparison among hospitals.

The AAMC and our member institutions strongly support providing patients with transparent and meaningful information about hospitals. However, the ratings system fails to account for the fact that teaching hospitals perform a wide array of complicated and common procedures, pioneer new treatments, and care for broader sociodemographic patient populations that may not have access to regular care, or other social supports that are essential to good health. Under the star ratings methodology, teaching hospitals are compared directly to hospitals with more homogenous, less complex, patient populations. In fact, teaching hospitals are compared to other hospitals that do not even perform the minimum number of procedures that are required to be counted for certain measures.

Currently, all IPPS hospitals that report a minimum of three quality measures in at least three measure domains are assessed using the same criteria, as long as one of the domains is for outcomes measures (readmissions, mortality, or patient safety). A far more equitable approach would be for CMS to stratify hospitals according to the numbers of outcome domains reported, the overall number of measures reported, or through another approach that will fairly and accurately compare similar institutions. Any of these options would help ensure that information about hospitals provided to patients is meaningful and enables them to compare hospitals that offer similar services and treat similar acuity of patients.

CMS also should account for socioeconomic status for the readmissions measures and certain other outcomes measures in the star ratings. An interim approach that could be immediately implemented, is a performance adjustment according to a hospital's proportion of dual eligible patients. This methodology will also be used by the Agency in determining penalties for the HRRP under the 21st Century Cures legislation. Experts have noted that patients with low SES require additional care and more resources to achieve the same outcomes as more advantaged patients. Adjusting for these factors will help to improve the fairness and accurateness of the

⁵ Lane Koenig, et al. "Complication Rates, Hospital Size, and Bias in the CMS Hospital-Acquired Condition Reduction Program." *American Journal of Medical Quality*. December 19, 2016. Retrieved from <http://journals.sagepub.com/doi/full/10.1177/1062860616681840>

hospital star ratings. The AAMC has discussed the flaws inherent with the overall hospital star ratings with CMS staff, and would welcome your leadership in addressing them.

Hospital Outpatient Departments Must Be Assured Adequate Payment

The Bipartisan Budget Act of 2015 (Pub.L. 114-74) included a new hospital payment policy (Section 603) that reduced payment rates at newly established off-campus HOPDs to equal those of physician offices or ambulatory surgical centers (ASC). As of November 2, 2015, any site that enters into a Medicare provider agreement but is not located on the hospital main campus and is located more than 250 yards away from the main campus must be paid according to the ASC prospective payment system or the Medicare Physician Fee Schedule (PFS). This so-called “site neutral” policy disregards the critical and real differences between HOPDs and physician offices, including the increased costs of providing care in an outpatient setting, the complex case mix of patients seen there, and their essential role in medical education. While existing HOPDs were grandfathered and not subject to the new payment policy, sites that were under development or “mid-build” were not addressed. The AAMC strongly supports policies that would grandfathered HOPDs that relocate, renovate, or add services.

The AAMC believes that CMS’s interpretation of section 603 goes beyond the changes that were contemplated when enacted by Congress. These changes are likely to lead to a reduction of services that affect vulnerable patient populations—especially those with complex medical problems—that receive care there, and may limit the ability of hospitals to train the next generation of health professionals in these outpatient settings. The Association urges CMS to consider the impact of changes to payments, especially limitations on clinical service line expansion and volume of services, and penalties imposed on hospital outpatient departments that relocate in order to better meet the needs of its patients. To that end, we ask that CMS delay implementation of changes to HOPD payments and limitations on relocation and that proposals that would limit expansion of services not be re-proposed.

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Skilled Nursing Facility (SNF) 3-Day Hospital Stay and Pay for Telehealth Services in More Locations

To better coordinate and improve care for patients, CMS should work with Congress to eliminate or modify the requirement that a patient spends three days as a hospital inpatient before being eligible for SNF services. While we recognize that complete removal of the requirement would require legislative action, at a minimum we recommend CMS use its administrative flexibility to create additional waivers of the SNF 3 day stay for alternative payment models. For a provider trying to reduce costs and improve quality, this poses an impediment. There are patients for whom the most appropriate care is to be admitted to a SNF after a short hospitalization, or after an observation stay. Yet, the most appropriate care would mean that the Medicare beneficiary would be entirely responsible for the SNF stay, an untenable situation for many beneficiaries.

The general Medicare rules related to payment for telehealth services are that the services must be provided to a patient in a rural area and at an originating site defined by CMS. The home is not included as the originating site. Patients in urban and other areas who do not have convenient access to a provider also could benefit from telehealth. Certain APMs, such as Next Generation

ACOs, have telehealth waivers available, but such waivers should be provided to other APMs. As Medicare payments move toward having a strong quality component, there is little risk that these services will be used for other than the best quality, most cost efficient care. CMS should eliminate policies that make impede good care and have the potential for imposing financial penalties on providers and patients alike.

Further Major Changes to IPPS, OPSS, and MPFS Should Not Be Implemented _

In recent years hospitals and physicians have experienced a wide array of regulatory changes that impact delivery system reform, reimbursement and reporting requirements. Under the new payment system finalized by CMS in the OPSS Interim Final Rule, CMS does not specify how to apply OPSS payment policy when items and services are bundle into a comprehensive APC are provided in locations that will be reimbursed differently under the new payment system. By way of example, how will CMS reimburse for services if the primary services are provided by a non-excepted, off-campus PBD and a portion of the packaged services are provided at an excepted HOPD. The patient has an outpatient clinic visit for assessment and management (CPT G0463) at a non-excepted, off-campus PBD, and then the patient has a laboratory test the next day at an excepted HOPD. Under the current OPSS policy, the laboratory service will be packaged with the clinical visit into APC 5012.

The AAMC is very concerned that the rapid pace of these changes exceeds both hospitals' adaptive capacity and the Agency's ability to accurately model and sufficiently explain the impact of either past or current proposals. In most cases, these changes interact with each other. Also of concern is that the rapidity with which new policies are being adopted leaves inadequate time to identify and address implementation issues and that data collection requirements impose a significant administrative burden. The Association urges CMS to review ongoing regulatory activity and to allow for sufficient time to fully understand the impact of such changes including analyzing data and seeing stakeholder feedback to measure the impact on hospitals and physicians.

SPECIAL PAYMENTS TO TEACHING HOSPITALS MUST CONTINUE AT LEAST AT THEIR CURRENT LEVELS

Fifty years ago, Medicare made a commitment not only to provide health care for the elderly but also to help train a sufficient number of physicians to meet the needs of the country. Medicare must continue to provide sufficient and stable funding for direct graduate medical education (DGME) and the indirect medical education (IME) adjustment. This funding supports teaching hospitals as they train new physicians to meet the increasing requirements of an aging population and helps pay for the additional patient care costs incurred by teaching hospitals for the services they provide and the patient populations they treat. In addition, while under the ACA the number of uninsured in this country decreased, safety net hospitals continue to need Medicare Disproportionate Share Hospital (DSH) funding to provide uncompensated care for the large numbers of patients who are still uninsured and underinsured. Finally, teaching hospital outpatient departments (HOPDs) are critical access points for many Medicare patients. These sites cannot sustain further payment cuts. The AAMC recognizes that these payments are authorized by legislation and asks that CMS continue to support them.

Medicare Must Continue to Provide Sufficient and Stable Funding for DGME Payments and the IME Adjustment

Major teaching hospitals and physician faculty practices serve a disproportionately large volume of Medicare beneficiaries. Teaching hospitals, many of which are safety net providers, care for vulnerable populations who often cannot seek treatment elsewhere. Simultaneously, teaching hospitals are tasked with training future physicians, as well as other health care providers, to meet the nation's health care needs. In 1997, as part of the Balanced Budget Act, a hospital-specific limit ("cap") was placed on the number of residents that a teaching hospital can count for purposes of receiving DGME and IME payments. However, because of their educational mission and the looming physician shortage, about half of the teaching hospitals are training residents in excess of their caps, with no additional IME or DGME payments. With shrinking clinical margins, if these payments are not maintained it will be a challenge for teaching hospitals to continue to support their teaching and clinical care missions.

The distinctive capabilities and responsibilities of teaching hospitals do not come without a price. Teaching hospitals incur significant costs associated with training new physicians and other health care professionals. They also have costs associated with using newly developed devices and technologies, maintaining standby services, treating patients with complex conditions, providing unfunded and underfunded health services, being sites for clinical research, and serving as safety net providers. These activities impose substantial financial burdens on teaching hospitals. Congress established several payment adjustments to help teaching hospitals with their operating costs. Teaching hospitals continue to rely on these payments to train new physicians and provide high-quality care to low-income patients. These unique services benefit not only Medicare beneficiaries but all patients in the community.

While the AAMC recognizes that the responsibility of teaching hospitals to train physicians to meet the nation's needs is authorized by legislation, we believe that CMS should continue to support these payments that are essential for the hospitals that are a major part of the nation's safety net. Cuts to funding would directly threaten teaching hospitals' ability to provide quality care to Medicare beneficiaries and other patients. With the growth of an aging population, communities around the country are already experiencing doctor shortages. By the year 2025, the United States will face a shortage of between 61,700 to 94,700 primary care and specialty physicians. Teaching hospitals need stable and predictable funding if they are to continue to train the nation's future physicians and carry out core missions to provide quality patient care, conduct research, and teach the next generation of this nation's physicians.

MEDICARE ACCESS AND CHIP REAUTHORIZATION ACT (MACRA)

Reduce Regulatory Burden to Encourage Maximum Participation and Success

The AAMC appreciates that CMS implemented the "Pick Your Pace" approach to allow more flexibility in the first year of the new physician payment system under MACRA. The AAMC is committed to working with CMS to ensure that MACRA promotes improvements in delivery of care and is not overly burdensome to clinicians and the organization for which they work. While CMS has taken steps to reduce burden and complexity, the AAMC recommends additional

modifications, including risk adjust outcome, population based measures and cost measures for clinical complexity and sociodemographic factors; address concerns with the cost category prior to implementation; and, continue to provide additional flexibility for 2018 as physicians transition to the new program.

To allow maximum participation under the alternative payment model (APM) payment track, CMS must use flexible requirements to determine which APM participants qualify. Additionally, CMS must continue to work with the Physician Technical Advisory Committee to enhance APM opportunities for specialists. Finally, the AAMC continues to urge CMS to establish systems that work effectively to provide timely, accurate, and actionable feedback reports to clinicians to help them understand and improve the quality and efficiency of care.

ALTERNATIVE PAYMENT MODELS

Continue to Develop and Test New Alternative Payment Models

The AAMC supports alternative payment model programs, such as accountable care organizations (ACOs), bundled payment initiatives, and other models that seek to promote high-quality, efficient care while retaining at their core the essential patient-physician relationship. Academic medical centers are leaders in delivery reform, with many participating in Centers for Medicare and Medicaid Innovation (CMMI) programs and commercial APMs. AAMC is also a facilitator-convener for the Bundled Payments for Care Improvement (BPCI) initiative for 30 hospitals and 19 health systems.

The Association believes that many of these programs have the potential to lower cost, promote care coordination and improve quality of care. Therefore, we urge the Administration to continue the work of the CMMI to build a portfolio of more APMs and to test and refine existing APMs. However, we recommend that the new Administration ensure that participation in these models is voluntary and make refinements as necessary to models to ensure sustained participation.

FRAUD AND ABUSE REGULATIONS

Improving Self-Referral and Anti-Kickback Regulations and Anti-Kickback Regulations to Accommodate Delivery Reform

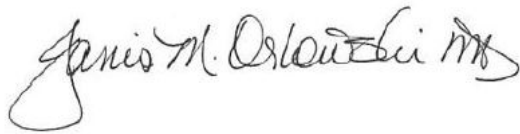
To achieve the goals of delivery system reform, there is a need for changes to federal laws and regulations affecting hospital-physician arrangements, including the Physician Self-Referral Law (also known as “Stark”), the Anti-kickback statute (AKS), and the Civil Monetary Penalties (CMP) Law. Since enactment of the self-referral law, there have been major changes in health care delivery and payment, including many initiatives to align payment with quality and to improve coordination of care. Provisions in these laws which were enacted to address issues in a fee-for-service system, present significant barriers to clinical and financial integration aimed at improving the quality of care, population health, and reducing costs.

CMS and the OIG should coordinate efforts so that a new safe harbor is created under the AKS and a new Stark self-referral exception also is created, putting in place safeguards that would

enable financial arrangements that involve risk sharing and gainsharing in alternative payment models when appropriate. These arrangements pose little risk of program or patient abuse and are intended to provide better quality care at reduced cost. Conditions set forth by OIG and CMS to obtain a waiver from the anti-kickback laws and self-referral laws for providers participating in the Bundled Payment for Care Improvement Model, the Shared Savings ACO program and the CJR model could be used as criteria for a waiver.

My staff and I are available to provide you with any additional information and would welcome the opportunity to meet with you to discuss the issues above. You can contact me at 202-862-6287 or jorlowski@aamc.org.

Sincerely yours,

A handwritten signature in black ink that reads "Janis M. Orlowski MD". The signature is written in a cursive style with a large initial "J" and a stylized "M" at the end.

Janis M. Orlowski, MD, MACP
Chief Health Care Officer
Association of American Medical Colleges