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Submitted electronically: CompetitionRFI@hhs.gov

Mr. John R. Graham
Acting Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services
200 Independence Ave, SW, Room 415F
Washington DC, 20201

Re: Request for Information: Promoting Healthcare Choice and Competition across the United States

Dear Mr. Graham:

The Association of American Medical Colleges (AAMC or Association) welcomes this opportunity to comment on the Department of Health and Human Services's Office of the Assistant Secretary for Planning and Evaluation's (ASPE's) *Request for Information: Promoting Healthcare Choice and Competition across the United States*.

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members comprise all 149 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their nearly 167,000 full-time faculty members, 88,000 medical students, and 124,000 resident physicians.

The AAMC appreciates the opportunity to respond to this Request for Information. Academic medical centers (AMCs), which include clinical faculty providing care to patients at teaching hospitals, are leaders in delivering coordinated care for clinically complex and vulnerable patients while also performing innovative research and training the next generation of clinicians. Within this unique environment, AMCs must comply with federal regulations and policies. While regulations have important roles, such as ensuring consistency and protecting individuals, they should be examined from time to time and modified if they are an impediment to delivery system reform and innovation and do not improve patient care. HHS has asked for comments on State and Federal laws, regulations and policy. Our comments will be limited to Federal requirements as HHS runs Federal programs, with Medicaid being a Federal-State partnership. We focus on ways the Department of Health and Human Services could reduce regulatory burden for our member hospitals and physicians and increase choice and access for patients

through improving reporting requirements under MACRA, optimizing telehealth, providing for exceptions or safe harbors for Stark and Anti-Kickback laws to facilitate coordinated care, and ensuring transparency of benefits and cost-sharing for plans offered on the Exchanges.

Medicare Access & CHIP Reauthorization Act of 2015 (MACRA)

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established a physician payment system that took effect with physician reporting beginning January 1, 2017 that impacts 2019 payments. This new payment program requires a significant learning curve for physicians and requires major operational changes for physician practices. The AAMC appreciates that CMS developed the Pick Your Pace program for 2017 and believes is it important for the Centers for Medicare and Medicaid Services (CMS) continues to transition slowly to the new framework for physician payment and to reduce clinician burden and complexity of the program.

Adequately Account for Clinical Complexity and Sociodemographic Factors in MIPS Measures

In the Merit-based Incentive Payment System (MIPS) program, CMS has implemented numerous measures for the four performance categories: quality, cost, performance improvement activities, and advancing care information. The AAMC is supportive of measures that are meaningful to providers and consumers, and lead to quality improvement. However, it is essential that CMS ensure that measures used in the program are valid and reliable, risk adjusted as appropriate, and do not lead to unintended consequences. We remain concerned that outcome measures, cost measures, and population based measures are not appropriately risk adjusted for clinical complexity and sociodemographic factors given that many of the physicians at academic medical centers care for a vulnerable population of patients who are sicker, poorer, and more complex than many patients treated elsewhere.

Reports from the National Academies of Science, Engineering and Medicine and Assistant Secretary for Planning and Evaluation (ASPE) have clearly acknowledged that sociodemographic status (SDS) variables (such as low income and education) may explain adverse outcomes and higher costs. Without accounting for these factors, the scores of physicians that treat vulnerable patients will be negatively and unfairly impacted and their performance will not be adequately represented to patients. Differences in patient severity, rates of patient compliance with treatment, SDS, patient engagement, patient preferences for treatment approaches, and sites of care, can all drive differences in average costs.

Appropriate risk adjustment is essential so that differences in patient characteristics that are beyond a health care provider's control do not have an unfair impact on a provider's resource use performance score. The AAMC believes that CMS should appropriately adjust for SDS by incorporating identified factors into the risk adjustment methodology. As more is learned further refinements can be made in the future.

Quickly Develop MIPS Eligible Identifier for Subgroups in Multi-specialty Practices

CMS has recognized multiple identifiers that allow MIPS eligible clinicians to be measured as an individual or through a group's performance. CMS acknowledges that groups, including multi-specialty groups, have requested an option that would allow a portion of a group to report as a separate subgroup on measures and activities that are more applicable to the subgroup and be assessed based on performance of that subgroup.

CMS should add a distinct subgroup identifier under MIPS, similar to the identifiers used for virtual groups or for Advanced Payment Models that would allow a subset of physicians within a large multi-specialty TIN to form their own subgroup that could be assessed under MIPS. This would allow for more accurate and meaningful measurement under the program. To allow participation in MIPS at a sub-group level, the AAMC recommends that CMS follow some of the policies set forth for virtual groups, which include:

- Establish a subgroup identifier
- Require the subgroup to make an election prior to the start of the applicable performance period under MIPS to be a subgroup.
- Request that a list of participants who would be part of the subgroup identifier be provided to CMS. A subgroup would submit each TIN and NPI associated with the subgroup, the name and contact information for a subgroup representative and a confirmation that each member of the subgroup is aware of their participation.
- Each MIPS eligible clinician who is part of the subgroup could be identified by a unique subgroup participant identifier which would be a combination of the subgroup identifier (established by CMS); 2) TIN and 3) NPI.
- Assess performance by a method that combines performance of all MIPS eligible clinicians in the subgroup across all four performance categories.

Depending on the practice, there are advantages and disadvantages to reporting under a subgroup MIPS identifier, an NPI, a TIN, or a combination. Under the MIPS program, the practices should be given the opportunity to assess the advantages and disadvantages and select whichever option works best. These groups should continue to make their own decision regarding the reporting option under MIPS. The AAMC would welcome the opportunity to work with CMS to ensure that this option is structured in a way that is not overly complex and would offer a more meaningful reporting option for certain physicians that are part of multispecialty groups.

Reduce the Number of Quality Measures and Align Across Payers

The number of quality measures that providers must report to CMS and other payers is increasing rapidly in the hospital and physician quality programs without a commensurate benefit to patient care. CMS should align the measures used by both the Medicare and Medicaid programs as well as commercial payers to reduce provider burden and prevent confusion. A key step would be the development of a national core measure set, with measures that apply across health settings and across payers, focusing on measures that are critical to driving the best

possible outcomes for patients. CMS should work with a variety of stakeholders, including the AAMC, to identify critical indicators of quality and safety that are meaningful to patients.

Physician Payment

Re-Vamp Evaluation and Management (E/M) Guidelines to Reduce Burden, Reflect Changes in Care Delivery, and Incorporate Current Standards of Care

The original E/M guidelines were developed at a time when medical records were maintained on paper and clinicians worked largely on their own. With the advent of electronic health records, and the movement to team-based care, the guidelines have become an impediment to good patient care and impose a huge administrative burden with little commensurate benefit. For AAMC-member institutions a unique consideration is that, because they are the places that teach the next generation of physicians and other health care professionals, it is essential their trainees learn to write notes that communicate the status of the patient, outline the planned medical care, and lead to optimal patient care. Our member institutions strive to ensure that trainees learn how to synthesize and summarize information and turn that into a plan of care. With this in mind, the AAMC has the following comments related to changes to the E/M guidelines:

- A patient's history is already recorded in the EHR. During a visit, relevant changes should be noted but the history should not be restated unless it provides new information, such as a different practitioner's view of the patient. A specific count of the history and physical exam components should not be used to determine the level of service.
- For surgical specialties and subspecialties a comprehensive exam is not always relevant. Even when a focused exam is needed, generally the medical decision-making will be moderate to high. For example; the examination of an acute abdomen may be the key component of the examination of a patient who is suffering an acute appendicitis while examining the eyes, skin or cranial nerves or this patient may be less important, or even unnecessary.
- The determination of the level of service should be dependent on medical-decision making. Required documentation should include such factors as:
    - Changes, additions, or significant clinical updates to the existing record
    - Nature and intensity and acuity of presenting problem/number of problems
    - Management of medications, including a review of medications, and comorbidities
    - Review of allergies, but only if there is a change
    - Diagnosis and treatment options
    - Coordination with other providers
    - If applicable, notes as to patient's expressed wishes for care options

Time alone should not be determinative of the level of service although time often is one indication of the complexity of the medical decision-making and bright-line determinations that X amount of time alone indicates a certain level of service should be avoided. CMS also should recognize that time spent face-to-face with the patient does not capture the medical decision-making which also concerns time spent reviewing labs, reviewing old medical records, calling or

e-mailing the patient, or coordinating with other providers, for example. Time should be combined with the factors listed in the bullet above to determine level of service

Changes Needed to Documentation Requirements When a Resident Is Involved In a Service

Current CMS documentation requirements for teaching physicians when a resident is involved in a service are burdensome to physicians and often impose an impediment to learners, including medical students. The AAMC currently is working with members to develop a recommended set of revisions. These will be shared with CMS soon.

Eliminate Inconsistent and Duplicative Audits

Medicare subjects providers to claims review by multiple entities including Medicare Administrative Contractors (MACs), Recovery Audit Contractors (RACs), Zone Program Integrity Contractors (ZPICs), and Comprehensive Error Rate Testing Contractors (CERT). These redundant and overlapping audits place an enormous burden on providers and have resulted in inappropriate denials. There is a need to streamline and eliminate these duplicative audits.

Revise Stark and Anti-Kickback Laws and Regulations

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 Laws (also known as "Stark"), the Anti-Kickback law, and the Civil Monetary Penalties (CMP) law. These laws were predicated on a fee-for-service reimbursement system. Since enactment of these laws, 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 present significant barriers to clinical and financial integration aimed at improving the quality of care, population health, and reducing costs. The AAMC encourages an approach that allows for maximum flexibility and supports innovation and changes that are needed to help move to a health care system that rewards providers for making the changes that are necessary to provide cost-efficient, patient-centered quality care. Physicians are barred from participating in innovative and cost-saving care models due to outdated regulations, including Anti-Kickback and complicated Stark prohibitions. While some safe harbors and exceptions exist in this area, they are limited in scope and may be difficult to obtain. CMS should create new exceptions or safe harbors for Stark and Anti-Kickback laws that facilitate coordinated care and promote cost reductions.

Revise Graduate Medical Education Rules to Ensure that *de minimus* Resident Rotations Do Not Establish a Hospital's Per Resident Amount

Direct graduate education (DGME) payments compensate hospitals for Medicare's "share" of the direct costs that are related to training residents. A hospital's payment for DGME is

determined by multiplying the hospital's per resident amount by the number of full time equivalent residents. The PRA is a one-time determination that is updated by an inflation factor. The FTE count for every hospital was capped starting in 1997 by the Balanced Budget Act (BBA). Medicare then pays its "share" of these costs which is the ratio of Medicare inpatients to total inpatients.

Under CMS rules, even if a *de minimus* number of residents rotate from an existing teaching hospital to a nonteaching hospital for training, the nonteaching hospital's PRA and cap are "triggered," This means that if in the future the nonteaching hospital wants to train more residents, it will be assigned a very low PRA, sometimes even $0, and a very low cap. Hospitals affected by this situation are reluctant to begin training residents because the reimbursement from Medicare will be far less than it should be merely because at some point in the past they accepted a few rotating residents. Given that we have a physician short, this has become a burden to the entire health care system.

CMS should revise its regulations to allow nonteaching hospitals that want to establish residency programs but in the past had a *de minimus* number of residents (less than 1 FTE) rotate to their institutions, thus inadvertently triggering a PRA and cap, to build a PRA and residency cap as if they never had resident rotators. In other words, these hospitals would be considered "virgin teaching hospitals" and would be more likely to start residency programs, knowing they will have the opportunity to establish a per resident amount and caps for DGME and IME.

Eliminate Skilled Nursing Facility Three-Day Rule

Currently, the statute requires that a patient spend three days as a hospital inpatient before they become eligible for Medicare coverage of inpatient skilled nursing facility (SNF) services. The requirement that patients spend three days as a hospital inpatient before becoming eligible for SNF services hinders coordination and care for patients. This requirement does not always align with patient needs or the most appropriate care for patients. For a provider trying to reduce costs and improve quality, it poses an impediment, as 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 substantial costs associated with a SNF stay, an untenable situation for many beneficiaries. CMS does offer a waiver to certain alternative payment models, which provides relief for providers participating in these models, and allows physicians to determine when it would be appropriate for a patient to transition to a skilled nursing facility.

Congress should enact legislation removing the requirement of a minimum 3 day inpatient hospitalization to be eligible for SNF coverage. The length of the inpatient stay should be determined by a physician's clinical judgment, based on the condition and needs of the patient. If Congress does not pass legislation, at a minimum we recommend CMS use its administrative flexibility to create additional waivers of the SNF 3 day stay for alternative payment models to better coordinate and improve care for patients.

Expand Services and Locations for Telehealth Visits

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. This significantly limits the number of patients who can access telehealth services, and limits physicians in their provision of these services.

Under these guidelines, patients must reside in a rural area and access telehealth services from a defined list of originating sites. The originating sites for telehealth services include hospitals, clinics, certain centers, and skilled nursing facilities. The home is not included as an originating site. Medicare coverage does not include remote patient monitoring in the home or other care settings. Many patients would benefit from telehealth services, but are unable to access a qualified originating site, disqualifying them from receiving telehealth services. Additionally, patients in urban and other non-rural areas who do not have convenient access to a provider also could benefit from telehealth, but are not generally permitted to access telehealth services. As currently defined, patients must present from an originating site located in a county outside of a Metropolitan Statistical Area (MSA) or a rural Health Professional Shortage Area (HPSA).

Congress should amend the statute to allow expansion of coverage of telehealth services by expanding the definition of originating sites to include other settings, such as the home and by eliminating the requirement that the services be provided in a rural area. This would allow more physicians to provide telehealth services to beneficiaries who have access challenges, even residing outside of a defined rural area, and would address additional access challenges by allowing the beneficiary to receive telehealth services in the home. If Congress does not amend the statute, CMS should uses its authority under U.S.C to expand the use of telehealth waivers to additional alternative payment models.

Plan Benefit and Payment Parameters

Ensure Transparency of Benefits and Cost-Sharing for Plans Offered on the Exchanges

The AAMC appreciates CMS's efforts to improve the availability of affordable health insurance coverage in the individual and small group markets. We agree that consumers must have access to high-quality, high-value health care providers, and addressing ways to make health insurance more affordable is one way to achieve this goal. However, the AAMC is concerned that the proposed changes in the individual market may limit consumer choice; segment the insurance market, leading to de-stabilization and premium increases for sicker individuals; restrict patient access to providers; and leave providers who treat these patients either underpaid or not paid at all.

The AAMC understands the need for state flexibility, and that the reduction of regulatory burden is a worthwhile goal. However, proposals to reduce or significantly eliminate Federal oversight to the states has the potential to jeopardize the ability of millions of Americans to obtain affordable, comprehensive health insurance coverage through the individual marketplace.

Furthermore, it is not patients alone who will feel the impact of these changes. Hospitals and physicians will find themselves treating more patients who are uninsured or underinsured. Patients may forego needed, routine care because of high cost-sharing responsibilities with the result that they will be sicker when they seek care, and thus will require an increased use of services and may wait until they need to come to an emergency room before seeing a provider. The AAMC supports engaging stakeholders to improve the marketplace by finding ways to bolster insurer participation, stabilize premiums, and ensure robust health insurance coverage options for all Americans.

Conclusion

The AAMC appreciates the opportunity to provide comment on this Request for Information. We are committed to reducing burden for all health care providers so that they may most effectively provide the necessary care to patients. If you have any questions concerning these comments, please feel free to contact Mary Mullaney, Director, Hospital Payment Policies at mmullaney@aamc.org or 202.909.2084 or Kate Ogden, Physician Payment and Quality Specialist at kogden@aamc.org or 202.540.5413.

Sincerely,

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Chief Health Care Officer

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