December 7, 2020

Regulatory and Executive Recommendations for the First 100 Days and Beyond

The AAMC (Association of American Medical Colleges) leads and serves the academic medicine community to improve the health of people everywhere. The association is uniquely poised to help develop a more equitable health care system and healthier future by drawing on the internal expertise of the AAMC as well as from our 155 U.S. medical schools, more than 400 teaching hospitals and health systems, including U.S. Department of Veterans Affairs medical centers, and more than 70 academic societies.

Together, our medical schools, teaching hospitals, faculty physicians, and scientists fulfill the four missions of providing health care, medical education, medical research, and community collaborations, with each area promoting and supporting the others.

Federal policies that affect health, including health care delivery, research, education, health equity, and more are imperative to support patients, communities, and the nation and helping academic medicine's complex, interrelated systems to thrive. We encourage the Biden Administration to reconsider the following Executive Orders, rules, regulations (both those that are already effective and those that are not), proclamations, and sub-regulatory guidance issued by the Trump Administration, in order to improve the health of people everywhere.

We acknowledge there are a variety of different actions the Biden Administration will need to take to address the problematic issues highlighted in this memo. In some cases, the incoming may be able to quickly reshape Trump Administration policy actions (for example, by issuing a regulatory freeze memo to prevent agencies from issuing rules underway at the end of the current administration, to delay final rules that have not already taken effect, and to begin planning new notice-and-comment rulemaking to unwind policies that the Trump Administration has finalized). For simplicity, we refer throughout this memo to recommendations for the Biden Administration to "rescind" certain Trump Administration actions; in many cases, the rescissions will require new rulemaking. We stand ready to support the Biden Administration in addressing these priorities.

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White House

Diversity Training

Executive Order 13850, September 22, 2020

This Executive Order, entitled Combating Race and Sex Stereotyping, classifies enumerated concepts as "divisive" forms of racial and sexual stereotyping and scapegoating, and prohibits them from being included in diversity training provided by Federal agencies, Federal contractors, or any entity using Federal grant funds. **The AAMC urges rescission of the Executive Order,** given that more – not less – education and training is needed to address the country's divisions.

Protecting the Expertise and Jobs of Federal Employees

Executive Order on Creating Schedule F in the Excepted Service, October 21, 2020

This October 2020 Executive Order created a new category of federal employees that would not have the protections typically afforded to career employees prior to termination by an administration. Under the Executive Order, each agency must identify the positions that are of a "confidential, policy-determining, policy-making, or policy-advocating character and that are not normally subject to change as a result of a Presidential transition" to be transferred to the new "Schedule F." Such positions would likely include the nation's most trusted and influential scientists, regulators, and policy experts. **The AAMC urges the immediate rescission of this Executive Order and abolishment of this Schedule F designation.**

Travel Ban

Proclamation 9645, September 24, 2017

The proclamation, which follows the March 6, 2017, Executive Order, indefinitely bars individuals from certain countries from entering the United States based on their nationality**. The AAMC urges the revocation of this proclamation** since a travel ban prevents entry of talented physicians and scientists based solely on their nationality, jeopardizes patient care and medical discoveries, and compromises the nation's health security.

340B Drug Pricing Program Requirements for Federally Qualified Health Centers (FQHC)

Executive Order 13937, July 29, 2020, Access to Affordable Life-Saving Medications, Health Resources and Services Administration (HRSA) September 28, 2020 Implementation of Executive Order 13937 Proposed Rule [85 Fed. Reg. 60748]

In response to the Executive Order, the proposed rule would require new FQHC grantees to provide insulin and injectable epinephrine to FQHC patients at no more than the 340B price, which would eliminate any savings and undermine the 340B program. FQHCs are already required to base patient cost sharing on a sliding scale based on income; therefore, this proposed rule is unnecessary. **The AAMC encourages the administration to rescind the Executive Order and HRSA not to finalize the proposed rule**.

Hospital Price Transparency – Hospital Compare

Executive Order 13951, October 1, 2020, An America-First Healthcare Plan

This Executive Order directs HHS to update the Medicare.gov Hospital Compare website to inform beneficiaries of hospital billing quality, including whether the hospital is in compliance with the Hospital Price Transparency final rule. In addition, Hospital Compare would include whether the hospital provides patients with an itemized receipt of hospital services upon discharge and how often the hospital pursues legal action against patients. Providing patients with itemized bills that do not reflect insurance payments will result in unnecessary anxiety for

patients and lead to greater confusion on patients' cost sharing liability. **The AAMC urges the administration to rescind the Executive Order.**

Executive Order on Reducing Regulation and Controlling Costs

Executive Orders 13771, Reducing Regulation and Controlling Regulatory Costs, January 30, 2017; 1377 Enforcing the Regulatory Agenda, February 24, 2017; 13563, Improving Regulation and Regulatory Review, January 18, 2011.

Executive Order 13777 directs federal agencies to eliminate at least two existing regulations for every new regulation issued and establishes a cap of zero dollars for each department or agency for the total incremental cost of all new regulations, including those repealed. Federal agencies have taken steps to implement Executive Order 13777 as required by the Executive Order on Enforcing the Regulatory Agenda, which directs agencies to establish Regulatory Reform Officers to oversee implementation. Executive Orders 13771 and 13777 have not been effective in reducing regulatory burden in a meaningful way, and **the AAMC supports their revocation, returning to the directives under Executive Order 13563, Improving Regulation and Regulatory Review**.

Creating a Presidential Bioethics Commission

Executive Order 13521, November 24, 2009, Establishing the Presidential Commission for the Study of Bioethical Issues

From 1996 through 2016, every President has established and looked to a bioethics commission to advise the White House on bioethical, legal, and social ethical issues related to health care, science, and technology. The most recent iteration of the commission, the Presidential Bioethics Commission for the Study of Bioethical Issues, was established in 2009 and issued reports on complex bioethical issues and developed recommendations for the research community. No such commission has been in place since 2017. In furtherance of the important activities undertaken by the 2009 Commission and its predecessors and in recognition of the critical bioethical issues raised by the COVID-19 pandemic, **the AAMC recommends this administration establish a new Presidential Bioethics Commission**.

Department of Health and Human Services

Extend Public Health Emergency (PHE)

Renewal of Determination That A Public Health Emergency Exists, October 2, 2020

HHS declared a public health emergency (PHE) on January 27 in response to the COVID-19 pandemic. The PHE was most recently renewed effective October 23 and previously renewed on April 21 and July 23. Continuing the PHE, which is set to expire on January 21, 2021, provides regulatory relief for AAMC members to continue to fight the COVID-19 pandemic. **The AAMC strongly encourages HHS to extend the PHE**.

Nondiscrimination in Health and Health Education Programs or Activities (Sect. 1557 of the Affordable Care Act)

Centers for Medicare & Medicaid Services; Office of Civil Rights (OCR), Office of the Secretary, HHS Final Rule, June 19, 2020, Nondiscrimination in Health and Health Education Programs or Activities

This regulation excluded non-discriminatory notice and tagline requirements, as well as provisions related to the definition of sex and gender identify. Given the potential for discrimination, the AAMC strongly encourages a rulemaking process to ensure the retention of these provisions. In the meantime, **the AAMC asks that the Biden Administration use its discretion to not enforce the discriminatory provisions of the rule**.

Anti-Discrimination and Conscience Rights in Health Care

Office of Civil Rights (OCR) May 21, 2019, Conscience Rights in Health Care Final Rule [84 Fed. Reg. 23170]

HHS OCR revoked and replaced the prior 2011 rule and substantially amended the protections in health care for individuals and entities on the basis of religious beliefs or moral convictions codified at 45 CFR 88. The 2019 rule broadly allows physicians and others to avoid any activity "with an articulable connection" to the objectionable procedure, which will create or exacerbate inequities in health care access for Americans, especially those in health professional shortage areas where access to certain services might functionally cease to exist. Additionally, the rule created burdensome reporting requirements that have no commensurate benefit. **The AAMC urges a return to the 2011 rule** to ensure that patients are put first and that conscience protections align with medical professionalism standards.

Protecting the Promise of Fetal Tissue Research

Statement from HHS, June 5, 2019 Implementing Restrictions on National Institutes of Health (NIH) Supported Research Involving Human Fetal Tissue

This statement from HHS prohibited the use of human fetal tissue in intramural research conducted at the NIH and required that prior to being funded by NIH, any grant application that included the use of human fetal tissue must undergo an additional layer of review by a new HHS-appointed, majority non-scientist panel, convened under the auspices of section 492A of the Public Health Service Act (42 U.S.C. 289 a-1). **The AAMC urges the Biden Administration to rescind this problematic policy** that has delayed and deterred promising research and to return the authority for funding scientifically meritorious and ethically sound research to the NIH in its sole discretion, following the standard peer review process for scientific grant review. **The AAMC additionally urges withdrawal of the June 2019 HHS policy prohibiting NIH intramural research involving human fetal tissue**.

Family Planning Grants

Compliance with Program Integrity Requirements Final Rule, May 4, 2019 [84 Fed. Reg. 7714]

HHS updated regulations under 42 CFR Part 59 concerning the Title X family planning program that blocks the availability of federal funds to family planning providers that also offer abortion services with other funds, prohibits grantees from referring pregnant patients to abortion providers if requested, and eliminates the requirement for grantees to provide non-directive counseling on options, including information about abortion. Additionally, it added onerous reporting requirements for Title X grantees. The rule undermines standards of medical professionalism, harms patients who rely on Title X providers as an essential source of their health care, and adds burdensome requirements without commensurate benefit**. The AAMC urges these changes be revoked in full.**

Grandfathered Health Plans

Grandfathered Group Health Plans Proposed Rule, July 15, 2020 [85 Fed. Reg. 42782]

This proposed rule would allow certain grandfathered group health care plans, including high-deductible health plans, to increase consumer cost sharing without losing their grandfathered status. **The AAMC urges HHS to not finalize this rule**.

Requirements for Reducing Administrative Burden for Researchers

21st Century Cures Act, P.L. 114-255, Section 2034, December 13, 2016 Reducing Administrative Burden for Researchers

The 21st Century Cures Act required federal agencies to take specific actions to reduce regulatory burden for researchers and institutions, including the establishment of a Research Policy Board (mandated by December 2017) to modify and harmonize existing policies and regulations. The Secretary of the Department of Health and Human Services was also directed

to review the regulations related to the disclosure of financial conflicts of interest (by December 2018). Neither of these essential reforms has been implemented. Given the increasing regulatory burden across the biomedical research enterprise**, the AAMC urges prompt establishment of the Research Policy Board and implementation of the additional reform efforts required by Section 2034**.

Information Blocking

Information Blocking Final Rule, May 1, 2020 [84 Fed. Reg. 25642] and Subsequent 85 Fed. Reg. 70064], Office of the National Coordinator for Health Information Technology (ONC)
The ONC finalized regulations implementing the 21st Century Cures Act requirement for rules prohibiting information blocking and the promotion of the access, exchange, and transfer of electronic health information (EHI). The ONC has delayed its initial compliance timeframe with an interim final rule extending compliance with the information blocking rules to April 5, 2021 due to the COVID-19 Public Health Emergency. **The AAMC supports increased interoperability and exchange of EHI but urges the Biden Administration to delay enforcement beyond April 2021** until it issues comprehensive interpretive guidance addressing key questions about clinical workflows to ensure health care providers are able to fully support the aims while preventing patient harm and protecting patient privacy.

Retroactive Rulemaking

Proposed Rule, November 4, 2020 [85 Fed. Reg. 70096]
This proposed rule issued by HHS would a require a retrospective review of every regulation subject to the Regulatory Flexibility Act within ten years of its effective date "to determine whether the regulation is still needed and whether it is having appropriate impacts." As proposed, any regulation that HHS fails to review in a timely way will expire without further review. While the regular evaluation of existing regulations is critical to assessing the burden to the regulated community and the impact of the rules, this blunt approach to all regulations could have the unintended effects of either the cursory review of complex regulations or scarce resources being wasted on unnecessarily burdensome review of lower priority rules. The AAMC conducted a multi-year project to assess one set of regulations through the AAMC Conflicts of Interest Metrics Project and fully appreciates the significant time, resources, and data required to do an effective retrospective review. **The AAMC suggests withdrawal of this proposed rule and identification of specific regulations that should be reviewed,** especially those required to be reviewed by the 21st Century Cures Act.

Centers for Medicare & Medicaid Services

Medicaid Fiscal Accountability Regulation (MFAR) Proposed Rule

MFAR Proposed Rule, November 8, 2019 [84 Fed. Reg. 63722]
The proposed MFAR rule would have wide-sweeping implications for how states finance their Medicaid programs, including by limiting how states can use supplemental payments and intergovernmental transfers to finance the non-federal share. The proposed rule would have major detrimental impacts on states, their Medicaid programs, and vulnerable Medicaid beneficiaries. It would also require increased and overly burdensome reporting of supplemental payments. **The AAMC strongly encourages CMS to not finalize and withdraw the proposed rule from the next regulatory agenda**.

Medicaid Work/Community Engagement Requirements (Section 1115 waiver guidance)

CMS State Medicaid Director Letter, January 11, 2018

In this Director Letter, states were given the option to impose work or other community engagement activities as a requirement for continued Medicaid eligibility or coverage for certain Medicaid beneficiaries. This requirement is overly burdensome for many Medicaid beneficiaries who, due to physical/behavioral limitations or caregiver responsibilities, are unable to fulfill these new requirements and subsequently lose Medicaid coverage. **The AAMC urges CMS to rescind 1115 waivers that require work or community engagement as a condition of Medicaid eligibility.**

Medicaid Block Grant/Per Capita Cap/Healthy Adult Opportunity Initiative (Section 1115 waiver guidance)

CMS State Medicaid Director Letter, January 30, 2020

In this Director Letter, states were given the option to offer certain Medicaid beneficiaries alternative benefit designs that are not required to provide all statutorily required Medicaid benefits. For this population, states could elect to receive funding either as an aggregated ("block grant") or per-capita cap financing model. Block grant or per-capita caps limit funding for Medicaid beneficiaries that could result in eligible beneficiaries not having access to needed medical services as required by law. **The AAMC encourages CMS to rescind the Healthy Adult Opportunity initiative and not allow block grants or per-capita cap financing in Medicaid.**

Expansion of Coverage and Payment for Telehealth Services

COVID-19 IFC-2, May 8, 2020 [85 Fed. Reg. 27750]

In response to the COVID-19 public health emergency (PHE), Congress and CMS established a number of waivers and flexibilities that have facilitated the widespread use of telehealth and other communication-based technology services. By using telehealth, physicians have been able to monitor non-critically ill COVID-19 positive patients, follow up on patients with chronic disease who can be cared for without risking a visit to the hospital or clinic, and provide care for many Medicare beneficiaries without imposing the burden of travel. **The AAMC urges Congress and CMS to make changes to legislation and regulations that will allow the current changes to telehealth, including the removal of geographic and site of service restrictions, to be made permanent while ensuring that reimbursement remains at a level that will support the infrastructure needed to continue provide telehealth services**.

Teaching Physicians' Supervision of Residents via Real-time Interactive Technology

COVID-19 IFC-1, April 6, 2020 [85 Fed. Reg. 19230], CY 2021 PFS Proposed Rule, August 17, 2020 [85 Fed. Reg. 50074], 2021 CMS physician fee schedule and QPP final rule (December 1, 2020)

During the public health emergency, CMS adopted a policy allowing teaching physicians to provide supervision via real-time, interactive audio/video technology to meet resident supervision requirements. In the 2021 final Physician Fee Schedule rule CMS states that they will allow virtual supervision of residents permanently after the PHE in rural sites. **The AAMC urges CMS to make these provisions permanent after the public health emergency in all geographic regions**. Continuing these policies will reduce risk exposure to all infectious diseases (e.g. coronavirus, seasonal flu, and others), increase the workforce capacity of teaching settings, increase access to care for patients, and allow important experience and training for the future physician workforce while appropriately supervised.

GME Resident Cap Setting: De Minimus Rotations

COVID-19 IFC-2, May 8, 2020 [85 Fed. Reg. 27750]

This interim final rule allows hospitals that unknowingly would have triggered their Medicare Graduate Medical Education cap / per resident amount (PRA) by having a medical resident rotate to their hospital during the PHE, to not have that happen and instead retain the ability to build a new resident cap / PRA so long as the cap / PRA is not above a minimum amount (de minimus). **The AAMC encourages CMS to introduce new regulations to maintain these provisions after the PHE**.

Change to Bed Count for Indirect Medical Education (IME) Payments

COVID-19 IFC-2, May 8, 2020 [85 Fed. Reg. 27750]

This interim final rule ensures teaching hospitals that increased their number of inpatient beds to accommodate the surge in patients during the PHE to not have their IME payments unfairly reduced by CMS. The rule dictates that a teaching hospital's bed count is equal to what it was the day before the PHE was declared for purposes of the intern and resident-to-bed ratio, which is a critical determinant in calculating IME payments. **The AAMC encourages CMS to introduce new regulations to maintain this provision after the PHE so that it is effective whenever a PHE is declared**.

340B Drug Pricing Program and the Outpatient Prospective Payment System (OPPS)

CY 2021 OPPS Final Rule, December 29, 2020

CMS is continuing OPPS reimbursement cuts to hospitals for drugs acquired under the 340B Program. Reimbursement for 340B-acquired drugs will continue to be paid at average sales price minus 22.5%. These continued reimbursement cuts subvert the congressional intent of the 340B Program, which allows safety-net hospitals to invest their 340B savings in a wide variety of programs to meet the needs of their local communities and help vulnerable patients at no cost to taxpayers. **The AAMC encourages CMS to not enforce this provision and instead propose a new rule overturning this provision.**

Marketplace (Section 1332 waiver guidance)

HHS Guidance, State Relief and Empowerment Waivers [83 Fed. Reg. 53575]

"State relief and empowerment" waivers allow states to offer insurance plans that do not meet the requirements set forth under the Affordable Care Act. These plans provide less comprehensive coverage, leaving consumers without access to needed medical care. Consumers may also have higher cost-sharing liability under these plans. **The AAMC urges CMS to rescind this guidance** to protect patients from increased financial risk while ensuring access to health care services**.**

Site-Neutral Expansion to Excepted Off-Campus Provider-Based Departments (PBDs)

CY 2021 OPPS Final Rule, December 29, 2020

CMS continued its policy to reduce payment for outpatient clinic visits (HCPCS code G0463) to the physician fee schedule equivalent rate, which is 40% of the OPPS rate, at off-campus PBDs that were originally excepted by Congress from the policy. Increases in outpatient services are due in large part to the shift in services from the inpatient to the outpatient setting, often as a result of CMS policies. **The AAMC encourages CMS to propose a new rule, overturning this provision and similar provisions implemented in previous rulemakings.**

Reduction in Payment for Physician Services in 2021

CY 2021 PFS Final Rule, December 1, 2020

In this final rule, CMS announces the dollar conversion factor that would be used to update the payment rates. For 2021, the conversion factor would be $32.41, which is a 10.2% reduction from the 2020 conversion factor. The drastic 10.2% reduction in the Medicare conversion factor is due to the proposed additional spending in the rule of $10.2 billion due to changes to E/M codes and other proposals in the rule. Payment reductions of this magnitude would be a major problem at any time, but to impose these large cuts at a time when teaching physicians and other health care professionals continue to be on the front lines treating patients with COVID-19 will be devastating. **The AAMC encourages CMS to support stakeholder's efforts to urge Congress to waive the budget neutrality requirements associated with the E/M code changes or temporarily hold harmless physicians and other health care professionals.**

Hospital Co-location Draft Guidance

Co-Location Guidance, May 3, 2019

This draft guidance would restrict co-located hospitals from using acute care staff for emergency situations. It is customary that co-located hospitals utilize acute care hospital staff to respond to emergencies. Acute care hospital code teams successfully manage and respond to a variety of emergency events throughout the hospital campus. Since early intervention by high-skilled health care professionals during medical emergencies often results in positive long-term health care outcomes, the AAMC believes that limiting a co-located hospital's ability to contract with the acute care hospital for these services would impact patient care. **The AAMC recommends that CMS not finalize this guidance**.

Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"

MCIT Proposed Rule, September 1, 2020 [85 Fed. Reg. 54327]

This proposed rule creates an MCIT pathway that would provide immediate national coverage for breakthrough devices beginning on the date of FDA market authorization and continuing for up to four years. Any item or service that receives a breakthrough device designation from the FDA would be considered "reasonable and necessary" for payment under Medicare. **The AAMC recommends that CMS not finalize the proposed rule as it does not provide safeguards for Medicare beneficiaries who might receive the breakthrough technology**. The proposed change in the definition of "reasonable and necessary" also should not be finalized as it would upend well-established guidance on how to make a "reasonable and necessary determination" and does not provide adequate support for the considering commercial coverage as a basis for Medicare coverage.

COVID-19 Reporting, Medicare Conditions of Participation

COVID-19 IFC-3, September 2, 2020 [85 Fed. Reg. 54820] and August 26, 2020 IFC-3 Guidance

These CMS directives link Conditions of Participation (CoP) compliance with the requirement that hospitals report on 38 COVID-related measures. The reporting is required through the end of the public health emergency. Hospitals had been voluntarily reporting this data since March 2020. Medicare Conditions of Participation are fundamental to the Medicare program and are the gateway to whether Medicare beneficiaries can receive services at hospitals. Particularly in a pandemic, and when most hospitals are complying, CoPs should not be used in this manner. **The AAMC encourages CMS to not enforce this rule. If effective prior to the next administration, the AAMC encourages CMS to propose a new rule, overturning this provision.**

3-Day Skilled Nursing Facility (SNF) Stay Waiver

COVID-19 IFC-2, May 8, 2020 [85 Fed. Reg. 27750]

The interim final rule with comment waives the requirement for 3-day hospital inpatient stay as a requirement for Medicare coverage of a SNF stay during the PHE. To better coordinate and improve care for patients, the **AAMC encourages CMS to work with Congress to maintain this flexibility after the conclusion of the COVID-19 public health emergency**. Eliminating the three-day stay would allow for physicians' judgment to ensure that their patients receive the most appropriate care in the most appropriate settings.

Inpatient Only (IPO) List Elimination

CY 2021 OPPS Final Rule, December 29, 2020

Beginning in CY 2021, the IPO list will be eliminated over a three-year period, which could lead to some procedures being inappropriately performed in the outpatient setting jeopardizing patient safety. The AAMC recommends CMS not enforce this policy. **The AAMC encourages CMS to propose a new rule, overturning this provision**.

Exclusion Criteria for Ambulatory Surgical Center Covered Procedures List (ASC-CPL)

CY 2021 OPPS Final Rule, December 29, 2020

CMS will remove five exclusion criteria, many of which impact patient safety, and are adding 267 new procedures to be performed in an ASC setting beginning CY 2021. The criteria removed generally exclude surgical procedures from the list that are prolonged, high risk, or directly involve major blood vessels. **The AAMC recommends CMS not enforce this policy**. The AAMC encourages CMS to propose a new rule, overturning this provision.

Prior Authorization

CY 2021 OPPS Final Rule, December 29, 2020

Beginning for dates of service on or after July 1, 2021, two new service categories will require prior authorization as a condition of payment: cervical fusion with disc removal and implanted spinal neurostimulators. CMS introduced the prior authorization policy in CY 2020 for certain HOPD services, which increases provider burden and potentially limits beneficiaries' access to needed medical services. **The AAMC recommends CMS not enforce the policy. We encourage CMS to propose a new rule, overturning these provisions**.

Appropriate Use Criteria

Fee Schedule Rules on Policy Codified at 2 CFR 414.95, November 16, 2015 [80 Fed. Reg. 70855; 71102-71106, 71380-71382]; 81 Fed. Reg. 80170, November 15, 2016; 82 Fed. Reg. 52976, November 15, 2017, and 83 Fed. Reg. 59688, November 23, 2018

Section 218(b) of the Protecting Access to Medicare Act of 2014 (PAMA) directed CMS to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. Under the law, as a condition of payment to a provider who furnishes imaging services, the health care provider ordering advanced diagnostic imaging services must consult AUC. This involves entering patient clinical data into an electronic decision tool, referred to as a clinical decision support mechanism (CDSM), to obtain information on the appropriateness of the services. The results of the AUC consultation must be documented on the claim submitted by providers furnishing imaging services in order to be paid by Medicare. While the AAMC supports the use of clinician-developed, evidence-based AUCs to improve the quality of care, and understands the statutory requirement, the association is concerned about the unreasonable burden placed on providers. **The AAMC urges a delay in implementation** to review the policy and to provide sufficient time for providers to learn and comply with this program.

Medicare Shared Savings Program (MSSP) Revenue Distinctions for ACO Participation

MSSP Final Rule, December 31, 2018 [83 Fed. Reg. 6781; 67831-67841]

CMS issued a new "Pathways to Success" set of policies to redesign aspects of the MSSP for accountable care organizations (ACOs) to participate in through the traditional Medicare fee-for-service (FFS) program. In part, CMS set new definitions for an ACO based on its total FFS revenue to limit the participation options for ACOs deemed to be a "High revenue ACO" under 42 CFR 425.20. The AAMC opposes the limitation of participation options for ACOs deemed to be "high revenue" as FFS revenue is not indicative of the ACO's ability to bear risk. The policy discourages ACOs from engaging hospitals as ACO Participants, in direct opposition of the goal of ACOs to incent coordination across all providers and reduces healthy market competition by creating an unlevel playing field for ACOs based on an arbitrary revenue standard. **The policy of incorporating revenue distinctions into the MSSP should be rescinded**.

New Mandatory Specialty Care Models

Specialty Care Model Final Rule, September 29, 2020 [85 Fed. Reg. 61114]

CMS finalized two new mandatory alternative payment models, the Radiation Oncology (RO) Model and the End-stage Renal Disease (ESRD) Treatment Choices (ETC) Model. The RO Model creates a 90-day bundled payments for radiation therapy services coupled with prospective capitation payments that do not vary based on the type of radiation therapy provided. The ETC Model applies two-sided payment adjustments to the standard billing processes for ESRD services to increase kidney transplants and home dialysis. CMS mandates participation for about 30% of radiation oncologists and nephrologists nationally, identified by zip code. **The AAMC urges an indefinite delay of both models until CMS is able to evaluate adequacy of the payment methodologies, potential unintended consequences for patients, and increased burden on providers as well as the impacts of the COVID-19 Public Health Emergency** if these models were to take effect.

Hospital Price Transparency Final Rule

Hospital Price Transparency Final Rule, November 27, 2019 [84 Fed. Reg. 65524]

The final rule requires hospitals to establish, update, and make public a list of their standard charges for the items and services that they provide, including both hospital services and physician / professional fees, if employed by the hospital. This includes five types of "standard charges" – gross charges – chargemaster rate; payer-specific negotiated rates – applies to all third-party payers other than Medicare and Medicaid fee-for-service; de-identified minimum rates; de-identified maximum rates; and, discounted cash price – for those who pay cash for services. **The AAMC encourages CMS to rescind the hospital price transparency final rule.** Patients want information about their specific cost sharing liabilities. Hospitals currently provide patients with online pricing tools and access to cost-sharing information.

National Institutes of Health

Promoting Data Sharing and Clinical Trials Results Reporting

Final NIH Policy for Data Management and Sharing and Supplemental Information, October 30, 2020 (85 FR 68890)

The NIH issued this new data sharing policy for the first time since 2003, promoting good data management and maximizing the expectation that researchers share scientific data. The AAMC strongly supports this goal and has worked closely over the past several years with its member medical schools and the NIH to facilitate the development of this new policy. We have additionally supported our institutions as they implement the 2016 final HHS rule and NIH policy expanding dissemination of clinical trials results. The movement to increase data sharing and transparency around clinical research is essential to advance medical discovery and

translation and promote responsible stewardship of federal resources. **The AAMC recommends that the NIH and other federal agencies work with researchers and institutions to ensure consistent and meaningful implementation of the policy and to develop templates and guidance** that will facilitate clear and effective policies for scientific data sharing.

Food and Drug Administration

Ensuring Independence of the Food and Drug Administration

Emergency Use Authorization for Vaccines to Prevent COVID-19, October 2020

Building and maintaining public trust in the objectivity and scientific integrity of federal agencies is particularly essential during a pandemic, when the health of our nation depends on individuals following public health recommendations and eventually choosing to get a SARS-CoV-2 vaccine. To increase this trust, the administration should take concrete steps to demonstrate through action and policy that the science-driven decisions of the FDA are adequately insulated from political interference. The AAMC was encouraged by the FDA's recent guidance on the *Emergency Use Authorization for Vaccines to Prevent COVID-19* and **encourages the Biden Administration to continue to identify mechanisms to demonstrate the agency's independence in its decision-making and insulation from political interference**.

Requirements for Harmonization of Protection of Human Research Subjects

21st Century Cures Act, P.L. 114-255, Section 3023, December 13, 2016, Protection of Human Research Subject

The 21st Century Cures Act required the harmonization of the Food and Drug Administration (FDA)'s human subject protection regulations (21 CFR Parts 50 and 56) with the Department of Health and Human Services regulations (45 CFR part 46, Subpart A, "Common Rule") by December 2019. The FDA has taken steps toward harmonization through issuance of limited guidance for immediate implementation but has yet to initiate rulemaking to harmonize its regulations with the Common Rule. **The AAMC encourages the FDA to move forward quickly with the rulemaking process** to fulfill its requirements and bring needed consistency to research overseen by the FDA and HHS**.**

Department of Education

Department of Education Investigation of Princeton University

Dept. of Education Investigation, September 16, 2020

In an September 16 letter, the Department announced an investigation into Princeton University after its president recognized racism as a significant problem within American higher education. The Department asserts Princeton has not complied with Title VI of the Civil Rights Act of 1964 by discriminating against people of color. The AAMC joined a higher education community letter that raised concern with the department's investigation into an institution's anti-racism initiatives and requested the Department to end the investigation. **The AAMC urges the new administration to drop its investigation into Princeton**.

Title IX Campus Sexual Harassment

Title IX Final Rule, May 6, 2020

This final rule, "Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance," significantly changes how an institution investigates a Title IX sexual harassment complaint. The rule, which was effective August 15, 2020, narrows the definition of sexual assault, requires live cross-examination of parties, and prohibits institutions from examining complaints that happen outside an institution's immediate

jurisdiction. **The AAMC recommends the Department rescind the rule and propose new standards for Title IX sexual harassment**.

Section 117 Foreign Gift Reporting

Foreign Gift Information Collection Request, February 10, 2020

The Department of Education released the information collection request regarding "Foreign Gifts and Contracts Disclosures," which exceeds the statutory basis for institutional reporting required under Section 117 of the Higher Education Act. The AAMC joined the higher education community in opposing the Department's proposed changes. **The AAMC encourages the administration to rescind the information collection request and encourages the Department to follow the collection procedures outlined in Section 117 of the Higher Education Act.**

Department of Justice

Race-Conscious Higher Education Admissions

February 25, 2020, Amicus Brief, and October 8, 2020 lawsuit

In *Students for Fair Admission Inc. v. President and Fellows of Harvard College,* the DOJ filed an amicus brief stating Harvard's use of race in admissions violates the Civil Rights Act. Additionally, the DOJ sued Yale University for similar practices, claiming discrimination against white and Asian applicants. **The AAMC opposes the efforts to stop the use of race in admissions and supports the use of holistic admissions, which looks at the applicant as a whole, not just their test scores and grades**. The AAMC joined the higher education community in an amicus brief supporting Harvard in their case and released a statement criticizing the administration's lawsuit against Yale.

Department of Homeland Security (DHS)

Public Charge

Final Rule, August 12, 2019

DHS released the "Inadmissibility on Public Charge Grounds" final rule to establish new standards about which public benefits, including some impacting access to medical care and social determinants of health, will be considered when legal immigrants seek to change their immigration status or enter the United States. **The AAMC requests the Biden Administration rescind the "public charge rule,"** noting the rule prevents legal immigrants from accessing vital federal programs, such as Medicaid, which will lead to worse health outcomes. The AAMC joined an amicus brief supporting legal challenges to the final rule.

Deferred Action for Childhood Arrivals (DACA)

DHS Memorandum, July 28, 2020, and U.S. Customs and Immigration Services (USCIS) memorandum, August 21, 2020

In response to the June 18, 2020, U.S. Supreme Court decision, DHS and USCIS issued memos retaining DACA but rejecting all new DACA and advance parole applications, and limiting DACA renewals to 1 year of work authorization. **The AAMC urges DHS and USCIS to rescind these memos, and return to the June 15, 2012, "Exercising Prosecutorial Discretion with Respect to Individuals Who Came to the United States as Children" memorandum** that established DACA and encourages Congress to immediately pass a permanent statutory pathway for undocumented youths to remain in the United States.

Duration of Status Proposed Rule

Proposed Rule, September 25, 2020

DHS issued a proposed rule, "Establishing a Fixed Time Period of Admission and an Extension of Stay Procedure for Nonimmigrant Academic Students, Exchange Visitors, and Representatives of Foreign Information Media," which replaces the long-standing "duration of status" policy with a specific end date for certain nonimmigrant visa categories, including F-1 student and J-1 exchange visitor visas. **The AAMC urges DHS to rescind the proposed rule** due to the potential impact on medical students, residents, PhD students, and postdoctoral researchers.

Department of Labor

Prevailing Wage and H-1B Visas

DOL and Department of Homeland Security (DHS) October 8, 2020, Interim Final Rules

The Department of Labor and Department of Homeland Security released interim final rules titled “Strengthening Wage Protections for the Temporary and Permanent Employment of Certain Aliens in the United States” and “Strengthening the H-1B Nonimmigrant Visa Classification Program,” respectively. **The AAMC recommends the rescission of these rules,** which will disrupt academic medicine’s ability to recruit the best and the brightest medical residents, physicians, and scientists, including postdoctoral researchers, that support the nation’s health care infrastructure.

Association Health Plans, Short-term Limited Duration Plans Final Rule

Association Health Plans Final Rule, June 21, 2020 [83 Fed. Reg. 28912]

The Association Health Plans and Short-term Limited Duration plans final rule expanded availability of these plans that are not required to provide comprehensive health insurance coverage. These plans often provide inadequate coverage and leave enrollees at risk for high out-of-pocket costs. **The AAMC urges DOL to rescind this rule**.

Environmental Protection Agency

Equipping the EPA with the Best Science to Support Regulatory Decision Making

Strengthening Transparency in Regulatory Science Proposed Rule, April 30, 2018 (83 FR 18768), Supplemental Notice of Proposed Rulemaking (85 FR 15396) and Strengthening and Improving Membership on EPA Federal Advisory Committees Directive, October 31, 2017

The EPA issued a proposed rule that sought to bar the agency from considering in its regulatory decision-making any research for which the underlying data is not publicly available. This would potentially prevent the agency from even considering the results of essential research, especially research in human subjects. The proposed rule thwarts the promise of evidence-based policymaking, squarely contradicting the requirement that the EPA use the ‘best available science’ to make its regulatory decisions**. The AAMC urges immediate withdrawal of the EPA Proposed Rule and Supplemental Notice. Further, the AAMC urges the EPA to rescind in its entirety the directive of October 31, 2017 on “Strengthening and Improving Membership on EPA Federal Advisory Committees.”** Despite the invalidation of some sections of the directive, EPA should clarify that investigators receiving EPA or other federal research grants are not *proforma* disqualified to serve on EPA advisory and other committees.

General Government

Commission on Evidence Based Policymaking

Evidence Based Policymaking Commission Act, Public Law 114-140, March 30, 2016 and *Commission on Evidence Based Policymaking; Final Report and Recommendations from the Commission on Evidence Based Policymaking, September 7, 2017*

The Evidence-Based Policymaking Commission Act of 2016 established the bipartisan Commission on Evidence-Based Policymaking ("the Commission") to examine the availability and use of government data to build evidence and inform program design. The final report contains 22 recommendations to better use evidence in policymaking. The AAMC supports the collection and use of evidence to ensure federal regulation and policy meet clear objectives and **recommends the Biden Administration take additional steps to facilitate the implementation of the recommendations from the Commission's report**.