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Submitted at www.regulations.gov

December 24, 2020

Eric Hargan
Deputy Secretary
Department of Health and Human Services (HHS)
200 Independence Avenue, SW
Washington, DC 20201

RE: Regulatory Relief to Support Economic Recovery; Request for Information (RFI); HHS-OS-2020-0016-0001

Dear Deputy Secretary Hargan:

The Association of American Medical Colleges (AAMC) appreciates the opportunity to respond to Regulatory Relief to Support Economic Recovery; Request for Information (RFI); HHS-OS-2020-0016-0001, 85 *Fed. Reg* 75720 (November 25, 2020).

The AAMC is a not-for-profit association dedicated to transforming health through medical education, patient care, medical research, and community collaborations. Its members are all 155 accredited U.S. and 17 accredited Canadian medical schools; more than 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and their more than 179,000 full-time faculty members, 92,000 medical students, 140,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

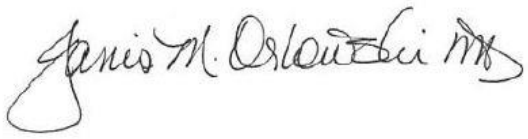
While the COVID-19 pandemic has posed enormous challenges and placed tremendous stress on our entire health care system, teaching hospitals, medical schools, and teaching physicians and researchers have mobilized on all fronts to treat and mitigate COVID-19 and to freely share the knowledge that they gain with others. We are grateful that HHS and its associated agencies and institutes have continued to be a partner the AAMC and our member institutions and appreciate the tremendous efforts made to quickly evaluate opportunities for flexibilities from current policies to ensure providers can deliver quality care for all patients during the public health emergency (PHE).

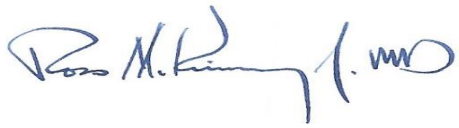
The AAMC's comments to the four Interim Final Rules with Comment issued by the Centers for Medicare and Medicaid Services (CMS), supported many of the regulatory flexibilities and

waivers and suggested that many be made permanent as they significantly reduce burden for both patients and providers. In the months since these flexibilities and waivers have been in effect, we believe the regulatory relief has worked well for both providers and patients, fulfilling the goal of "patients over paperwork," and we continue to support making many of them permanent. Our responses to the IFRs also requested that for those regulations that we do not believe need to be made permanent, CMS should extend the flexibilities and waivers for a year beyond the end of the PHE to provide institutions the necessary time to change workflows and reeducate those who are affected.

The attached table provides comments on selected regulatory changes implemented by the CMS, the Office of Civil Rights (OCR), the Food and Drug Administration (FDA) and the National Institutes of Health (NIH). For each we indicate whether we support making it permanent, provided that the agency has the statutory authority do so. For those that we do not support being made permanent we ask for a one-year extension beyond the end of the PHE for the reasons already stated: to allow for adequate time to change workflows and re-educate providers, researchers and others. The AAMC appreciates your consideration of the above comments. Should you have any questions, please contact Gayle Lee at galee@aamc.org or Ivy Baer at ibaer@aamc.org.

Sincerely,





Janis Orlowski, M.D., M.A.C.P.
Chief Health Care Officer

Ross McKinney, M.D.
Chief Scientific Officer

Action	Type of Action	Title of action	AAMC Comments
HHS Office for Civil Rights			
4	Other regulatory action	Notification of Enforcement Discretion for Telehealth Remote Communications.	*Beneficial on a temporary basis/ Maintain for one year beyond the PHE* The AAMC supports OCR's exercise of enforcement discretion to not impose penalties for HIPAA violations against healthcare providers in connection with their good faith provision of telehealth using remote communication technologies during the COVID–19 nationwide PHE. This change has been beneficial during the PHE to ensure that providers can meet the greater demand for and coverage of telehealth services, most critically by furnishing such services to patients via familiar applications. However, the expansion of applications available for telehealth remote communications must be balanced with privacy concerns, and to that end the AAMC believes the exercise of enforcement discretion should be maintained only for the duration of the PHE.
5	Other regulatory action	Notification of Enforcement Discretion for Business Associates.	*Beneficial on a temporary basis/ Maintain for one year beyond the PHE* The AAMC supports OCR's Exercise of enforcement discretion to not impose penalties for violations of certain provisions of the HIPAA Privacy Rule against covered health care providers or their business associates for the good faith uses and disclosures of protected health information (PHI) by business associates for public health and health oversight activities during the COVID–19 nationwide PHE. This change has been vital to support public health authorities and health oversight agencies, state and local health departments, and emergency operation centers who need access to COVID-19 related data, including PHI. Extending permission to business associates to share this data without risk of a HIPAA penalty for the duration of the PHE appropriately balances privacy concerns with the public's health, and should be maintained only for the duration of the PHE.

Action	Type of Action	Title of action	AAMC Comments
National Institutes of Health (NIH)			
7	Waiver	Flexibility with System for Awards Management "SAM" Registration (2 CFR § 200.205)	*Beneficial/Reinstate and then maintain during the PHE* The waiver issued as part of OMB Memo M-20-17 on March 19, 2020, provided useful flexibility related to registration and renewal in "SAM." The flexibility expired on June 16. On May 27, the AAMC joined the Council on Governmental Relations, Association of American Universities and the Association of Public and Land-grant Universities in a letter to OMB requesting that the flexibilities contained in memo M-20-17 be extended in their entirety through at least September 30, 2020. This waiver was not extended by OMB memo M-20-26 or any other mechanism. **The AAMC was disappointed that this waiver was not extended and notes that it would still be beneficial**

Action	Type of Action	Title of action	AAMC Comments
National Institutes of Health (NIH)			
			today as federal grantees struggle with the challenges of conducting research during COVID-19.
8	Waiver	Flexibility with Application Deadlines (2 CFR § 200.202)	*Beneficial/Reinstate and then maintain during the PHE* The waiver issued as part of OMB Memo M-20-17 allowed NIH to accept late applications. The flexibility expired on June 16. As described above (see notes under AAMC Comments for Action 7), AAMC urged OMB to extend this and several other flexibilities through at least September 30, 2020. This waiver was not extended by OMB memo M-20-26 or any other mechanism. **The AAMC was disappointed that this waiver was not extended and notes that it would still be beneficial today as institutions struggle with the challenges of conducting research during and in response to COVID-19.**
9	Waiver	Waiver for Notice of Funding Opportunities (NOFOs) Publication. (2 CFR § 200.203)	*Beneficial/Reinstate and then maintain during the PHE* The waiver issued as part of OMB Memo M-20-17 allowed NIH to issue short response time funding opportunities more easily. The flexibility expired on June 16. As described above (see notes under AAMC Comments for Action 7), AAMC urged OMB to extend this and several other flexibilities through at least September 30, 2020. This waiver was not extended by OMB memo M-20-26 or any other mechanism. **The AAMC was disappointed that this waiver was not extended and notes that it would still be beneficial today to allow NIH to respond nimbly to the research needs of COVID-19.**
10	Waiver	No-cost extensions on expiring awards. (2 CFR § 200.308)	*Beneficial/Reinstate and then maintain during the PHE* The waiver issued as part of OMB Memo M-20-17 allowed NIH to grant no-cost extensions on expiring awards that had been slowed or halted by the impact of COVID-19. The flexibility expired on June 16. As described above (see notes under AAMC Comments for Action 7), AAMC urged OMB to extend this and several other flexibilities through at least September 30, 2020. This waiver was not extended by OMB memo M-20-26 or any other mechanism. **The AAMC was disappointed that this waiver was not extended and notes that it would still be beneficial today as institutions struggle with the challenges of continuing ongoing research during COVID-19.**
11	Waiver	Abbreviated non-competitive continuation requests. (2 CFR § 200.308)	*Beneficial/Reinstate and then maintain during the PHE* The waiver issued as part of OMB Memo M-20-17 allowed NIH to accept brief statements of the ability to continue ongoing research. The flexibility expired on June 16. As described above (see notes under AAMC Comments for Action 7), AAMC urged OMB to extend this and several other flexibilities through at least September 30, 2020. This waiver was not extended by OMB memo M-20-26 or any other mechanism. **The AAMC was disappointed that this waiver was not extended**

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National Institutes of Health (NIH)			
			and notes that it would still be beneficial today as institutions struggle with the challenges of conducting research during and in response to COVID-19.
12	Waiver	Allowability of salaries and other project activities. (2 CFR § 200.403, 2 CFR § 200.404, 2 CFR § 200.405)	*Beneficial/Reinstate and then maintain during the PHE* The waiver issued as part of OMB Memo M-20-17 allowed grantees to charge salaries to grant awards under certain circumstances where the research could not be conducted for periods of time due to COVID-19. As described above (see notes under AAMC Comments for Action 7), AAMC urged OMB to extend this and several other flexibilities. This waiver was extended by OMB memo M-20-26, but with significant restrictions on its use and an expiration date of September 30. **The AAMC is disappointed that this waiver has now expired and notes that it would be beneficial today as institutions struggle with the challenges of conducting research during and in response to COVID-19, especially if surges of cases in specific geographic areas require the closing of campus facilities.**
13	Waiver	Allowability of Costs not Normally Chargeable to Awards. (2 CFR § 200.403, 2 CFR § 200.404, 2 CFR § 200.405)	*Beneficial/Reinstate and then maintain during the PHE* The waiver issued as part of OMB Memo M-20-17 allowed grantees to charge certain costs to grant awards such as cancellation costs for events or travel as a results of COVID-19. This waiver was extended by OMB memo M-20-26, but with significant restrictions on its use. It has not expired and would still be beneficial today as institutions struggle with the challenges of conducting research during and in response to COVID-19, especially if surges of cases in specific geographic areas require the closing of campus facilities. **The AAMC was disappointed that this waiver was not extended and notes that it would still be beneficial today as institutions struggle with the challenges of managing research budgets with uncertainty about the ability to travel to events during COVID-19.**
14	Waiver	Prior approval requirement waivers. (2 CFR § 200.407)	*Beneficial/Reinstate and then maintain during the PHE* The waiver, issued as part of OMB Memo M-20-17, on March 19, 2020, provided useful flexibility for grant awardees. As described above (see notes under AAMC Comments for Action 7), AAMC urged OMB to extend this and several other flexibilities through at least September 30, 2020. This waiver was not extended by OMB memo M-20-26 or any other mechanism. **The AAMC was disappointed that this waiver was not extended and notes that it would still be beneficial today as institutions struggle with the challenges of continuing ongoing research during COVID-19.**
15	Waiver	Exemption of certain procurement requirements.	*Beneficial/Reinstate and then maintain during the PHE* The waiver, issued as part of OMB Memo M-20-17, on March 19, 2020, provided useful flexibility for grant awardees. As described above (see notes under AAMC Comments for Action 7), AAMC urged

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National Institutes of Health (NIH)			
		(2 CFR§ 200.319(b), 2 CFR§ 200.321)	OMB to extend this and several other flexibilities through at least September 30, 2020. This waiver was not extended by OMB memo M-20-26 or any other mechanism. **The AAMC was disappointed that this waiver was not extended and notes that it would still be beneficial today as institutions struggle with the challenges of continuing ongoing research during COVID-19.**
16	Waiver	Extension of financial, performance, and other reporting. (2 CFR§ 200.327, 2 CFR§ 200.328)	*Beneficial/Reinstate and then maintain during the PHE* The waiver, issued as part of OMB Memo M-20-17, on March 19, 2020, provided useful reporting flexibility for grant awardees. As described above (see notes under AAMC Comments for Action 7), AAMC urged OMB to extend this and several other flexibilities through at least September 30, 2020. This waiver was not extended by OMB memo M-20-26 or any other mechanism. **The AAMC was disappointed that this waiver was not extended and notes that it would still be beneficial today as institutions struggle with the challenges of continuing ongoing research during COVID-19.**
17	Waiver	Extension of currently approved indirect cost rates. (2 CFR§ 200.414(c))	*Beneficial/Reinstate and then maintain during the PHE* The waiver, issued as part of OMB Memo M-20-17, on March 19, 2020, provided useful procedural and approval flexibility for grant awardees. As described above (see notes under AAMC Comments for Action 7), AAMC urged OMB to extend this and several other flexibilities through at least September 30, 2020. This waiver was not extended by OMB memo M-20-26 or any other mechanism. **The AAMC was disappointed that this waiver was not extended and notes that it would still be beneficial today as institutions struggle with the challenges of continuing ongoing research during COVID-19.**
18	Waiver	Extension of closeout. (2 CFR§ 200.343)	*Beneficial/Reinstate and then maintain during the PHE* The waiver, issued as part of OMB Memo M-20-17, on March 19, 2020, provided grant awardees with the ability to extend closeout deadlines. As described above (see notes under AAMC Comments for Action 7), AAMC urged OMB to extend this and several other flexibilities through at least September 30, 2020. This waiver was not extended by OMB memo M-20-26 or any other mechanism. **The AAMC was disappointed that this waiver was not extended and notes that it would still be beneficial today as institutions struggle with the challenges of continuing ongoing research during COVID-19.**
19	Waiver	Extension of Single Audit submission. (2 CFR § 200.512)	*Beneficial/Reinstate and then maintain during the PHE* The waiver issued as part of OMB Memo M-20-17 provided extensions of deadlines for filing single audits to the Federal Audit Clearinghouse without requesting them. As described above (see notes under AAMC Comments for Action 7), AAMC urged OMB to extend this and several other flexibilities. Moderate extensions to single audit deadlines were granted extended by OMB memo M-

Action	Type of Action	Title of action	AAMC Comments
National Institutes of Health (NIH)			
			20-26, but all have now expired. **The AAMC suggests that such extensions would still be beneficial today as institutions struggle with the challenges of conducting research during and in response to COVID-19.**
20	Waiver	OMB Memo M-20-20: Repurposing Existing Federal Financial Assistance Programs	*Beneficial/Reinstate and then maintain during the PHE* The waiver allowed the NIH to repurpose some Federal assistance awards to support the COVID-19 response, including the critical donation of personal protective equipment. **The AAMC suggests that HHS to retain this ability to address emerging needs of the COVID-19 pandemic throughout the public health emergency, with the requirement that agencies are transparent about when these funds are repurposed.**
21	Waiver	National Research Service Awards	*Beneficial/Reinstate and then maintain during the PHE* The waiver allowed NRSA recipients to continue charging stipends to NIH awards while no worked was performed due to COVID-19, an essential flexibility to ensure support for trainees when campus facilities were closed. **The AAMC urges HHS to retain this waiver throughout the public health emergency as institutions and especially trainees struggle with the challenges of continuing ongoing research during COVID-19.**

Action	Type of Action	Title of action	AAMC Comments
U.S. Food and Drug Administration (FDA)			
24	Guidance	Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)	*Beneficial/Maintain during the PHE* The guidance issued by FDA has served to increase the availability of face masks for both the general public and particulate filtering face piece respirators (including N95 respirators) for healthcare personnel. This is an essential component of the nation's response to COVID-19. **In the face of significant shortages of personal protective equipment (PPE) including face masks, the AAMC urges FDA to maintain this flexibility through the public health emergency while maintaining its oversight role in ensuring that inadequate or unsafe PPE is removed from the market.**
33	Guidance	Institutional Review Board (IRB) Review of Individual Patient Expanded Access Requests for Investigational Drugs and	*Beneficial/Maintain during the PHE* **The AAMC supports the FDA's guidance, *IRB Review of Individual Patient Expanded Access Requests for Investigational Drugs and Biological Products During the COVID–19 PHE,* and recommends that it be maintained for the duration of the PHE. We also support the FDA's**

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U.S. Food and Drug Administration (FDA)			
		Biological Products During the COVID–19 Public Health Emergency. https://www.fda.gov/media/138496/download	**interest in facilitating patient access to drugs through the agency's expanded access program beyond the PHE through reassessing and replacing the guidance with appropriate changes within 60 days following the termination of the PHE.** During the PHE, the FDA has received a substantially increased number of requests for COVID-19 investigational drugs and we agree that IRBs would benefit from additional guidance on how to best satisfy the requirements of 21 C.F.R. part 56. Specifically, the guidance outlines the procedures and factors IRBs should consider when reviewing patient access requests, including a plan for how IRBs should ensure patient informed consent for expanded access products and highlights other critical components of IRB review. This serves as an important step toward responding to the current challenges faced by IRBs on how to best review expanded access treatments for individual patients during the PHE and create policies for processing individual expanded access requests. The AAMC also notes that IRBs and patients need to understand the difference between the FDA's effective expanded access program and the rules under the "right to try" legislation.
34	Guidance	FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID–19 Public Health Emergency	*Beneficial/Maintain during the PHE* **The AAMC supports the FDA's guidance on the conduct of clinical trials during the COVID-19 PHE and believes it should be retained for the duration of the PHE.** The FDA has identified thirteen considerations for sponsors as it relates to ongoing or upcoming clinical trial activities, noting that "[e]nsuring the safety of trial participants is paramount," discussing briefly the potential for continuing recruitment and need to keep study participants informed of deviations or changes to study and monitoring plans. The AAMC recognizes this guidance was recently updated in December and appreciates the FDA's interest in receiving public comments throughout the duration of the PHE. In further support of the considerations outlined, especially related to the recruitment and protection of trial participants and how sponsors should respond to and manage study conduct and disruptions, the FDA should look to its June 2020 *Guidance for Industry on the Development and Licensure of Vaccines to Prevent COVID-19* which outlines key considerations for trial design and encourages sponsors to enroll diverse populations in all phases of clinical trials. The approaches discussed are critically relevant to this guidance and should be incorporated as appropriate.

Action	Type of Action	Title of action	AAMC Comments
Centers for Medicare & Medicaid Services (CMS)			
106	Interim Final Rule	Merit-Based Incentive Payment System	*Beneficial/Modify to extend the reporting deadline for 2020 MIPS performance period due to ongoing nature of PHE* The first interim final rule with comment (IFC-1) extended the deadline to submit an application for reweighting the quality, cost and improvement activities performance categories based on extreme and uncontrollable circumstances from 12/31/19 to 4/30/20 and modified existing policy for the 2019 performance period/2021 MIPS payment year only. The AAMC supports extending the deadline to submit an application for reweighting the quality, cost and improvement activities performance categories based on extreme and uncontrollable circumstances. **We recommend extending this deadline further as needed during the public health emergency to avoid penalizing providers.**
107	Interim Final Rule	Update to the Hospital Value- Based Purchasing (VBP) Program Extraordinary Circumstance Exception (ECE) Policy.	*Beneficial/Maintain permanently, after the expiration of the PHE* The second interim final rule with comment (IFC-2) permanently updated the extraordinary circumstances exception (ECE) policy for the VBP Program to align with the ECE policies of the other hospital reporting and programs. The AAMC continues to support this permanent change and appreciates the move toward consistency of ECE policies across hospital reporting and performance programs.
108	Interim Final Rule	Quality Reporting: Updates to the Extraordinary Circumstances Exceptions (ECE) Granted for Four Value-Based Purchasing Programs in Response to the PHE for COVID–19, and Update to the Performance Period for the FY 2022 SNF VBP Program.	*Beneficial but Prematurely Terminated/Modify to extend broad quality reporting exceptions due to ongoing nature of current PHE and Maintain permanently for future national PHEs.* The AAMC supports the CMS policy included in the third interim final rule with comment (IFC-3) that the agency may propose in the future to not apply payment adjustments in program years where it determines that, as a result of measure reporting exceptions, it has insufficient data to reliably calculate national performance. The AAMC believes this should be a permanent change to the programs' extraordinary circumstances exception (ECE) policies where such circumstances render similarly insufficient data. In assessing sufficiency and reliability of the data, the AAMC urges CMS to take a data driven approach to conducting such analyses. CMS should be fully transparent to hospitals and the public on the results of such analysis, regardless of whether CMS decides not to apply hospital value program payment adjustments in upcoming years impacted by performance data due to a national PHE or wide-reaching ECE grants.

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Centers for Medicare & Medicaid Services (CMS)			
			The AAMC also supports the action taken via guidance in March 2020 to not use data from the first two quarters of 2020, invoking the quality reporting and performance programs' ECE policies to make reporting optional. We agree that where reporting is optional, the limited data submitted in response may result in biased performance comparisons and unfair program performance calculations. **The AAMC remains disappointed by the abrupt end to hospital quality reporting relief and urges CMS to consider the impacts of the continuing COVID-19 PHE on hospital performance in 2020 and suspend the hospital quality performance programs for the duration of this public health crisis.**
109	Interim Final Rule	National Coverage Determination (NCD)	*Beneficial/Maintain permanently, after the expiration of the PHE* IFC-1 in response to COVID-19 waives NCDs and Local Coverage Determinations (LCDs) for respiratory related devices, oxygen and oxygen equipment, home infusion pumps, and home anticoagulation therapy, for the duration of the PHE. **The AAMC supports this change, which permits beneficiaries that do not otherwise require inpatient care to use these devices at home, and provides flexibility for hospitals treating patients and managing capacity issues caused by the PHE.**
111	Interim Final Rule	Communication-Based Technology	*Beneficial/Maintain changes for consent permanently, after the expiration of the PHE* IFC-1 allows communication-based technology services (e.g. remote patient monitoring, interprofessional consults, and virtual visits) to be furnished to both new and established patients during the PHE. It also allows the required annual consent to receive these services to be obtained at the time a service is furnished and that such consent may be documents by auxiliary staff under general supervision during the PHE. The AAMC supports these policies in response to the PHE, and recommend that the consent requirement in particular be made permanent to ease burden on patients and providers alike.
112	Interim Final Rule	Direct Supervision by Interactive Telecommunications Technology	*Beneficial/Maintain during the PHE* IFC-1 revises the definition of direct supervision to include virtual presence of the supervising physician or practitioner using interactive audio/video real-time communications technology to reduce infection exposure risk to the patient and/or practitioner. The AAMC supports this policy as it will reduce additional infection exposure risks.
113	Interim Final Rule	Telephone Evaluation and Management (E/M) Service Codes	*Beneficial/Maintain payment for audio-only services permanently, after the expiration of the PHE* IFC-1 allows separate payment for telephone E/M Service Codes (99441-99443) and CPT codes for the duration of the PHE. IFC-2 cross walked these services to analogous office/outpatient E/M codes for payment rates. **The AAMC strongly supports coverage and payment for the audio-**

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Centers for Medicare & Medicaid Services (CMS)			
			only E/M codes during the PHE and recommends coverage remain permanently after the PHE ends. Many services can be clinically appropriate when provided via an audio-only interaction, and that option should exist for patients. Coverage of these audio only services is particularly important for Medicare beneficiaries who may not have access to, or may not feel comfortable with, interactive audio/video technologies. Initial reports suggest that lack of video services or discomfort regarding the use of video may particularly affect vulnerable populations, including the elderly, those with low socioeconomic status, certain races and ethnicities. In addition, patients in rural areas and those with lower socio-economic status are more likely to have limited broadband access, making it more difficult to receive telehealth services by audio and video interactions. For these patients, their only option to receive services remotely is through a phone. Therefore, eliminating coverage for these important audio-only services will result in inequities in access to services for specific populations.
117	Interim Final Rule	Frequency Limitations on Subsequent Care Services in Inpatient and Nursing Facility (NF) Settings, and Critical Care Consultations and Required ‘‘Hands-on’’ Visits for ESRD Monthly Capitation Payments	*Beneficial/Modify to change the limitation on subsequent visits via telehealth and maintain permanently, after the expiration of the PHE* IFC-1 removed the frequency restrictions for a specific set of codes for subsequent NF visits furnished via telehealth for the duration of the PHE. The AAMC supports the removal of frequency limits for subsequent inpatient visits and subsequent NF visits furnished via telehealth for the duration of the pandemic. It is important to eliminate these restrictions so that patients can receive necessary services while mitigating their risk of exposure to COVID-19. We support changing the time frames in the future after the PHE to enable access to telehealth services on a more frequent basis, which CMS did in the final physician fee schedule rule. We support the change of the limitation on NF subsequent visits via telehealth from 30 days to 16 days.
118	Interim Final Rule	Inpatient Hospital Services Furnished Under Arrangements Outside the Hospital	*Beneficial/Maintain permanently, after the expiration of the PHE* IFC-1 provides payment during the PHE for routine nursing and related services, use of hospital facilities, and medical social services as inpatient hospital services, even when the hospital provides the services under arrangements outside of the hospital. **The AAMC supports this flexibility, which allows hospitals to leverage settings outside the hospital as needed to care for beneficiaries, compensating for capacity and equipment limitations caused by the COVID-19 PHE.**

Action	Type of Action	Title of action	AAMC Comments
Centers for Medicare & Medicaid Services (CMS)			
125	Interim Final Rule	Payment for Medicare Telehealth Services Under Section 1834(m) of the Act	*Beneficial/Maintain permanently, after the expiration of the PHE* **The AAMC strongly supports changes made in the CMS interim final rules related to the PHE that waived patient location restrictions that applied to telehealth services.** Under this change, CMS pays for telehealth services furnished by physicians and other health care providers to patients located in any geographic location and at any site, including the patient's home, during the PHE. This has allowed patients to remain in their home, reducing their exposure to COVID-19 and reducing the risk that they expose another patient or their physician to COVID-19. It also means that patients who find travel to an in-person appointment challenging can receive care which may be particularly important to patients with chronic conditions or disabilities who need regular monitoring. The AAMC acknowledges that CMS does not have the authority outside of the PHE to make these changes permanent. However, **we encourage CMS to work with Congress to waive the rural site requirements and allow the home to be an originating site.** During the PHE, CMS pays the same rates for telehealth services as in person services. **The AAMC strongly recommends that providers be paid the same for furnishing telehealth services as services delivered in person.** In discussions with faculty practice plan leaders, members report significant infrastructure costs to fully integrate their electronic health record systems with HIPAA-compliant telehealth programs. Physicians employ medical assistants, nurses, and other staff to engage patients during telehealth visits and to coordinate care, regardless of whether the services are furnished in person or via telehealth.
136	Interim Final Rule	Laboratory Tests: Payment for COVID–19 Specimen Collection to Physicians, Non-Physician Practitioners and Hospitals	*Beneficial/Maintain permanently, after the expiration of the PHE* IFC-1 provides reimbursement for COVID-19 specimen collection to physicians, non-physicians practitioners and hospitals. . **The AAMC appreciates and supports payment for COVID-19 specimen collection, which aids integral COVID-19 tracking, monitoring, and containment efforts that serve to protect beneficiaries.** The AAMC also urges CMS to make payment for this service permanent, as testing will play a crucial role in monitoring the virus beyond the PHE.
137	Interim Final Rule	Indirect Medical Education (IME)	*Beneficial/Modify and maintain permanently after the expiration of the PHE* IFC-1 ensures that during the PHE, when determining a hospital's IME payment amount, a hospital's available bed count is considered the same as it was the day before the PHE was declared. **The AAMC supports this flexibility, as it enables teaching hospitals to increase the number of inpatient beds to accommodate and care for patients during surges without negatively impacting IME payments**. We also request that CMS modify the policy to apply during future declarations of PHEs.

Action	Type of Action	Title of action	AAMC Comments
Centers for Medicare & Medicaid Services (CMS)			
138	Interim Final Rule	Medical Education: Time Spent by Residents at Another Hospital during the COVID–19 PHE	*Beneficial/Modify and maintain permanently after the expiration of the PHE* IFC-1 allows teaching hospitals, for direct graduate medical education (DGME) and IME purposes, to claim the time spent by residents training at other hospitals during the PHE, provided that the hospital claiming the resident pays the resident's salary and benefits. Additionally, the presence of residents in a non-teaching hospital will not trigger establishment of per resident amounts (PRAs) or full-time equivalent (FTE) resident caps at those non-teaching hospitals. **The AAMC supports this flexibility, which allows residents to provide care for beneficiaries at other hospitals, including non-teaching hospitals, without compromising critical teaching opportunities in the future.** Continuing these policies beyond the PHE would allow for increased opportunities for residents to train in different settings without triggering a non-teaching hospital's PRA or cap.
139	Interim Final Rule	Medicare Shared Savings Program (MSSP)	*Beneficial/Modify to address impact of PHE on risk adjustment and Maintain permanently for future national PHEs* IFC-2 removes payment amounts for COVID-19 episodes from MSSP expenditure and revenue calculations for Performance Year (PY) 2020 and any subsequent PY that starts during the COVID-19 PHE. The AAMC supports this adjustment as this will ensure more equitable cost comparisons. In addition to this policy change, the AAMC asks CMS to further address the impact of the PHE on prospective CMS-HCC risk scores, which are central to risk adjustment to ACO financial benchmarks. Prospective risk scores use the prior year's diagnoses to predict costs in the current year, and the AAMC remains concerns that such models will need significant adjustments to accurately account for the changes in care delivery, treatment costs for COVID-19, and future costs for delayed care to ensure that 2020 does not negatively and unfairly impact risk adjustment for the 2021 performance period and beyond.
143	Interim Final Rule	Payment for Remote Physiologic Monitoring (RPM) Services.	*Beneficial/Maintain for duration of the PHE* IFC-2 allows RPM codes to be billed for a minimum of 2 days of data collection over a 30-day period, rather than the required 16 days of data collection over a 30-day period as provided in the CPT code descriptor. The AAMC supports the changes to payment for remote physiologic monitoring services during the PHE that allows RMB codes to be billed for a minimum of 2 days of data collection over a 30-day period rather than the required 16 days of data collection over a 30-day period. This will increase access to care and improve patient outcomes. While it is possible that remote physiologic monitoring would be used to monitor a patient with COVID-19 for 16 or more days, many patients with COVID-19 who need monitoring require fewer days of monitoring.

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			Providers are only just beginning to understand the "post-COVID" care needs for patients, and the AAMC may provide further recommendations in regard to RPM services as we better understand the lasting medical complications and effects of COVID-19.
147	Interim Final Rule	COVID–19 Serology Testing	*Beneficial/Maintain permanently, after the expiration of the PHE* IFC-1 provides reimbursement for COVID-19 serology (antibody) testing for the duration of the PHE. **The AAMC appreciates and supports payment for COVID-19** serology testing**, which aids integral COVID-19 tracking, monitoring, and containment efforts that serve to protect beneficiaries.** The AAMC also urges CMS to make payment for this service under the permanent, as testing will play a crucial role in monitoring the virus beyond the PHE.
148	Interim Final Rule	Additional Flexibility under the Teaching Physician Regulations.	*Beneficial/Maintain permanently, after the expiration of the PHE* IFC-1 and IFC-2 provided additional flexibility under the current teaching physician rules. CMS will allow the teaching physician to meet the requirement to review the service with the resident, during or immediately after the visit, through virtual or remote means via interactive audio/ video real-time communications technology. The AAMC supports the policy adopted by CMS that on an interim basis the requirement to bill Medicare Part B for the presence of a teaching physician during the key or critical portion of the service furnished with the involvement of the resident can be met using audio/video real-time communications technology. In addition, we support the policy that for the primary care exception (under section 415.174(c)), the teaching physician can direct the care furnished by the resident, and review the services furnished by the resident during or immediately after the visit, remotely using audio/video real-time communications technology. In the final 2021 physician fee schedule rule, CMS makes these supervision policies permanent in rural sites after the PHE ends. **AAMC commends CMS for adopting these virtual supervision policies as they have been critical in reducing exposure to COVID-19 and enabling expanded access to health care services.** We believe these policies should be made permanent in all regions of the country after the PHE ends. 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. We believe that the teaching physician is able to exercise full, personal control over the management of the key portion of the care to bill Medicare Part B when the services are furnished by the resident with the teaching physician present through audio/video real time communications technology. The teaching physician should have the discretion to determine whether it is appropriate

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			to be present virtually rather than in person depending on the services being furnished and the experience of the particular residents involved. During the PHE, CMS has allowed residents to furnish telehealth services that are virtually supervised by the teaching physician. In the physician fee schedule final rule, CMS states that this policy regarding telehealth will be allowed on a permanent basis in rural sites. **We recommend that CMS allow residents to provide telehealth services permanently while a teaching physician is present via real-time audio-visual communications technology after the PHE ends in all regions of the country.** Resident education is a crucial step of professional development before autonomous clinical practice and requires varying levels of faculty supervision depending where the resident is in training and developing competency. As part of this development, it is essential for residents to have the experience with telehealth visits while supervised as they will be providing them in the future to their patients when they practice autonomously. This change to CMS policy will improve patient access to care while also enhancing the resident's skills.
149	Interim Final Rule	Updating the Medicare Telehealth List on a Sub-regulatory Basis	*Beneficial/Maintain permanently, after the expiration of the PHE* AAMC supports CMS emergency rulemaking during the PHE to add a number of services to the telehealth list on an interim basis and CMS's modification of the process for adding or deleting services from the telehealth list to allow for an expedited sub-regulatory process during the PHE. **We believe that experience during the COVID-19 pandemic has demonstrated the clinical utility of providing these services by telehealth and encourage the provision of telehealth services when clinically appropriate after the PHE ends.** The placement of codes on the Medicare telehealth list allows physicians and other health care professionals and their patients to determine whether delivering a service via telehealth is clinically appropriate. In the final physician fee schedule rule, CMS finalized a new Category 3 group of services which would be included on the Medicare telehealth list until the end of the calendar year in which the PHE ends to allow more time to study the benefit of providing these services outside the context of the pandemic. This new Category 3 would provide a basis for adding or deleting services from the Medicare telehealth list on a temporary basis where there is likely clinical benefit, but where there is not yet sufficient evidence available to permanently consider the services under Category 1 or 2 criteria. CMS believes that adding services to the Category 3 list will provide sufficient time to develop clinical evidence to be used to request additions to the telehealth list on a permanent basis through the normal rulemaking cycle. We support the establishment of Category 3 as an option to temporarily allow services to be billable, while the benefits are studied. **However, we believe that the time frame proposed in the rule for coverage of Category 3 services is insufficient.**

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			Instead of linking it to the end of the calendar year in which the pandemic ends, we recommend that a defined time period be set, such as the end of 2022, for providers to collect data and perform analysis on the clinical benefit of the telehealth services. We also recommend CMS consider implementing the concept of Category 3 as a permanent option to allow potential Category 2 codes time to be considered a telehealth service and obtain sufficient evidence demonstrating the benefit of providing the service be telehealth.
156	Waiver	Written policies and procedures for appraisal of emergencies at off campus hospital departments	*Beneficial/Maintain for one year beyond the PHE* During the PHE, CMS waives the requirement for surge facilities to have written policies and procedures in place for staff to use when evaluating emergencies. **The AAMC supports this change, which allows hospitals to leverage off-campus hospital departments as surge facilities to care for beneficiaries, compensating for capacity and equipment limitations caused by the COVID-19 PHE.** This waiver was made in concert with other policies that crucially enable hospitals to use additional sites of care during surges to assess, treat, and refer patients during the PHE.
164	Waiver	Physical Environment	*Beneficial/Maintain for one year beyond the PHE* During the PHE, CMS waives certain Medicare conditions of participation to allow non-hospital buildings and spaces to be used for patient care and quarantine sites to handle surges. **The AAMC supports this change, which allows hospitals to leverage non-hospital facilities to care for beneficiaries, compensating for capacity and equipment limitations caused by the COVID-19 PHE.** This waiver was made in concert with other policies that crucially enable hospitals to use additional sites of care during surges to assess, treat, and refer patients during the PHE.
176	Waiver	SNF 3-day prior hospitalization	*Beneficial/Maintain permanently after expiration of PHE* CMS waives the requirement for a 3-day prior hospitalization for coverage of a SNF stay, which provides temporary emergency coverage of SNF services without a qualifying hospital stay, for those people who experience dislocations, or are otherwise affected by COVID–19. AAMC supports this waivers and recommends that the SNF 3-day prior hospitalization requirement be eliminated permanently to better coordinate and improve care for patients. Eliminating the three-day stay would rely on physicians' judgment to ensure that their patients receive the most appropriate care in the most appropriate settings, without creating the possibility of an unforeseen financial burden on the patient.

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188	Waiver	Medicare Graduate Medical Education (GME) Affiliation Agreement	*Beneficial/Maintain for one year beyond the PHE* CMS extended the Medicare GME affiliation agreement deadline for submitting new or updated agreements, most recently to Jan. 1, 2021. **The AAMC appreciates and supports this flexibility, which acknowledges that teaching hospitals and their affiliates have needed to devote their time and resources to address the needs of their communities during the PHE. The AAMC requests that this extension last for 6 months beyond the end of the PHE.** Additional flexibility will be necessary for teaching hospitals to work with affiliates on new or existing agreements as they and their affiliates assess the long-term financial impacts of the PHE on their institutions. Extending the deadline beyond the PHE would ensure hospitals have adequate time to address these crucial agreements, which help provide care to beneficiaries in underserved areas and provide important and diverse training opportunities for residents.
189	Interim Final Rule	Allow use of audio-only equipment to furnish audio-only telephone E/M, counseling, and educational services	*Beneficial/Maintain for the duration of the PHE* CMS waived the requirements of section 1834(m)(1) of the ACT and 42 CFR § 410.78(a)(3) for use of interactive telecommunications systems to furnish telehealth services, to the extent they require use of video technology, for certain services. The AAMC supports the waiver that allows use of audio-only equipment to furnish services described by the codes for audio-only telephone E/M services and behavioral health counseling and educational services.
191	Waiver	Hospital Care of Patients	*Beneficial/Maintain for one year beyond the PHE* For the duration of the PHE, CMS waived requirements that Medicare beneficiaries be treated under the care of a physician. **The AAMC supports this change, as it permits flexibility for hospitals responding to the PHE to provide care using a variety of able, licensed practitioners while physician demand continues to climb during the PHE.**
201	Interim Final Rule	Practitioner Locations	*Beneficial/Maintain flexibility with regard to payment for services permanently, beyond the PHE* CMS temporarily waived requirements that out-of-state practitioners be licensed in the state where they are providing services when they are licensed in another state. The AAMC supports CMS's policy of allowing providers to be reimbursed by Medicare for telehealth services across state lines during the PHE. This waiver creates an opportunity to improve patient access to services and to help to improve continuity of care for patients that have relocated or who have traveled to receive their surgery or other services from a specialist in another state. While CMS has the authority to allow for payment, states need to act to allow practice across state lines to occur. **We urge CMS to continue this flexibility with regard to payment for services and to encourage states to participate in interstate medical licensure compacts or other mechanisms that would allow**

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			care delivery across state lines in the future after the pandemic ends. In addition, we urge CMS to support the Temporary Reciprocity to Ensure Access to Treatment (TREAT) Act (S. 4421, HR. 8283), which would provide temporary licensing reciprocity for health care professionals in all states for all types of services during the COVID-19 pandemic.
206	Waiver	Physician Visits in Skilled Nursing Facilities/Nursing Facilities	*Beneficial/Maintain for duration of the PHE* CMS waived the requirement in 42 CFR 483.30 for physicians and non-physician practitioners to perform in-person visits for nursing home residents and allow visits to be conducted, as appropriate, via telehealth options. The AAMC supports waiving the requirement for physicians and non-physician practitioners to perform in-person visits for nursing home residents and allow visits to be conducted, as appropriate, via telehealth options. This is critical for enabling access to critical services for nursing home residents.
210	Waiver	Remote Patient Monitoring Reporting	*Beneficial/Maintain for duration of the PHE* Under waiver authority, clinicians can now provide remote patient monitoring services to both new and established patients for the duration of the PHE. These services can be provided for both acute and chronic conditions and can now be provided for patients with only one disease, for the duration of the PHE. The AAMC supports allowing remote patient monitoring services for both new and established patients.
211	Waiver	Remote Evaluations, Virtual Check-Ins, & E-Visits	*Beneficial/Maintain for duration of the PHE* Under waiver authority, clinicians may now provide remote evaluation of patient video/images and virtual check-in services (HCPCS codes G2010, G2012) to *both* new and established patients during the PHE. The AAMC supports allowing remote evaluation of patient video images and virtual check in services (G2010, G2012) to both new and established patients during the PHE. This has enabled patient access to important services while limiting risk of exposure to COVID-19.
215	Waiver	Eligibility for Telehealth	*Beneficial/Maintain for duration of the PHE* Pursuant to the CARES Act, which broadened waiver authority under section 1135 of the Social Security Act, CMS waived the requirements specifying the types of practitioners that may bill for services furnished as Medicare telehealth services from a distant site. The AAMC supports the waiver that allows additional practitioners (e.g. physical therapists, occupational therapists, etc) to bill for telehealth services during the PHE. This allows access to these important services for Medicare beneficiaries.

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220	Guidance	Accelerated/Advance Payments	*Beneficial/Maintain for one year beyond the PHE* Through legislation, waivers, and guidance, CMS provided accelerated payments to hospitals and advanced payments to physicians and other providers to minimize the effects of revenue shortfalls caused by the COVID-19 PHE. **The AAMC strongly supports the provision of accelerated and advanced payments for hospitals, physicians, and other providers during the PHE.** We acknowledge and appreciate the modified repayment terms introduced by the Continuing Appropriations Act, 2021 and other Extensions Act in October, which gave hospitals and other providers that received Medicare accelerated and advance payments one year from when the first loan payment was made to begin making repayments and requires the loan be paid back in full 29 months after the first payment. If any money remains unpaid at that time, an interest rate of 4 percent will be charged instead of the 10% initially required.While we, appreciate these modified terms, hese and any future payments should not create additional cash flow issues for providers once the repayment period begins. As such, for any accelerated or advanced payments to provide financial assistance for providers responding to COVID-19 and other emergencies, we recommend that the repayment period before interest begins to accrue is a minimum of 36 months and that the interest rate is no more than two percent.
230	Guidance	Medicare Provider Enrollment Relief	*Beneficial/Maintain for six months beyond the PHE* CMS used its waiver authority to establish toll-free hotlines to allow certain providers and suppliers to enroll and receive temporary Medicare billing privileges and to waive certain screening requirements for providers and suppliers (e.g., finger-print based criminal background checks, site visits, etc.). The AAMC supports the waiver of screening requirements for providers and suppliers so that enrollment applications can be expedited. This is especially important to ensure that an adequate workforce is available to treat patients during the PHE. We recommend that CMS extend this waiver for six months beyond the PHE to allow the necessary time for providers and practices to get back to normal operations.
249	Waiver	Expanded Ability for Hospitals to Offer Long-term Care Services (‘‘Swing-Beds’’) for Patients Who do not Require	*Beneficial/Maintain for one year beyond the PHE* For the duration of the PHE, CMS waives eligibility requirements to allow hospitals to establish SNF swing beds payable under the SNF prospective payment system (PPS) for hospitals with patients who no longer require acute care but are unable to find placement in a SNF. **The AAMC supports this flexibility, which allows hospitals to better devote limited resources to provide acute**

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		Acute Care but do Meet the Skilled Nursing Facility (SNF) Level of Care Criteria as Set Forth at 42 CFR 409.31	**care for beneficiaries that require it, while still attending to beneficiaries that no longer need acute care with an appropriate level of monitoring.**
254	Waiver	Temporary Expansion Locations	*Beneficial/Maintain for one year beyond the PHE* For the duration of the PHE, CMS waives certain Medicare conditions of participation to facilitate the availability of temporary expansion locations. The waiver allows for temporary expansion locations, including beneficiaries' homes, to become PBDs of a hospital and bill for services furnished under the OPPS during the PHE. **The AAMC supports this change, which allows hospitals to rapidly create temporary expansion locations in order to care for beneficiaries, compensating for capacity and equipment limitations caused by the COVID-19 PHE**. However, the AAMC also requests that CMS eliminate the requirement for hospitals to submit the addresses of temporarily relocated PBDs to the CMS Regional Office. Members have cited this requirement as burdensome, shifting scarce resources away from managing other aspects of the PHE, including ensuring that beneficiaries continue to have access to care.
N/A	Interim Final Rule	New Hospital Data Reporting Conditions of Participation (CoPs) for COVID-19 and Influenza	*Harmful as implemented/Modify to remove link to CoPs and Maintain only during PHE* In March 2020, the Department of Health and Human Services (HHS) requested that hospitals report, on a daily basis, COVID-related data, including intensive care unit bed capacity, drug and personal protective equipment inventory and acquisition issues. While this reporting was not mandated, almost all hospitals complied with the request, even when reporting requirements frequently changed. As hospitals continued to voluntarily report this data, the AAMC and its members were disappointed when CMS released an interim final rule with comment (IFC) September 2 announcing that that hospital reporting of this data would be mandatory and linked to compliance with the Medicare CoPs. **The AAMC strongly opposes making COVID-related hospital reporting a requirement for Medicare Conditions of Participation (CoPs),** as we discussed in our comments to IFC-3**.**

Action	Type of Action	Title of action	AAMC Comments
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N/A	Guidance	Routine Survey Process	*Beneficial but Prematurely Terminated/Modify to extend broad quality reporting exceptions during current PHE and Maintain permanently for future national PHEs.* In response to the initial challenges presented by the COVID-19 pandemic, CMS took a number of steps to waive certain regulatory requirements and provide necessary flexibilities allowing for a swifter and more agile response. The AAMC supported these efforts to allow providers to focus on patients. However, this summer CMS prematurely began to reinstate requirements for states and private accreditors with deeming authority to resume in-person routine compliance surveys. Such regulatory relief is critical for hospitals to continue to respond to the COVID-19 PHE, especially at time when hospitals are facing worse surges than in the spring. The AAMC urges CMS to consider the impacts of the continuing COVID-19 PHE on hospital surge operations and suspend requirements for routine survey process for the duration of the national PHE.