March 18, 2022

The Honorable Bruce Westerman
United States House of Representatives
Washington, D.C., 20515

The Honorable Brad Wenstrup, D.P.M.
United States House of Representatives
Washington, D.C., 20515

The Honorable John Joyce, M.D.
United States House of Representatives
Washington, D.C., 20515

Dear Representatives Westerman, Wenstrup, and Joyce:

The Association of American Medical Colleges (AAMC) appreciates the opportunity to respond to the House of Representatives Republican Healthy Future Task Force Subcommittee on Treatments Request for Information (RFI) on medical innovation. The nation’s medical schools and teaching hospitals are important centers of innovation stemming from their diverse mission areas and play a critical role in the discovery and delivery of cutting-edge therapies, and we are pleased to provide relevant feedback to the RFI.

The AAMC is a not-for-profit association dedicated to transforming health through medical education, health 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.

AAMC-member institutions are major centers of cutting-edge medical research, with scientists and clinicians at medical schools and teaching hospitals conducting over 50% of extramural research funded by the National Institutes of Health (NIH). These anchor institutions foster an environment of discovery that has laid the scientific groundwork for nearly every major medical intervention in practice today – including transplants, immunotherapies for cancer, laparoscopic surgery, the COVID-19 vaccines, and countless other diagnostics, medications, vaccines, and other countermeasures – and that continues to promote the latest advances in medicine.

In addition to their integral role in advancing discovery, our members provide the world’s most advanced and expert patient care informed by the latest innovations in fundamental and clinical
research. In partnership with their physician faculty from affiliated medical schools, AAMC-member teaching hospitals represent 5% of all hospitals but provide 65% of burn unit beds, 98% of comprehensive cancer centers, 63% of all Level 1 Trauma Centers, and 61% of pediatric intensive care unit (ICU) beds. Our members are well established and respected regional referral centers and centers for tertiary care. They also provide treatment for a disproportionately high percentage of Medicare and Medicaid beneficiaries, as well as for those who are uninsured.

In other words, our member academic medical centers not only play a fundamental role in creating the breakthroughs of the future, they also are actively putting such innovations into practice for a diverse array of patients. Their seat at this nexus of research and care delivery gives the experts internally at AAMC and at our member medical schools and teaching hospitals a unique perspective both on the urgency with which patients and their providers seek new and more effective treatments, as well as the challenges and opportunities to accelerate our progress.

Below we have addressed the specific goals outlined in the RFI reflecting the input of internal experts at the AAMC.

**Goal 1: Evaluate potential innovative payment solutions for expensive curative therapies in Medicare and Medicaid**

*Collaborate with CMMI to Investigate Innovative Payment Methodologies for Expensive New Therapies*

The rising costs of new and innovative drugs and therapies endanger both the physical and financial health of Americans. An increasing number of patients who receive care at AAMC member institutions cannot afford the cost of their treatment. The financial burden associated with these drugs and therapies may lead patients to neglect drug regimens or forego care, resulting in inadequate treatment and worse health outcomes. The AAMC supports efforts to reduce the costs of prescription drugs and improve access to care for patients.

The AAMC recognizes that existing reimbursement models, such as the Medicare Inpatient Prospective Payment System (IPPS), do not sufficiently account for the high prices associated with new and innovative technologies. Through the IPPS, Medicare reimburses hospitals under a set of single, bundled payments (known as Medicare-severity diagnosis related groups or MS-DRGs), which often do not adequately capture the additional costs associated with expensive new treatments. One existing policy to remedy this reimbursement challenge is the New Technology Add-On Payment (NTAP), a supplemental payment to the MS-DRG payment designed to account for a hospital’s use of new and innovative technologies in patient care. Although the AAMC previously supported an increase in the NTAP, we maintain that the NTAP is not a panacea for the problems engendered by manufacturers’ high prices for innovative technologies. Notably, the NTAP does not discourage pharmaceutical manufacturers’ use of exorbitant launch prices, which both limit patients’ access and also drive up costs in our health care system. In addition, the NTAP designation is temporary, lasting approximately two to three years, and once it expires, prices for these new technologies remain high. As such, following the expiration of the NTAP designation, it becomes substantially more difficult for providers to ensure patients’ access to new curative therapies under standard IPPS payment rates.

For this reason, the AAMC encourages Congress to work with experts at the Center for Medicare and Medicaid Innovation (CMMI) at CMS to evaluate existing episode-based payment models
for specialty care and develop new solutions. Academic medical centers are on the cutting edge of implementing innovative treatments to optimize patient care. AAMC member institutions have successfully participated in CMMI Demonstration models addressing the total cost of care, including prescription drugs costs billed through Medicare Parts B and D, such as:

- The Oncology Care Model;
- The Bundled Payment for Care Improvement (BPCI) Advanced Model;
- The Medicare Shared Savings Program (MSSP); and
- The Next Generation Accountable Care Organization Model.

The AAMC and our members look forward to participating in new, voluntary models from CMMI that both reduce the costs associated with expensive curative therapies and improve patient outcomes. The AAMC encourages Congress to work with CMMI to understand how evidence from existing CMMI Demonstration models may be leveraged to inform future reimbursement models.

**Explore Alternative Reimbursement Models for Curative Therapies to Promote Patient Access**

Although the AAMC appreciates the task force’s interest in investigating new reimbursement models to improve access to high-cost therapies, we do not endorse a singular model for reimbursement for all therapies. We believe that this type of reimbursement would impede patients’ access to medically necessary curative therapies.

Chimeric antigen receptor (CAR) T-cell immunotherapies and Hepatitis C drugs are fundamentally different therapies. Chimeric antigen receptor (CAR) T-cell therapy is a promising new scientific development that has proven effective in treating certain types of cancer, including those that may be resistant to other treatment methods. CAR T-cell therapy is an infusion therapy that re-engineers a patient’s own cells to cure disease. CAR T-cell therapy is typically performed in the inpatient setting, often requiring care in the intensive care unit.

By contrast, direct-acting antivirals (DAAs) used in the treatment of hepatitis C disrupt replication of the hepatitis C virus in the body until there is an undetectable level of viral RNA in the blood (a stage referred to as “sustained virologic response”). Direct-acting antivirals can be administered to the patient via oral tablet and are generally safe and well tolerated. For these reasons, unlike CAR T-cell therapy, it is clinically appropriate for patients to take their DAA treatment course in the comfort of their home.

In other words, these two therapies require a different site of service, which involve very different costs. The inputs required to safely and effectively deliver care in an inpatient setting vastly differ from those needed to deliver care in an outpatient setting or at home. **For this reason, the AAMC does not endorse a singular model for reimbursement for these two treatments.**

**Protect Safety-Net Programs in Value-Based Purchasing Models for Drugs Covered by Medicaid**

On December 21st, 2020, the Trump Administration finalized a rule entitled “Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing for Drugs Covered in Medicaid, Revising Medicaid Drug
Rebate and Third Party Liability (TPL) Requirements,” 85 Fed. Reg. 37286. This rule was intended to provide states with regulatory flexibility to enter into value-based purchasing agreements with drug manufacturers by establishing multiple “best prices” for drugs.

Although the AAMC supports well-designed value-based purchasing arrangements as a strategy to address exorbitant drug prices, we urge the Task Force to engage stakeholders to better understand the impact of the final rule on safety-net providers.

The “best price” methodology is the foundation of the Medicaid Drug Rebate Program (MDRP) and the 340B Drug Pricing Program, two safety-net policies intended to expand access to care for Medicaid beneficiaries and other patients and communities. Under the law, pharmaceutical manufacturers that wish to have their drugs covered through federal programs must enter into an agreement with the Secretary of the of the Department of Health and Human Services (HHS) to offer state Medicaid agencies and 340B covered entities the “best price” for their drugs. This price is calculated according to the Average Manufacturer Price (AMP), minus a minimum rebate of 23.1 percent, as well as additional discount should a drug’s price rise faster than the annual rate of inflation.

The 340B Drug Pricing Program and the Medicaid Drug Rebate Program expand access to care for underserved patients. The savings generated by the 340B Drug Pricing Program enable hospitals to provide high-quality, affordable prescription drugs and health care services to low-income and rural patients. The Medicaid Drug Rebate Program provides essential savings that allow state Medicaid agencies to balance their budgets while ensuring access to care for low-income beneficiaries. The AAMC strongly believes that any proposals to curb prescription drug prices should preserve, protect, and strengthen these two programs.

As the AAMC articulated in our original comment letter in response to this proposed rulemaking, we are concerned that changes in the best price calculation may erode MDRP savings accrued to states, likely resulting in a significant increase in Medicaid drug costs.

Eliminate barriers to patient adoption of digital technology in antikickback laws

In November 2020, as part of HHS’ Regulatory Sprint to Coordinated Care, CMS published final rules to modernize and reform the regulations that interpret the federal antikickback statute and Physician Self-Referral Law (Stark). These rules removed many regulatory barriers to increase participation in value-based care arrangements and enable providers to coordinate care for patients while maintaining safeguards to protect patients against fraud and abuse. In the antikickback final rule, CMS chose to list entities that are ineligible to use each value-based safe harbor, including: pharmaceutical manufacturers, distributors, and wholesalers; pharmacy benefit managers; laboratory companies; pharmacies that primarily compound drugs; manufacturers of
devices or medical supplies; entities that sell or rent durable medical equipment, prosthetics/orthotics, and supplies (DMEPOS); and medical device distributors and wholesalers.

There is a special pathway that would allow certain medical device manufacturers and DMEPOS companies to participate as “limited technology participants” in protected care coordination arrangements that involve digital technology as long as certain requirements are met. We recommend eliminating barriers in the antikickback laws that would limit the role of companies provided that they are supporting care coordination and management through the provision of digital health technology. Innovative technologies that electronically capture, transmit, aggregate, or analyze data can be very beneficial in coordinating and managing patient care. The COVID-19 pandemic has demonstrated how critical these technologies are in patient care.

*Improve abilities of providers to furnish technologies*

We also recommend changes be made to enable providers to furnish technologies, such as wearable devices, to patients in order to facilitate their care. While the patient engagement and support safe harbor allows provision of technology to patients, there is a $500 annual limit on the amount that is allowed, which may be a barrier to providing this technology. We further support allowing arrangements where one provider, such as a hospital, could provide digital health technology to another provider (such as a physician or Skilled Nursing Facility (SNF)) to enable care coordination.

*Make telehealth flexibilities permanent*

AAMC member teaching hospitals, faculty physicians, and other providers have responded to the COVID-19 public health emergency (PHE) by rapidly implementing telehealth in their hospitals and practices in order to provide continued access to medical care for their patients. Telehealth provides both patients and providers with a variety of benefits and both maintains and expands access to care, especially to those in rural, urban, and other underserved areas. The AAMC believes telehealth is an important method to deliver health care in many circumstances and urges Congress to make legislative changes that would preserve these new practices and the gains we have made in telehealth to date, and to ensure that reimbursement remains at a level that supports the infrastructure needed to provide this level of telehealth services.

*Extend the Acute Hospital Care at Home program waiver*

The Centers for Medicare and Medicaid Services (CMS) launched the Hospital Without Walls program in March 2020 to allow hospitals to provide services beyond their existing walls to help address the need to expand care capacity and to develop sites dedicated to COVID-19 treatment. The Acute Hospital Care at Home (AHCAH) program waiver is an expansion of this initiative that allows eligible hospitals to have regulatory flexibility to treat certain patients, who would otherwise be admitted to the hospital, in their homes and receive Medicare payment under the Inpatient Prospective Payment System.

AHCAH launched with six health care systems that had experience with providing acute hospital care in a patient’s home. To date, 202 hospitals within 92 systems located in 34 states – including many teaching hospitals – have received waivers from CMS to participate in the
The increase in hospital participation underscores the critical need for continued flexibility to meet the health care needs of certain patients without having to admit them into the inpatient setting. As teaching hospitals have surged to meet the capacity demands imposed on them by the PHE, AHCAH programs have become a valuable resource to both alleviate capacity issues and provide patients access to care.

AAMC member teaching hospitals report positive outcomes and high patient satisfaction from their AHCAH patients. Hospitals have made robust investments in their programs with some viewing their AHCAH programs as a long-term solution to ongoing capacity issues. However, teaching hospitals and their patients face uncertainty regarding the future of the program due to its reliance on the consistent renewal of the PHE. The AAMC urges Congress to extend this waiver for at least two years after the PHE to ensure that hospitals that patients’ access to this program is not interrupted, and that hospitals’ investments in the program do not come to a halt.

Enable Peer-Mentored Care and Provider-to-Provider Telehealth Modalities to Support Behavioral Health Access

Provider-to-provider telehealth modalities and peer-mentored care are key tools to help support access and care coordination through IBH. These tools include interprofessional consults (e.g., eConsults), synchronous tele- and video-consultation, and Project ECHO, which help to expand the scope of practice for primary care and community-based providers and other front-line staff. eConsult programs help to increase primary care comprehensiveness and provide a pathway for PCPs to solicit feedback and guidance from their specialist colleagues. The AAMC has worked with over 40 academic health systems across the country to support implementation of eConsults throughout their health care systems. One of these partners, Oregon Health & Science University (OHSU), launched their eConsult program in March 2016 and it is now available in 26 adult and seven pediatric specialties throughout OHSU, including Adult and Women’s Psychiatry, with over 13,300 eConsults completed. Improvement in the current structure of the interprofessional consult codes used by eConsults would benefit patients by removing barriers and promoting the use of interprofessional consults.

Goal 3: Continue U.S. leadership in medical innovation

Supporting medical research to improve the health of all

To remain a global leader in accelerating the development of life-changing cures, pioneering treatments, novel diagnostics, and innovative prevention strategies, it is essential that Congress sustain robust increases in the NIH budget. Millions of patients rely on critical research taking place in labs at medical schools, teaching hospitals, and other institutions across the United States, with support from the National Institutes of Health (NIH). This work not only brings us closer to cures that improve health and alleviate suffering, it also has a multiplicative effect on local economies nationwide, creating over 536,000 jobs and generating $91 billion in economic activity.2

1 https://qualitynet.cms.gov/acute-hospital-care-at-home/resources
2 United for Medical Research. (2021 March). NIH’s Role In Sustaining The U.S. Economy.
Congress’s longstanding, bipartisan commitment to NIH has been instrumental in driving discovery and our fundamental understanding of disease and disability, especially in recent years as NIH has been recovering the purchasing power lost over a decade and half of effectively flat or reduced budgets. Yet even with the recent investment, the ingenuity of scientists in the U.S. continues to create even more opportunities to advance our medical knowledge, and the number of promising research proposals continues to substantially outpace the resources available. We must ensure that the nation continues to recognize sustained, meaningful funding increases for NIH as a key national priority, particularly as global competitors invest aggressively in research.3

An additional opportunity to enhance efficiency in medical research would be to avoid the consequences associated with the all-too-common cycles of delayed appropriations. Repeated continuing resolutions create uncertainty that is disruptive to the long-term endeavor of medical research and impose unnecessary delays on the pathway to cures. As a result, NIH staff is forced to delay promising new initiatives, patients must wait longer for the hope of better health, and researchers cannot recruit the next generation of scientists to their labs. Finalizing annual appropriations as close to the start of the fiscal year as possible is key to preventing such inefficiencies, and identifying potential opportunities to introduce greater stability in funding would help as well.

Regarding reproducibility in research, the AAMC supports the efforts currently being taken by the NIH to improve rigor and reproducibility, including the requirements for grant applications to focus on rigor of the prior research, robust experimental design, and more. The AAMC believes that all research funding agencies should clearly define their goals for increasing the rigor of research, highlight any relevant application instructions and review criteria, and provide training and resources to assist investigators and trainees in most effectively incorporating these standards into their research. As with all federal policies, harmonization of requirements and expectations across funding agencies increases efficiency and consistent implementation by grantee organizations. Congress should provide reliable and robust funding growth for research agencies to assist agencies in incentivizing efforts in rigor and reproducibility.

The AAMC previously provided feedback on the topics of research rigor and integrity to the White House Office of Science and Technology Policy in January 2020.

Another opportunity to enhance efficiency in the medical research pipeline is to address administrative burden in research. One of the key recommendations of the 2016 report from the National Academies of Sciences, Engineering, and Medicine “Optimizing the Nation’s Investment in Academic Research” was the formation of a Research Policy Board, a recommendation that we appreciate was incorporated into the bipartisan 21st Century Cures Act and has also been included in the Cures 2.0 Act H.R. 6000 in the 117th Congress. This body, comprised of federal and non-federal members, was intended to make recommendations “regarding the modification and harmonization of regulations and policies having similar purposes across research funding agencies to ensure that the administrative burden of such research policy and regulation is minimized to the greatest extent possible and consistent with


maintaining responsible oversight of federally funded research.” This essential function to streamline regulations and minimize burden has not been implemented, and we support additional Congressional efforts to ensure the formation of the Research Policy Board as already directed by Congress.

**Consider health equity to improve digital technology uptake**

With respect to the work that FDA is doing with digital health technologies, we believe that it is important for developers and regulators to also consider how innovations may exacerbate health disparities and understand their influence on patient engagement when developing digital technologies to improve health care. Efforts to advance digital technologies in health care should also account for populations with low literacy, limited English proficiency, and inadequate internet access that may make engagement with electronic platforms more difficult.

Furthermore, research has shown that health care providers’ explicit and implicit biases disadvantage racial and ethnic minorities in the health care system and must be accounted for when devising new technologies to ensure relevant information is present, appropriately represents diverse populations, and fosters enhanced patient-provider relationships.\(^4\)\(^5\) Research has also shown that minority and underserved populations are less likely to participate and engage with health technology due to mistrust.\(^6\) To improve levels of trust and uptake, we recommend that Congress incentivize health IT vendors and developers to engage with minority-serving community organizations during the design, implementation, elevation, refinement, and dissemination of digital health technologies. The AAMC Center for Health Justice [Principles of Trustworthiness Toolkit](https://www.aamc.org/principles-of-trustworthiness-toolkit/) can serve as a useful tool to help federal agencies facilitate discussions and develop strategies with community members to address pervasive issues, including ongoing inequities in awarding contract and subcontracts.

**Goal 4: Increase access to medical innovation**

**COVID-19 lessons learned in developing therapies and preventive measures**

The rapid development of diagnostic tests, treatments, and vaccines are all dependent on continued progress in scientific research, including an advanced understanding of virus biology and studies of vaccine types and efficacy. To be positioned to tackle future infectious disease challenges, the government needs to continually invest in sustained and predictable funding growth for biomedical research, through the NIH as well as other federal research agencies that fund basic research, interdisciplinary work, and translational science. (Importantly, this investment should be coupled with robust investment in our nation’s public health and health care preparedness infrastructure as well.)

The federal government plays an irreplaceable role in supporting medical research, particularly as it relates to fundamental research for which there is not immediate commercial potential. Private companies may require federal incentives to pursue public health related research and

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development opportunities. Through public-private partnerships with academia and industry, federal agencies can help advance potential solutions to otherwise intractable challenges or lay the groundwork for science to overcome challenges that have yet to manifest. To fully optimize the nation’s potential to advance new therapeutics, diagnostics, preventive interventions, and cures, and lay the groundwork for the scientific “miracles” that the next pandemic will necessitate, it will be essential to ensure that the nation sustains a commitment to robust growth for research agencies, like the NIH, over the long term.

During the COVID-19 pandemic, the remarkable success of the Biomedical Advanced Research and Development Authority (BARDA)-supported Operation Warp Speed in accelerating vaccine development and distribution was the result of the rapid partnerships between the federal government and industry, facilitated by the investment over time in BARDA, with the science built on decades of previous funding in basic research. In a February 2022 House Energy and Commerce Committee hearing on biomedical research, Rep. Fred Upton highlighted the thousands of known diseases without any cures. The ability to quickly address existing and newly emerging diseases will require active engagement from the government, academia, and industry, and federal agencies should continue to identify strategies to support such partnerships ahead of the next threat.

In addition, a healthy research enterprise equips public health officials with knowledge and tools to respond to threats, and a robust public health foundation enables officials to deliver the outcomes of research to the population widely. As such, support for medical research is a critical complement to—and, importantly, not a substitute for—sustained investment in the public health infrastructure.

The AAMC previously provided additional detail on opportunities to strengthen our preparedness in a January 31 letter to the Healthy Future Task Force Security Subcommittee and a June 2021 letter to Energy and Commerce Committee Chair Frank Pallone and Ranking Member Cathy McMorris Rodgers.

**Improving clinical trials and the patient experience**

The AAMC is supportive of the decentralized clinical trials model in an effort to increase clinical trials participation, to better understand and address barriers that may prevent diverse participation in clinical trials, and to ensure a more user-friendly experience, especially for participants from marginalized racial and ethnic groups. The AAMC encourages community participation in the design, implementation, and evaluation of clinical research and recommends specific inclusion of local community partners in discussions regarding improving public awareness of clinical trials opportunities and the utility of ClinicalTrials.gov for this purpose. The AAMC previously provided detailed feedback to the Food and Drug Administration on clinical trials diversity and enrollment practices in 2019 and opportunities to engage patients in drug development in 2018.

Relatedly, the AAMC Center for Health Justice, in partnership with community stakeholders, released *10 Principles of Trustworthiness* and a corresponding toolkit in 2021 to guide organizations, including government entities, in their efforts to equitably partner with communities and build trust among members of those communities. The principles and toolkit, which reflect core tenets of bidirectional learning and shared leadership, integrate local
perspectives around trust, COVID-19, and clinical trials participation, with established precepts for community engagement. In addition, the Center for Health Justice recently released polling data on the public’s trust in institutions and willingness to share personal health information.

In addition, health care providers and their patients can experience many benefits from the use of remote patient monitoring (RPM), including reduced readmissions, shortened hospital stays, improvements in quality of life, and lower costs. The continuous monitoring of RPM services is beneficial in academic medicine whose physicians serve patients who are often sicker than the average patient and from low socioeconomic backgrounds. These services allow physicians to track their patients’ health metrics without requiring multiple in-person visits from patients whose schedules cannot accommodate greater time commitments.

The AAMC encourages the use of RPM services and supports permanently extending and finalizing the waivers put in place by the Centers for Medicare & Medicaid Services during the public health emergency, which would decrease the requirement for monitoring from 16 days to 2, allowing individuals who would benefit from shorter periods of monitoring to receive care. Allowing fewer than 16-days of data transmission by a patient in a given month greatly increases access to care and promotes high value use. Similarly, allowing new patients to receive RPM services further improves access to care. The AAMC also supports changing CMS’s RPM rules to allow patients to manually enter their physiologic readings by a device into a platform for remote transmission. This would allow physicians to collect additional information that requires self-reporting data such as pain, appetite, and other subjective metrics which could be beneficial when managing the patient’s care.

Thank you for considering our recommendations on the important issue of improving the health of the nation. We look forward to continuing to engage with you and all of Congress on these and other critical issues. If you have any additional questions, please do not hesitate to contact me directly, Len Marquez (lmarquez@aamc.org), Senior Director, Government Relations & Legislative Advocacy, or Tannaz Rasouli (trasouli@aamc.org), Senior Director, Public Policy & Strategic Outreach.

Sincerely,

Karen Fisher, JD
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