



**Association of
American Medical Colleges**
655 K Street, N.W., Suite 100, Washington, D.C. 20001-2399
T 202 828 0460 F 202 862 6161
www.aamc.org

Darrell G. Kirch, M.D.
President and Chief Executive Officer

December 2, 2016

The Honorable Mitch McConnell
Majority Leader
United States Senate
Washington, DC 20510

The Honorable Harry Reid
Democratic Leader
United States Senate
Washington, DC 20510

Dear Majority Leader McConnell and Democratic Leader Reid:

I write to express the continued support of the Association of American Medical Colleges (AAMC) for the 21st Century Cures Act passed by the House of Representatives on November 30, 2016 (House Amendment to the Senate Amendment to H.R. 34). In particular, the AAMC commends Congressional leaders and leadership of the Senate Health, Education, Labor and Pensions (HELP) and Finance Committees, as well as the House Energy & Commerce and Ways & Means Committees for recognizing the importance of sustained investments in medical research, taking important steps to address the administrative burden on researchers, addressing the role of socioeconomic status (SES) in the Medicare Hospital Readmissions Reduction Program (HRRP), and clarifying that off-campus teaching hospital outpatient departments (HOPDs) under development should continue to receive Medicare outpatient payment rates.

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members comprise all 147 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their nearly 160,000 faculty members, 83,000 medical students, 115,000 resident physicians, and thousands of graduate students and postdoctoral trainees in the biomedical sciences.

We commend Senate HELP Chair Lamar Alexander (Tenn.), Ranking Member Patty Murray (Wash.), House Energy & Commerce Chair Fred Upton (Mich.), Rep. Diana DeGette (Colo.), Ranking Member Frank Pallone (N.J.), and all members of the HELP and Energy and Commerce

Committees, for their landmark effort through the 21st Century Cures Act to enhance the process for getting safe treatments, devices, and cures to patients, and to support the critical role of the National Institutes of Health (NIH) and NIH-supported researchers in that process. We praise the bipartisan approach to crafting Division A and the concerted effort throughout the process to better understand the challenges that the patient and research communities face in seeking improved health for all.

As the nation's premier hubs of medical discovery and innovation, medical schools and teaching hospitals welcome the legislation's recognition of medical research funding as a top national priority through the Innovation Account, which will enable appropriators to enhance the budgets of the NIH and Food and Drug Administration (FDA) over several years (Sec. 1001 and Sec. 1002). These dedicated resources will offer added funding stability to specific, multi-year initiatives at the agencies, including the Precision Medicine Initiative, the Cancer Moonshot, and the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative.

Coupled with timely enactment of the annual spending bills, this targeted funding will be an important supplement to the yearly NIH base budget increases that are essential to advance the full spectrum of research to study all diseases. We are grateful that the bill reauthorizes NIH with continued, steady budget growth (Sec. 2001). To maximize the potential of medical research, the scientific community has supported a budget trajectory that keeps pace with and enables additional growth above inflation, and we will work with lawmakers toward that goal. We also urge Congress to pass before January a full fiscal year (FY) 2017 NIH appropriation of \$34.1 billion, as approved by the Senate Appropriations Committee, and avoid the delays and inefficiencies that further continuing resolutions would impose on life-saving research. The commitment to ensure that the NIH Innovation Account augments, rather than supplants, the base NIH appropriation in FY 2017 and beyond is consistent with the intent of the original legislation and subsequent iterations, and is especially important since funding in the Innovation Account is half of the level originally approved in H.R. 6. We also strongly urge lawmakers to include the FY 2017 funding provided through this bill in any spending package enacted in December to allow its immediate use.

The AAMC applauds the bill's provisions to address some of the administrative burdens that detract from time and resources that could be invested in medical research. In particular, the AAMC is strongly supportive of Sec. 2034, which would implement many of the recommendations of the National Academies of Sciences, Engineering, and Medicine report *Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century: Part 1*. For example, the AAMC is pleased that the bill would establish a Research Policy Board as the Academies recommended but broadened the membership to include individuals with relevant expertise as urged by AAMC. We also strongly support the provisions that would reduce obligations related to monitoring subrecipients of NIH grants, require a review of various regulations concerning conflicts of interest and for research with laboratory animals to streamline and harmonize these requirements, and require a review of requirements on the reporting of financial expenditures.

This thoughtful approach to mitigating the burden of excessive or outdated federal policies will help researchers maximize their efforts toward the pursuit of cures while maintaining the highest level of integrity and transparency in their work. Similarly, we appreciate Sec. 3023, which requires the Secretary of Health and Human Services to harmonize differences in human subject regulations at federal agencies, and Sec. 3024, which allows the FDA the same flexibility as NIH and HHS in informed consent requirements for clinical trials with minimal risk.

Additionally, we praise the bill's authors for their efforts to strengthen mechanisms at NIH to assemble better data to address health disparities, improve utilization of diverse study populations, and enhance collaboration and coordination across NIH-funded clinical research projects (Sec. 2038). These provisions will greatly enrich the quality of research and better inform efforts to promote health equity. The AAMC also welcomes the bill's attention to the next generation of researchers (Sec. 2021), by reinforcing the directions that NIH and the research and research training communities have been taking to support early-career investigators. We support NIH efforts to coordinate policies and programs focused on promoting opportunities for new researchers and earlier career independence, and we support efforts around career development of trainees.

We appreciate the authors' interest in regenerative medicine, as stem cell therapies hold great promise. The bill requires regenerative medicine products to complete Phase 3 clinical trials with the opportunity for accelerated FDA approval, which would allow such therapies to advance on the basis of surrogate endpoints. In this burgeoning field of medicine, the AAMC strongly supports managing such therapies through the FDA regulatory process to ensure demonstration of safety and effectiveness before resulting therapies are used widely by patients.

With respect to the hospital and health care provisions in Division C of the package, the AAMC thanks Senate Finance Committee Chair Orrin Hatch (Utah), Ranking Member Ron Wyden (Ore.), House Ways & Means Committee Chair Kevin Brady (Texas), Health Subcommittee Chair Pat Tiberi (Ohio), Ranking Member Sander Levin (Mich.), Health Subcommittee Ranking Member Jim McDermott (Wash.), and members of both committees for their ongoing support and inclusion of the bipartisan "Helping Hospitals Improve Patient Care Act of 2016" (H.R. 5273). The AAMC strongly supports several provisions included in Division C, including language that incorporates SES into the HRRP and exempts off-campus HOPDs that either attested that the regulatory requirements were met prior to December 2, 2015 or were "mid-build" upon passage of the Bipartisan Budget Act of 2015 (BBA '15) from so-called "site-neutral" payment policies.

The AAMC strongly supports Sec. 15002 as a first step towards inclusion of SES factors into hospital quality programs. The section is based on the "Establishing Beneficiary Equity in the Hospital Readmission Program Act of 2015" (S.688/H.R. 1343), bipartisan, bicameral legislation introduced by Sens. Rob Portman (Ohio) and Joe Manchin (W.Va.), and Reps. Jim Renacci (Ohio) and Eliot Engel (N.Y.). AAMC-member teaching hospitals work hard to prevent every potentially avoidable readmission. However, the causes of hospital readmissions are complex.

Those that are related to poor quality or poor care coordination should be the targets of continual vigilance. Other admissions, however, are the result of patient-level or community-level factors that make it harder for patients to thrive upon release from the hospital. Failure to adjust for these factors particularly affects major teaching hospitals, whose missions include caring for the underserved in their communities. The SES provision in the hospital package represents an important effort toward minimizing the likelihood that teaching hospitals are unfairly penalized for factors outside their direct control.

We also strongly support Sec. 16001 which would exempt off-campus HOPDs that were under-development upon passage of the BBA '15 from so-called "site-neutral" payment policies. The AAMC is extremely concerned about the impact of reductions in HOPD reimbursement as this will lead to a reduction of services that affect vulnerable patient populations, especially those with complex medical problems, and may limit the ability to fully train the next generation of health professionals in these outpatient settings. Major teaching hospital HOPDs care for more challenging patient populations and are frequently the sole sources of care for low-income and otherwise underserved populations of Medicare beneficiaries, accepting patients who otherwise face difficulty being seen in physician offices.

While the AAMC appreciates the mid-build exemption, we were disappointed that bipartisan, bicameral flexibility championed by Sens. Portman and Charles Schumer (N.Y.) and Reps. Devin Nunes (Calif.) and Joe Crowley (N.Y.) that would allow for relocation of grandfathered off-campus HOPDs was not included in the compromise legislation. Off-campus HOPDs tailor the services they provide in response to the needs of their communities, and payment cuts due to relocation will directly impact these communities. Additionally, rapid advances in technology and treatments demand that HOPDs adapt and change to offer state of the art services to patients. These changes sometimes necessitate expansion of existing buildings or even relocation to new sites. We strongly believe that exempted HOPDs should not lose their ability to bill under the OPPI if they choose to relocate in response to changes in clinical care and the needs of their patients. We look forward to working with the 115th Congress to address these concerns.

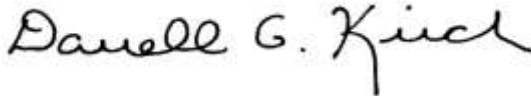
Similarly, though the bill includes some welcome language with respect to the unintended barriers that privacy regulations impose on research, we are disappointed that the updated package does not directly address these challenges. For example, the impediments to research arising from the HIPAA Privacy Rule have been well-documented by the Institute of Medicine and others. The protection of the privacy and well-being of research subjects should be adequately addressed through overarching regulations such as the Common Rule, and the inclusion of research data as protected health information has necessitated authorizations under the Privacy Rule separate and apart from the informed consent required elsewhere, a duplicative and confusing process for researchers and research subjects. Rather than appointing a new working group (Sec. 2063) to repeat a long-studied conclusion, the provision in H.R. 6 to treat research as health care operations under the Privacy Rule would have helped remove obstacles to research without jeopardizing or disadvantaging patients or research subjects.

The Honorable Mitch McConnell
The Honorable Harry Reid
December 2, 2016
Page 5

We also must register our concern that Sec. 5009 of the package repurposes scheduled increases in the Prevention and Public Health Fund, rather than investing new resources into the worthy initiatives supported through this legislation. We recognize the difficult choices lawmakers faced in crafting this package, but reallocating existing investments across the health continuum ultimately will be counterproductive to making cures more accessible to all Americans. We are heartened that, in addition to the initiatives described above, the bill supports critical investments in opioid abuse prevention and treatment activities, and we look forward to working with Congress to better preserve the important resource that the Prevention Fund provides for public health activities vital to the nation's health and well-being.

Once again, we appreciate the unrelenting dedication and commitment of lawmakers to advance this important legislation and the health of America's patients. We urge its swift passage.

Sincerely,

A handwritten signature in black ink that reads "Darrell G. Kirch". The signature is written in a cursive, slightly slanted style.

Darrell G. Kirch, MD
President and Chief Executive Officer