AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Diana DeGette
United States House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Fred Upton
United States House of Representatives
2183 Rayburn House Office Building
Washington, DC 20515

Dear Representatives DeGette and Upton:

The American Medical Association (AMA) appreciates the opportunity to provide comments on H.R. 6000, the "Cures 2.0 Act." The AMA is strongly committed to advancing the adoption of digital health, supporting innovative health tools, increasing diversity in clinical trials, ensuring access to genetic testing, and reinforcing the nation's public health infrastructure and preparedness for future pandemics and public health emergencies. We look forward to working with Congress to ensure that these goals are achieved through the passage of Cures 2.0.

Telehealth

The AMA strongly supports the "Telehealth Modernization Act of 2020" and applauds the inclusion of this bill in Cures 2.0. It is critically important that Medicare beneficiaries continue to be able to access telehealth services from their physicians without arbitrary restrictions throughout the COVID-19 public health emergency and beyond. This bill would provide this coverage by eliminating section 1834(m) statutory restrictions on originating site and geographic location, thereby ensuring Medicare coverage of telehealth services regardless of where the patient is located.

Telehealth services have played a critical role in allowing physicians to continue to manage their patients' care while remaining at a safe physical distance from medical practice staff and other patients during the COVID-19 pandemic, as well as avoiding contact that can occur during transportation to and from medical appointments. It is critical that access to telehealth services continue beyond the public health emergency. Besides their use to manage care for patients with respiratory and other symptoms that could reflect COVID-19, telehealth is being used for: patients with a variety of symptoms and acute and chronic conditions that can be evaluated and managed remotely; those who need hospice or palliative care; following up after hospital and emergency department services; behavioral health and addiction treatment; and pain management.

Access to telehealth services can help reduce inequities in care for underserved communities by providing access to services for patients regardless of where they are located. Patients in rural areas or underserved urban communities often have to travel long distances to access care, especially specialty services including emergency and critical care. Provision of telehealth services to patients in their home or other location is a huge advantage for patients with mobility or functional impairments or other problems that make travel difficult, and it is preferable for immunocompromised patients and those with communicable diseases. It allows physicians to see patients who have functional impairments in their usual living environment, instead of examining them after what may have been an arduous and stressful travel

experience to obtain in-person care. In addition, it allows physicians to see patients with sporadic symptoms when these symptoms occur and improves care for conditions where seeing the patient's living environment can inform treatment plans. Telehealth also facilitates team-based care by allowing other physicians, health professionals, caregivers, and family members to join patient visits from their own location.

Congress enacted much-needed reform last year to permanently waive origination and geographic restrictions for patients needing mental health services via telehealth; however, this expansion only applies to mental health services and requires a patient to have an in-person evaluation within six months of the first telehealth visit with their provider, despite a lack of evidence demonstrating this had a clinical impact or the lack of a similar requirement on substance use disorder (SUD) or co-occurring SUD/mental health conditions. We urge Congress to eliminate this arbitrary restriction, expand the ability to use telehealth services to all Medicare beneficiaries, and allow medical specialty societies to determine when it is appropriate to treat a patient or establish a doctor-patient relationship.

In conjunction with expanded access to telehealth services, the AMA supports Congressional efforts to expand high-speed broadband internet access to underserved communities and increase digital literacy education efforts. Patients cannot take advantage of telehealth services if they do not have the requisite internet connection to access them or the appropriate skills to use digital technologies. Providing digital literacy skills is particularly important for non-English speaking patients and is another crucial aspect of ensuring health equity. Solving this problem requires enhanced funding for broadband internet infrastructure in rural areas and support for underserved urban communities and households to gain access to affordable internet access, as well as support for patient education on how to use digital tools.

The success of telehealth technology adoption during the COVID-19 public health emergency has made it abundantly clear that this technology should be available to all Medicare patients regardless of where they live or how they access telehealth services.

Genetic Testing and Precision Medicine

The AMA supports coverage of genetic testing and other precision medicine services when medically necessary. As a result, we are concerned that the current approach may disincentivize payer coverage of these services because a section 1115 demonstration project approach may give the impression that these services are experimental or that additional studies are needed to support their use.

We note in particular that, currently, for Medicaid beneficiaries under 21 years of age, coverage of diagnostic testing is not restricted by any given state's general Medicaid policies thanks to the Early and Periodic Screening, Diagnosis and Treatment (EPSDT) benefit. The EPSDT benefit requires states to cover a full array of medically necessary treatments and interventions, including diagnostic testing, for Medicaid beneficiaries < 21 years of age regardless of whether such services would normally be covered by that state's Medicaid program. Since the services described in section 407, including exome and genome sequencing (ES/GS), are not experimental, states should already be covering them for children when medically necessary (although we note that each state has their own definition for medical necessity). Under AMA policy, children should be offered diagnostic testing for conditions for which there are effective measures to prevent, treat, or otherwise ameliorate. Additional information from the states about how often different types of genetic sequencing tests are requested by a provider, how often those requests are denied, reasons for denial, and whether alternative testing is recommended, would be

useful to better understand how the EPSDT benefit is currently used and may help better define a demonstration project or coverage requirements.

The AMA agrees that state-led genetic testing programs should be coupled with robust administrative support, as studies indicate that Medicaid patients receive significantly fewer genetic tests than those with private insurance (including for conditions with the highest clinical utility, such as ovarian cancer or drug prescribing). In addition, the AMA encourages any state-led program to include a comprehensive plan for if and when providers should communicate any potential incidental findings (i.e., medically relevant results that were unrelated to the initial goal of testing) to the patient and/or family at risk of carrying the same traits. Such a plan should be clearly defined and clearly communicated to the patient prior to testing, which may include a discussion on the medical and psychological impacts testing may have on relatives who have not provided consent at the time of testing.

With genetic testing becoming a more powerful tool for predictive and preventive care, especially in pediatric populations, the AMA also encourages Congress to consider expanding non-discrimination protections for genetic information. Recently, the AMA's House of Delegates expanded their support for the Genetic Information Nondiscrimination Act of 2008 (GINA) to include life insurance, disability insurance, and long-term care insurance. As a landmark piece of consumer protection legislation, GINA protects patients from having their genetic information be used in a discriminatory manner in health insurance and employment, but lacks the key protections listed. Patients and their guardians should not have to refuse genetic testing if they fear the results could lead to severe economic repercussions later in life, especially given the immense health benefits that can be realized through early detection.

The AMA appreciates Congressional interest and action in ensuring access to genetic testing and would be happy to work with Congress and other stakeholders to help identify the best approach to achieve coverage for necessary genetic testing.

Public Health

The AMA supports the provisions in Cures 2.0 on further understanding the implications of long-COVID, including directing the Secretary of Health and Human Services (HHS) to conduct a large national survey of patients who self-identify as having long-COVID to assess sources of health coverage, long-term care coverage, and disability coverage and to convene ongoing long-COVID learning collaborative meetings with individuals and organizations representing key sectors of the health care community. The AMA also strongly supports the provision directing the National Academy of Medicine to conduct a study to evaluate disparities in long-COVID; COVID-19 has disproportionately impacted communities of color, including Black, Hispanic, American Indian, and Alaska Native individuals, who continue to experience challenges in accessing health care. In addition, the AMA supports the inclusion of portions of the COVID-19 Long Haulers Act that direct the HHS Secretary to develop and disseminate education and awareness programs on long-COVID to providers and the public.

The AMA strongly supports the provisions on improving health literacy to promote better outcomes for patients. This is especially critical in terms of health equity and improving health disparities for underserved communities, especially those living in rural areas and marginalized communities. Likewise, the AMA supports the provisions designed to increase diversity in clinical trials. Moreover, the AMA supports allowing Medicare to cover the costs of their beneficiaries in PCORI-funded clinical trials. However, the AMA does not believe this should be limited only to PCORI-funded clinical trials; we support mandating third-party payer coverage of patient care costs (including co-pays/co-

insurance/deductibles) of nationally approved, scientifically based research protocols or those scientifically based protocols approved by nationally recognized peer review mechanisms.

Pandemic Preparedness and Funding Advanced Research Through ARPA-H

The AMA strongly supports Congressional efforts to ensure America is better prepared for future pandemics. The Cures 2.0 Act includes a number of provisions that are vitally important to help prevent the development of a future pandemic as well as meet the demands of a pandemic when it occurs, including supporting vaccination and immunization programs, increasing funding for the discovery of new antibiotics, and mandating a national strategy to prevent and respond to pandemics.

The AMA believes there are a number of areas that can be improved upon and are critical to combatting future pandemics that can be incorporated into Cures 2.0 and its implementation. These areas include:

- Creating better coordination across federal and state governments and streamlining pandemic response logistics;
- Improving and reinforcing diagnostic testing infrastructure, organization, and regulation;
- Ensuring accelerated vaccine and therapeutic development is funded and guided by evidence that protects the health of subjects and patients;
- Enhancing state and federal stockpiles and improving the system for acquisition and distribution of medically necessary supplies;
- Creating and maintaining a comprehensive, well-coordinated, and culturally sensitive data collection strategy that provides appropriate privacy and security protections with regard to individual data;
- Ensuring digital contact tracing efforts are built around privacy and transparency to promote trust;
- Protecting physicians and other health care professionals on the front line of pandemic response from increased liability arising from situations outside of their control by making liability protections automatic when a public health emergency is declared;
- Providing consistent, sustainable funding to support our public health infrastructure; creating incentives, including loan forgiveness and debt reduction, to help strengthen the governmental public health workforce in recruiting and retaining staff; modernizing public health data and data governance efforts as well as supporting efforts to promote interoperability between health care and public health; and efforts to ensure equitable access to public health funding and programs; and
- Supporting the legal authority of health officials to enact reasonable, evidence-based public health measures, including mandates, when necessary to protect the public from serious illness, injury, and death.

The AMA also strongly supports Congressional commitments to increased funding for advanced research, including through the creation of Advanced Research Projects Agency for Health (ARPA-H). We have long standing policy supporting research innovation and funding (for NIH) and believe this program would expand on our priorities of public and private investment in innovation.

Breakthrough Device Coverage

The AMA strongly supports the policies that establish a clear and predictable pathway to payment for innovative technologies that are supported by high quality, clinically validated data that help advance the

quadruple aim of enhancing the patient experience of care and outcomes, improving population health, reducing overall costs for the health care system while increasing value, and supporting the professional satisfaction of physicians and the health care team. Improving communication between the FDA and CMS over breakthrough therapies, fast track-designated products, or products eligible for accelerated approval, as section 305 of the bill proposes, is necessary to ensure that coverage decisions on such products can be made as quickly as possible. However, we have concerns with mandating coverage for products without a determination by HHS that such coverage is reasonable and necessary for the Medicare program, particularly where the evidence supporting market authorization may not meet FDA's typical standards.

The U.S. Food and Drug Administration's (FDA) Breakthrough Device program is designed to allow for speedy market access for devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions where no approved or cleared alternatives exist and the breakthrough technology offers significant advantages over available alternatives. Upon receiving a breakthrough designation, the FDA provides interactive advice during the early development stages of the device and prioritizes review when a full application is submitted to the Agency. In addition, a breakthrough device application may be granted without a pre-approval inspection of quality controls if the device is granted market authorization under a premarket approval (PMA). The PMA approval or 510(k) notification for a breakthrough device may be predicated on novel study designs and be approved or granted clearance based on less evidence than would typically be required because of the potentially impactful benefits of the technology. In those cases, the FDA will require additional postmarketing studies to confirm the safety and efficacy of the device.

This bill would accelerate coverage of breakthrough devices by mandating coverage of a breakthrough device upon the date of market authorization for up to four years. This proposal would include a presumption of coverage after the four-year period if the Secretary does not identify additional necessary studies after the first year in the four-year automatic coverage period or propose to modify the coverage within the first two years of the four-year automatic coverage period.

The AMA is also concerned that the provisions for coding could interfere with normal processes for determining payment and coverage and could also impact coverage of similar products in the future. The proposal, if implemented, would assign a "unique code" for each breakthrough device, which may make it more difficult to provide coverage for follow on devices.

In addition, the AMA believes that greater transparency surrounding breakthrough-designated devices is necessary in order to clarify to clinicians and payors the potential number of devices that may be approved and ultimately covered through this pathway. The FDA should disclose breakthrough designations as they are made to clarify which devices may be eligible for this pathway if they receive approval through the Breakthrough program, which would provide stakeholders with additional transparency into a process which, as proposed, offers little. Currently, the FDA does not disclose devices which have requested and received breakthrough designation under the Food, Drug, and Cosmetic Act. Instead, the Agency relies on companies to disclose this information as they see fit.

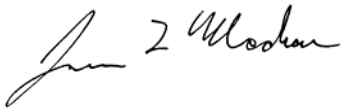
Finally, we have concerns that mandated coverage could lead to increased costs to CMS and could have negative impacts on paying for other services, depending on how it would eventually be implemented and appropriated.

The AMA remains steadfastly supportive of clear, predictable, least burdensome pathways to coverage for innovative technologies. However, we must ensure that the technologies we provide to our nation's Medicare beneficiaries are safe, effective, high quality, and meet the goals of the quadruple aim. We look forward to working with Congress to ensure that any plan to cover new technologies meets these aims.

Conclusion

The AMA appreciates the opportunity to provide comments on the Cures 2.0 Act and looks forward to working with Congress and other stakeholders to ensure policies support and promote physicians' ability to practice medicine in the innovative health care environment of the 21st Century through new technologies and cures.

Sincerely,



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