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American College of Medical Genetics and Genomics
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July 30, 2024

The Honorable Diana DeGette
U.S. House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Larry Bucshon
U.S. House of Representatives
2313 Rayburn House Office Building
Washington, DC 20515

Re: Cures 2.0 Request for Input (June 2024)

Dear Representatives DeGette and Bucshon:

The American College of Medical Genetics and Genomics (ACMG)[1] appreciates the opportunity to provide feedback on topics for the Cures 2.0 legislative initiative. While some policies in Cures 2.0 have advanced, there are still important policies in Cures 2.0 that need additional attention. One of the original goals of Cures 2.0 was to reform Medicare coding, coverage, and payment to better support patient access to medical therapies. Related to this, we have highlighted some specific sections of Cures 2.0 that still need to be addressed.

Sec. 402: Strategies to Increase Access to Telehealth under Medicaid and Children's Health Insurance Program

Section 402 of Cures 2.0 focused on improving telehealth services for kids, especially those covered under Medicaid and the Children's Health Insurance Program (CHIP). While the availability and use of telehealth has improved in recent years, there are still many challenges that remain, including some that are specific to pediatric visits. First, telehealth visits for children, just like in-person visits, require the presence of a parent or guardian. However, provisions are generally not made to assist the parent or guardian to appear together with

[1] The ACMG is a prominent authority in the field of medical genetics and genomics and the only nationally recognized medical professional organization solely dedicated to improving health through the practice of medical genetics and genomics. The only medical specialty society in the US that represents the full spectrum of medical genetics disciplines in a single organization, the ACMG provides education, resources and a voice for more than 2,500 clinical and laboratory geneticists, genetic counselors and other healthcare professionals. ACMG's mission is to improve health through the clinical and laboratory practice of medical genetics as well as through advocacy, education and clinical research, and to guide the safe and effective integration of genetics and genomics into all of medicine and healthcare, resulting in improved personal and public health.

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the child during the workday, which requires them to stay home from work or interrupt their workday and co-locate with the child in a private, internet-enabled space. Daycare businesses and workplaces are not configured for this, nor are community centers. Further, homes may not be technically enabled for videoconferences. When it comes to telehealth policies for pediatrics, consideration must be given to the requirements for the entire sphere of the telehealth visit environment.

In many jurisdictions and health systems, signing a written consent for diagnostic genetic testing is required by state law or local policy. Such signatures are not able to be obtained during a telehealth visit, complicating and often delaying access to medically indicated diagnostic testing. This signature requirement is at odds with the accepted policy of documentation in medical records of verbal consent for any other procedure or consent-appropriate activity. Such laws and policies that require different treatment of diagnostic procedures just because they are genetic are not based on science, medical, or legal value. Such state laws and policies should be prohibited at the Federal level, at least in the context of a telehealth visit, to the extent possible by federal regulations and law.

Sec. 403: Extending Medicare Telehealth Flexibilities

Section 403 of Cures 2.0 focused on policies to improve access to telehealth, however there are many telehealth policies that are only permitted by temporary waivers. For example, geographic restrictions require a patient to live in a rural area to use telehealth services. However, the past several years have demonstrated the value of telehealth services for a range of patients, regardless of their proximity to a clinic or major medical center.[2] Telehealth visits reduce unnecessary exposure to infectious diseases, such as during the peak of the COVID-19 pandemic, which is critical for those who are immunocompromised. Further, travel barriers impacting access to healthcare are not limited to travel distance, such as general lack of transportation, child

[2] Williams HE, Aiyar L, Dinulos MB, Flannery D, McClure ML, Lloyd-Puryear MA, Sanghavi K, Trotter TL, Viskochil D; ACMG Advocacy and Government Affairs Committee. Electronic address: documents@acmg.net. Considerations for policymakers for improving health care through telegenetics: A points to consider statement of the American College of Medical Genetics and Genomics (ACMG). *Genet Med*. 2022 Nov;24(11):2211-2219. doi: 10.1016/j.gim.2022.07.017. Epub 2022 Aug 30. PMID: 36040445.

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or elder care for other family members, difficulty traveling due to mobility or other health issues, and limitations with taking time off from work. Telehealth also expands access to providers in specialties with smaller workforces and/or critical workforce shortages, such as medical genetics and genetic counseling.[3] For example, individuals affected by rare genetic disorders may only receive informed, adequate care and treatment at a healthcare center with expertise in their specific disorder. Often this may be two or more states away. Current telehealth proximity regulations, even with waivers, assume all appropriate care can be found nearby which is often not the case for rare disorders. Patients with rare disorders have an additional burden of having to physically travel to a center of excellence to receive disease-informed care. Permitting telehealth visits for patients with rare disorders to centers with high expertise anywhere across the country would not only improve care, but it would also enable larger patient cohorts to accrue to study rare disorders and test new therapies. Carving out exceptions for rare and genetic conditions where disease-specific expertise does not exist in the geographically permitted telehealth region would greatly facilitate both better care and faster advancement of care innovations. Further, there remains a need to address current state licensing rules that require physicians with expertise in these rare conditions to have active medical licenses in the states that the patients are accessing the telehealth services. In some parts of the country, this would require individual physicians to have five or more medical licenses to provide telehealth follow-up visits even if seen in person for the initial visit.

There are also technological barriers in access to telehealth, such as access to smart devices or computers, broadband internet, or sufficient wireless data packages. While policies are needed to improve access to audio-visual technology, there are many types of healthcare services that can be appropriately delivered via audio-only technology.[4] Thus, coverage of audio-only telehealth services is another critical aspect of expanding access to telehealth flexibilities.

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[3] Government Accountability Office. Genetic Services: Information on Genetic Counselor and Medical Geneticist Workforces. GAO-20-593. July 30, 2020. https://www.gao.gov/products/gao-20-593.

[4] Williams HE, Aiyar L, Dinulos MB, Flannery D, McClure ML, Lloyd-Puryear MA, Sanghavi K, Trotter TL, Viskochil D; ACMG Advocacy and Government Affairs Committee. Electronic address: documents@acmg.net. Considerations for policymakers for improving health care through telegenetics: A points to consider statement of the American College of Medical Genetics and Genomics (ACMG). *Genet Med*. 2022 Nov;24(11):2211-2219. doi: 10.1016/j.gim.2022.07.017. Epub 2022 Aug 30. PMID: 36040445.

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During the nationally declared COVID-19 public health emergency (PHE), the Centers for Medicare and Medicaid Services (CMS) was able to waive many policies that limited access to telehealth, including geographic site restrictions and use of audio-only technology. However, they do not have the authority to make these waivers permanent. Since the end of the PHE, Congress has acted annually to extend these waivers, but the lack of permanent policies creates challenges for long-term planning. It requires that Congress and healthcare advocates spend time every year pushing for the same policy extensions. It also creates policy and medical billing challenges for CMS who must determine the best use and valuation of new CPT codes for certain telehealth services. For example, since certain telehealth flexibilities authorized by Congress are set to expire at the end of this year, CMS's proposed rule for CY 2025 Physician Fee Schedule payment policies had to be written with the assumption that those flexibilities won't exist in CY 2025.[5] With regard to geographic site restrictions, CMS notes in the proposed rule that, since the flexibilities were only authorized through CY 2024, "*most Medicare telehealth services will once again, in general, be available only to beneficiaries in rural areas and only when the patient is located in certain types of medical settings*". Further, clinics must account for these uncertain policies when planning and scheduling patient visits for the subsequent year. It is critical that the extended telehealth waivers, especially those for geographic site and audio-only technology, be made permanent for the benefit of patients and community health.

Sec. 407: Expanding Access to Genetic Testing

Thanks to our growing understanding of genetics and how it relates to human diseases, we are seeing a surge in the development of therapies for rare diseases and unique subsets of more common diseases. However, before we can take full advantage of these new therapies, we must be able to identify and diagnose those who are likely to benefit from such therapies. Although advances in testing technology are enabling faster, more precise diagnoses, access to and coverage of these tests has not kept up. We must ensure patient access to clinical testing services before we can understand how best to treat them.

[5] Centers for Medicare and Medicaid Services. Medicare and Medicaid Programs: Calendar Year 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; etc. Jul7 31, 2024. 2024-14828.

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Section 407 of Cures 2.0 included policies which aimed to increase access to genetic testing for pediatric patients with rare and undiagnosed diseases. Payer coverage of clinical sequencing (genome and exome) as well as many gene panels remains severely limited, including for Medicare and Medicaid. Patients should have access to clinical genetic testing services when recommended by an appropriately trained professional. Further, coverage should not be limited to a specific type of testing technology. There are benefits and limitations to the various types of genetic testing, and an appropriately trained healthcare professional may recommend sequencing (e.g., genome, exome, or a gene panel) based on an individual patient's medical history, family history, and results from other tests.

Patients also need to access such testing in a timely manner. For example, a patient with certain medical complexities may be a good candidate for testing, and they should receive genetic testing as early as possible to ensure they are able to benefit from the potential diagnosis and possible interventions. Waiting until symptoms are so severe that the patient is admitted to an intensive care unit, and transferred emergently to a specialized treatment facility, may be too late and ultimately costs the healthcare system more to care for these individuals.

Although section 407 focused on pediatric patients, coverage of clinical genetic testing services for all medically complex patients should be explored. In all cases, coverage for reuse and reanalysis of genomic sequences must also be available to minimize the potential need for resequencing later, and to recognize the value of laboratory professionals in this important work. Unlike many other laboratory tests that check for clinical markers or findings that change over time, an individual's genetic sequence does not change. However, our knowledge of the association of specific genetic variants to disease is continually evolving. Reanalysis of a genome does not require that the testing itself be repeated, but a trained laboratory genetics professional must spend time to redo the computational and interpretive analysis of the existing sequence data which is often not reimbursed by payers.

While some states have passed policies for coverage of rapid genome sequencing in critically ill neonates, these policies only exist in a handful of states, are limited to a specific type of technology, and are largely limited to neonates. Policies are needed to support improved access to genetic testing services nationally for patients of all ages suspected of having a genetic

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condition, regardless of testing methodology. There is also a need to address payer prior authorization policies which often lead to unnecessary delays in accessing testing and diagnoses for many now treatable diseases.

Sec. 408: Medicare Coverage for Pharmacogenetic Consultations

Section 408 of Cures 2.0 would provide Medicare coverage for pharmacogenetic consultations by qualified clinical pharmacists. Pharmacogenetic tests provide information about natural genetic variation that may alter the way a person responds to or metabolizes certain medications. Such genetic differences can result in severe, even life-threatening events, while others diminish or block the medicine's intended therapeutic effects. Without knowing if a patient has such genetic variations, which are quite common, through testing, trial-and-error is the only prescribing approach available. Also, having that information before prescribing is much more useful than after a treatment failure or costly or deadly side-effect has occurred. Scientifically valid clinical guidelines exist for changing medications in the face of genetic prescribing mismatches, including those in the FDA's own Table of Genetic Biomarkers and independent organizations like the Clinical Pharmacogenetics Implementation Consortium (CPIC).[6] Yet Medicaid coverage of pharmacogenomic testing is poor and inconsistent across the country and is also very limited in most Medicaid environments. In this context, licensed pharmacologists and pharmacists are best suited to integrate genetic information into prescribing, including knowledge of drug-drug interactions, drug-disease interactions, and drug availability/accessibility, in addition to the drug-gene interaction. While the original language in Cures 2.0 included genetic counselors in this proposed coverage policy, that would only be appropriate for genetic counselors that are specifically trained in this area. We also note that genetic counselors are not trained in prescribing medications.

As more pharmacogenetic tests become available for routine clinical use, education of healthcare professionals relying on such test results is increasingly important. The Right Drug Dose Now Act of 2024 (HR 7848) would help by requiring development of guidance for healthcare professionals using such test results. The bill would also require development of guidance for healthcare professionals, leaders, and administrators on improving electronic health

[6] Clinical Pharmacogenetics Implementation Consortium. CPICPGX.org. Accessed July 24, 2024.

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records (EHRs), including electronic prescribing systems and real-time pharmacy benefit checks, to identify when pharmacogenomic testing is appropriate, identify drug-gene interactions, and improve reporting of adverse drug event information to the FDA Adverse Event Reporting System (FAERS).

Commercial software that integrates into EHR systems is available. It alerts prescribing healthcare professionals when they are about to prescribe a medication or a dose for which a potential problem exists in the patient's known genetic information. These tools are essential for the safe and effective implementation of pharmacogenetic test usage since the test may have been ordered by another clinician unbeknownst to the current prescriber. These tools also ensure that every prescription need not result in a consultation with a pharmacogenetically-trained pharmacist. This component of a properly implemented pharmacogenetics system in healthcare systems is often overlooked or perceived to be harder than it is. Educating healthcare systems on how to approach this EHR enhancement should be a critical goal or even a requirement.

In relation to section 406, "Secretary of HHS Report on CMS Computer Systems: requires the Secretary of HHS to submit a report on the current capabilities and deficiencies of CMS's computer systems," it would not be unreasonable to suggest that CMS develop or contract for a national resource for storing and querying known clinically relevant genetic data, especially pharmacogenetic results from testing paid for by CMS. This would greatly facilitate the safest and most effective prescribing among tested Medicare beneficiaries, regardless of where they obtain their CMS-paid healthcare, by eliminating the need to replicate data across all healthcare systems that a patient visits.

<u>Sec. 501: Advanced Research Projects Agency for Health</u>

There remain multiple critical barriers to transforming scientific, health management, and novel healthcare approaches into routine healthcare practice. NIH's traditional research funding mechanisms were not designed for that, and certain innovations, like using pharmacogenetic information in routine practice, are not addressable by commercial enterprise stepping up. There is a role for CMS, through ARPA-H or other less NIH-like endeavors, to not just fund but also facilitate and actively support efforts to modernize medical practice. The magnitude of our existing system's "negative momentum" is staggering and was only exacerbated by the COVID-19

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pandemic and the subsequent financial cliffhanger. To overcome that, facilitating systematic practice introductions not sought by financially strapped health systems by practitioners who are neither researchers nor project managers is essential. We hope that CMS can expand such efforts to rapidly modernize medicine, especially advances that use an individual's inherited genetic information (not just variants in their cancers) to improve preventive care, prescribing, and therapies.

Other: Access to Clinical Testing Services

Clinical testing services are critical for healthcare, but the Food and Drug Administration's (FDA) recently finalized rule to regulate laboratory developed tests (LDTs) as medical devices threatens access to testing services throughout the United States by placing enormous and potentially unmanageable burdens on clinical testing laboratories. For example, in its Final Regulatory Impact Analysis, the FDA estimated that the cost of a premarket approval application for a single test could be upwards of $4.3 million. Yet, this exceeds the average annual revenue of most laboratories impacted by the rule. Further, a single laboratory needs to offer numerous tests to meet patient needs, especially when they are servicing clinics and academic medical centers that cover multiple medical specialties. The financial burdens of the FDA rule are unrealistic for clinical testing laboratories. As a result, many clinical testing laboratories, especially those at academic medical centers, will be forced to significantly consolidate testing menus or even shut down altogether. The downstream effects of such impacts include market consolidation to fewer labs, primarily commercial reference labs, increased turnaround time for test results, and reduction in quality of patient care overall. Increased turnaround time negatively impacts care, particularly for critically ill individuals, sick newborns, and patients awaiting an organ transplant. As another example, a rapid turnaround time for pharmacogenomic testing results is critical for hospitalized patients being prescribed new medicines; pharmacogenetic testing has been reported to reduce length of hospital stay, for example, among COVID-19 inpatients.

Additionally, LDTs are clinical testing services and thus the medical device regulatory pathway does not align well with LDTs. We recognize that there is much interest in Congress to address this issue through regulation, including many members who believe that FDA does not have the authority to regulate LDTs as medical devices. There is also a pending lawsuit challenging the FDA's

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authority over LDTs. Earlier this year, many stakeholders responded to a request for information (RFI) from the Senate HELP Committee. The RFI sought information on regulatory reforms needed for in vitro diagnostics (IVDs), such as manufactured test kits that are boxed and shipped to laboratories throughout the United States, and regulatory needs for LDTs. We appreciate that this RFI recognized that the regulatory reform needs for IVDs and LDTs may be different, and we encourage Congress to pursue such legislation and stop implementation of this FDA rule which will ultimately harm patients by negatively impacting clinical testing laboratories and access to the services they provide.

ACMG appreciates the opportunity to provide input on policies to advance the goals of Cures 2.0. For questions or additional information, please contact ACMG's Public Policy Director, Michelle McClure, PhD at mmcclure@acmg.net. We look forward to continuing to work with your office on the Cures 2.0 initiative.

Sincerely,

Susan D. Klugman, MD, FACMG
President
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