

December 16, 2019

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

The Honorable Fred Upton  
U.S. House of Representatives  
2183 Rayburn House Office Building  
Washington, DC 20515

Sent electronically to: [cures2@mail.house.gov](mailto:cures2@mail.house.gov)

## Re: Cures 2.0 Request for Input

Dear Representatives DeGette and Upton:

The American College of Medical Genetics and Genomics (ACMG) appreciates the opportunity to provide feedback on topics for the Cures 2.0 legislative initiative. ACMG is the only nationally recognized professional membership organization dedicated to improving health through the practice of medical genetics and genomics. Our membership includes over 2,300 genetics professionals, nearly 80% of whom are board-certified clinical and laboratory geneticists and genetic counselors.

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. For this reason, some of the comments below focus on access to clinical testing. While our comments are separated out to reflect the four main goals described in the Cures 2.0 call for input, we note that many of these topics span more than one category.

### 1. Access and coverage of digital health technologies

- Avoidance of overly burdensome regulatory barriers and implementation delays  
Unnecessary or overly burdensome regulatory oversight can result in barriers for implementation of and access to digital health technologies. There are many types of technologies for which either the regulatory oversight approach is unclear or the technologies are being subjected to regulatory processes that were not designed for such technologies. Clinical decision support modules, artificial intelligence/augmented intelligence (AI) algorithms, chatbots, and multianalyte algorithm assays (MAAAs) are some examples of newer technologies that pose

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challenges. Although the 21<sup>st</sup> Century Cures Act attempted to address some of these, there remains a lot of uncertainty regarding which technologies fall under the jurisdiction of FDA or other regulatory bodies. Regulatory oversight policies need to be rational and designed to ensure patient safety without creating unnecessary barriers or delays in implementation. Many of these technologies may need to be updated frequently, and regulatory review of every change may not be realistic. Innovative post-market oversight strategies for digital health technologies should be explored, and as end users it will be important that physicians and patients are included in any pilots to explore new post-market surveillance approaches. Any premarket oversight should ensure that quality data is used in the development of digital health technologies and that the diversity of data used is appropriate for the intended patient population. Manufacturers need to clearly disclose limitations in their data to the end users.

- Coverage policies for digital health technologies that complement physician services  
A 2016 American Medical Association (AMA) study on physicians' motivations and requirements for adopting digital clinical tools showed that most physicians see the potential for digital tools to improve patient care and many of them are enthusiastic about using new digital solutions. To continue to encourage adoption by physicians, it is important that there are coverage and reimbursement policies for these tools that do not result in reduced reimbursements for physician services. Digital technology tools compliment and improve the efficiency of physician services rather than replace them, and reimbursement should be consistent with this.
- Clear liability coverage and assurance of data privacy  
Adoption of digital health technologies also requires that there are clearly established liability expectations and assurances of data privacy. For example, chatbots are being developed and implemented that cover pretest education and counseling for patients considering genetic testing. If there is a problem with the chatbot or its algorithms and a patient sues, who is liable? With regard to data privacy, many AI algorithms work by collecting data and adjusting their algorithms based on that data. Patients may want to benefit from the AI algorithms, but they need to know that their data that is being collected is protected and will be kept private. In the event of data breaches involving technologies such as this, there is again the question regarding who is held liable (e.g., the provider using the technology or the manufacturer who developed the technology).
- Reduction in health disparities  
Digital health technologies are intended to improve public health and the delivery of healthcare. There needs to be robust coverage and reimbursement of digital health technologies that demonstrate a clear healthcare benefit so they can be accessed by all patients and implemented in clinical settings throughout the United States. Without robust coverage and reimbursement, implementation of digital health

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technologies may only be feasible for larger healthcare systems, and access to such therapies may not be feasible for low income, underserved, or rural populations. If left unaddressed, this situation would only increase health disparities.

## **2. Reform of Medicare coding, coverage, and payment to better support patient access to medical therapies**

- Appropriate coding system for the vast number of available genetic tests  
The current procedural terminology (CPT) is a code set that allows payers to understand what is being purchased. The CPT system, however, is not set up to establish codes for all 70,000 or more genetic tests that are on the market. Therefore, many tests are coded for using general codes that do not facilitate transparency for payers regarding the exact gene tested. This also impedes the payers' ability to make decisions on medical services indicated for patients based on that test result and impedes health research on outcomes of patients with positive or negative test results for a given test. The coding system should simplify the billing process without losing transparency. Further, there is a catch-22 in that creation of an analyte-specific code (e.g., a code for a specific gene) often requires data to support the need for that code, but data cannot be collected unless there is an analyte-specific code to track usage of that test. Large private laboratories sometimes have enough data to support creation of a new code, but some refuse to share their data and consistently do not submit information to government-funded public databases such as ClinVar and others. Sharing of variant information to such databases is critical for identifying medical trends and correlation with disease, especially for rare diseases and unique subsets of more common diseases. Incentives are needed to encourage consistent sharing of data across all types of laboratories.
- Medicare system reform to reduce administrative burdens  
The Centers for Medicare and Medicaid Services (CMS) has acknowledged that there are high administrative burdens associated with Medicare and has made targeted modifications to some aspects of documentation to try to reduce these burdens. However, innovative system-level reforms should be explored that would better facilitate streamlined utilization management, authorization, and payment as part of administrative oversight. There is also a need to create innovation opportunities to explore novel approaches tied to outcomes, and this could be facilitated through waiver opportunities, flexibility for local coverage decisions, etc.
- Appropriate CLFS approach for clinical laboratory testing  
The molecular genetic test coding system does not account for complexities of tests, and CMS does not consider the complexities when determining rates for each code on the clinical laboratory fee schedule (CLFS). CMS has begun making rate determinations based on the number of exons a gene contains, in other words the

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number of regions in a gene that provide instructions for making a protein. However, there are many other factors that contribute to the complexity of sequencing methods which are independent of the number of exons, such as the presence of areas of high homology or pseudogenes. Such factors can cause great variance in the cost of sequencing two genes with the same number of exons, but Medicare currently does not take this into consideration. As another example, in 2012 CMS removed a code for test interpretation from the CLFS and explained that interpretation and report services would be covered as part of the overall CLFS payment for molecular pathology CPT codes. However, the complexity of interpretation and report services also varies widely depending on the test performed, and therefore the cost to perform these services also varies greatly. CMS currently does not consider such costs when setting rates.

○ Access to laboratory-developed tests

The majority of genetic tests are legally marketed as laboratory-developed tests (LDTs). Clinical laboratories develop LDTs to assist in patient care, particularly for patients with medical conditions for which a commercial test does not exist or when an existing test does not meet changing clinical needs. LDTs are held to high standards of analytical and clinical validity, and their use is regulated by CMS through the Clinical Laboratory Improvement Amendments (CLIA) program. To date, the Food and Drug Administration (FDA) has chosen to use enforcement discretion for LDTs and only asks that certain tests go through premarket review. However, CMS will generally only include FDA-cleared or approved tests in their national coverage determinations (NCDs). In some cases, they may provide Medicare administrative contractors (MACs) the option of covering LDTs through local coverage policies, but they are never nationally covered. For numerous genetic conditions, the molecular diagnostic test is only available as an LDT meaning Medicare beneficiaries often cannot access those tests. If a patient cannot receive a diagnosis, then they will not be able to benefit from the available treatments.

○ Novel approaches for rare, ultrarare, and undiagnosed diseases

For rare, ultrarare, and undiagnosed diseases, robust clinical utility data is often impeded by the very small number of patients affected. Alternative reimbursement models are needed for rare, ultrarare, and undiagnosed diseases for which population evidence of clinical utility is unlikely to be developed. For example, provisional approval or reformed coverage with evidence development models could be considered.

○ Coverage of preventive medicine

Our understanding of genetics and its correlation with disease is also being applied to preventive healthcare. For example, screening for genetic variants associated with an increased risk for cancer can help guide medical decisions for high risk patients. However, federal laws currently prohibit Medicare from covering such

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screening services. The goal of preventive healthcare is to help people stay healthy and avoid diseases, and Medicare should support patient health by covering such services.

### **3. Building on current real-world evidence (RWE) efforts across the federal healthcare landscape to harness data to empower patients and improve health**

#### ○ Incentives for data sharing

When dealing with rare diseases and even small subsets of more common diseases, sharing of findings is crucial. It is especially important for understanding the correlation between genetic variations and clinical presentations. Government-funded databases such as ClinVar have been created to support sharing of this type of information, however data submission is voluntary. In 2018, FDA formally recognized the Clinical Genome Resource (ClinGen) Expert Curated Human Variant Data, which relies on data voluntarily submitted to ClinVar, as valid scientific evidence that can be used to support clinical validity of genetic tests in premarket submissions. Increasing publicly available data could improve our understanding of the genetic components of both rare and common conditions and lead to more accurate diagnoses and treatments. Incentives for sharing such information are needed, and one potential could be to tie incentives to Medicare and Medicaid reimbursements. For example, there could be increased payments to laboratories and clinics that share data, or reimbursement could require data sharing. In either scenario, a process to verify submission of data would be needed. Incentives could also be tied to clinical trial data leading to FDA approvals of drugs and in vitro diagnostics.

#### ○ Portability of genomic information through the healthcare system

To facilitate harnessing of genetic information, that information must be able to move through the healthcare system with the patient. In addition to the need for electronic health record (EHR) interoperability, EHRs must also be able to accommodate the extremely large data files that result from some types of genomic information, such as results from genome-wide sequencing.

#### ○ Patient trust in obtaining and sharing of genetic information

Harnessing genomic information also requires that patients feel comfortable sharing their genetic and genomic information. This may be addressed through increased patient education regarding what can be learned from different types of genetic information, transparency in how their information will be used, and increased protections around discrimination and inappropriate uses of genetic information. For example, the Revised Common Rule put in place restrictions around reidentification using genetic information without consent. However, these provisions only apply to federally funded research, and patients may have concerns about other attempts to reidentify genetic information. Regarding discrimination,

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the Genetic Information Nondiscrimination Act (GINA) of 2008 prohibited genetic discrimination by health insurers. However, patients may be concerned about discrimination for life or disability insurance.

#### **4. Increasing family and caregiver health literacy, including enabling patients and their families, caregivers, and providers to be better informed of their options for treatment, services, and associated costs**

- Access to genetics-trained healthcare professionals

The increasing use of genetic and genomic information to diagnose and treat patients is being observed in almost every field of medicine. However, the majority of healthcare professionals are not trained in genetics, and recent studies have shown that many physicians are uncomfortable ordering, interpreting, and/or delivering results of genetic tests. The medical genetics specialty is very small compared to many other medical specialties, however as our understanding of the human genome expands the need for their expertise increases. Because of the shortage of medical geneticists who are trained and board-certified to practice genetics, many people currently do not have access to a medical geneticist due to geographic barriers. Some have to travel long distances for access, and even then the wait times to get an appointment can be very lengthy. It is crucial that the medical geneticist workforce is robust enough to meet the needs of patients. Genetic counselors also play a crucial role by helping patients understand genetic risk, navigate healthcare and family planning decisions, and understand the implications of a genetic diagnosis. Although more abundant than medical geneticists, there is also a shortage of genetic counselors. At the request of Congress, the Government Accountability Office (GAO) is currently performing an assessment of the medical genetics workforce to identify shortages and areas that lack access to medical geneticists and genetic counselors. In addition to strengthening the entire medical genetics workforce, additional resources are needed to increase patient access to medical geneticists and genetic counselors. Barriers may include costs, geographic barriers, rurality, and other aspects of disparity. Telemedicine is often touted as one mechanism by which geographic barriers could be overcome, but this is still limited by other barriers such as lack of broadband access in rural areas or lack of access to computers and other technologies. The inability for physicians to practice across state lines without having a license in each state is also a potential barrier.

- Clinical decision support tools and education of non-genetics-trained healthcare professionals

Even with a robust medical genetics workforce, non-genetics specialties will still need to be able to manage ordering, interpreting, and returning of results for some conditions. Education of non-genetics-trained healthcare professionals is one way to improve their comfort with managing genetic information, and incorporating genetics into continuing education programs could be beneficial. However, the field

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of genetics is rapidly evolving, and education alone may not be sufficient. The development of clinical decision support tools is needed, and integration of these tools with EHRs should be a priority.

## 5. Other considerations

- Medicaid state options for coverage of advanced genetic testing  
Coverage of clinical sequencing (genome and exome) as well as many gene panels remains severely limited, especially for Medicare and Medicaid. Over the past year, two bills (HR 4144 and HR 4393) were introduced that aimed to improve coverage for critically ill children by allowing state Medicaid programs the option to use federal medical assistance for certain types of genetic testing. Patients should have access to clinical sequencing services when recommended by an appropriately-trained physician, and these bills would seek to achieve that for a targeted population. Further, coverage should not be limited to a specific type of sequencing. There are benefits and limitations to the various types of sequencing, and an appropriately-trained physician 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 be able 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. Waiting until symptoms are so severe that the patient is admitted to an intensive care unit may be too late. Although the current bills focus on children from birth and possibly up to 26 years of age, coverage of clinical sequencing services for all indicated 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 at a later time.

ACMG appreciates the opportunity to provide input on needs for modernizing healthcare and would be happy to meet to discuss potential legislative solutions. For questions or additional information, please contact ACMG's Public Policy Director, Michelle McClure, PhD at [mmcclure@acmg.net](mailto:mmcclure@acmg.net). We look forward to continuing to work with your offices on the Cures 2.0 initiative.

Sincerely,

*Max Muenke*

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