ACMG
American College of Medical Genetics and Genomics
Translating Genes Into Health®

July 28, 2021

The Honorable Diana DeGette
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Fred Upton
2183 Rayburn House Office Building
Washington, DC 20515

Re: Comments on the Cures 2.0 Discussion Draft

Dear Representatives DeGette and Upton:

The American College of Medical Genetics and Genomics (ACMG) appreciates the opportunity to provide feedback on the Cures 2.0 Discussion Draft. ACMG is the only nationally recognized medical professional organization solely dedicated to improving health through the practice of medical genetics and genomics, and the only medical specialty society in the US that represents the full spectrum of medical genetics disciplines in a single organization. The ACMG is the largest membership organization specifically for medical geneticists, providing education, resources and a voice for more than 2,500 clinical and laboratory geneticists, genetic counselors and other healthcare professionals, nearly 80% of whom are board certified in the medical genetics specialties. 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.

As the medical specialty society representing medical geneticists in the US, we want to provide comments on the following sections of the Cures 2.0 Discussion Draft:

- Section 407. Expanding Access to Genetic Testing
- Section 408. Medicare Coverage for Precision Medicine Consultations

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Section 407. Expanding Access to Genetic Testing

Access to appropriate genetic testing is critical for establishing a diagnosis and plan for medical management and treatment of affected individuals. For heritable conditions, understanding the genetic causes of disease is important for family planning as well as medical management of the condition. When applying the concepts of precision medicine, diagnosis means selecting the right test for the right patient at the right time in order to choose the right treatment. We appreciate the intention of Sec. 407 which focuses on improving coverage of "DNA clinical sequencing services" for children covered by Medicaid, but we are concerned that the current approach may disincentivize payer coverage of these services. Relying on the section 1115 demonstration project approach may give the impression that these services are experimental or that additional studies are needed to support their use (see additional discussion below). Moreover, if only 5 states are included, that may disincentivize other states from covering those same services for the duration of the demonstration project. In ACMG's view, such testing is well-supported by clinical evidence and currently should be covered by all payers in accordance with professional guidelines and recommendations.

Further, ACMG recommends that DNA clinical sequencing be considered as a first- or second-tier test for certain pediatric patients. The discussion draft defines DNA Clinical Sequencing Services as a determination of an exact sequence of DNA bases in the genome (i.e., genetic sequencing), including genome sequencing (GS) and exome sequencing (ES). Such genetic sequencing tests are frequently used by medical geneticists to diagnose individuals with inherited conditions, and their clinical utility is well supported by existing evidence. Even the utility of advanced applications of genetic sequencing, such as ES/GS, is supported by clinical evidence. For example, ACMG recently published an evidence-based guideline to support use of ES/GS in pediatric patients with one or more congenital anomalies (CA) with onset prior to age 1 year or developmental delay (DD) or intellectual disability (ID) with onset prior to age 18 years.[1] The guideline is supported by available clinical evidence summarized in ACMG's related systematic evidence review.[2] Genetic sequencing, including ES/GS, is a well-established diagnostic approach and in itself is not novel or experimental. The increased use of ES/GS has led to increased diagnostic yield leading to improved patient outcomes. Therefore, ACMG recommends consideration of ES/GS as a first- or second-tier test for these patients, and this evidence also supports the need for public and private payer coverage of these services. Additional types of genetic tests may also be necessary to reach a diagnosis, and such tests should also be covered as supported by existing clinical evidence.

We also are concerned that Sec 407 may confuse some state Medicaid programs. Currently, for Medicaid beneficiaries under 21 years of age, coverage of diagnostic testing is not restricted by any

[1] Manickam, K., McClain, M.R., Demmer, L.A. et al. Exome and genome sequencing for pediatric patients with congenital anomalies or intellectual disability: an evidence-based clinical guideline of the American College of Medical Genetics and Genomics (ACMG). *Genet Med* (2021). https://doi.org/10.1038/s41436-021-01242-6

[2] Malinowski, J., Miller, D.T., Demmer, L. et al. Systematic evidence-based review: outcomes from exome and genome sequencing for pediatric patients with congenital anomalies or intellectual disability. *Genet Med* **22**, 986–1004 (2020). https://doi.org/10.1038/s41436-020-0771-z

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 of age regardless of whether such services would normally be covered by that state's Medicaid program. Since the services described in Sec. 407, including 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).

While we have information about Medicaid coverage of genetic testing, we do not have information about how often these services are covered through the EPSDT benefit. Sec. 407 is intended to improve coverage of such testing. In order to do so, however, it would be beneficial to have 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. This information would help us better understand which genetic sequencing tests we should focus on with respect to the EPSDT benefit. The current Sec. 407 language would require a Centers for Medicare and Medicaid Services (CMS) report on Medicaid coverage of DNA clinical sequencing services, but it does not specify the additional information that is needed with respect to the EPSDT benefit to understand actual coverage for children.

ACMG is very supportive of the goals of section 407. However, before providing more specific edits on the current language, additional discussion is needed to identify the best approach for achieving improved coverage. It would also be beneficial to seek technical assistance from CMS.

Section 408. Medicare Coverage for Precision Medicine Consultations

Section 408 would amend the Social Security Act to allow Medicare to cover "genomic precision medicine consultations" provided by a qualified pharmacist. However, as noted in the definition of "genomic precision medicine consultations", the scope of this section is actually focused on pharmacogenetic/pharmacogenomic (PGx) tests. PGx tests assess how a patient's genetic makeup may affect their metabolism and response to a given drug, the results of which may inform drug selection and dosing recommendations. Precision medicine refers to tailoring disease prevention and treatment by taking into account differences such as patients' genes, proteins, environments, and lifestyles. PGx is a subset of precision medicine and is not synonymous with the term precision medicine. Since this section is specifically focused on PGx testing, we recommend replacing "genomic precision medicine consultation" with "pharmacogenetic consultation".

Further, we recommend that Section 408(a)(2)(lll)(1) be revised as follows:

> The term '~~genomic precision medicine~~ pharmacogenetic consultation' means, with respect to a genetic or genomic test ~~(including next generation sequencing)~~ furnished to an individual, ~~an interpretation of such test (or~~ a consultation with respect to such test~~)~~ requested by ~~provided to~~ the physician treating such individual to provide such physician ~~[based on such test]~~ with advice and recommendations regarding the dosage, safety, and efficacy ~~and propriety~~ of

particular drugs, biologicals, and other treatments ~~for~~ based on the individual's pharmacogenetic test result.

ACMG appreciates the opportunity to provide feedback on the Cures 2.0 Discussion Draft and looks forward to continued engagement on this draft legislation. For questions or additional information, please contact Dr. Michelle McClure at mmcclure@acmg.net.

Sincerely,

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