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

September 11, 2023

Administrator Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CY 2024 Physician Fee Schedule Proposed Rule (CMS-1784-P)

Dear Administrator Brooks-LaSure:

The American College of Medical Genetics and Genomics (ACMG)[1] appreciates the opportunity to comment on the proposed rule for *Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program* (CMS-1784-P).

Telehealth & Reporting Home Address

During the public health emergency (PHE), CMS allowed practitioners to render telehealth services from their home without reporting their home address on their Medicare enrollment while continuing to bill from their currently enrolled location. In a notice issued on July 20, 2023[2], CMS indicated that this waiver

[1] Founded in 1991, the American College of Medical Genetics and Genomics (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 2,600 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.

[2] https://www.cms.gov/files/document/physicians-and-other-clinicians-cms-flexibilities-fight-covid-19.pdf

7101 Wisconsin Avenue, #Suite 1101
Bethesda, MD 20814
Telephone: 301-718-9603
Fax: 301-381-9379
www.acmg.net

would continue through December 31, 2023. The current proposed rule, however, does not acknowledge this waiver. Over the past few years, the use of telehealth has significantly increased. In many instances, healthcare professionals (HCPs) may provide services from their official practice location or from a home address. The waiver to allow HCPs to list their enrolled location rather than their home address should be made permanent. Requiring HCPs to disclose their home address would reveal personal information and expose them to unnecessary safety risks. Without making this waiver permanent, HCPs may be forced to choose between exposing themselves to unnecessary risks or reducing their telehealth offerings to patients. Therefore, we request that CMS extend, or preferably make permanent, the waiver allowing HCPs to use their enrolled practice address even when telehealth services are provided from their home.

Request for Information: Histopathology, Cytology, and Clinical Cytogenetics Regulations Under the Clinical Laboratory Improvement Amendments (CLIA) of 1988

ACMG provides the following comments in response to CMS's request for information on clinical cytogenetics regulations.

CMS Question 1: Under what circumstances should CLIA allow remote locations or testing facilities to examine clinical cytogenetics images without obtaining a separate CLIA certification?

ACMG Response: Employees (directors or staff) should be competent in all aspects of cytogenetic testing and formally affiliated with a CLIA-certified laboratory with a full cytogenetics service (i.e., wet bench and analysis).

CMS Question 2: Under what circumstances would the examination of clinical cytogenetics images be unacceptable for the remote location scenario?

ACMG Response: Remote examination would be unacceptable when the visualization of the cytogenetics images cannot be performed under secure conditions or with the appropriate image resolution. That said, with current technology, meeting these two requirements can be easily achieved. Access

7101 Wisconsin Avenue, #Suite 1101
Bethesda, MD 20814
Telephone: 301-718-9603
Fax: 301-381-9379
www.acmg.net

to the images must be performed using an institutional computer or secure access (i.e., VPN) to the institution's network. Implementation of institutional systems that ensure secure access of digital images to remote sites is essential to maintain confidentiality of personal health information. Of note, the remote location/employee should have access to information regarding the entire case workflow, not just the last part of image generation.

CMS Question 3: What clinical cytogenetics testing processes should the primary laboratory have in place to ensure the remote site complies with the CLIA requirements?

ACMG Response: As mentioned above, the primary laboratory should put in place access to all information pertinent to a cytogenetics case so that the remote location employee can analyze the images while informed on all aspects of testing. The latter includes tissue culture information, harvest/ slide dropping, FISH slide preparation, hybridization protocol, etc.

CMS Question 4: What "conditions" or "criteria" would be necessary for the remote location to ensure quality testing for the examination of clinical cytogenetics images?

ACMG Response: This question can be rephrased into two questions:

1. Can cytogenetics analysis be done digitally?
2. Can this digital analysis be done remotely?

First, can cytogenetics analysis be done digitally? Yes, cytogenetic analysis can be done digitally, and this has already been the standard in cytogenetic laboratories for more than two decades. Even within the walls of a traditional CLIA-certified laboratory, most laboratories scan their slides into a digital system and then use that digital system to analyze the cells. In fact, this practice has increased efficiency in the laboratory and avoided time wasted on manual search for metaphase cells under the microscope. Appropriate validation of these digital systems is essential and must ensure that the instrumentation meets the performance requirements of the workflow. It must also be determined, during the early stages of validation, the situations which require a manual review of the original slide. One such example is when there is a question of whether an incomplete digital metaphase spread is due to overspreading or due to clonal chromosome loss – the laboratory must have a process in place for a technologist to go back to the actual slide and look for

7101 Wisconsin Avenue, #Suite 1101
Bethesda, MD 20814
Telephone: 301-718-9603
Fax: 301-381-9379
www.acmg.net

the uncaptured chromosome in another field. This can be accomplished either through that same technologist pulling the original slide or through a collaboration between the technologists working remotely and those that are in the same physical space as the slide. Because cytogenetics operation entails wet bench processes, there will always be technologists who are on site to accommodate slide review when needed.

Second, can this digital analysis be done remotely? Yes. Nowadays, the same considerations can be applied for any remote testing system, be it within a cytogenetics laboratory or a molecular laboratory, as much of the data generated from clinical genetics laboratories are stored and accessed digitally within medical laboratory information systems (LIMS). These are designed to be accessed from any securely networked computer. This is true for gene sequencing data, digital images of a Southern blot, PCR fragment length profiles, or digitized images of metaphase spreads or fluorescence in-situ hybridization signals within a cell. Since remote molecular testing work has been allowed, the same should apply to cytogenetics.

In summary, remote analysis and case sign-out of cytogenetic data produced in a CLIA-certified laboratory and accessed through secure data portals, such as a VPN, should be considered a virtual extension of the primary CLIA-certified site.

For questions or additional information, please contact Michelle McClure, PhD, ACMG Director of Public Policy, at mmcclure@acmg.net.

Sincerely,

Susan D. Klugman, MD, FACMG
President
American College of Medical Genetics and Genomics

7101 Wisconsin Avenue, #Suite 1101
Bethesda, MD 20814
Telephone: 301-718-9603
Fax: 301-381-9379
www.acmg.net