

Congress of the United States
Washington, DC 20515

March 7, 2017

The Honorable Thomas E. Price, M.D.
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Francis J. Crosson, M.D.
Chairman
Medicare Payment Advisory Commission
425 I Street, NW, Suite 701
Washington, DC 20515

Dear Secretary Price and Chairman Crosson:

We are writing to request that you examine how the federal government can help improve patient access to genetic testing. Investments in genomics research have led to the development of technologies that present nearly limitless opportunities to implement better diagnosis and treatment methods, enhance patient outcomes, and reduce health care costs. Especially with the passage of the *21st Century Cures Act* and continued funding for the Precision Medicine Initiative and Cancer Moonshot, we remain committed to advancing medical innovation and considering the uniqueness of each and every patient.

Despite these important developments, many patients do not have access to genetic testing through their health insurance plans that could make state-of-the-art medical approaches a reality for them. Both the absence of health insurance coverage, including under Medicare and Medicaid, and barriers like pre-approval and extended waiting periods for genetic counseling prevent patients from undergoing testing, understanding their results, and utilizing these results to tailor treatment. Additionally, we understand that some insurance providers have been hesitant to reimburse for genetic tests without a significant amount of data on their clinical utility. However, since these tests would not be as widely used without insurance coverage, it would be difficult to collect such data given the current coverage landscape. As we continue to push for genomics innovation, it is evident more dialogue and analysis on the coverage of genetic tests and other factors that affect patient access is needed to ensure we can effectively utilize the resulting technologies.

Therefore, we ask that you initiate studies to evaluate how the federal government can promote access to genetic testing for use in clinical settings. We request the Department of Health and Human Services, in coordination with the National Academy of Medicine, conduct a study to—

- examine how genetic testing can improve preventative care measures and precision medicine initiatives;
- make recommendations on how the federal government can—
 - encourage the expansion of health insurance coverage of genetic testing, including diagnostic, predictive, presymptomatic, and whole genome sequencing,
 - support the development of evidence for the clinical utility of genetic tests, and
 - strengthen related workforce training efforts, including increasing the number of genetic counselors; and,
- analyze how the utilization of genetic testing can reduce health care expenditures.

We further ask the Medicare Payment Advisory Commission to initiate a study to—

- review how the current Medicare and Medicaid coverage determination framework may restrain the use of genetic tests that can improve clinical outcomes,
- develop recommendations on how the Centers for Medicare and Medicaid Services can make coverage determinations that better suit a precision medicine approach to treatment, and
- analyze how the utilization of genetic testing can reduce expenditures for the federal government.

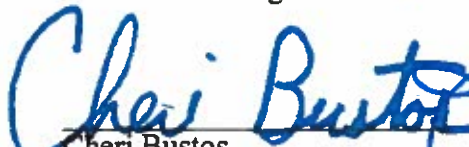
We look forward to working with you to help improve access to genetic testing. Thank you for your consideration of our request.

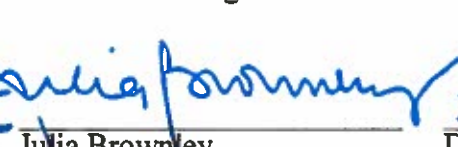
Sincerely,

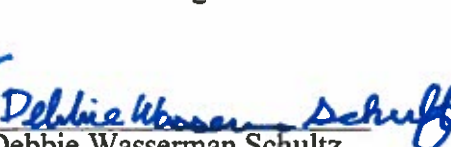

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