March 3, 2022

The Honorable Charles Schumer Majority Leader United States Senate Washington, DC 20510

The Honorable Mitch McConnell Minority Leader United States Senate Washington, DC 20510 The Honorable Nancy Pelosi Speaker United States House of Representatives Washington, DC 20510

The Honorable Kevin McCarthy Minority Leader United States House of Representatives Washington, DC 20510

Dear Majority Leader Schumer, Minority Leader McConnell, Speaker Pelosi, and Minority Leader McCarthy:

We commend Congress for enabling broad access to healthcare via telehealth through enacting waiver authorities in pandemic response legislation in 2020, and we write to you today to request that you extend these regulatory flexibilities beyond the public health emergency (PHE). These policy changes were critical to ensuring a continuation of health care during a very disruptive time in history, and they led to a dramatic increase in the utilization of telehealth in the past two years. According to a report released in December by the Department of Health and Human Services (HHS), the share of Medicare fee for service visits conducted via telehealth increased 63-fold, from approximately 840,000 in 2019 to 52.7 million in 2020.¹

Providers have integrated digital tools into their practices and patients have embraced telehealth as a valuable method to improve access to care. We hope that you will consider making these regulatory changes permanent or at least, extend them for a period of time to allow for continued assessment of its benefits and appropriate utilization. As Congress continues to consider the various legislative proposals to that effect, we caution against including unproven guardrails that have the potential to stifle access to clinical laboratory services without effectively preventing Medicare fraud and waste.

In particular, we write in opposition to the requirement for a face-to-face visit prior to ordering a high-cost laboratory test via telehealth as included in H.R. 6202, the Telehealth Extension Act, and S. 3593, the Telehealth Extension and Evaluation Act. We are dedicated to the responsible use of telehealth and other digital health technologies and share your concern that schemes that involve fraudulently billing Medicare for laboratory tests are detrimental to our health care system and erode trust in laboratories offering these services. However, the requirement of a face-to-face visit has the very real potential to block legitimate and clinically appropriate

¹ https://www.hhs.gov/about/news/2021/12/03/new-hhs-study-shows-63-fold-increase-in-medicare-telehealth-utilization-during-pandemic.html

patient access to much needed laboratory tests without any evidence that this is the most effective approach to addressing fraud.

Data from utilization of telehealth over the past two years should be assessed to better understand how patients engaged in virtual care, the impact of telehealth on healthcare outcomes, its ability to address disparities and inequities, etc., before enacting any legislation that would restrict access to telehealth in any way. Proceeding with evidence-based policymaking is critical, because many patients are still dependent on these technologies which allow them to safely access healthcare despite the high transmission of SAR-CoV-2 in many areas of the country.

Beyond the pandemic, telehealth has huge potential to expand access to high-quality care for all Americans and we now have the data to make informed, evidence-based policymaking. For example, a recent report published by the American Association for Cancer Research found that as a result of the pandemic, nearly 10 million cancer screenings were missed from January to July 2020 and patients diagnosed with inoperable or metastatic cancer from March through December 2020 increased by 11% compared to those months in 2019.² Focusing specifically on screening for lung cancer, telehealth screenings were found to be just as effective as in-person screenings and the use of telehealth during the COVID-19 pandemic preserved access to screening for a safety net hospital's large African American patient population.³ Telehealth is also proving to be particularly desirable and beneficial among patients for use with at-home sample collection and testing for sexually transmitted infections (STIs). In fact, to address increasing rates of STIs during the pandemic and fill the gap created by public health departments needing to shift personnel to pandemic response, California enacted a law to mandate coverage of telehealth and at-home STI testing.

These are just a few examples of how telehealth has the potential to increase access to care, address health inequities, and improve health outcomes for patients. We hope that Congress will recognize the importance of telehealth and work to extend the telehealth waivers granted during the PHE. However, we strongly caution against including guardrails into legislation until we fully assess all of the implications and understand the potential unintended consequences they will have on patient access, including to laboratory services.

Thank you very much for considering our concerns as you work on telehealth legislation, and if we may be of further assistance, please contact Jennifer Leib at <u>jennifer@ipolicysolutions.com</u>.

Sincerely,

American Association of Kidney Patients (AAKP) American Cancer Society Cancer Action Network American Clinical Laboratory Association

² https://www.aacr.org/professionals/research/aacr-covid-19-and-cancer-report-2022/

³ https://www.eurekalert.org/news-releases/932355

American College of Medical Genetics and Genomics Association for Molecular Pathology BioReference Laboratories, an OPKO Health Company Everly Health FORCE: Facing Our Risk of Cancer Empowered Fulgent Genetics, Inc Gene Matters, Inc GeneDx Genome Medical Services Genome Medical, Inc. GO2 Foundation for Lung Cancer Guardant Health ICAN, International Cancer Advocacy Network International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis) Invitae Corporation **KidneyCAN** Laboratory Access and Benefits Coalition Laboratory Corporation of America Holdings LetsGetChecked My Gene Counsel Myriad Genetics National Society of Genetic Counselors Personalized Medicine Coalition Quest Diagnostics Rite Aid Sema4 The Coalition for 21st Century Medicine