September 10, 2021

The Honorable Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services U.S. Department of Health and Human Services 7500 Security Boulevard Baltimore, MD 21244

Re: Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements (CMS-2021-0119)

Dear Administrator Brooks-LaSure:

Thank you for the opportunity to submit comments on the calendar year 2022 Physician Fee Schedule, specifically the provisions expanding access to care via virtual care. The undersigned organizations represent millions of people living with diabetes. During the COVID-19 public health emergency, our delivery system has demonstrated a growing capacity to successfully deploy virtual care services. We consider virtual care services to encompass the totality of ways in which technology is utilized to interact, monitor, educate, and care for people with diabetes.

Our organizations have a unique perspective on the evolving nature of virtual care, how it continues to positively impact the health of those living with diabetes, and the importance of continued support from CMS. Given this perspective we are supportive of making permanent those policies adopted during the public health emergency that expanded access to virtual care services, particularly telehealth and remote patient monitoring. Where CMS has the ability, we urge the continuation of coverage and reimbursement of telehealth, remote patient monitoring, and other virtual care services, including waiving in-person requirements for beneficiaries utilizing continuous glucose monitors, insulin pumps, and closed loop systems.

According to the Centers for Disease Control and Prevention (CDC), more than 34 million Americans have diabetes and another 88 million adults, 1 in 3, have prediabetes, which place them at high risk of developing type 2 diabetes. The majority of those are diagnosed with diabetes, roughly 95%, have type 2 diabetes (T2D) and 1.6 million Americans currently live with type 1 diabetes (T1D). There are nearly 8 million Americans with diabetes that need intensive insulin therapy to manage their diabetes. These Americans require continuous and ongoing access to therapies and support from the diabetes care team.

As an example of the existing gap in care in which telehealth offers a potential solution, the United States is facing a nationwide shortage of endocrinologists, with an analysis projecting a shortage of 2,700 endocrinologists by 2025.¹ The distribution of diabetes care is additionally concerning, with only 25% of counties having a practicing endocrinologist. The 75% of counties without a practicing

¹ Vigersky, R. A., Fish, L., Hogan, P., Stewart, A., Kutler, S., Ladenson, P. W., McDermott, M., & Hupart, K. H. (2014). The clinical endocrinology workforce: current status and future projections of supply and demand. The Journal of clinical endocrinology and metabolism, 99(9), 3112–3121. https://doi.org/10.1210/jc.2014-2257

endocrinologist are concentrated in the Southeast, Midwest, and Mountain West, making telehealth and virtual care services especially critical for beneficiaries in these areas to access specialty care.²

In 2017, diabetes cost the nation an estimated \$327 billion, including \$237 billion in direct medical expenditures and \$90 billion from reduced productivity.³ More than two-thirds of all diabetes-related expenditures in America are paid by government programs: Medicare, Medicaid, and the military. Medicare has become the nation's diabetes payer of last resort, covering hospitalizations, emergency room visits and other expensive, often preventable acute care. Sixty percent of Medicare beneficiaries with diabetes have an inpatient hospital stay annually.⁴ About 90% of these Medicare beneficiaries experience an inpatient stay or emergency room visit.⁵ Evidence suggests that these adverse outcomes could be avoided with consistent access to telehealth and remote patient monitoring, which would allow people with diabetes and their providers to better manage diabetes care.^{6,7}

The current COVID-19 pandemic laid bare many of the deep systemic flaws and inequities in the U.S. health care system. It also presented our delivery system, policymakers, providers, and beneficiaries, with the opportunity to adapt in ways previously thought impossible. The explosion of telehealth and virtual care is perhaps our best example of a new, positive landscape that has emerged from our response to the pandemic.

We are encouraged by the proposed provisions in the 2022 Physician Fee Schedule that would remove geographic and originating site requirements, provide reimbursement for audio-only interactions, and expand flexibilities to Federally Qualified Health Clinics (FQHCs) and Rural Health Clinics for certain mental health services on a permanent basis. We also applaud CMS's continued coverage of the Category 3 list of telehealth and virtual care through 2023. Demonstrated improvements in health and glycemic control for those with diabetes utilizing continuous glucose monitors have led to ever increasing use. Continued CMS coverage of remote monitoring services is vital to this crucial therapy continuing to be available to Medicare enrollees and we are encouraged by CMS's proposed expansion of these services.

While we are supportive of CMS's expansion of the Medicare Diabetes Prevention Program (MDPP), we remain disappointed by CMS's decision to not expand the modalities by which the MDPP can be delivered reimbursed. Given the demonstrated value of virtual care in diabetes prevention programs⁸ and the demand of program participants utilizing virtual care via the current waiver, we urge CMS expand reimbursement to include services delivered via distance and online learning modalities and to allow CDC-recognized virtual suppliers to deliver the MDPP set of services to beneficiaries.

² Oser, S. M., & Oser, T. K. (2020). Diabetes Technologies: We Are All in This Together. Clinical diabetes: a publication of the American Diabetes Association, 38(2), 188–189. https://doi.org/10.2337/cd19-0046

³ Economic Costs of Diabetes in the U.S. in 2017. (2018). Diabetes Care, 41(5), 917–928. https://doi.org/10.2337/dci18-0007 ⁴ National Minority Quality Forum Diabetes Index. 2017 Medicare Fee-for-Service data.

⁵ Ibid.

⁶ Tchero, H., Kangambega, P., Briatte, C., Brunet-Houdard, S., Retali, G. R., & Rusch, E. (2019). Clinical Effectiveness of Telemedicine in Diabetes Mellitus: A Meta-Analysis of 42 Randomized Controlled Trials. Telemedicine and E-Health, 25(7), 569–583. https://doi.org/10.1089/tmj.2018.0128

⁷ Rubinger, L., & Bhandari, M. (2020). Cochrane in CORR [®]–Interactive Telemedicine: Effects on Professional Practice and Health Care Outcomes. Clinical Orthopaedics & Related Research, 478(9), 1971–1973. https://doi.org/10.1097/corr.00000000001440

⁸ Aberer, F., Hochfellner, D. A., & Mader, J. K. (2021). Application of Telemedicine in Diabetes Care: The Time is Now. Diabetes Therapy, 12(3), 629–639. https://doi.org/10.1007/s13300-020-00996-7

Studies have repeatedly shown that those living with diabetes have better glycemic control when telehealth and other virtual care services are utilized in their care.⁹ An review of 42 studies analyzing the impact of telemedicine on those with diabetes found those with type 2 diabetes and older adults saw the most significant benefit in managing their diabetes especially as telehealth was applied over a longer period of time.¹⁰ COVID-19 has only heightened what we have known for years – the availability of telehealth and virtual care services improves the health and lives of those living with diabetes. Availability of virtual care services for MDPP, diabetes self-management training (DSMT), and provider visits for diabetes technology, particularly telehealth and remote patient monitoring, will continue to be vital beyond COVID-19 given the endocrinology shortage and significant gaps in the geographic distribution of specialists.

As CMS considers which services to make permanent once the public health emergency waiver expire, we encourage CMS to consider conditions and diseases, such as diabetes, that have demonstrated improved outcomes from the availability of telehealth and virtual care services. We again applaud the efforts CMS has made to promote and expand access to telehealth and virtual care both prior to and throughout the COVID-19 public health emergency. Our organizations stand ready to support CMS's efforts to build on the knowledge we've gained during this pandemic to improve the experience and health for all Medicare enrollees living with diabetes.

Thank you for the opportunity to provide our comments to the proposed 2022 Physician Fee Schedule. We support CMS's continued efforts to expand virtual care options to beneficiaries to improve their health. We stand ready to assist in any way we can. If you have any questions, please contact Aaron Turner-Phifer (<u>aturner-phifer@jdrf.org</u>) with JDRF.

Sincerely,

Advanced Technologies & Treatments for Diabetes (ATTD) American Association of Clinical Endocrinologists (AACE) Association of Diabetes Care & Education Specialists (ADCES) Beyond Type 1 Children with Diabetes Diabetes Leadership Council Diabetes Patient Advocacy Coalition Diabetes Patient Advocacy Coalition Diabetes Technology and Therapeutics Journal Diabetes Technology Society DiabetesMine The diatribe Foundation The Helmsley Charitable Trust JDRF Take Control of Your Diabetes (TCOYD) Tidepool

⁹ Ibid.

¹⁰ Tchero, H., Kangambega, P., Briatte, C., Brunet-Houdard, S., Retali, G. R., & Rusch, E. (2019b). Clinical Effectiveness of Telemedicine in Diabetes Mellitus: A Meta-Analysis of 42 Randomized Controlled Trials. Telemedicine and E-Health, 25(7), 569–583. https://doi.org/10.1089/tmj.2018.0128