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Chairwoman Eshoo, Ranking Member Guthrie, and Members of the Health Subcommittee of the Committee on Energy and Commerce, thank you for the opportunity to testify today on behalf of the American Heart Association and its more than 40 million volunteers and supporters. My name is Dr. Donald Lloyd-Jones, and as the President of the American Heart Association I serve as the chief volunteer scientific and medical officer, responsible for the oversight of all medical, scientific, and public health matters, and those related to public policy. I am also the Chair of the Department of Preventive Medicine, the Eileen M. Foell Professor of Heart Research, and Professor of Preventive Medicine, Medicine, and Pediatrics at Northwestern University's Feinberg School of Medicine.

As an epidemiologist and board-certified practicing cardiologist for more than 23 years, I understand firsthand the burden of cardiovascular disease. I have a broad and deep understanding about what individuals and families need to promote health, prevent disease, cure illness, and manage chronic health conditions. As a volunteer with the American Heart Association for more than 24 years, I have been proud to advance the organization's mission to be a relentless force for a world of longer, healthier lives for all. I am also proud to represent the American Heart Association as a major advocate for population health at the federal, state, and local levels, as a supporter of healthy communities, and as a champion for health equity.

The American Heart Association is the largest nonprofit funding source for cardiovascular and cerebrovascular disease research, next to the federal government. We have funded 14 Nobel Prize winners and several important medical breakthroughs, including techniques and standards for cardiopulmonary resuscitation (CPR), the first artificial heart valve, implantable pacemakers, cholesterol inhibitors, microsurgery, and drug-coated stents. The American Heart Association is also the largest and most experienced provider of CPR training—training millions of individuals, first-responders, and health care workers worldwide each year through a vast network of more than 3,500 Authorized Training Centers and more than 400,000 instructors.

Chronic diseases represent 7 of the 10 leading causes of death in the United States,¹ and they account for 90 percent of the nation's \$3.8 trillion in annual health care costs.² Heart disease remains our nation's number one killer. By 2035, nearly half of the U.S. population will have some form of cardiovascular disease. In 2018, stroke accounted for about 1 of every 19 deaths in

¹ Centers for Disease Control and Prevention. <u>Leading causes of death</u>. *Morality in the United States*, 2019. Accessed online February 17, 2021.

² Buttorff C, Ruder T, Bauman M. <u>Multiple Chronic Conditions in the United States</u>. Santa Monica, CA: Rand Corp.; 2017 and Martin AB, Hartman M, Lassman D, Catlin A. <u>National Health Care Spending In 2019: Steady Growth for The Fourth Consecutive Year</u>. *Health Aff*. 2020;40(1):1-11.

the United States.³ Together, stroke and heart disease cost \$555 billion in medical care and lost productivity in 2016 alone. By 2035, they are expected to cost our nation \$1.1 trillion annually. These numbers will likely worsen as the long-term health effects of the pandemic on chronic conditions and health care access, as well as the long-term effects of COVID-19 infection itself, unfold in the population.

The burden of chronic diseases is growing faster than our ability to arrest that growth, putting an increasing strain on the health care system, health care costs, our productivity, educational outcomes, military readiness, and well-being.⁴ The COVID-19 pandemic has only exacerbated these challenges. For example:

- COVID-19 poses elevated health risks—including severe illness and death— for people with chronic conditions, and may lead to heart failure, stroke, kidney failure, chronic lung disease, blood pressure abnormalities, neurological conditions, and other long-term health complications in people who have survived the virus.
- Deaths from ischemic heart disease and hypertensive diseases in the United States increased during the COVID-19 pandemic. Globally, COVID-19 was associated with significant disruptions in cardiovascular disease testing, diagnosis, and timely treatment.⁵
- Individuals gained, on average, 19 pounds during pandemic-related shelter-in-place disruptions and physical activity levels worsened from already low levels as individuals limited everyday activities such as going to work or school, using fitness facilities, and accessing outdoor and community areas. Obesity, a leading risk factor for heart disease and stroke, makes individuals more susceptible to infectious disease. Indeed, patients with obesity, particularly those with severe obesity, experienced some of the worst outcomes of all patients hospitalized with COVID-19, including increased risks for blood clots, the need for breathing assistance and dialysis, and death. The added risk from severe obesity was magnified in younger patients, specifically adults under age 50.

For more than 40 years, the American Heart Association has advocated for public policies that advance health equity, and today, health equity is incorporated in each of our advocacy priorities, including access to care, tobacco prevention, child nutrition, physical activity, medical research, and public health infrastructure.⁸ I am pleased to testify today about the ways in which the

³ Heart Disease and Stroke Statistics—2021 Update: A Report From the American Heart Association https://www.ahajournals.org/doi/10.1161/CIR.0000000000000050

⁴ Heidenreich PA, Trogdon JG, Khavjou OA, et al. Forecasting the future of cardiovascular disease in the United States: a policy statement from the American Heart Association. Circulation. 2011;123:933-944.

⁵ COVID-19 Pandemic Indirectly Disrupted Health Disease Care. American College of Cardiology. January 11, 2021. Accessed online February 17, 2021.

⁶ Lin AL, Vittinghoff E, Olgin JE, Pletcher MJ, Marcus GM. Body Weight Changes During Pandemic-Related Shelter-in-Place in a Longitudinal Cohort Study. JAMA Netw Open. 2021 Mar 1;4(3):e212536. doi: 10.1001/jamanetworkopen.2021.2536.

Centers for Disease Control and Prevention. Obesity, Race/Ethnicity, and COVID-19. Accessed online October 15, 2021
 Churchwell K, Antman E, Birnbaum J, Desai NR, Harrington RA, Holubowich EJ, Ivy KN, Schoeberl M, Warner JJ, White CJ, Whitsel LP, Yancy C; American Heart Association Advocacy Coordinating Committee. Nonprofit Advocacy at the American Heart Association: Creating a Visionary Way Forward at Our 40th Anniversary: An American Heart Association Policy Statement. Circulation. 2021 May 11;143(19):e947-e958. doi: 10.1161/CIR.00000000000000972. Epub 2021 Apr 12. PMID: 33840208.

bipartisan bills under your consideration, namely, the Increasing Access to Quality Cardiac Rehabilitation Care Act of 2021 (H.R. 1956) and the Cardiovascular Advances in Research and Opportunities Legacy (CAROL) Act (H.R. 1193), would improve heart health for all.

I thank Representative Lisa Blunt Rochester for her work with Representative Adrian Smith to champion the Increasing Access to Quality Cardiac Rehabilitation Care Act, which would significantly expand patient access to cardiac rehabilitation services. Cardiac rehabilitation, or "cardiac rehab" for short, is a medically supervised program for patients who have experienced a serious cardiac event. It includes monitored exercise training (including blood pressure and heart rate response), education about heart-healthy lifestyle and health behaviors, and counseling to reduce stress—with a goal of helping patients return to an active lifestyle and recover more quickly.

Cardiac rehab offers a multifaceted and highly tailored approach to optimize a patient's overall physical, mental, and social functioning. While cardiac rehabilitation does not change a patient's past, it can help improve their heart's future. Evidence shows that cardiac rehab programs can benefit numerous types of patients, including those who have had a heart attack, have stable angina, received a stent or angioplasty, have heart failure with reduced ejection fraction, or have undergone coronary bypass surgery, heart valve surgery, or heart or heart-lung transplant surgery.

Beyond helping individuals recover from a cardiovascular event and make the necessary lifestyle changes to reduce the chances of further heart problems, participation in cardiac rehab has been shown to significantly reduce the risks of death from any cause, including cardiac causes, and sudden cardiac death, as well as result in decreased hospital readmissions. ^{9,10} As a clinician, I am an avid user of cardiac rehab services for all of my qualifying patients, and in addition to its proven benefits for health outcomes, I can also attest to its less tangible benefits. My patients who have participated in cardiac rehab routinely tell me that it teaches them what symptoms they need to pay attention to, and, crucially, it restores their sense of well-being and their ability to trust their body as they return to normal life and activities.

Despite the clear benefits of cardiac rehab, participation by a significant proportion of patients who suffer from cardiovascular diseases is severely lacking. Only one-third of patients eligible for cardiac rehab will ever receive it. Among Medicare beneficiaries, participation is even lower—only 1 out of every 4 Medicare patients eligible for cardiac rehab ever receives these services, and an even lower proportion completes a full course of cardiac rehab, which is typically 32 sessions over approximately 10 weeks. There are also major geographic disparities in participation, with participation being 30 percent lower for individuals who live outside of metropolitan areas, and 42 percent lower for those who live in economically-deprived urban

⁹ Patrick R.Lawler, Kristian B.Filion, Mark J.Eisenberg. Efficacy of exercise-based cardiac rehabilitation post–myocardial infarction: A systematic review and meta-analysis of randomized controlled trials. *American Heart Journal*. 2011;162(4):571-584.e2.

¹⁰ Shannon M.Dunlay, Quinn R.Pack, Randal J.Thomas, Jill M.Killian, Véronique L.Roger. Participation in Cardiac Rehabilitation, Readmissions, and Death After Acute Myocardial Infarction. *The American Journal of Medicine*. 2014;127(6):538-546.

communities.

One of the issues preventing higher participation in cardiac rehab is that many patients are simply not being referred by their clinicians. Sometimes when patients are discharged following an adverse cardiac event, they face long referral wait times, which have been shown to reduce enrollment in cardiac rehab programs. For every extra day a person must wait to begin cardiac rehab, that person is increasingly less likely to enroll.

The elderly, women, people of color, those living in rural areas, and patients with lower socioeconomic position are all less likely to be referred to cardiac rehab. Unfortunately, they also are less likely to take that first critical step to enroll after referral. This is of great concern because women and people of color are far more likely to die within five years after a first heart attack than their white male patient counterparts. According to one analysis, 7 percent of the Black versus white all-cause mortality gap could potentially be reduced by equitable cardiac rehab referral.

The American Heart Association is committed to public policies that increase access to these vital programs and reduce the cardiac rehab treatment and referral gap. The Increasing Access to Quality Cardiac Rehabilitation Care Act would improve health equity by enabling greater patient access to cardiac and pulmonary rehab in rural and underserved communities and by facilitating the timely referral of patients to these vital programs.

Medicare currently has a "direct supervision" requirement for cardiac rehab programs, which means a physician must be immediately available and accessible at all times when services are being furnished under these programs. Congress previously acknowledged that Medicare imposes a more stringent requirement for direct physician supervision than should be required. With the passage of the Bipartisan Budget Act in 2018, Congress authorized physician assistants, nurse practitioners, and clinical nurse specialists—referred to collectively as advanced practice providers (APPs)—to begin supervising patients' day-to-day cardiac and pulmonary rehabilitation care beginning in 2024. While we applaud this progress, patients cannot wait until 2024 for these changes to take place.

For too long, these requirements have made it a challenge for cardiac and pulmonary rehab programs to operate in areas where physicians are scarce, imposing unnecessary costs in both underserved rural and urban areas, while limiting patient access. This bill before you today would allow advanced practice providers to begin supervising patients' day-to-day cardiac and

¹¹ Gary J. Balady, Philip A. Ades, Vera A. Bittner, et al. Referral, Enrollment, and Delivery of Cardiac Rehabilitation/Secondary Prevention Programs at Clinical Centers and Beyond. *Circulation*. 2011;124(25):2951-2960. doi:https://doi.org/10.1161/CIR.0b013e31823b21e2

¹² Castellanos LR, Viramontes O, Bains NK, Zepeda IA. Disparities in Cardiac Rehabilitation Among Individuals from Racial and Ethnic Groups and Rural Communities—A Systematic Review. *Journal of Racial and Ethnic Health Disparities*. 2019;6(1):1-11. doi:10.1007/s40615-018-0478-x

¹³ Shanshan Li, Gregg C. Fonarow, Kenneth Mukamal, et al. Sex and Racial Disparities in Cardiac Rehabilitation Referral at Hospital Discharge and Gaps in Long-Term Mortality. *Journal of the American Heart Association*. 2018;7(8):e008088. doi:https://doi.org/10.1161/JAHA.117.008088

pulmonary rehab care beginning in 2022 instead of 2024. The bill also goes a step further and would authorize advanced practice providers to order cardiac rehab for patients—a change that would facilitate faster referral of patients and help close the referral gap.

It is important to note that advanced practice providers are routinely on the front line in critical care environments, such as hospitals and hospital clinics, emergency rooms, and intensive care units, and they collaborate closely with physicians as part of a patient's care team. They are highly trained providers who are qualified to order and supervise these safe and effective services. APPs are fully trained in the skills needed to monitor patients during supervised exercise in cardiac rehab, and fully trained to call 911 and respond rapidly in cases of emergency, including administration of life support and CPR in the rare cases it is needed. The legislation would eliminate obstacles, delays, and unnecessary paperwork that can prevent patients from beginning rehabilitation services on a timely basis.

Expanding the provider pool for ordering and supervising cardiac rehab with the adoption of Increasing Access to Quality Cardiac Rehabilitation Care Act would make great strides toward expanded access to cardiac rehab services, particularly in rural and under-resourced areas of the country.

Beyond this legislation, the American Heart Association strongly supports the Centers for Disease Control and Prevention's (CDC) Million Hearts® initiative, which set a national goal to increase participation in cardiac rehab to 70 percent of eligible patients. Working to improve awareness about the value of cardiac rehab, combined with reducing system and patient barriers to participation through this legislation, are critical steps to improving the referral, enrollment, and participation rates in cardiac rehab programs.

It is also important to recognize that even with timelier referral and increased program capacity, some patients may continue to face access issues due to transportation barriers and responsibilities at home or work. For example, patients living at a distance from a cardiac rehab program are less likely to participate, compared those who live closer to a program. The American Heart Association supports alternative models to traditional center-based cardiac rehab programs, including home-based and "virtual" cardiac rehabilitation. During the COVID-19 pandemic, virtual options have allowed many patients to continue cardiac rehab even though 71 percent of in-center cardiac rehab programs closed temporarily during the pandemic. 15

The American Heart Association is also pleased to support the CAROL Act. I would like to express my deepest sympathy to Representative Andy Barr and his family for the tragic loss of his wife Carol. We profoundly thank him for sponsoring this legislation to advance our understanding and awareness of heart valve disease, a condition that kills approximately 25,000

Association of Cardiovascular and Pulmonary Rehabilitation, the American Heart Association, and the American College of Cardiology. *Circulation*. 2019;140:e69–e89. https://doi.org/10.1161/CIR.000000000000663.

Valencia HE, Savage PD, Ades PA. Cardiac rehabilitation participation in underserved populations: minorities, low socioeconomic, and rural residents. J Cardiopulm Rehabil Prev. 2011; 31:203–210. doi: 10.1097/HCR.0b013e318220a7da
 Thomas RJ, Beatty AL, Beckie TM, Brewer LC, Brown TM, Forman DE, Franklin BA, Keteyian SJ, Kitzman DW, Regensteiner JG, Sanderson BK, Whooley MA. Home-Based Cardiac Rehabilitation: A Scientific Statement From the American

people each year. ¹⁶ With this bill, we could help prevent more families from enduring a similar tragedy. I want to add that the American Heart Association is honored to partner with Carol's friends and family in establishing the Carol Barr Fund to support STEM education for young women in Kentucky.

The CAROL Act authorizes funding for the National Heart, Lung, and Blood Institute (NHLBI) to conduct life-saving research on heart valve disease. This investment will help address gaps in our understanding of heart valve disease, including what causes sudden cardiac death in a small number of people, and predominantly women, due to mitral valve prolapse (MVP).

MVP is a degenerative heart valve condition that led to the untimely death of Carol Barr. It is a condition in which the two leaflets of the mitral valve don't close together properly—instead they bulge (prolapse) upward into the left atrium. MVP is also known as click-murmur syndrome, Barlow's syndrome, or floppy valve syndrome. When the heart pumps, part of one or both leaflets of the valve collapse backward into the left atrium. In some cases, the prolapsing valve does not seal, allowing blood to flow backward through the valve, an issue termed mitral regurgitation, that may cause a heart murmur that is audible with a stethoscope. In most cases, this is mild and harmless, though it merits ongoing monitoring. Most people who have the condition are unaware of it. However, in some cases treatment and even valve repair or replacement are required.

MVP occurs in approximately 2 percent of the population.¹⁷ A person can be born with the genetic risk for developing MVP. It also can be caused by other health problems, including some connective tissue diseases. MVP rarely becomes a serious condition. However, in the most serious cases, it can cause heart failure or abnormal heart rhythms (arrhythmias) that may eventually become life-threatening. This happens because when the valve leaks, it can cause the atrium to enlarge and fluid to build up in the lungs. An enlarged atrium may also lead to heart rhythm problems such as atrial fibrillation, which may cause blood clots to form. When clots travel from the heart to the arteries or the brain, it can lead to a stroke or heart attack.

Significant MVP poses a substantially elevated relative risk of sudden cardiac death, with an estimated 26,000 individuals in the United States at risk. Risk for sudden cardiac arrest in patients with MVP is at least three times higher than the risk of sudden cardiac arrest in the general population. Thus, identifying risk reduction strategies for those with MVP is imperative. The challenge is designing ways to identify patients at risk of sudden cardiac arrest and assessing an appropriate medical treatment such as medication or surgery to address the

¹⁶ CDC: Facts About Valvular Heart Disease, https://www.cdc.gov/heartdisease/valvular_disease.htm Accessed 10/14/2021

¹⁷ Problem: Mitral Valve Prolapse, American Heart Association, https://www.heart.org/en/health-topics/heart-valve-problems-and-causes/problem-mitral-valve-prolapse Accessed 10/14/2021

¹⁸ Association Between Malignant Mitral Valve Prolapse and Sudden Cardiac Death: A Review, Muthukumar,

¹⁸ Association Between Malignant Mitral Valve Prolapse and Sudden Cardiac Death: A Review, Muthukumar, Jahangir, Jan, et.al, JAMA Cardiology, September 2020, Volume 5, Number 9.

¹⁹ Ibid.

condition. Establishing standards for identifying MVP patients that are suitable for an implantable defibrillator that may prevent sudden cardiac arrest are also needed.

One of the most troubling aspects of MVP is just how much we still don't know about its causes, about factors that lead to progressive problems, about when is the best time to intervene, and about what increases risk for sudden cardiac death. I have had many patients whom we have followed over years with MVP, and it can be a frustrating process for both the patient and the doctor since the natural history can vary widely from patient to patient, leaving substantial uncertainty in what to do and when to intervene with treatments. The CAROL Act would take a crucial step in identifying potential risk factors and treatment options for MVP by authorizing the convening of a workshop of subject matter experts and stakeholders to identify research needs and opportunities to develop guidelines for the treatment of patients with MVP. The legislation also directs the Director of the National Institutes of Health, in coordination with NHLBI, to issue grants or contracts for conducting research on valvular heart disease in response to the findings and recommendations of this workshop.

The CAROL Act also would instruct the CDC to carry out projects to reduce the incidence of sudden cardiac death caused by valvular heart disease. These programs may include the implementation of public information and education programs for the prevention of sudden cardiac death and for broadening the awareness of the risk factors, symptoms, and consequences of valvular heart disease. The bill also would invest in efforts to increase screening, detection, and diagnosis of heart valve disease. According to an awareness survey, 3 out of 4 Americans report knowing little to nothing about heart valve disease. Many people living with heart valve disease, particularly women, are never diagnosed or they are diagnosed later in the course of the disease, leading to missed opportunities for treatment. Currently, there is no heart valve disease screening recommendation from the U.S. Preventive Services Task Force, nor is screening part of the "Welcome to Medicare" preventive visit or the yearly "Wellness" visit. It is important for both the public and clinicians to be aware of patients' risk for valve disease, to recognize the symptoms, and to have an accurate and timely diagnosis. Earlier detection and diagnosis can lead to earlier treatment before the onset of worsening symptoms or elevation in risk for sudden cardiac death.

Finally, the CAROL Act includes an important element that would prevent the tragic loss of life caused by sudden cardiac arrest by authorizing funding for the surveillance of out-of-hospital cardiac arrest. This would improve patient outcomes and help the medical community establish who is most at risk for sudden cardiac arrest. Annually, more than 350,000 people fall victim to sudden cardiac arrest outside of a hospital environment.²¹ Sudden cardiac arrest is the acute loss of blood perfusion to the vital organs, usually because of a catastrophic change in the heart rhythm (sometimes caused by MVP). In the setting of a sudden cardiac arrest, seconds count in

²⁰ Public Awareness of Heart Valve Disease: Results of National Survey Research for The Alliance for Aging Research, June 2016, https://www.agingresearch.org/document/heart-valve-disease-surveys/

the response of bystanders and the emergency system to restore a normal heart rhythm and blood pressure, and they determine the difference between life and death or the chance for a meaningful neurological recovery. Unfortunately, only about 1 in 10 victims survives this dramatic event, and many survivors are left with permanent heart and brain damage.²² This new investment would support the goals outlined by the National Academy of Medicine to improve cardiac arrest survival including through the establishment of a national registry of cardiac arrest.

Registry data collection is critical to monitoring trends in the population, identifying geographic and sociodemographic "hot spots," targeting public health resources, improving rapid response capabilities and systems of care to advance the chain of survival, and improving in-hospital patient care and survival rates. It also allows communities and public health organizations to monitor quality of care, compare patient populations, measure interventions and outcomes, and ascertain whether resuscitation is provided according to evidence based guidelines. Finally, surveillance registries can help us understand what interventions are working in our fight to improve survival rates in sudden cardiac arrest. The CAROL Act could provide the necessary resources to expand to nationwide the Cardiac Arrest Registry to Enhance Survival (CARES) founded by the CDC and Emory University Department of Emergency Medicine in 2004. CARES currently includes 29 state-based registries covering 51 percent of the U.S. population. This includes more than 2,500 EMS agencies and 2,000 hospitals nationally. Without uniform and reliable data collection in every state, communities cannot ascertain the effectiveness of their sudden cardiac arrest response systems, nor can they assess the impact of interventions designed to improve survival rates. In other words, you cannot improve what you do not measure.

As the pandemic has demonstrated, chronic diseases and infectious diseases are inextricably linked, and health disparities remain all too pervasive. The bills under consideration today will advance equity by improving access to care for cardiac rehabilitation, and expanding our understanding and treatment for heart valve diseases, including MVP, and their consequences. I thank you for the opportunity to offer my perspective today, and for your continued leadership to improve cardiovascular health and wellness for all through these and other bills under your jurisdiction. I look forward to your questions.

²² Ibid.