

**American Heart Association/American Stroke Association  
Strategic Policy Agenda  
2014-2017**

**I. Introduction**

The American Heart Association's public policy agenda provides our federal, state and local advocacy staff with strategic guidance and direction on policy issues and positions that align with and support the Association's mission and strategic priorities. The document attempts to capture the breadth of the Association's policy portfolio over the next three years, however, it is possible that issues will emerge during that time that could not be forecasted and might become a priority for the American Heart Association and incorporated into our work. Additionally, the Association scans the political landscape annually to identify leading opportunities and establishes federal and state priorities that serve to focus our immediate advocacy efforts on those issues that present the greatest opportunity for success in achieving mission and strategic priority around health impact through public policy.

This document provides a comprehensive summary of the policy priorities of the American Heart Association in the areas of heart disease and stroke research, cardiovascular health (nutrition, physical activity, obesity treatment and prevention, tobacco cessation and prevention, and air pollution), high quality/high value of heart disease and stroke care, appropriate and timely access to heart disease and stroke care and protection of the non-profit environment. Included in each of these areas is the Association's commitment to eliminate health disparities. Working with our local affiliates and You're the Cure grassroots advocates, the Association can address legislative and regulatory opportunities that advance our mission through public policy at the federal, state, and local level. Table 1 summarizes the policy and advocacy strategies in each of these priority areas and illustrates the impact of AHA's advocacy work on our mission, including health impact, engagement, positioning, and revenue generation.

The American Heart Association's Advocacy Coordinating Committee (AdCC), a committee of the Association's national board, is responsible for establishing the Association's policy positions, public policy agenda, and annual legislative and regulatory priorities. The public policy agenda and annual priorities are a product of a rigorous internal process that is informed by our science, guided by our 2020 health impact goal and strategic plan, and refined through the advice and counsel provided by AHA staff and volunteers. These priorities, which are predicated on extensive policy research and analysis, are realized through legislative and regulatory advocacy conducted by staff, media advocacy efforts, and You're the Cure volunteer advocates.

**II. Heart and Stroke Research**

In working to achieve its mission, the American Heart Association makes medical research a top priority. The association believes that basic research is the starting point for all medical advances and is an essential function of the federal government that the private sector cannot fill. Learning more about the life processes of the cardiovascular system is the only sure way the association can continue to treat—and prevent—heart disease and stroke and promote cardiovascular health for all Americans.

Although the association is the largest supporter of heart and stroke research outside of the federal government and the pharmaceutical industry, the American Heart Association cannot accomplish its mission without the help of research supported by the federal government, primarily the National Institutes of Health (NIH), but also the Centers for Disease Control and Prevention (CDC), comparative effectiveness research, including PCORI, CMS Innovation Fund, demonstration projects, the Agency of Healthcare Research and Quality (AHRQ); and the various state agencies. The association also advocates for the identification of additional federal funding sources to supplement, not reduce, monies awarded through the appropriations process. This section focuses on several areas of the association's advocacy/policy agenda on heart and stroke research.

The association's research priority includes all forms of scientific studies, including basic science as well as clinical, translational, health services (outcomes), genomics, and comparative effectiveness research and the overall research environment. Effectively preventing and treating disease depends on accurate knowledge about its causes, on how disease affects the body, on drugs that combat disease, on devices that are safe and work, and on operations that cure as well as clinical research that helps enable health care professionals to assist their patients and their families in building the skills they need to adopt and maintain a healthy lifestyle. The knowledge, material and skills on which prevention and treatment are based have come from a variety of sources, including information that can only be obtained from research on both animals and humans. Animal research has improved the health and welfare of both animals and humans. The decline in death rates in the United States from heart disease and stroke since the 1960s is due to lifestyle changes and new methods of treatment and prevention, many of which are based on animal research. The association generally opposes legislation and regulations that would curtail necessary heart disease and stroke research or make it unduly difficult or costly.

### ***Demographics***

Death rates from coronary heart disease have fallen 40 percent from 1999 to 2009 and have dropped for stroke nearly 37 percent during that same time period.<sup>1</sup> This decline is directly related to heart and stroke research, with scientists on the verge of new and exciting discoveries that could lead to innovative treatments and even cures for heart disease and stroke. However, as baby boomers age, heart disease, stroke and other forms of cardiovascular disease will cost more lives and money. Heart disease and stroke are the number 1 and 4 causes of death, respectively, in the U.S.<sup>1</sup> By age 45, lifetime risk for cardiovascular disease (CVD) is 2 in 3 for men and more than 1 in 2 for women.<sup>1</sup> As the baby boomers age, heart disease deaths are projected to increase 2.5 times faster than the population, and the prevalence of heart disease is projected to increase by 16% each decade.<sup>2</sup> A recent study projects that more than 40% of adults in the U.S. will live with cardiovascular disease at a cost of \$1.5 trillion annually by year 2030.<sup>3</sup> This same study forecasts that direct costs for stroke will escalate 238 percent and prevalence will increase 25 percent over the next 20 years.<sup>3</sup> Treatment costs for CVD are expected to rise 64-84 percent by 2025.<sup>4</sup> Costs to treat heart failure are expected to more than double by 2030 as the U.S. population ages and the number of people with heart failure could climb 46 percent.<sup>3</sup> By 2030, costs to treat stroke are projected to more than double and the number of people suffering strokes may increase 20 percent.<sup>5</sup> Americans now 45-64 years old are expected to have the highest increase in stroke at 5 percent.<sup>5</sup>

### ***Research Can Save Money***

Heart and stroke research can reduce healthcare costs. For example, every \$1 spent in technological improvements in treating heart attacks saves \$7.<sup>6</sup> NIH research has shown that ordinary aspirin, with or without other anti-platelet drugs, can reduce the risk of recurrent stroke.<sup>7</sup> The drug, tPA (tissue plasminogen activator) is the only FDA-approved emergency treatment for the most common type of stroke.<sup>8</sup> Patients treated with tPA within 3 hours of onset of stroke symptoms are 30% more likely to have minimal or no disability at a 3-month follow-up.<sup>8</sup> A study estimates the original National Institute of Neurological Disorders and Stroke (NINDS)-funded tPA trial resulted in a 10-year net benefit of \$6.47 billion.<sup>9</sup> NINDS's Stroke Prevention in Atrial Fibrillation (AF) Trial 1 showed treatment with aspirin or Warfarin could reduce stroke in AF victims by 80%, resulting in a 10 year net benefit of \$1.27 billion, with a savings of 35,000 quality-adjusted life years.<sup>9</sup> Death rates from heart disease has dropped by more than 60 percent and from stroke by 70 percent since 1940, in large part as a result of NIH-funded research.<sup>10</sup> Eliminating deaths from heart disease would generate about \$48 trillion in economic value from increased life expectancy.<sup>11</sup> Eliminating deaths from heart disease would generate about \$48 trillion in economic value from increased life expectancy.<sup>11</sup>

### ***Research Improves Care***

Heart and stroke research has revolutionized patient care. The following are some examples of life-saving treatments:

Revolutionary clot-busting drugs reduce disability from heart attack or stroke by dissolving the blood clots that cause the attack.

- The use of drugs to lower cholesterol has reduced the average cholesterol level in the U.S. to the ideal range for the first time in about 50 years;<sup>12</sup>
- Small, wire-mesh stents are one option for widening narrowed arteries in the heart or neck;
- Pacemakers, implantable cardiac defibrillators, automated external defibrillators (AEDs), and minimally invasive surgical techniques have significantly improved health care outcomes;
- FDA has approved the first totally implanted permanent artificial heart for patients with advanced heart failure;
- An international research consortium that conducted one of the largest genomic studies ever, identified 29 genetic variations that influence blood pressure, a leading risk factor for heart attack and the major one for stroke. More than half of these genetic variants were previously unknown. This will provide insights into the biology of blood pressure and may lead to novel therapeutic strategies.
- Constraint-induced Movement Therapy—a rehabilitative method forcing use of a partially paralyzed arm—can help stroke survivors regain arm function. Rehabilitation can also include prosthetic valves including those deployed percutaneously, closure devices that can be deployed without surgery.
- Those at highest risk for a second stroke should be treated with aggressive medical therapy alone rather than with a brain stent (NINDS SAMMPRIS 2011)

## **The AHA's Policy Agenda to Address Heart and Stroke Research**

### ***Restore and Protect Funding***

#### *The National Institutes of Health*

The NIH is our nation's premier medical research agency and includes 27 Institutes and Centers. According to the NIH, it is the primary federal agency for conducting and supporting basic, clinical and translational medical research, and it investigates the causes, treatments, and cures from both common and rare diseases. To reduce disability and death from heart disease, stroke and other forms of cardiovascular disease, the Association seeks to restore funding lost to the sequester, cover medical research inflation and provide modest growth for 2013-2023, including for heart disease, stroke, cardiac arrest, and other cardiovascular diseases. Stable and sustained funding is essential to capitalize on past investments. Sustained funding will permit aggressive implementation of priority initiatives. (The sequester is the result of the Budget Control Act that requires Congress to reduce spending over the next 10 years by \$2.1 trillion. The first year of the sequestration cuts took place on March 1, 2013. NIH lost \$1.5 billion or 5% of its budget, cut evenly across all programs, projects and activities. Therefore, about 700 fewer competitive research project grants will be awarded this year. In addition, under this year's sequestration cut, 20,500 jobs across the United States will be lost and a \$3 billion cut in new economic activity.) This includes medical research programs of the

- National Heart, Lung, and Blood Institute: the NHLBI plans, conducts, and supports research related to the causes, prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases; and sleep disorders. The Institute also administers national health education campaigns on women and heart disease, healthy weight for children, and other topics; and
- National Institute of Neurological Disorders and Stroke: the NINDS is the nation's leading funder of research on the brain and nervous system. The Institute's mission is to reduce the burden of neurological disease—a burden borne by every age group, by every segment of society, by people all over the world.

Attention should also be given to other 20 to 22 NIH institutes (out of 27), centers and divisions that conduct heart and stroke research, primarily the:

- National Institute on Aging (NIA): the NIA leads the federal effort supporting and conducting research on aging and the medical, social and behavioral issues of older people;
- National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK): the NIDDK conducts and supports basic and clinical research and research training on some of the most common, severe and disabling conditions affecting Americans. The Institute's research interests include: diabetes and other endocrine and metabolic diseases; digestive diseases, nutrition, and obesity; and kidney, urologic and hematologic diseases; and
- National Institute of Nursing Research (NINR): the NINR supports basic and clinical research that develops the knowledge to build the scientific foundation for clinical practice, prevent disease and disability, manage and eliminate symptoms caused by illness, and enhance end-of-life and palliative care.

NIH-supported research has revolutionized patient care and holds the key to finding new ways to treat and prevent heart disease and stroke and promote cardiovascular health for all Americans, resulting in longer, healthier lives and reduced health care costs. In addition, NIH generates economic growth, creates jobs and preserves the U.S. role as the world leader in pharmaceutical and biotechnology industries. Specifically, NIH invests resources in every state and in 90 percent of congressional districts. Further, the typical NIH grant supports seven mainly high-tech full-time or part-time jobs.<sup>13</sup> Every dollar that NIH distributes in a grant returns more than \$2 in goods and services to the local community in one year.<sup>14</sup> Over the last decade, NIH has lost 20 percent of its purchasing power.

#### *Agency for Healthcare Research and Quality*

The AHRQ develops scientific evidence to improve health care for Americans, AHRQ provides patients and caregivers with valuable scientific evidence to make the right health care decisions. AHRQ's research also enhances quality and efficiency of health care, providing the basis for protocols that prevent medical errors and reduce hospital-acquired infections, and improve patient confidence, experiences, and outcomes. To reduce disability and death from heart disease and stroke, the Association advocates for stable and sustained federal funding for AHRQ.

#### *Centers for Disease Control and Prevention (CDC)*

The CDC, based in Atlanta, GA works to protect public health and safety by providing information, and conducting surveillance and programming to enhance health decisions, and promote health through partnerships with state health departments and other organizations. The CDC focuses national attention on developing and applying disease prevention and control, environmental health, occupational safety and health, health promotion, prevention and education. The American Heart Association works closely with CDC across several areas and advocates for funding for CDC and its initiatives. The CDC remains under-funded to fully achieve its mission in cardiovascular health—prevention of risk factors, detection and treatment of risk factors, early identification and treatment of heart attacks and strokes, and prevention of recurrent cardiovascular events—with unfulfilled potential to translate knowledge into public health practice through policy/environmental/system change and to evaluate the impact of these changes on improved cardiovascular health of the nation. The Association advocates for stable and sustained federal and state funding for CDC's work, supporting activities focused on surveillance, chronic disease prevention, school-based health, and population-based prevention. The Association strives to decrease the percentage of people at risk for heart disease, stroke and other cardiovascular diseases that effectively reduce the risk factors to goal levels established by the Association's guidelines for primary and secondary prevention. In particular, the Association is focused on stable and sustained federal funding for the Division for Heart Disease and Stroke Prevention, which manages initiatives on surveillance, evaluation, research, WISEWOMAN, and Million Hearts. The Association works to secure and protect dedicated state appropriations for state Heart Disease and Stroke Prevention Programs in state health departments. Other areas are the tobacco cessation and prevention work within the Office of Smoking

and Health, and obesity prevention, nutrition, and physical activity grants, and surveillance and programming within the Division of Adolescent and School Health.

### ***State Health Departments and other regulatory agencies***

In collaboration with departments of health in each state the American Heart Association works to maximize both federal and state resources for heart disease and stroke prevention programs. While working to secure and protect dedicated state appropriations aligned with the American Heart Association's strategic plan the association also works to support program implementation in the states. American Heart Association staff teams in each state explore opportunities to generate and direct additional fiscal resources for state heart disease and stroke prevention programs and initiatives. The association supports other public health initiatives and evaluation targeted at heart disease, stroke and related risk factors, and the disparities that exist in these areas. The American Heart Association's work with regulatory agencies most frequently involves following through on recently adopted legislation to confirm the promulgation of necessary rules to confirm successful implementation in the states. During that process the association makes comments to proposed rules to confirm and ensure the intent of the legislation. In addition the staff teams in each state closely monitor opportunities for public comment to other proposed regulatory rules and procedures.

### ***Remove Barriers to Medical Research***

Unfortunately, participation in clinical trials is very low: Only 6 percent of patients with severe chronic illnesses participate. These low participation rates mean that research takes longer, costs more, and ultimately results in delays in the development of new therapies or a lag in evidence about the safety and effectiveness of existing therapies. Over the years, medical research has faced various barriers, including proposed constraints on animal research, undue constraints within the Institutional Review Board processes and HIPAA regulations, and removal of insurance barriers to patients' participation in research. The AHA advocates on several of these issues to limit the following barriers to effective medical research.

#### ***Animal Research Constraints***

A small group of extreme animal-rights activists will not rest until all animal research is banned. For example, after more than a decade, these activists were successful in banning the use of U.S. Department of Agriculture licensed and regulated Class B dealers as a source of non-purpose bred dogs and cats in medical research for NIH grant recipients, beginning in 2015. In addition, they strive to discourage pounds from providing unwanted animals for medical research. They wanted to end Class B dealers based on an erroneous assumption that these dealers routinely sell abused or stolen animals to scientific laboratories. Prohibition of the use of these Class B dealers would jeopardize cardiovascular disease research because certain studies and training to fight this condition are best performed on dogs that are large in size, older and represent a genetically diverse population. In many areas, suitable animals of these types are only available from Class B dealers. To fill this void, NIH is working to increase the capacity of Class A vendors to supply the types of dogs that currently come from Class B random source dealers. The association wants to ensure that suitable animals required for all types of medical research will be accessible and affordable.

#### ***Institutional Review Board Processes/HIPAA Regulations***

Institutional Review Board processes and HIPAA privacy rules do create patient and research participant confusion, inhibit recruitment of research subjects and impose costly administrative procedures. (2008) Research conducted by the AHA has shown that respondents felt their research was "impacted" by HIPAA, public trust in research is not enhanced and others said the "research enterprise" is damaged—specifically 49% of respondents said recruitment is decreased, 67% said submissions are more complex, 78% said costs are increased and 79% said studies are longer. Additional research from AHA has shown that potential subjects were overwhelmed with minutiae to the point

where the aim of the study was lost in "necessary text" making a full reading of the form nearly impossible for patients. This in turn discouraged many patients from participating in clinical research; and some researchers noted that it is often difficult to get busy clinicians to make contact with families to ask them "permission" for a third party to contact them about research. AHA research also found that current process requirements lead to more administrative costs including additional staff and/or increased number of meetings with legal, compliance, administration, to discuss roles, business relationships, and procedures that need to be followed; and delays now inherent in IRB review and re-review nearly ensure delays unacceptable to funding agencies.

#### *Insurance Coverage for Clinical Trials*

According to a June 2013 survey by Research!America, knowing that their medical bills would be covered if an injury results is an important consideration for patients when deciding whether to participate in a clinical trial, with 88 percent of those surveyed saying this would be an important factor in the decision to participate. Many insurers have refused to cover the routine costs for patients participating in clinical trials, and participation in clinical research should therefore be encouraged through the removal of insurance barriers.

As part of its work on the Affordable Care Act, the association has worked to address this barrier. Section 2709 of the ACA requires health plans to cover the routine medical costs for individuals with life-threatening conditions participating in approved clinical trials, effective January 1, 2014. However, the Department of Health and Human Services has not issued regulations to implement this section of the law, instead indicating that it is self-implementing. The association will need to closely monitor implementation of this provision to ensure that its promise is fulfilled for patients.

#### *Increase Participation of Underrepresented Groups in Clinical Research*

Women, racial and ethnic minorities, and the elderly have historically been underrepresented in clinical trials for a variety of reasons. It is important that clinical trials include diverse populations to the maximum extent possible and appropriate to ensure that clinicians and patients have the best information possible when making decisions about what treatment will be safest and most effective for them. According to an August 2013 study by the Food and Drug Administration, while progress has been made in the inclusion of women, minorities, and the elderly in clinical trials used for approval of new medical products, gaps remain in the extent of their inclusion in research, in demographic subgroup analyses, and in the public availability of subgroup specific information. The Association will continue to work to ensure that women, minorities, and the elderly are adequately represented in clinical research, that subgroup analysis is conducted, and that health care providers and their patients have access to subgroup specific safety and efficacy information.

### **III. Prevention and Healthy Lifestyle**

#### *Physical Activity*

Regular physical activity is associated with a healthier, longer life and with a lower risk of heart disease, high blood pressure, diabetes, obesity, and some cancers.<sup>15</sup> Being physical active is one of the most important health behaviors people can do to maintain cardiovascular health and quality of living. The *2008 Physical Activity Guidelines for Americans*<sup>16</sup> recommend that children engage in at least 60 minutes of moderate-vigorous physical activity each day to include aerobic, muscle, and bone strengthening exercises and adults should engage in 150 minutes/week of moderate-intensity, or 75 minutes a week of vigorous-intensity aerobic physical activity that includes muscle-strengthening activity two or more days a week. Adults and children should avoid long periods of inactivity through the day. A key public health goal is to move the very sedentary part of the population to at least some exercise -- some physical activity is better than none, and adults who participate in any amount of physical activity gain a certain level of health benefits. In order to promote physical activity across the U.S. population, the National Physical Activity Plan highlights the major sectors where policy, environment, and programmatic changes, including transportation, business/industry, schools, parks/recreation, healthcare, will facilitate active living. The following areas are prioritized by the American Heart Association to improve physical activity levels and address one of the seven important health factors that impact the cardiovascular health of our population.

***Address the quality and increase the frequency of physical education in schools and promote regular moderate-vigorous physical activity before, during, and after the school day.***

The quality and quantity of physical education in the nation's schools is an important part of a student's comprehensive, well-rounded education program and a means of positively affecting life-long health and well-being. The optimal physical education program will foster a long-term commitment to physical activity as part of a healthy lifestyle that will help children prevent chronic disease and numerous other conditions, including abnormal cholesterol, high blood pressure, obesity, and heart disease. Quality physical education also should be supplemented, but not replaced, by additional school-based physical activity.

Physical education teaches students the basics of physical literacy and how to integrate exercise into their lives in order to establish a lifetime of healthy living. The Institute of Medicine recommends that children have adequate opportunities to get 60 minutes of physical activity every school day.<sup>17</sup> Physical education should be an important part of that physical activity time.

Unfortunately, many youth are increasingly sedentary throughout their day, meeting neither physical education nor national physical activity recommendations. Physical education in schools has been decreasing in recent years.<sup>18</sup> Only 3.8% of elementary, 7.9% of middle, and 2.1% of high schools provide daily physical education or its equivalent for the entire school year.<sup>19</sup> Twenty-two percent of schools do not require students to take any physical education at all.<sup>15</sup> Nationwide, only 51.8% of high school students attend at least some physical education (PE) classes and 31.5% of those students have daily physical education.<sup>20</sup> Recent analysis shows that physical education continues to decline in schools while opportunities for school-based sports programs have increased for some students.<sup>18</sup>

Public support exists for increasing physical education in schools. The vast majority of parents of children under 18 (95%) think physical education should be part of a school curriculum for all students in grades K-12.<sup>21</sup> The majority of parents believe that physical education is at least as important as other academic subjects ranging from 54% to 84%, depending on the subject being compared.<sup>22</sup> Numerous professional associations, medical societies, and government agencies formally support the need for physical activity for youth and for quality physical education in schools.<sup>23</sup>

A large number of studies have focused on the impact of improving physical education in schools by updating physical education curricula, increasing the number of classes offered, and improving teacher training, often in coordination with additional educational or home-based components.<sup>24,25,26,27,28,29</sup> In a systematic review of physical education programs that increased the amount of time that students were physically active, students' aerobic and physical fitness increased.<sup>30,31</sup> One systematic analysis has shown that mandated physical education policy in schools may have the greatest physical-activity-related energy expenditure for school and community-based policies.<sup>32</sup> Compliance with state physical education laws or regulations where states have requirements for the time in physical education is critical for seeing improvement in student fitness.<sup>24</sup> The benefits of modifying the school physical education curricula are experienced across diverse racial, ethnic, and socioeconomic groups, among boys and girls, elementary- and high-school students, and in urban and rural settings.<sup>21</sup> A six-month exercise program among obese children and adolescents reduced body mass index, diabetes risk factors and low-degree inflammation and demonstrated that regular exercise can restore blood vessel function and improve cardiovascular risk factors.<sup>33</sup> Evidence from the Early Childhood Longitudinal Study showed that physical education programs do have an impact on improving risk factors in young overweight girls.<sup>34</sup>

A growing body of evidence demonstrates that the benefits of physical education are beyond the classroom. Physical fitness can have a positive impact on cognitive ability, avoiding tobacco use, and reducing insomnia, depression, and anxiety.<sup>16</sup> Physically fit children have higher scholastic achievement, better classroom behavior, greater ability to focus, and less absenteeism than their unfit counterparts.<sup>35,36,37</sup> School-based physical activity correlates with the improved academic performance.<sup>38,39,40</sup> Several large-scale studies found improvements in students' academic performance and cognitive ability with increased time spent in physical education.<sup>41</sup>

Additionally, children who spent time in physical education in place of a classroom activity performed no worse academically than students not enrolled in physical education.<sup>42</sup>

In addition to quality physical education, other opportunities exist to increase the level of physical activity at school. Classroom-based physical activity, recess, walking or biking to school, and before and after school physical activity including sports programs, intramurals, or physical activity-related clubs, should supplement physical activity provided through physical education. Increasing other school-based physical activity should not be an excuse to cut or substitute for the quantity of physical education. Physical activity is neither an equivalent to nor substitute for physical education, but both can contribute meaningfully to the development of healthy, active children.<sup>43</sup> Physical activity is bodily movement of any type and may include recreational, fitness, and sport activities such as jumping rope, playing soccer, basketball, biking, swimming, and lifting weights, as well as daily activities such as walking, taking the stairs, or gardening.<sup>44</sup>

#### **Specific American Heart Association Advocacy Priorities for Physical Education:**

- Require all school districts to develop and implement a planned, K-12 sequential physical education curriculum that adheres to national and state standards for health and physical education.
- Require all schools districts to provide all students with 150 minutes per week of physical education in elementary schools and 225 minutes per week in middle schools and high schools.
- School-age children should accumulate at least 60 minutes per day of physical activity and avoid prolonged periods of inactivity. The key method for achieving this goal is physical education supplemented by additional opportunities for physical activity before, during, and after the regular school day.<sup>17</sup>
- Require physical education credit(s) for graduation from high school with appropriate accommodations and considerations for children with disabilities and medical conditions.
- Require that students be active in moderate-vigorous physical activity for at least 50% of physical education class time.
- School districts and schools should complete comprehensive self-assessments of their physical education programs using existing tools. The results of the assessment should be integrated into the district or school's long-term strategic planning, School Improvement Plan, or school wellness policy, to address the quality and quantity of physical education offered.
- School districts and schools should report the findings of their assessment to parents and members of the community through typical communication channels such as websites, school newsletters, school board reports, and presentations.
- Hire a physical education coordinator at the state level to provide resources and offer support to school districts across the state. Hire a physical education coordinator in the school district to provide support to physical educators in the school district.
- Offer regular professional development opportunities to physical education teachers that are specific to their field and require teachers to keep current on emerging technologies, model programs, and improved teaching methods.
- Require physical education teachers to be highly-qualified<sup>1</sup> and certified (as per state requirements).
- Add requirements for fitness, cognitive, and affective assessment in physical education that are based on student improvement and knowledge gain. Student assessments should be aligned with state/national physical education standards and the written physical education curriculum.
- Assure that physical education programs have appropriate equipment and adequate facilities. Require class size consistent with other subject areas.
- Disallow automatic waivers or substitutions for physical education. Disallow the ability of states and school districts to assign or withhold physical activity as punishment.
- Do not allow waivers for students with disabilities, but rather allow modifications or adaptations that allow

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<sup>1</sup> "Highly-qualified" is defined by the No Child Left Behind Act as fully certified and/or licensed by the state, holding at least a bachelor's degree from a four-year institution, and demonstrating competence in each core academic subject area in which the teacher teaches.

physical education courses to meet the needs of disabled students.

- Do not allow students to opt out of physical education to prepare for other classes or standardized tests.
- Schools should implement programs to support evidenced-based physical education, activity, and fitness, and nutrition by promoting activities that increase and enable active student participation; are comprehensive; help students understand, improve, or maintain their physical well-being; enhance the physical, mental, social, and emotional development of students; and establish lifelong healthy lifestyles.
- States should develop or enhance data collection systems so local leaders have the information they need to improve physical education and activity within their schools and communities.
- Schools should include opportunities for parents and guardians to support their children in leading a healthy and active life.
- Continue to advocate for the Fitness Integrated with Teaching Kids (FIT Kids\_ Act to educate policymakers on the importance of physical education as well as look for legislative opportunities to advance the bill.

***Promote Recreational Spaces, Changes to the Built Environment, Shared Use of School Recreational Spaces, Street Level Design and Community Development that Promote Opportunities for Physical Activity and Active Transport***

It is imperative to find ways to increase physical activity opportunities and recreational spaces where people live, work, learn and play to promote ways to become or stay more physically fit. Fewer than two in 10 adults in the U.S. get the recommended amount of physical activity each day, and more than a quarter of adults do not devote any time to physical activity.<sup>45</sup> More than 62% of children do not get daily vigorous physical activity,<sup>45</sup> and only 5% report any kind of vigorous activity.<sup>46</sup>

To compound the problem, traditional transportation and community planning often overlook the effect on health and as a result, the U.S. population has an overwhelming reliance on cars for transportation. Our communities are frequently “recreational deserts” without green spaces or connected walking and biking routes. Integrating health objectives within transportation and community planning would create more active communities, more balanced transportation systems and a cost-effective opportunity to improve public health, as well as improve economic health by improving property values and enticing businesses to open in these kind of communities.<sup>47</sup> It is a priority to make our communities optimal for healthy living.

Several studies have found that the way communities are designed and developed can have an effect on physical activity opportunities and obesity rates. Safe sidewalks, green spaces, parks, public transportation, and ready access to fruits and vegetables lower the risk for developing diabetes and other chronic disease as compared with those communities that do not have these resources.<sup>48</sup> We must make opportunities for physical activity more accessible. People who are sitting throughout their day have roughly twice the risk of having heart attacks, heart surgeries, strokes, or other cardiovascular events compared to those who are more active.<sup>49</sup>

Cities and communities across the U.S. are exploring ways to become vibrant and attractive places to live. One option is to convert vacant lots or brown fields to spur economic development. Community gardens, small parks, and open green spaces are excellent options for these areas. Studies have shown that community gardens and walking/biking trails have a positive impact on surrounding residential properties, by increasing rates of home ownership and spurring economic redevelopment.<sup>50</sup> Other studies have found that building bike/pedestrian trails reduces health care costs associated with physical inactivity. For every dollar invested in building these trails, nearly \$3 in medical cost savings may be achieved.<sup>51</sup> Additionally, linking different parts of the community with trails and walkways opens up the opportunity for community integration, more efficient land use, lower traffic congestion, and better quality of life.

Research has shown that people who have parks or recreational facilities nearby and live in communities with well-connected streets exercise much more than those who do not have easy access.<sup>52,53</sup> Unfortunately, lower-income

communities, especially in predominantly Latino or African-American neighborhoods, often have fewer resources to support active lifestyles and places to play and exercise.<sup>54</sup> Programs targeted to low-income, racially and ethnically diverse populations can increase active commuting and are associated with higher overall levels of moderate to vigorous physical activity throughout the day.<sup>55</sup> Community-based physical activity interventions are cost-effective, reducing new cases of many chronic diseases and improving quality of life.<sup>56</sup>

There are various ways to promote physical activity and active transportation in the community:

- **Street Level Design/Complete Streets** policies consider the needs of all users in all transportation projects incorporating walking, bicycling, public transportation, and driving.
- **Smart Growth Design** communities are designed with active living as the focus. Communities are connected with street patterns that make it easy to walk or bike to destinations. Developers try to locate essential services like schools and stores closer to homes to encourage walking and provide green spaces for recreation.
- **Shared Use of School Facilities** These agreements allow schools to share their physical activity facilities (gyms, running/walking tracks, multi-purpose rooms) with the community for recreation and exercise opportunities. Public schools are located in all communities and often have physical activity facilities and spaces that can be shared with community members. The American Heart Association (AHA) supports policies enabling schools to share their physical activity spaces with individuals and community groups and this is also a strategy of the US National Physical Activity Plan<sup>57</sup>, an objective of Healthy People 2020(PA-10),<sup>58</sup> a recommendation of the 2010 White House Task Force on Childhood Obesity,<sup>59</sup> and is in line with recommendations of leading public health authorities.<sup>17,60,61</sup> The shared use of school recreational facilities can provide safe and affordable places for communities. Studies suggest that challenges to shared use include additional cost, liability protection, communication among constituencies interested in sharing space, and decision-making about scheduling and space allocation. The American Heart Association and other public health partners have developed resources to overcome these barriers and support communities in expanding shared use opportunities.
- **Transportation Alternatives** Under MAP-21, states and localities can use Transportation Alternatives funding to construct, plan, and design on-road and off-road trail facilities for pedestrians, bicyclists, and other nonmotorized forms of transportation; construct, plan, and design infrastructure-related projects and systems that will provide safe routes for non-drivers, including children, older adults, and individuals with disabilities to access daily needs; convert and use of abandoned railroad corridors for trails for pedestrians, bicyclists, or other nonmotorized transportation users. These funds can also be used for **Safe Routes to School**, which enables more children to safely walk and bike to school. Community leaders prioritize the safety of these routes and are working to reduce traffic congestion and improve health and the environment.

| <i>American Heart Association Policy Recommendations for Active Communities and Recreational Spaces</i> |
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| <ul style="list-style-type: none"> <li>● Support provisions in transportation reauthorization and other initiatives that create more livable and active communities.</li> <li>● Protect the Safe Routes to School program, incorporate significant evaluation and provide technical assistance to communities.</li> <li>● Support sustained concentrated funding to assist communities in implementing active transportation networks.</li> <li>● Work with state DOTs and communities to take advantage of all Transportation Alternatives funding opportunities to be used toward active transportation projects.</li> <li>● Support regulatory opportunities to incorporate healthy design elements into homes and communities</li> <li>● Require state departments of transportation, metropolitan planning organizations and local municipalities to adopt complete streets/street level design policies to consider the needs of all users in all transportation projects — whether walking, bicycling, public transportation, or driving — to reduce the need to retrofit existing roads and paths.</li> <li>● Provide tax incentives to support school construction and physical activity facilities.</li> <li>● Incorporate health impact assessments into community planning.</li> <li>● Integrate shared use agreements into the existing federal and state programs and statewide recreation plans (SCORPs).</li> </ul> |
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- Promote physical activity through shared use of School recreational spaces
- Support physical activity opportunities through economic and other tax incentives such as tax relief for development of recreational spaces/community revitalization or reimbursement for physical activity equipment and memberships.

***Advocate for Revision and Regular Update of the Physical Activity Guidelines for Americans***

In a landmark achievement, the United States Department of Health and Human Services published the first ever Physical Activity Guidelines for Americans in 2008. These guidelines established the United States as a world leader in pulling together the consensus science around physical activity and fitness. This science-based guidance helps guide Americans aged 6 and older in efforts to improve and maintain their health and avoid disease through appropriate and regular physical activity and serves as the foundation for federal, state, and local physical activity policy. The Guidelines also help physicians provide advice to their patients and help people learn the health benefits of physical activity, the amount of exercise to do each day to improve or maintain health and how to be physically active, while reducing the risks of injury. Unlike the Dietary Guidelines for Americans that are evaluated every five years for an update, the Physical Activity Guidelines have no such mandate from Congress.

Since the U.S. population is becoming more sedentary, diabetes rates are continuing to climb, and obesity remains an epidemic, it is more important than ever that we continue to actively promote regular physical activity to the U.S. population through whatever means are available. As part of this effort, the United States is in need of a regularly-updated set of Physical Activity Guidelines to guide efforts and reduce sedentary behavior through a review of the latest science. The update process for federal dietary and physical activity guidelines maintains the United States' global leadership on physical activity and requires a financial commitment to conduct the update and communicate the guidelines to the public.

**American Heart Association Recommendations for the Physical Activity Guidelines for Americans**

- Congress should mandate a review of the PAGs every five years as is done with the Dietary Guidelines, in order to determine if there is enough emerging science for interim guidance and at least every ten years there should be a mandatory comprehensive update.
- There should be a coordinated dissemination and communication strategy with an accompanying physical activity campaign to assure that all Americans know about the Guidelines and how to incorporate them into their daily lives.

***Nutrition***

***Advocate for calorie labeling in all restaurants and quick-serve outlets with additional nutrition information available on site. Support consumer education that helps put calorie intake into context with daily energy needs.***

The American Heart Association (AHA) believes that educated consumers, armed with the right nutrition information, can make healthier choices when they are eating out. Better menu labeling can also inspire industry innovation toward smaller serving sizes or different recipe formulations. Americans spend nearly half (46%) of their food budget on foods eaten away from home, in restaurants, fast-food chains, cafeterias, and other public places.<sup>62,63</sup> As a result, it is all the more important for consumers to have nutritional information available in order to make healthy food choices at restaurants, just as they do in a grocery store. Foods eaten away from home are typically served in larger portion sizes and have more calories than those eaten at home.<sup>64</sup> Additionally, people most often underestimate the calories in the foods they eat.<sup>65</sup>

Research documents the link between more frequent eating out and increased body weight.<sup>66,67</sup> Obesity is not only a major health risk factor but it threatens to reverse all of the improvements in cardiovascular health made over the last fifty years.<sup>68,69</sup> Indeed, with Americans eating more than 30% of their daily caloric intake outside of the home,<sup>70</sup> adverse health consequences such as type 2 diabetes, high cholesterol and high blood pressure have begun to emerge.<sup>71</sup>

The American Heart Association supports the federal menu labeling law that requires restaurants with 20 or more locations to post calories on menus and menu boards (including boards at drive through service) and make other nutrition information available in the restaurant. To put this information in context with overall diet, restaurants are required to include a daily calorie intake statement. In addition, vending machine operators with more than 20 machines must post calories on or next to the machines. At the state level, the association will be advocating for restaurants with less than 20 locations to follow the federal menu labeling law.

Although the federal menu labeling law has not yet been fully implemented, several studies have investigated the impact of menu labeling especially on purchasing behavior in areas of the country where menu labeling has been put into practice through state law or local ordinances. In some studies, customers who reported seeing and using the posted calorie information purchased fewer calories, especially women and parents choosing for their children.<sup>72,73,74,75,76</sup> Other research, has not shown significant effect of calorie labeling on decreased purchasing or consumption<sup>70,77,78,79,80</sup> or an impact of the calorie statement on facilitating understanding of the overall dietary intake.<sup>81</sup> The format in which the calorie information is presented may contribute to its efficacy.<sup>82,83</sup> Continued research will be necessary as the federal law is implemented to gauge its effectiveness and effect on health status, industry innovation, consumption behavior, and purchasing decisions.<sup>84</sup>

#### **Summary of American Heart Association Policy Priorities on Menu Labeling**

- Robust and timely implementation of the federal menu labeling law when the final rule is released
- An accompanying consumer education campaign to help people “know their energy needs” and understand how many calories they should eat in a day to achieve or maintain a healthy weight
- Monitoring and evaluation of menu and vending machine labeling initiatives, tracking consumer purchasing and consumption, industry innovation, and the impact on public health
- Menu labeling at the state and local level that addresses all restaurants not covered by the federal law, assuring that they display calorie counts on their menus and menu boards and offer nutrition information in a manner consistent with federal law.

#### ***Monitoring and Providing Input for the Revision and Update of the Dietary Guidelines for Americans***

As mandated in the National Nutrition Monitoring and Related Research Act of 1990, the Dietary Guidelines for Americans are reviewed, updated, and published every five years, led by a joint effort between the Department of Health and Human Services (Office of Disease Prevention and Health Promotion) and the US Department of Agriculture (Center for Nutrition Policy and Promotion). During each five year process, a Dietary Guidelines Advisory Committee (DGAC), consisting of nationally recognized experts in the field of nutrition and health, is appointed to develop recommendations to the federal government which the agencies then develop and publish as the Dietary Guidelines for Americans policy document. The DGAC reviews all of the latest scientific and medical literature to determine areas of focus and update for the next iteration of the Guidelines. The Dietary Guidelines for Americans provide recommendations for all people 2 years and over, including those at risk of chronic disease and are the basis for federal food and nutrition policy and education initiatives.

The American Heart Association is actively involved in the process to update and revise the Guidelines by nominating members for the DGAC, providing written comments during open public comment periods, offering our scientific statements and guidelines as input into the process, attending the DGAC meetings and providing comments to the Committee, and meeting with the relevant agencies when there is a particular topic of concern.

### ***American Heart Association Recommendations for the Dietary Guidelines for Americans***

The American Heart Association will actively engage throughout the entire process of updating and revising the Dietary Guidelines for Americans to assure that the best possible evidence base is informing the final policy document and providing guidance to improve the cardiovascular health of the US population.

#### ***Reducing the Marketing and Advertising of Unhealthy Foods to Children***

Inappropriate consumption of low nutrient, high calorie foods contributes to energy imbalance and poor health. Additionally, electronic media use is significantly correlated with childhood obesity<sup>85,86,87,88</sup> and advertising unhealthy foods contributes to children's food preferences, requests, and diet.<sup>89,90,91,92</sup> Even children up to the age of 12 have a difficult time identifying the persuasive intent of food advertising and marketing.<sup>93</sup> Consequently, the American Heart Association sees no health, ethical, political, scientific, or social justification for marketing and advertising low-nutrient, high-calorie foods to children and supports efforts to diminish its occurrence in the United States.

Television and other electronic media have a pervasive influence on children's lives. Young people see more than 40,000 advertisements per year on television alone.<sup>94</sup> They are also bombarded with carefully crafted marketing tactics employed in multiple environments designed to improve brand recognition and increase sales. Newer digital marketing strategies allow instantaneous and constant contact with peers, provide opportunities for self-expression, identity exploration, and social interaction, and facilitate mobility and independence and are connecting to kids through ubiquitous connectivity, personalization, peer-to-peer networking, engagement, immersion, and content creation, at a minimal expense to the companies.<sup>95</sup> Young people are both shaping and being shaped by this digital marketplace and further research is needed to understand its potential role in impacting health. A recent study showed that although food advertising was not all-pervasive on popular kids' websites, the foods that were promoted were primarily candy, cereal, quick-serve restaurant foods, and snacks.<sup>96</sup> By developing a presence with these established and emerging technologies, the food industry is reaching children in a domain where parents have little or no oversight or consent.

A recent report<sup>97</sup> from Packaged Facts, a market research firm, predicts a 40% growth in sales of products targeting two to twelve year- olds by 2015, exposing 43 million children in this age bracket to the accompanying marketing and advertising used to promote those products. According to the report, this demographic represents about one-seventh of the population, a \$10 billion market, and is the most influential demographic for marketers as these young people are establishing life-long dietary habits and brand loyalty.<sup>92</sup> This illustrates why it is more important than ever that industry is accountable for the quality of the foods they are marketing and promoting to children.

Although many European countries rigidly control or ban food advertising to children,<sup>98</sup> it is not well regulated in the United States. In 2006, the FTC obtained data from the food industry through a compulsory process and found that the 44 major food and beverage marketers spent \$1.6 billion to promote their products to children under 12 and adolescents ages 12 to 17 in the United States.<sup>99</sup> There are additional roles for FTC in regulating unhealthy food and beverage advertising based on whether food advertisements are deceptive or unfair.<sup>100</sup> Although broader rule making under the unfairness authority would take an act of Congress, there are possibilities for rule making under the deception doctrine and FTC could strengthen mechanisms for making voluntary initiatives more meaningful.

Brand licensing is becoming more and more pervasive, where a program or its licensed characters are used to promote purchase of a particular food. Grocery store shelves are filled with examples such as Dora the Explorer on sugary fruit snacks. One study showed that the majority of cereals marketed to children (66%) did not meet national nutrition standards and were especially high in energy, added sugars and sodium when compared to cereals marketed to adults.<sup>101</sup>

## **American Heart Association Policy Recommendations for Reducing Unhealthy Food Marketing and Advertising to Children**

- Ultimately advocate for federal regulatory oversight of foods marketed and advertised to children since voluntary standards have not shown a significant impact on health outcomes.<sup>102,103</sup>
- In the interim, work to strengthen voluntary initiatives to include more participation by industry, a more comprehensive definition of the media/technology that is used to target children, and robust enforcement of the nutrition standards.
- There should be no unhealthy food and beverage advertising to children in schools, on buses or education materials because children should have a learning environment free of commercial influence and pressure.
- Supports measures that restrict food advertising and marketing to children including, but not limited to allowing only healthy foods to be marketed and advertised to children, discouraging the product placement of food brands in multiple media technologies, eliminating the use of toys in unhealthy kids' restaurant meals, and using licensed characters on only healthy foods.<sup>104</sup>

### ***Food Labeling***

Consumers, manufacturers, third party organizations such as the American Heart Association, and retailers realize the benefit of informing purchasers how to facilitate healthy purchasing by providing symbols and other messaging on the food packaging or retail shelves. Consequently, health-related icons have proliferated in the marketplace across the U.S. and internationally from third-party organizations, retail outlets and manufacturers. Some publicize the criteria used by their systems and others are proprietary and do not release their algorithms or criteria to the public. Even if the criteria are transparent, they may vary dramatically across each system. Consequently, even though consumers indicate they would like front-of-package labeling to help them make quicker decisions as they shop, many do not trust the systems in the marketplace or find the plethora of symbols confusing. They, along with health professionals, are perplexed as to what these symbols mean. Experts question whether the icons currently in use are of any value in helping people make healthy food choices at point-of-purchase.

Research on the effects of food labels has shown that the label format is important, but there is inconclusive evidence on the impact of the label on dietary preferences and food consumption. In terms of influence on consumer behavior, when compared with standard nutritional label formats, some studies have shown that the use of elaborate symbols and placing less emphasis on raw quantitative data on nutritional labels is more effective.<sup>105 106 107</sup> Further, the use of familiar symbols and color-coded lighting schemes (i.e. the UK's "Traffic Light" system) has been shown to be particularly effective at increasing consumers' ability to ascertain healthier food choices,<sup>108 109 110 111</sup> but they don't influence dietary preferences.<sup>112</sup>

Color codes and graphic symbols have been used on front-of-package labels (FOP), which have shown to be more effective than traditional labels.<sup>113 114</sup> However, the influence of such labels in and of themselves has been shown to be inconclusive. For example, some studies have shown that FOP labels may increase the knowledge base of consumers with low-nutrition education,<sup>113</sup> yet others have indicated they disproportionately benefit those with a high-nutrition education.<sup>115,116</sup>

Research has also been inconclusive on the effects of FOP labels on consumers' food decisions. Notably, some studies have shown that consumers do not alter their dietary behavior based on the type of information displayed on FOP labels, nor are they swayed from choosing unhealthy foods at the initial point of purchase.<sup>117 118</sup> Moreover, FOP labels do not lead to an increase in product sales,<sup>119</sup> nor to an increase in consumer knowledge on unhealthy nutrients (i.e. salt, sugar) and they may actually lead to an increase in the purchase of unhealthy foods due to the negative taste perception consumers have of products with low quantities of unhealthy nutrients.<sup>120</sup> They may also be misleading.<sup>121</sup>

However, in contrast, some researchers have shown that FOP-labeling systems can have a positive impact on consumers' reported diets, leading to reduced consumption of negative nutrients (e.g., salt and sugar).<sup>122 123 124 125 126</sup> For example, individuals who purchase products with FOP logos or symbols consume a lower fat diet, are more likely to lose weight, and may consume less unhealthy nutrients.<sup>127</sup> However, these studies underscore a wide gap between FOP labels' influence on those who are educated and motivated to consume nutritional information and those who are not.

The American Heart Association created its Food Certification program in 1995 because it recognized the value of an on-package consumer education program in adopting heart-healthy dietary guidelines at the time and place that consumers make selection decisions and because the FDA did not have sufficient resources to monitor or manage such a program. The public had made it clear that it desired this type of guidance from the association.

Evolving research, public demand, and changes in the market place have created a window of opportunity for the establishment of a unified nationwide science-based system. Consumers are increasingly receptive to this type of information to inform and guide their dietary purchasing and choices. The association ultimately favors the establishment by the FDA of a directed, standardized, comprehensive front-of-package food labeling program and icon system with unified criteria based upon the best available science and consumer research, featuring consumer education as a primary goal along with healthier food selection and consumption. In the meantime, systems currently in the marketplace and additional research will determine which type of guidance works best for educating the consumer and facilitating healthier food choices.

If a single, unified system is created, sufficient resources must be committed to the management and enforcement of the program, criteria and rules. The system should be generalized to the entire U.S. population, (it should not be disease-specific) highlighting foods and nutrients that are “good for you” and those that should be avoided. All foods and beverages should be considered for display of the icon, with manufacturers responsible for full disclosure of nutritional components that cannot be evaluated by examining the Nutrition Facts Panel (e.g. added sugars) as well as producing current lab analyses for their products. Government or third-party oversight would confirm this testing with regular spot-checks. The process should be objective and specific, transparent, adaptable to accommodate a wide range of foods and beverages, easily understandable to the general public and financed without the appearance of conflict of interest. The process for implementing such a system, monitoring and updating needs to be streamlined, timely, and efficient. The American Heart Association is concerned that until such a comprehensive program is established, competing health-related icons will continue to proliferate in the marketplace. The association will evaluate the environment carefully to determine its role in the evolution of a unified system.

The optimal program should reference the Dietary Guidelines for Americans and the National Academy of Sciences Dietary Reference Intakes Reports. There should be an effective, tested, and proven accompanying nutrition education campaign focused on calories, saturated fat, trans fat, sodium, added sugars, nutrient density and portion control. Consumer testing should be conducted in advance of establishing any system to validate that it will be easy to understand, relevant and useful to consumers. Importantly, the program must include appropriate and robust enforcement and monitoring, including components such as random sampling in the marketplace. Finally, the program should be evaluated every five years to ensure its standards are consistent with current Dietary Guidelines for Americans and the Dietary Reference Intakes and if not, the standards should be modified to comply.

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| <b><i>American Heart Association Recommendations</i></b> |
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| <ul style="list-style-type: none"><li>• Support the eventual development of a single, on-package labeling system overseen by the FDA.</li><li>• Continue to inform the regulatory agencies with our own research on the best approaches to help consumers make healthier decisions at point of purchase.</li></ul> |
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***Reducing Sugar-Sweetened Beverage Consumption***

Sugar-sweetened beverages are the largest single source of added sugars in the U.S. diet.<sup>128</sup> A recent meta-analysis provides evidence that sugar-sweetened beverage consumption promotes weight gain in children and adults.<sup>129</sup>

Children and adolescents derive around 10% to 15% of their total calories from sugar-sweetened beverages and 100% fruit juice.<sup>130</sup> In 2005, children between the ages of 12 and 19 spent an estimated \$159 billion on food, candy and soft drinks.<sup>131</sup> Because youth are more responsive to price change than adults, the potential exists for an even greater impact on consumption by youth.<sup>132</sup>

Indications are that beverage consumption rates are high in all ages and as consumption of these drinks increases, there is a concomitant rise in energy intake or “empty calories.”<sup>133,134</sup> Soft drink consumption is associated with lower

intakes of milk, calcium, and other nutrients and an increased risk of several medical problems including diabetes.<sup>133,135,136,137</sup>

In the United States, at least 17 states have implemented taxes on SSBs and syrups, primarily as a means to generate state income rather than to improve health, but the overall amounts are generally small and have not been systematically assessed.<sup>138,139</sup> And there is a significant need to understand the systemic impact of the price change on the purchase of SSBs and other categories of beverages to understand whether consumers substitute choices or eliminate SSBs from their diets when prices increase. This kind of full analysis would provide a better picture of the impact of SSB taxation on consumer behavior and health.

Research demonstrates that beverage consumption varies across age, sex, and race/ethnicity. A 2006 study published in the *Journal of the American Dietetic Association* revealed that in general, males consume more beverages than females, African Americans consume more fruit drinks and Caucasians drink more carbonated soft drinks than other race/ethnic groups.<sup>140</sup> These results underscore the point that taxation policy should cover all beverages with added sugars to reach diverse segments of the population.

Although there is limited research on the impact of these taxes in the area of food and beverages, there is certainly strong economic and public health evidence on the impact in the areas of tobacco and alcohol excises taxes.<sup>141</sup> Additionally, a recent comprehensive, systematic review of 160 studies looked at the effect of price on food demand and consumption behavior in the United States and focused on the price elasticity of demand for major food categories. Food eaten away from home, soft drinks, juice and meats were the most responsive to price changes (0.7-0.8).<sup>142</sup> All of these were cross-sectional studies and only a very few examined direct and cross-elasticities and the total effect on diet. The only study which has done this and examined net effect on caloric intake is a recently published longitudinal study that followed price changes [both increases and decreased] for 20 years in a sample of young adults. This CARDIA study showed that a rise in price in away-from-home foods and soda was associated with lower energy intake, lower weight, and lower insulin resistance.<sup>143</sup> All other studies are cross sectional but support the notion that sugar-sweetened beverages are price elastic and a price increase would considerably reduce their consumption and in turn, reduce weight gain.<sup>144</sup> The systematic review of this cross sectional literature suggests that a 10% price increase would conceivably decrease consumption by about 8-10%.<sup>15</sup> There is an assumption inherent in these results that consumers will not substitute other caloric beverages for full-calorie beverages. Vulnerable populations, especially those who are low-income, and less educated, as well as children and adolescents, are especially price-sensitive.<sup>142,145,146</sup>

The American Heart Association supports a multi-pronged approach to address the nation's obesity epidemic which includes creating policies that improve access and affordability of healthy foods to all people. The association also considers the concept of pricing less healthy foods and beverages higher to discourage consumption as a possible policy alternative to bring food and beverage pricing in line with the American Heart Association's Diet and Lifestyle Recommendations and federal dietary guidelines where possible. However, the association believes additional research is necessary to determine the impact of these types of sales taxes or excise taxes on consumption rates, and shifts in consumer choice with special consideration for disparate populations. The association supports initiatives in certain states to pilot this policy strategy with comprehensive surveillance to discern real-world impact on consumption trends and dietary behavior. To determine if the association might support a sugar-sweetened beverage tax proposal as a pilot opportunity to assess/evaluate efficacy, the following criteria were developed as a baseline for support: At least a portion of the money is dedicated for heart disease and stroke prevention and/or obesity prevention, the tax is structured so as to result in an increase in price for sugar sweetened beverages (e.g., imposed at the time of sale as opposed to the manufacturer that can spread the cost of the tax among all products), the amount of tax is anticipated to be sufficient to result in a reduction in consumption of sugar sweetened beverages (at least 1 cent/oz), there is money dedicated for evaluation with guidance that assures rigorous evaluation including health outcomes, there is a standard definition of "sugar sweetened beverage," and there is no sunset. The association also believes there should be careful consideration of unforeseen, unintended consequences of these

types of policies and prioritizes evaluation as the most important component to determine impact on consumer behavior.

#### **American Heart Association priorities to reduce sugar-sweetened beverage consumption**

- Robust nutrition standards in schools that eliminate or reduce sugar-sweetened beverages in meals and competitive foods
- Robust standards for early childhood programs that eliminate access to sugar-sweetened beverages
- Support efforts to pilot programs within the Supplemental Nutrition Assistance Program and other government feeding programs that reduce purchase of sugar-sweetened beverages
- Support SSB taxes of at least once cent/oz. that meet other criteria established by AHA including evaluation and that at least a portion of the revenue goes to obesity prevention programs

#### ***Reduce Sodium in the Food Supply***

The American Heart Association recommends that all Americans consume less than 1,500mg of sodium per day. This recommendation is based on a careful review of the science which shows a link between excess sodium intake and high blood pressure.<sup>147,148</sup> Diets high in sodium are linked to the development and worsening of high blood pressure and increased risk for heart attack, stroke, and kidney disease. Unfortunately, the average American consumes 3,400mg of sodium per day, more than twice the amount the Association recommends.<sup>149</sup>

Research has shown that lowering sodium consumption can have significant health benefits. A reduced sodium intake can prevent and treat hypertension and reduce the risk of adverse cardiovascular and stroke events. Even a gradual reduction in sodium consumption to 2,200mg should result in 280,000 to 500,000 fewer deaths over 10 years.<sup>150</sup> A national effort to reduce sodium consumption would also save \$10 to \$24 billion in healthcare costs annually.<sup>147</sup>

The association is aware, however, that there are some who question the need to reduce sodium consumption, arguing that the evidence does not show that reducing sodium intake results in better cardiovascular outcomes and may instead be harmful.<sup>151,152</sup> The American Heart Association has reviewed these claims and found the evidence for harm to be unpersuasive and methodological issues with these studies limit their usefulness. The vast majority of research shows the benefits of lowering sodium consumption.<sup>153 154 155 156 157</sup> It is the strength of this scientific evidence relating excess sodium intake to high blood pressure, cardiovascular disease and stroke that form the basis for the associations's recommendation to limit sodium consumption.

It is difficult, however, for consumers to control the amount of sodium they consume because of the high content of sodium in the food supply. More than 75% of the sodium we consume comes from salt added to processed and restaurant foods.<sup>158</sup> To achieve significant reductions in sodium consumption, the sodium content of the food supply must be reduced.

#### **The American Heart Association's Priorities on Sodium Reduction**

- Play a leading role in reducing the sodium content of the food supply
- Advocate for implementation of the recommendations in the Institute of Medicine's 2010 report "Strategies to Reduce Sodium Intake in the United States," including modification of the GRAS status of salt and the establishment of national standards for the sodium content of foods<sup>159</sup>
- Lower the amount of sodium recommended in upcoming editions of the Dietary Guidelines for Americans
- Lower the sodium limit in the Daily Value on the Nutrition Facts Panel
- Support efforts to include robust sodium limits in procurement standards, government feeding programs, including the National School Lunch and Breakfast Programs, school competitive foods, and meeting/conference guidelines
- Enhance U.S. surveillance/monitoring of sodium intake to understand the effectiveness of national and statewide interventions

### ***Promote Nutrition Standards for Foods in Schools and other Government Feeding Programs***

Schools, child care programs, community programs for elder adults, and government feeding programs like the Supplemental Nutrition Assistance Program, the Women, Infants, and Children Program, and the Child and Adult Care Food Program provide important access to healthy foods, and can address food insecurity and health promotion in vulnerable segments of the U.S. population. These programs can help establish a foundation for a lifetime of healthy behaviors.

In December 2010, the Healthy, Hunger-Free Kids Act became law, giving the U.S. Department of Agriculture (USDA) the authority to update national nutrition standards for school meals and establish nutrition standards for other foods, called competitive foods, sold on school campuses throughout the school day. The law strengthens local wellness policies by creating more accountability and better implementation; includes funding to help schools establish school gardens and source local foods into their cafeterias. These provisions will help schools give children the jump start they need for long, healthy lives. There is still room for state and local advocacy to bolster the law and help schools implement the provisions well across the entire country.

#### **The American Heart Association's Priorities for Nutrition Standards for Foods in Schools and Government Feeding Programs**

- Increase the number of states and local districts that are consistent with and implement the beverage and snack guidelines in the USDA Interim Final Rule Nutrition Standards for all foods sold in schools.
- Work with states and districts to limit exemptions to the USDA standards for all but occasional fundraisers
- Work with states and districts to extend the USDA standards beyond the school day to cover after school activities (except where there are a majority of adults present)
- Improve resources for implementation which could address any one or more of the following:
  - a. professional development for food service staff or other responsible parties to implement the standards
  - b. improved food provided through commodities
  - c. increased capital improvement/resources for healthy food procurement, storage, refrigeration, preparation, and service
  - d. incentives for achieving US Healthier School Challenge Gold or other equivalent recognition status
  - e. require increased transparency to parents in regards to school/district compliance with the standards such as addressing on district website or including all a la carte foods to be listed on school menus.
  - f. increase accountability for meeting standards such as requiring goals tied to the school nutrition environment to be included on School Improvement
  - g. plans or progress reports included on district report cards.
- Support robust nutrition standards for the Women, Infants, and Children Program, the Supplemental Nutrition Assistance Program, the Child and Adult Care Food Program and other similar government feeding programs that reach vulnerable populations and provide access to healthy foods.

### ***Access to Healthy, Affordable Foods in the Community***

Providing access to healthy foods in all communities across the United States is a priority for the American Heart Association.

- ***Support increased funding for and implementation of Healthy Food Financing Initiatives (HFFI) at the local, state and federal level***

In 2009, USDA mapped out the nation's access to supermarkets and grocery stores and found that about 2.3 million households are in areas considered "food deserts."<sup>160</sup> Healthy food financing addresses this issue and is the effort to bring full-service grocery stores or supermarkets to rural and urban communities to provide equitable access to

healthy foods such as fruits and vegetables, low-fat dairy, whole grains, seafood, and lean meats. Led by Pennsylvania's Fresh Food Financing Initiative that began as a result of public/private funding in 2004, other states and cities are now pursuing these programs. The economic impact and community development resulting from these projects has been significant. Since the efforts are relatively new, evidence on the health impact is still accumulating. Several larger cross sectional studies have found that greater accessibility to neighborhood supermarkets is associated with more healthful dietary habits and lower body weight.<sup>161,162,163,164,165,166,167,168,169,170,171</sup> However, some studies have not found an impact on obesity or other health factors.<sup>172,173,174,175</sup> Further analysis of the health impact of these initiatives should be incorporated into evaluation of healthy food financing projects.

The American Heart Association supports healthy food financing initiatives at the local, state, and federal level especially those that integrate in-store and out of store marketing strategies to increase the availability and affordability of healthy foods once stores are built or renovated in order to help shoppers choose healthy foods. Members of the community should be involved in creating these marketing strategies. Plans for sustainability should be in place since HFFI projects are typically one-time grants or loans. Evaluation should be incorporated into these initiatives to assess not only economic impact and community revitalization, but also the health impact and consumer purchasing behavior in communities, especially for disparate populations

- ***Fresh Fruit and Vegetable Program***

A diet high in fruits and vegetables can reduce the risk for many leading causes of death and can play an important role in weight management.<sup>176</sup> Fewer than 1% of U.S. children meet the five components that American Heart Association uses to define a healthy diet and only 0.3% of adults achieve this standard.<sup>1</sup> The beginning of CVD (atherosclerosis, fatty streaks in the arteries) can start early in life and is influenced by modifiable risk factors, including a healthy diet, over the course of a lifetime.<sup>177</sup>

The American Heart Association supports maintaining current funding levels for the Fresh Fruit and Vegetable Program (FFVP) and protect the integrity of the program. The FFVP is a wildly successful and popular program that began as a pilot in the 2002 Farm Bill and has now expanded nationally to all 50 states, the District of Columbia, and the U.S. Territories<sup>178</sup> with \$1.2 billion in funding from the last Farm Bill provided over 10 years. An independent evaluation found that the FFVP increased students' average fruit and vegetable consumption by a health-promoting 15% in participating schools, but did not increase overall caloric intake, suggesting that children replaced less healthy foods in their diets with fruits and vegetables.<sup>179</sup> While the American Heart Association recommends that fruit and vegetable consumption come from a variety of means: fresh, canned, and frozen, FFVP targets the most vulnerable students in the country, many of whom do not have an opportunity to consume a fresh fruit or vegetable outside of this program.

- ***Farmers' Markets***

Farmers markets may bring healthier foods to low income, urban, and rural communities and help improve regional food systems. They can create social hubs and a safe place to shop for healthy food in underserved communities. Key strategies for promoting farmers' markets are site location, transportation options, affordable pricing, including Supplemental Nutrition Assistance Program (SNAP) and FMNP benefits, as well as support for incentive programs like Philly Food Bucks, Wholesome Wave, Roots of Change, and Double Up Food Bucks, transportation options, and integrated nutrition education. Farmers' markets can be integrated into other community events and are an important partnership opportunity with State or Local Departments of Health to integrate health and nutrition education programming. Farmers' markets can serve multiple purposes: community engagement, economic impact, social outlet, access to healthy affordable foods, agritourism, sustainability, and support of local agricultural systems and horticulture.

| <b><i>American Heart Association Policy Priorities for Access to Healthy Foods</i></b>  |
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| <ul style="list-style-type: none"> <li>• Protect and advocate for a robust Title IV in the farm bill. Ensure any cuts to the title are minimal and focus on program efficiencies, rather than cutting much needed nutrition aid and programs to vulnerable Americans</li> <li>• Maintain funding levels and program integrity for the Fresh Fruit and Vegetable Program and other similar programs like the Farm-to-School Program, community/school gardens and programs that might be developed at the state and local level</li> </ul> |

- Maintain funding for SNAP Nutrition Education and strengthen the program to ensure low-income Americans have the ability to make healthy choices, increase fruit and vegetable consumption, and reduce their risk of chronic disease and obesity. Incorporate physical activity into SNAP education
- Establish a multistate incentive pilot to promote increased SNAP purchases of fruits and vegetables at farmers markets and other healthy food retailers and support private/public partnerships and programs like Wholesome Wave, Philly Food Bucks, Roots of Change and Double Up Food Bucks that have shown great success<sup>180</sup>
- Maintain funding for and promote the Agricultural Marketing Service's Farmers' Market Promotion Program (FMPP). The FMPP is a competitive grant program that makes funds available to eligible entities for projects to establish, expand, and promote farmers markets, roadside stands, community-supported agriculture programs, agritourism activities, and other direct producer-to-consumer opportunities
- Provide grants and loans for value-added agriculture to develop the small and mid-sized processing and distribution systems needed to get products from family farmers into local, regional, and national markets
- Increase the availability of fruits and vegetables in school meals and remove barriers which prevent local farmers from selling products to local schools.
- Foster community-led approaches to improve consumer access to healthy and fresh foods in low income neighborhoods
- Assure the USDA commodity program continues to increase the healthy foods that are provided to states and government feeding programs
- Ensure the affordability of healthy and fresh foods for low-income families and seniors through purchases of fresh foods directly from farmers and other agricultural producers.
- Provide incentives and crop insurance to small and mid-size farms to produce specialty crops like fruits and vegetables and distribute locally and regionally
- Limit use of SNAP benefits in fast-food restaurants except for homeless, disabled, and some seniors
- Support pilot programs with robust evaluation components to provide incentives to SNAP beneficiaries to purchase healthier foods
- Support continued evaluation of all programs that provide local access to healthy, affordable foods

### ***Comprehensive Prevention Efforts in Schools, Worksites, and Communities*** ***Mobile Health Technologies***

Nearly 30 million people die from cardiovascular-related diseases, annually.<sup>181</sup> For the most part, the underlying causes of these diseases can be avoided. For example, in 10 years after quitting smoking, consumers experience nearly a 50% reduction in the likelihood of developing lung cancer.<sup>182</sup> In 20 years after quitting, the likelihood of developing cardiovascular disease rivals that of those who have never smoked.<sup>183</sup> Additionally, weight loss reduces the likelihood of developing cardiovascular disease, particularly among the obese.<sup>184</sup>

Improving and expanding the treatment of prior cardiovascular conditions also decreases death rates. The use of such measures as ACE inhibitors, beta blockers, and lipid reducers all decrease cardiovascular mortality rates by nearly 25% each.<sup>185 186 187 188</sup> Further, an increased focus on prior cardiovascular conditions necessitates consumers taking on a more interactive role in the treatment of their disease. Because patients choose whether to seek health care and whether to obey doctor orders, improving and developing self-management prophylactics can promote and improve individual and public health.<sup>189 190</sup>

The burgeoning influence of such treatment measures should lead health care providers to implore their patients to assume healthier lifestyles and self-treat ongoing conditions. However, the amount of information, encouragement, and support that can be conveyed during consultations, within existing service infrastructures, is scant.

Mobile health devices are gateways for administering endemic support and care to consumers. Such interventions are geared towards promoting healthy lifestyles and enhancing chronic disease management.

Recent advances include, but are not limited to, PDAs, handheld videogame consoles, mobile phones, smartphones, smartbooks, and portable media players. Their potential uses span from cellular conversation via voice, text, and visual media, to Internet access and digital software applications. Technological advances and improved computer processing power mean that single mobile devices such as smart phones and PDAs are increasingly capable of high level performance in many or all of these functions.

The functions of mobile health technologies that are apt for healthcare self-management are promoted by their user-friendliness, adaptability, and mobility. The allure of such technology has led to soaring ownership rates, which makes their potential footprint for healthcare delivery substantial and expansive. As of 2013, nearly 75% of the global population owns some sort of mobile technology. In many developed nations, mobile phone ownership exceeds the total number of citizens.<sup>191</sup> In developing nations, mobile technology is a highly-influential economic force with a substantial population footprint.<sup>192</sup>

The potential of mobile technology continues to evolve at a dramatic rate. Current advances foster economical interventions. Consumers of health care, for example, can download software applications, view multi-media resources, and receive text messages that can monitor changes in their behavior and motivate them to assume healthier lifestyles. The technology supports interactivity, which allows people to receive supplemental healthcare assistance when needed or desired. Interventions can be tailored to suit any demographic or health care issue.<sup>193 194</sup>

Research to date has assessed the effects of particular technologies, their functions, and their relationship with the management of particular diseases.<sup>195 196 197 198 199 200 201</sup> Results on the benefits of these measures have been inconclusive. For example, research has shown that multi-stage anti-tobacco text messages can lead to smoking cessation,<sup>202</sup> as well as short-term improvements in asthma control,<sup>203</sup> physical activity,<sup>204</sup> and the likelihood of receiving cardio pulmonary resuscitation training.<sup>205 206</sup> However, text messaging in support of the self-management of diabetes has yielded insignificant effects.<sup>207</sup> Similarly, research on diet and diet with physical activity interventions on weight has also shown insignificant effects.<sup>208 209 210</sup>

Research on the effects of mobile technology on consumer health behaviors has also been inconclusive. From the positive end, research has shown that cell phone-based counseling can lead to the cessation of smoking in the short-term.<sup>211</sup> Further, cell phone-based interventions can lead to pregnant smokers setting a quit date,<sup>212</sup> the reduction of portion sizes,<sup>213</sup> and decreases in blood pressure.<sup>214,215</sup> Lastly, the ability to perform cardio pulmonary resuscitation is enhanced by cell phone-based audio<sup>216</sup> and video instructions.<sup>205</sup>

However, clinical trials assessing the effects of video-based interventions have yielded no significant changes in smoking behavior,<sup>217</sup> nor have they shown to decrease the amount of time taken to locate an automated external defibrillator in emergency situations outside of a hospital.<sup>218</sup> Similar conclusions have been reached on the effects on obesity of mobile phone diaries,<sup>219</sup> text message based interventions,<sup>220</sup> and social and multi-media based interventions.<sup>221</sup>

| <b><i>American Heart Association Priorities on Mobile Health Technologies</i></b>   |
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| <ul style="list-style-type: none"><li>• Monitor the impact of these technologies on delivery systems of care</li><li>• Advocate for additional research to determine efficacy on cardiovascular health and secondary prevention</li></ul> |

### ***Worksite Wellness Programs/Incentives***

The American Heart Association supports comprehensive worksite wellness programs as an important means to achieving the Association's goal of improving the cardiovascular health of all Americans and reducing cardiovascular and stroke mortality. Evidence demonstrates that these programs do have positive impact on

employee health in an environment where adults spend a large part of their time.<sup>222</sup> The Association also maintains that the use of rewards and penalties tied to health status should not jeopardize an employee's access to affordable, quality health care or be used as subterfuge for discrimination based on health status.

On May 29, 2013, the U.S. Departments of Health and Human Services, Labor and the Treasury issued final rules on employment-based wellness programs. The final rules incorporated feedback from numerous consumer groups and employers and support workplace health promotion and prevention as a means to reduce the burden of chronic illness, improve health, and limit growth of health care costs. Significantly, the final rules add additional consumer protections to ensure that these programs are not a form of medical underwriting where health costs are shifted from healthier employees to less healthy employees or where individuals are penalized if they have a preexisting condition or are genetically predisposed to a disease or risk factor. These consumer protections require that health-contingent wellness programs be reasonably designed, be uniformly available to all similarly situated individuals, and accommodate recommendations made at any time by an individual's physician based on medical appropriateness.

The final rules continue to support "participatory wellness programs," which generally are offered to employees without regard to an individual's health status. These include programs that reimburse for the cost of membership in a fitness center, that provide a reward to employees for attending a monthly, no-cost health education seminar, or that reward employees who complete a health risk assessment, without requiring them to take further action.

The rules also outline standards for nondiscriminatory "health-contingent wellness programs," which generally reward individuals who meet a specific standard related to their health. Examples of health-contingent wellness programs include programs that provide a reward to those who do not use, or reduce their use of tobacco, or programs that reward those who achieve a specified health-related goal such as cholesterol level, weight, or body mass index, as well as those who fail to meet such goals but take certain other healthy actions.

The final rules do allow significant flexibility for employers to design their own programs and allow employers to vary health care premiums/deductibles by 30% for achieving a health factor and up to 50% for tobacco use. The final rules will be effective for plan years beginning on or after Jan. 1, 2014.

A recent study by RAND, commissioned by the Department of Health and Human Services and the Department of Labor and authorized by the Public Health Service Act summarized a comprehensive review of the scientific and trade literature as well as a national survey, statistical analyses of health plan claims and wellness program data from several employers, and case studies of five employers with established wellness programs.<sup>223</sup> Key findings of the report were:

- Wellness programs are popular
- Program availability increases with employer size where larger employers have more extensive offerings (disease management, lifestyle interventions, more comprehensive screening).
- Typically, programs are implemented with some kind of screening combined with lifestyle intervention or disease management
- Employers find it fairly easy to get employees to participate in screening, but harder to participate in interventions. Program uptake is helped with healthy worksite culture, leadership role modeling and buy-in, and multiple communication channels.
- Employers are optimistic about the impact of wellness programs, however very few were able to provide cost and health impact data since they are rarely doing formal evaluation of their programs
- Programs do have a health impact for those who participate but the effect does decrease over time, except with tobacco cessation where there is more of a lasting impact. Weight does improve slightly over time in participants and there is a more of a substantial impact on morbidly obese employees.

- Health care costs level out for participants, but go up linearly in non-participants.
- Financial incentives commonly used are in the \$100 range. Employers are not anywhere near the currently allowed 20% variation when these incentives are tied to a health plan, the average is ~9%. There is a small effect of incentives in promoting Health Risk Assessment completion (about 4% increase for every \$25 invested). Rarely are incentives tied to disease management programs; smoking is the area where there are higher incentives for results (i.e. bigger sticks/and carrots). For other health factors, the difference between incentives for participation vs. outcome-based are not significant.
- We cannot at this point conclude what effect incentives have on program participation, health outcomes, access to health care, and unintended consequences.
- The database does not have more recent data (during the time that more outcomes-based incentives were implemented) and is not longitudinal enough to draw significant conclusions around incentives.

The American Heart Association maintains that the final rules around wellness programs have added some important consumer protections to help employees maintain access to affordable, employer-based health care. With these new rules, employers retain a great deal of flexibility in designing their wellness programs and managing their health care costs. However, as long as employees are making an effort at trying to improve their health, they should be able to achieve the reward or avoid the penalty and maintain the affordability of their health care.

We are anxious to see how these final rules are implemented by employers, and strongly support continued evaluation to determine the impact of outcomes-based incentives on employee health, access to health care, and worksite culture. The AHA will be contributing to the research on what constitutes the most effective worksite wellness programs with our KKR study.

***Healthy Meetings and Conference Guidelines and Procurement Standards***

Creating a culture of health in the workplace environment where many adults spend a majority of their day, is an important way to help meet the federal dietary and physical activity guidelines for Americans, foster healthier work environments, and begin to promote social norms around healthy choices and behaviors. Ensuring healthy food and beverage choices through quality food service, robust procurement policy standards, providing physical activity opportunities, and requiring a tobacco-free environment should be major areas of focus for employers. With more than 130 million Americans employed across the United States each year, these standards can provide a means of improving the health of a large segment of the adult population. These policies can be implemented within a broad range of worksites or public/private environments including government buildings, hospital systems, college/university campuses, schools, child care centers, assisted living facilities, church/faith-based organizations, private corporations, theme parks, resorts, prisons, libraries, and non-profit organizations. One of the important ways to foster a culture of health during meetings, conferences, and throughout the work environment is to support healthy choices, provide leadership and role modeling, and begin to create a social norm around healthy choices and healthy behaviors.

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| <p><b>American Heart Association Recommendations around procurement and meetings/conference guidelines</b></p> <ul style="list-style-type: none"> <li>• The American Heart Association supports robust procurement, food service, vending, and meeting/conference standards for nutrition, physical activity, and tobacco free work environments implemented through organizational policy, regulation, or legislation.</li> <li>• Evaluation should be conducted to assess the effectiveness of implementation and any health impact.</li> </ul> |
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### ***Healthy Early Child Care***

The American Heart Association advocates for strong health promotion and obesity prevention programs in early childhood programs. Child care settings are an important environment for forming good health habits around children's dietary intake, physical activity, and energy balance and thus combating the childhood obesity epidemic.<sup>224</sup> The 2005 National Household Education Survey reports that 74% of all US children aged 3 to 6 years not yet in kindergarten were in some form of non-parental care, and 57% were in a center-based child care program making this an ideal setting for obesity-prevention interventions targeting this age group.<sup>225</sup> Furthermore, it has been reported that many children from low-income backgrounds consume 50% to 100% of their Recommended Dietary Allowances in a child care setting and many children spend the majority of their waking hours out-of-home.<sup>226</sup> In the federal Head Start program alone there are more than 1 million children and 200,000 staff members across the United States, not to mention the multitudes of children from infancy to age 5 who are in private and public day care and preschool programs. Children are spending many waking hours in these programs and they should be safe, healthy, and smoke-free environments. Reaching young children and their families is an essential strategy for primary prevention of cardiovascular disease and associated risk factors.

### **Background**

Overall, 1 in 8 or 12% of preschoolers are obese while 1 in 5 or 19% of black children and 1 in 6 (16%) of Hispanic children between the ages of 2 and 5 are obese.<sup>227</sup> After decades of rising, obesity rates among low-income preschoolers began to level off between 2003 and 2008 and most recently have actually shown small declines in several states. Despite these gains, the existing rates of obesity in preschool children are still too high and these numbers set the stage for an unhealthy future for these children since obesity generally tracks into adulthood.<sup>182</sup>

Despite the importance of addressing health promotion in childcare settings, researchers know relatively little about either their nutrition or the physical activity offerings. The research that does exist suggests that the nutritional quality of meals and snacks may be poor and activity levels may be inadequate.<sup>228</sup> More uniform standards are needed to apply to foods eaten or physical activity programs.

Poor diet and physical inactivity that begin at an early age increase the chance for developing serious health problems. A substantial number of overweight 8-14 year olds have at least 3 risk factors for heart disease, such as high cholesterol, high blood pressure, or high blood sugar, meaning that overweight in early adolescence may put children at increased risk for adult-onset cardiovascular disease and/or type 2 diabetes by early adulthood.<sup>229</sup> Research provides evidence that if overweight begins before age 8, obesity in adulthood is more severe.<sup>230</sup> These findings illustrate why it is so important to intervene in early childhood to prevent obesity and related cardiovascular disease risk factors.

Preschool children are also consuming too many high calorie, sweetened beverages and foods with low nutrient value.<sup>231, 232</sup> The American Heart Association recommends that the diets for those aged 2 and older should rely on fruits and vegetables, whole grains, low-fat and nonfat dairy products, beans, fish, and lean meat.<sup>233</sup> Assuring that healthy foods are served in age-appropriate portion sizes is extremely important for overall health and effective dietary patterns. One study found that the most powerful determinant of the amount of food consumed at meals was the amount served and if children were given portion sizes that were too large, they were less able to control the amount of food they ate and were less able to tell when they were satiated.<sup>234</sup>

A recent study of children in the Women, Infants and Children (WIC) Feeding Program found that on average, the children spent more than twice as much time watching television and using computers as they did engaging in physical activity.<sup>235</sup> The American Heart Association recommends that children get at least 60 minutes of moderate-vigorous physical activity every day.<sup>236</sup> Although rates of childhood obesity among the general population are alarmingly high, they are even higher in ethnic minority and low-income communities where television watching rates are generally higher.<sup>224</sup> Culturally proficient diet and physical activity interventions have been shown to reduce body mass index in young children in low income areas.<sup>237</sup> Reducing sedentary behavior and increasing physical activity opportunities are critically important in early childhood to lay the important foundation for healthy, lifelong behaviors.

Food advertising and marketing is another important causative factor in the obesity epidemic.<sup>238</sup> Exposure to food advertisements and industry marketing strategies produces substantial and significant increases in energy intake in all children and the rise is largest in obese children.<sup>239</sup> Aggressive advertising of high-calorie, low nutrient-dense foods contributes to higher consumption of those foods and should not be allowed in child care settings.

Preventing and controlling childhood obesity will require multifaceted and community-wide programs and policies with parents playing a critical role. One of the most important factors influencing children's health behaviors are parent's eating and physical activity behaviors and their level of education.<sup>240,241</sup> Parents are important role models and are largely responsible for physical activity opportunities, the type of food presented to young children, the portion sizes offered, and the emotional context in which food is eaten.<sup>242</sup> Successful intervention efforts must work directly with parents from the earliest stages of child development to support healthful practices both inside and outside the home.<sup>243</sup>

The American Heart Association and Nemours have launched Healthy Way to Grow, a technical assistance program for child care centers across the country aimed at decreasing obesity among children ages birth to five years old with inaugural funding provided by The William G. McGowan Charitable Fund. The program provides direct, hands-on assistance, customized training, resources and tools to support healthy lifestyles in child care environments. Components of the program include: developing and adopting a center wellness policy, providing training and technical assistance, engaging parents, and encouraging and recognizing progress towards best practices and policies for physical activity, screen time, food and beverage choices, and infant feeding. The American Heart Association will be able to support this programmatic and technical assistance effort with policy work around professional development for teachers and staff, credentialing and licensing, and nutrition, physical activity, and screen time standards for the early childcare environment.

#### ***Local Wellness Policies***

The Child Nutrition and WIC Reauthorization Act of 2004 (P.L. 108-265, Section 204) required school districts participating in the National School Lunch Program (NSLP; [42 U.S.C.1751 et seq.]) or other child nutrition programs (42 U.S.C. 1771 et seq.) to adopt and implement a wellness policy starting with the 2006-07 school year. The Healthy, Hunger-Free Kids Act of 2010 (P.L. 111-296) extended this requirement and requires the U.S. Department of Agriculture (USDA) to develop regulations that provide a framework and guidelines for local wellness policies that include, at a minimum:

- Goals for nutrition promotion and education
- Goals for physical activity and other school-based activities that promote student wellness
- Nutrition guidelines for all foods and beverages available on each school campus during the school day that are consistent with the federal school meal standard and standards for foods and beverages sold outside of school meal programs
- Permission for stakeholders to participate in policy development, implementation, review and updates
- A requirement for the district to inform and update the community about the wellness policy content and implementation
- A requirement for the district to report and measure wellness policy implementation periodically, alignment with model wellness policies, and a description of progress made in attaining the wellness policy goals.
- Designating one or more district and/or school officials responsible for ensuring school-level compliance with the wellness policy.

Previous assessment of wellness policies implemented since 2006-07 has shown gaps in implementation, comprehensiveness, strength, and evaluation of their efficacy so the new requirements under the 2010 law should address some of these concerns.<sup>244</sup>

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| <b><i>American Heart Association Priorities for Local School Wellness Policies</i></b> |
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| <ul style="list-style-type: none"><li>• Inform the regulatory process for updating local school wellness policy requirements to assure effective implementation, more comprehensive development, and robust evaluation</li></ul> |
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## ***Coordinated School Health***

Health-related programs and policies in schools across the United States have resulted from a wide variety of federal, state, and local mandates through regulation and legislation with various funding streams. Coordinating the many parts of school healthy into a systematic approach can help schools develop effective policies, communication strategies, and programs that address student health and well-being while consolidating their resources. A commitment to coordinated school health programs allows that to happen. The different aspects to Coordinated School Health include health education, physical education, health services, nutrition services, counseling/psychological/and social services, healthy and safe school environment, health promotion for staff, and family/community involvement.

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| <b><i>American Heart Association Priorities for Coordinated School Health</i></b> |
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| <ul style="list-style-type: none"><li>• Increase funding for and implementation of coordinated school health at the federal and state level.</li></ul> |
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### ***Advocate for the Prevention and Public Health Fund to keep it intact and prevent it from sustaining further cuts***

We know that 80 percent of CVD is preventable through measures such as eating right, getting physical activity, and not using tobacco. And although we are placing a greater emphasis on prevention, we still have a long way to go. Only 18 percent of U.S. adults follow three important measures recommended by the American Heart Association for optimal health: not smoking, maintaining a healthy body weight, and exercising at moderate-vigorous intensity for at least 30 minutes, five days per week.

The federal government has already recognized the value of prevention by creating the Prevention and Public Health Fund (Prevention Fund). The Prevention Fund provides \$12.5 billion in mandatory funding over ten years to communities to improve health and reduce illness. Early successes of the fund include: \$173 million in grants award to 101 government entities and nonprofits organizations, touching the lives of 129.2 million Americans in 2011 and 2012. The Prevention Fund is the first federal mandatory funding stream dedicated for prevention. However, it has had a target on its back for cuts ever since its inception, and has sustained cuts from both Congress and the Administration. This fund is vital for supporting programs that help Americans adopt healthy habits and make the easy choice the healthy choice, making it so important to protect the fund from further cuts. Lifestyle habits are difficult to change – particularly in environments that make the healthy choice the most difficult one. The programs supported by the Fund are designed to identify and address barriers to optimal health and reduce the number of individuals with preventable health conditions throughout their life span.

In addition to the Prevention Fund, the Affordable Care Act created:

- A National Prevention Strategy and Plan to find more way across the federal government to support better health.
- National Prevention Council, which is comprised of 17 federal departments, agencies, and office, led by the U.S. Surgeon General, and leads the government’s efforts in prevention, wellness, and health promotion. This is the first time heads of all these department and agencies have gotten together to discuss their role in public health and wellness.

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| <b>Summary of American Heart Association Policy Priorities on the Prevention Fund</b> |
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| <ul style="list-style-type: none"><li>• Oppose use of the Prevention Fund as an offset for other legislation or programmatic efforts</li><li>• Strongly support the Prevention Fund to remain intact</li><li>• Educate and advocate to policymakers about the importance and successes of the Prevention Fund</li><li>• Use the data and evidence beginning to be collected from the Prevention Fund to support the argument that evidenced-based prevention works</li><li>• Help support the CDC with promotion and advocacy in light of litigation against grant recipients</li></ul> |
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### ***Million Hearts™***

Million Hearts™ is a public/private initiative established by the Department of Health and Human Services with supporting public and private partners designed to prevent one million heart attacks and strokes by 2017.<sup>245,246,247,248</sup> The American Heart Association is one of those partners and is contracted by the Centers for Disease Control and Prevention to offer support for implementation in the field. The tactics of Million Hearts™ focus on two broad objectives: (1) implement public health interventions to reduce the risk of cardiovascular disease through the dietary reduction of sodium and *trans* fats and the reduction of smoking in the environment and (2) ensure clinical interventions around the ABCS (aspirin use when appropriate, blood pressure control, lipid reduction, and smoking cessation).

#### ***American Heart Association priorities for Million Hearts™***

- Advocate for continued funding and implementation of Million Hearts™
- Continue to monitor and support interagency coordination of implementation efforts
- Support robust evaluation of the initiative

### ***Obesity diagnosis, prevention, and treatment in the healthcare environment***

The American Heart Association acknowledges that effectively addressing pediatric and adult obesity requires adequate diagnosis, prevention and treatment within the healthcare environment. The American Heart Association endorses the recommendations of the American Medical Association Expert Committee on the assessment, prevention and treatment of child and adolescent overweight and obesity. The association also advocates for regular BMI assessment during clinical visits and diet, behavioral and physical activity counseling for those at risk for or diagnosed with obesity. Providers play a key role in the fight against obesity and need to be given the support and training necessary to be effective in the clinical environment to address this condition with their patients. In addition to assessment and counseling and adequate health care provider training, the AHA recommends follow-up metabolic assessment with patients to determine if there are other cardiovascular risk factors such as high triglycerides, low HDL cholesterol, high LDL cholesterol, elevated blood pressure, or elevated glucose levels that are often co-morbidities that put the patient at particular cardiovascular risk.

#### ***American Heart Association Recommendations for Assessment, Diagnosis, Prevention, and Treatment of Obesity in Adults and Children***

- Adequate provider training for assessment and treatment of obesity in the clinical environment
- Reimbursement for regular BMI assessment during clinical visits
- Reimbursement for behavioral, dietary, and physical activity counseling/health coaching in both the clinical and community setting with appropriately licensed and credentialed health professionals.

### ***Before/After School Programs***

Before and after school programs offer another opportunity to provide healthy food offerings and physical activity opportunities during the day for children with either supervised or free play activities. Approximately 8.4 million children attend after school programs and 18.5 million would participate in them if they were available.<sup>249</sup> Research has shown that these programs may have a significant impact on obesity prevention efforts.<sup>250, 251.</sup>

#### **American Heart Association Recommendations for Before/After School Programs**

- Increase availability of before and after school programs
- Incorporate robust nutrition and physical activity standards
- Facilitate teacher training and professional development
- Incorporate and support robust nutrition and physical activity standards in the President's proposed universal early education initiative

## ***Tobacco***

Cigarette smoking continues to be the leading cause of preventable disease and death in the United States claiming approximately 467,000 lives prematurely every year.<sup>1</sup> Smoking not only claims the lives of those who use tobacco, but also those who are exposed to second-hand smoke. Smoking costs the U.S. economy more than \$301 billion per year, including workplace productivity losses of \$67.5 billion, premature death at \$117 billion, and direct medical expenditures of \$116 billion.<sup>252</sup> Tobacco control efforts by the American Heart Association have contributed to a decline in U.S. cigarette consumption by more than 24% over the last decade.<sup>253</sup> Despite this progress, 21.3 percent of men and 16.7 percent of women in the U.S. still smoke<sup>3</sup> and our efforts have stalled in the last five years, especially for people living below the poverty line and for those with low educational attainment. Additionally, 88 million nonsmokers are still exposed to second hand smoke, especially in the home where children are disproportionately affected.<sup>254</sup>

The American Heart Association has long advocated for strong public health measures that will reduce the use of tobacco products in the United States and limit exposure to secondhand smoke. The various policies prioritized by the Association and its national partners include adequate funding for tobacco cessation and prevention programs, comprehensive smoke-free air laws, taxation of tobacco products, and FDA regulation of tobacco.

### ***Advocate for Comprehensive Clean Indoor Air Laws and Regulation***

Advocating for comprehensive smoke free air laws at the state and local level is a pillar of the associations' tobacco control advocacy efforts. These laws should be in compliance with the Fundamentals of Smoke-free Workplace Laws guidelines ([http://www.no-smoke.org/pdf/CIA\\_Fundamentals.pdf](http://www.no-smoke.org/pdf/CIA_Fundamentals.pdf))<sup>255</sup> that were developed with several national partners in the public health community to guide and maximize the impact of smoke free policy efforts and increase the number of workers and residents in the United States who are protected from second hand smoke in workplaces and public places.

There is abundant evidence that comprehensive smoke free laws significantly improve public health.<sup>256</sup> Studies from around the world have now provided evidence for a reduction of heart attacks and hospitalizations after implementation of smoke-free air laws.<sup>257</sup> Pooled data show that smoke-free legislation can reduce the incidence of acute coronary events by 10%.<sup>258</sup>

More than 88 million non-smokers over the age of 3 are exposed to second-hand smoke in the United States.<sup>254</sup> Second hand smoke causes heart disease, cancer, lung disease and other illnesses to both children and adults who don't smoke.<sup>259,260</sup> Evidence shows immediate adverse effects on heart function, blood platelets, inflammation, endothelial function and the vascular system with exposure.<sup>261</sup>

- Estimates are that second hand smoke (also called passive smoking) causes 21,800-75,100 heart disease deaths and 38,100-128,900 heart attacks annually.<sup>262</sup>
- Long-term exposure to second hand smoke, such as that occurring in a home or workplace, is associated with a 25%–30% increased risk for coronary heart disease in adult nonsmokers.<sup>263</sup>
- A recent study linked exposure to dementia in adults.<sup>264</sup>
- Those people exposed to high levels of passive smoking were 44% more likely to suffer memory loss and difficulty in making calculations.<sup>259</sup>
- In infants and children, second hand smoke is a risk factor for heightened asthma attacks, acute respiratory illness, Sudden Infant Death Syndrome, and ear infections.<sup>256</sup>
- Pregnant women exposed to second hand smoke show a greater risk of giving birth to low-birth-weight babies.<sup>256</sup>
- Unfortunately, exposure can disproportionately affect minorities<sup>256</sup>, women, and those in lower socioeconomic groups since many of these individuals are employed in the hospitality industry. Blue collar workers are less likely than white collar indoor workers to be covered by smoke-free policies.<sup>259</sup>

Physicians should counsel patients that exposure to second-hand smoke is a fully preventable cause of death. The direct and indirect health care costs associated with disease caused by second hand smoke exposure are

estimated at \$10 billion each year.<sup>265</sup> If recent trends in the reduction in the prevalence of passive smoking continue, the health and economic burden of passive smoking in the U.S. would be cut annually by approximately 25%–30%.<sup>9</sup> This potential reduction has important ramifications for lowering Medicare, Medicaid, and private insurance costs.

There are other important economic arguments. The hospitality and tobacco industries often promote the idea that business will suffer after these laws are passed. However, increasing evidence from municipalities, states, and countries where these laws have been passed show no significant impact on sales data and in many instances business actually increases.<sup>259</sup> Additional benefits for businesses are lower cleaning costs, lower worker absenteeism, and increased productivity.<sup>259</sup>

According to the American Non-Smokers Rights Foundation, in August 2103, 36 states, along with the District of Columbia, American Samoa, the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands, have laws in effect that require non-hospitality workplaces **and/or** restaurants **and/or** bars to be 100% smokefree. Please see (<http://no-smoke.org/pdf/mediaordlist.pdf>) for updated statistics as new laws and regulations are passed. Currently, 24 states, along with the District of Columbia, Puerto Rico, and the U.S. Virgin Islands, have a law in effect that requires non-hospitality workplaces, restaurants, **and** bars to be 100% smokefree. Despite this tremendous progress, it is estimated that 25-40% of the U.S. population is still exposed to cigarette smoke and its inherent risks so there remains significant work to be done.<sup>9</sup>

| <b>Summary of American Heart Association Policy Priorities on Clean Indoor Air Laws</b> |
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| <ul style="list-style-type: none"><li>• Smoke free air laws that are comprehensive and apply to all workplaces and public environments including restaurants and bars.</li><li>• No preemption of local ordinances</li><li>• No exemptions for hardship, opting out, or ventilation.</li><li>• No exemptions for casinos and gaming organizations, or private clubs.</li></ul> |
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### ***Support Comprehensive Smoke Free Policy in Multi-Unit Housing***

As states and localities accomplish policy priorities, health advocates are increasingly looking for other policy strategies to address the impact of tobacco use on health. Smoke-free policies in multi-unit housing are emerging as an important strategy to address smoking and exposure to tobacco smoke in homes where children, adolescents, the elderly and the disabled are especially vulnerable. Research has shown that smoke-free policies in the home reduce second-hand smoke exposure for all residents, can increase cessation among smokers, and can decrease relapse in former smokers.<sup>266,267,268,269,270</sup>

Accordingly, the American Heart Association supports comprehensive smoke-free policies in multi-unit housing. In public housing, these policies could be mandated as part of regulation since taxpayer dollars are used to subsidize the health and economic consequences of smoking. In privately-owned housing, legislation or regulation could provide incentives to owners such as insurance discounts, or funding for education, communication, and cessation resources as motivation to adopt comprehensive smoke-free policies. While advocating for comprehensive smoke-free policies, the American Heart Association wants to assure that smokers are not denied access to public housing as they can abide by policies which allow for outdoor smoking areas.

About 40 million Americans live in multi-unit housing properties (apartments, condominiums, and townhouses), representing 31.5% of all housing units in the United States.<sup>271</sup> Recent federal government data show that approximately 7.1 million Americans live in subsidized housing.<sup>272</sup> Of these individuals, about 2.1 million live in public housing where the housing is owned or operated by a Housing Authority.<sup>6</sup> Determining public and subsidized housing can be complex as ownership and administration is often decentralized and fragmented between the federal government and local public housing authorities.<sup>273</sup> For example, there are publicly-owned and subsidized apartment buildings and there are voucher programs for privately owned properties where tenants receive a subsidy from the federal government to help cover their private housing rent. Additionally, states offer supplemental public housing programs that operate without federal funding. Despite the complexity, in each of these cases, at least some tax dollars are being used to subsidize all or a

portion of the housing costs.

Surveillance data show that the smoking rate is higher in subsidized housing where 32.7% of adults use tobacco compared with 20.6% in the general population.<sup>254,274</sup> As more states and localities have passed smoke-free air laws for public spaces and workplaces, the home is the most significant source of exposure to second-hand smoke, especially for children.<sup>275</sup> Americans on average, spend about two thirds of their time each day in their residences.<sup>276</sup> However, only half of U.S. households with both children and smokers have complete home smoking bans and unfortunately bans are less common among smoking families with older children, in African-American and Hispanic households, and in households in states where there is a higher smoking prevalence.<sup>277</sup>

Even if people living in multi-unit housing have a smoke-free policy for their own home, they may still suffer incursions from others in the complex. Research has documented the transfer of second-hand smoke in the air<sup>278,279,280,281,282,283,284</sup> and transfer of second-hand smoke constituents through heating, ventilation, air conditioning systems and other connections between units.<sup>6,285,286,287</sup> As many as half of multi-unit housing residents report that smoke has entered their unit from elsewhere in the building or complex<sup>288,289</sup> and detectable levels of nicotine have been documented in multi-unit buildings where smoking is permitted.<sup>290,291,292</sup>

In 2009, the U.S. Department of Housing and Urban Development encouraged smoke-free policies in public housing to prevent the migration of second-hand smoke between housing units in an attempt to lower exposure especially among the most vulnerable tenants including the elderly, children, and people with chronic illnesses.<sup>293</sup> In public housing, children and adolescents are 39 percent of residents while older Americans comprise 15 percent of residents.<sup>294</sup> There is evidence that exposure to second-hand smoke disproportionately affects minorities,<sup>295,296</sup> women, and those in lower socioeconomic groups since a larger number of these individuals are residing in subsidized housing.

One recent study<sup>297</sup> estimated the annual cost-savings associated with smoke-free policies in multi-unit housing by calculating savings for second-hand smoke related health care costs, renovations of housing units that permit smoking, and smoking-attributed fires. Renovations or repairs include paint to cover smoke stains, cleaning of ducts, replacing stained window fixtures, and replacing carpets. The calculations from this study showed that prohibiting smoking in all U.S. subsidized housing could save approximately \$521 million per year, including \$341 million in second-hand smoke-related health care expenditures, \$108 million in renovation expenses, and \$72 million in smoking-attributable fire losses. Just prohibiting smoking in public housing alone would save approximately \$154 million annually. Another study of multi-unit housing owners in California showed that comprehensive smoke-free policies implemented statewide could save owners over \$18 million a year.<sup>298</sup> Clearly there are economic motivations for smoke-free policies that go beyond the critically important health benefits.

Studies show that second-hand smoke transfer in multi-unit housing is common, the current prevalence of policies is low (even though there is growing momentum), and a clear majority of tenants in multi-unit housing would choose a smoke-free building over housing where smoking is permitted if other amenities are equal. Additionally, property managers who adopt no-smoking policies indicate that they are likely to continue doing so.<sup>298</sup> No level of second-hand smoke exposure is safe.

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| <b>Summary of American Heart Association Policy Recommendations on Smoke Free policies in Multi Unit Housing</b> |
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| <ul style="list-style-type: none"><li>• In privately owned housing units support voluntary adoption of comprehensive smoke free policies; through regulation and legislation offer incentives or resources to owners who implement them</li><li>• In housing units subsidized by public funding, mandate comprehensive policies through regulation and legislation</li></ul> |
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***Increase Tobacco Excise Taxes and Assure All Tobacco Products are included and advocate for equitable tax rates so that all tobacco products are taxed at the same level***

The American Heart Association advocates for significant increases in tobacco excise taxes at the state, federal, county or municipal levels that cover all tobacco products. These taxes are a health win that reduces tobacco use, saves lives, raises revenue for cash-strapped governments, and lowers health care costs. They are also often popular with voters. A report from the Campaign for Tobacco Free Kids calculated that if every state and Washington, DC, raised their cigarette tax rates by \$1 per pack, they would: raise \$9.1 billion in new annual state revenues; save \$52.8 billion in immediate and long-term health care costs; prevent more than 2.3 million kids from becoming smokers; prompt more than 1.2 million adult smokers to quit; and prevent more than 1 million premature deaths from smoking.<sup>299</sup> A more recent report calculated that if the federal excise tax was raised by .94, it would prevent 1.74 million kids from becoming addicted adult smokers over the next 18 years, save 989,800 Americans from premature death from smoking, and save \$63.39 billion in long-term health care costs from adult and youth smoking declines.

Many studies have examined the impact of cigarette tax increases on smoking prevalence, especially in youth. Most have found that higher taxes reduce consumption, especially cessation rates in young smokers.<sup>300</sup> The general consensus is that for every 10% increase in the real price of cigarettes, the increased cost reduces overall cigarette consumption by approximately 3-5%, lowers the number of young-adult smokers by 3.5%, and cuts the number of kids who smoke by 6 or 7%.<sup>301</sup> Other estimates are that a 40% tax-induced cigarette price increase would reduce smoking prevalence to 15.2% in 2025 with large gains in cumulative life years (7 million) and quality adjusted life years (13 million) for a total cost-savings of \$682 billion.<sup>302</sup> Philip Morris calculated that the 1982-83 price increases caused two million adults to quit smoking and prevented 600,000 teenagers from starting to smoke.<sup>303</sup> The Institute of Medicine has concluded that the most direct and reliable method for reducing tobacco use is to increase the price of tobacco products, thus encouraging cessation and also reducing the number of kids who start using cigarettes or other tobacco products.<sup>304</sup> Cigarette price and tax increases work even more effectively to reduce smoking among males, Blacks, Hispanics, and lower-income smokers where smoking rates are often higher.<sup>305,306</sup>

The federal government has imposed excise taxes, most recently with the expansion of the Children's Health Insurance Program. A cigarette tax increase of 61.66 cents per pack went into effect on April 1, 2009 making the current total federal tax \$1.01 per pack. There were also increases in the federal tax rates on other tobacco products such as smokeless products, small cigars, roll-your-own tobacco, and regular cigars.<sup>307</sup> States have concurrently imposed tobacco excise taxes with a current nationwide average of \$1.53/pack (major tobacco states have an average of 48.5 cents/pack while other states' average is \$1.67/pack)<sup>308</sup> This is an increase from an average of 44.4 cents in January 2002, an incredible public health achievement.<sup>11</sup>

The state of New York raised its cigarette tax in June 2010 by \$1.60 to give it the highest cigarette tax in the nation at \$4.35/pack.<sup>123</sup> The highest combined state-local tax rate is \$5.85 in New York City, with Chicago, IL second at \$5.66 per pack.<sup>123</sup> States received nearly \$244 billion in tobacco settlement and excise taxes from cigarettes from 1998-2010. Unfortunately, only 2.8% of this (\$8.1 billion) is dedicated for state tobacco control programs, which in recent years have faced drastic budgetary cuts, resulting in their near-elimination.<sup>309</sup> A recent study found that a multi-pronged effort - implementing well-funded tobacco prevention programs, increasing the price of cigarettes through higher taxes and implementing strong smoke-free air laws - was the most effective method to discourage youth smoking. Together, these efforts reduced the number of youth smokers by nearly 220,000 from 2002-2008. These programs, which have faced significant cuts in recent years, will need strong political support in order to be effective once again.<sup>310</sup>

Industry documents show that the tobacco companies understand the impact of tax increases on consumption and have developed pricing strategies. Such strategies include development of lower cost generic brands and price-related marketing efforts such as multi-pack discounts and couponing to offset the impact of the taxes and diminish the benefit to public health.<sup>311</sup> The tobacco control movement has to continue to adapt to these industry tactics to maintain the health impact and value of tobacco tax strategies.

Current tax loopholes and unequal tax rates encourage use of lower-taxed tobacco products and create incentives for tax avoidance. The current system for taxing tobacco products is neither simple nor equitable.

Tobacco products are taxed in different ways and at different rates, which has created large disparities in the tax levied on similar products. Such disparities have created opportunities for manufacturers to make small modifications to products or their labeling so that they qualify for lower tax rates – including a recently revelation that cigar companies use kitty litter in their products to make them heavier and avoid higher taxes for lower-weighted products. The availability of these lower-taxed products can dissuade tobacco users from quitting and encourage youth to initiate tobacco use.

An April 2012 GAO report highlights how certain manufacturers have avoided paying higher taxes on roll-your-own tobacco by re-labeling the product as “pipe” tobacco, which is taxed at substantially lower rates under the current tax code. The GAO also noted that some manufacturers have avoided the higher tax rates for cigarettes and small cigars by slightly modifying their products to qualify as large cigars. GAO estimates that federal revenues lost as a result of these two loopholes range from \$615 million to \$1.1 billion from April 2009 to September 2011.<sup>312</sup>

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| <b>American Heart Association Policy Recommendations for Tobacco Excise Taxes and Tax Parity</b> |
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| <ul style="list-style-type: none"><li>• Significant increases in tobacco excise taxes at the state, county, or municipal levels that cover all tobacco products</li><li>• Allocation of at least some of these revenues generated toward tobacco control, prevention, and cessation programs, as well as other health-related initiatives such as improving access to health care</li><li>• Support the President’s proposal of a 94 cent tax increase on cigarettes with a per-ratio increase for all other tobacco products</li><li>• Support the Tobacco Tax Equity Act</li><li>• Look for opportunities to promote equitable tax treatment of all tobacco products</li></ul> |
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### *Increase Funding for Tobacco Cessation and Prevention Programs*

To help save these lives, the association advocates for sustainable funding for state tobacco prevention and cessation programs to levels that meet or exceed Centers for Disease Control and Prevention (CDC) recommendations. Tobacco control programs should be comprehensive, developed in accordance with CDC recommendations, staffed appropriately, and administered effectively. CDC’s best practices help reduce tobacco use, address social norms around smoking, develop robust school programs, enforcement of existing regulations and laws, statewide programs, cessation programs, counter marketing efforts (including paid broadcast and print media), media advocacy, public relations, public education, and health promotion activities, surveillance and evaluation, and administration and management.

In 1998, the four largest U.S. tobacco companies and the attorneys general of 46 states signed the Tobacco Master Settlement Agreement (MSA), settling the states’ Medicaid lawsuits against the tobacco industry for recovery of their tobacco-related health care costs. Under the agreement states received up-front payments of \$12.74 billion with the promise of an additional \$206 billion over the next 25 years. Additionally, many states have increased excise taxes on cigarettes, generating millions of dollars in new revenue. Unto themselves, these tax increases have significantly lowered tobacco use prevalence.<sup>313</sup> Ideally, however, states would use the MSA and/or tobacco tax revenue to fully fund tobacco control programs that follow Centers for Disease Control and Prevention best practices. Unfortunately, only North Dakota currently funds its tobacco prevention programs at CDC recommended levels. Revenue from the MSA and tobacco taxes continues to flow toward other parts of state budgets despite the fact that state tobacco control program expenditures have been shown to be independently associated with overall reductions in smoking prevalence.<sup>314</sup>

In 2012, it is estimated that states collected \$25.6 billion in revenue from the tobacco settlement and tobacco taxes, but spent only 1.8% of it — \$456.7 million — on tobacco prevention and cessation.<sup>315</sup> States are sacrificing long-term health benefits and health care cost savings for short-term budget fixes. If all states had funded their tobacco control programs at the minimum or optimal levels recommended by the CDC since the

Master Settlement Agreement, there could have been millions of fewer smokers just over a decade later.<sup>129</sup>

| <b>American Heart Association Priorities for Tobacco Prevention and Cessation Programs</b>  |
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| <ul style="list-style-type: none"><li>• The American Heart Association advocates for sustainable funding for state tobacco prevention and cessation programs to levels that meet or exceed CDC recommendations.</li><li>• Tobacco control programs should be comprehensive in accordance with CDC recommendations, staffed appropriately, and administered effectively with periodic evaluation</li><li>• Protect the Prevention and Public Health Fund</li></ul> |



***Advocate for Comprehensive Coverage of Tobacco Cessation Services in Private and Public Health Insurance***

The American Heart Association advocates for comprehensive coverage of tobacco cessation services in public and private health insurance programs that includes medications and counseling. In general, tobacco cessation treatment remains highly cost-effective, even though it is very difficult for people to quit this deadly, addictive habit.<sup>316</sup> There is a strong relationship between the length of time patients have in behavior counseling sessions, the amount of time they are able to spend with their health care providers and successful treatment outcomes.<sup>317</sup>

Available forms of nicotine replacement therapy (gum, transdermal patch, nasal spray, inhaler, and lozenges) increase quit rates by 50-100% compared with not using any of these products at all; however, fewer than one in five smokers making a quit attempt take advantage of these therapies.<sup>318</sup> The most successful programs have a 1-year quit rate of approximately 35% (compared with 5% for cold-turkey attempts) and cost about \$1500/ quitter at a cost of \$202 per life year saved with an ROI of \$5.45 for every \$1.<sup>319</sup>

In July 2006, the Massachusetts health care reform law mandated tobacco cessation coverage for the Massachusetts Medicaid population. Upon implementation of the benefit, MassHealth subscribers were allowed two 90-day courses per year of FDA-approved medications for smoking cessation, including over-the-counter medications like nicotine replacement therapy, and up to 16 individual or group counseling sessions. Within the first two years of implementation, over 70,000 Massachusetts Medicaid recipients used the benefit, and the smoking rate declined from 38% to 28%.<sup>320</sup> There was also a decline in the utilization of other costly healthcare services (38% decrease in hospitalizations for heart attacks, 17% drop in emergency room and clinic visits due to asthma, and a 17% drop in claims for adverse maternal birth complications, including pre-term labor).<sup>10</sup> Additional research with the program showed that the comprehensive coverage led to reduced hospitalizations for heart attacks and a net savings of \$10.5 million, or a \$3.07 return on investment for every dollar spent.<sup>321</sup> Savings will likely continue to increase as time goes on and the impact of quitting in this population increases.

A recent study showed that while the retail price of a pack of cigarettes in the US is on average \$5.51, the combined medical costs and productivity losses attributable to each pack of cigarettes sold are approximately \$18.05 per pack of cigarettes. The ratio of benefits to cost varies from \$0.86 to \$2.52 saved per dollar spent on smoking cessation programs, depending upon the type of intervention.<sup>322</sup>

The health benefit of cessation and relapse therapy during pregnancy is even more apparent, minimizing low birth weight, placental abruption, sudden infant death syndrome, and other illnesses and life-threatening conditions for mother and child.<sup>323</sup> Quitting tobacco also leads to increased productivity at work, less disability and chronic disease, and less medical expenditures.<sup>324</sup> One study showed that if regular counseling was offered to smokers, more than 70,000 lives could be saved each year.<sup>13</sup>

Implementation of the Affordable Care Act (ACA) requires state Medicaid programs to cover comprehensive tobacco cessation treatments with no cost sharing for pregnant women. This provision went into effect on October 1, 2010. States have a tremendous opportunity to save even more lives by applying tobacco cessation treatments to all smokers in Medicaid. Nationwide, 36.6% of people in Medicaid smoke, compared to 22.6% of the general population<sup>325</sup> and smoking-related medical costs are considered responsible for 11% of Medicaid costs.<sup>326</sup>

The Affordable Care Act also requires private insurers offering non-grandfathered group or individual health insurance plans to cover preventive services rated as A (“strongly recommended”) & B (“recommended”) by the U.S. Preventive Service Task Force without cost sharing. Tobacco cessation services fall into this category since they are highly recommended and have shown evidence-based outcomes. Comprehensive tobacco cessation services should be offered in all public and private health care plans.

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| <b>American Heart Association Policy Recommendation</b> |
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| <ul style="list-style-type: none"><li>• Private and public health insurers to cover comprehensive cessation services for all current tobacco users including both counseling and pharmacotherapy without cost sharing.</li></ul> |
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***Advocate for strong regulations from the FDA to continue to implement the Tobacco Control Act. Push FDA to be more expeditious in releasing some of the pending regulations. Protect gains and progress already made in implementing the law.***

The American Heart Association worked with Congress to pass the 2009 Family Smoking and Tobacco Control Act and continues to work with the FDA and the Center for Tobacco Products (CTP) to implement the provisions. This legislation for the first time ever gave the FDA to regulate tobacco products and finally hold tobacco companies accountable and restrict efforts to addict more children and adults.

Since the bill was signed into law, CTP has issued rules: deeming authority over cigarettes and smokeless tobacco products; prohibiting the use of light, low, mild, and other similar descriptors in all advertising, labeling, and marketing of cigarettes and smokeless products; restricting the sale, distribution, marketing, and use of cigarettes and smokeless tobacco to individual under 18; banning candy and fruit-flavored cigarettes and smokeless tobacco geared toward children; graphic warning labels (which is currently under litigation); exempting substantial equivalent requirements; prohibiting health claims without FDA review; banning sponsoring sports and entertainment events; and banning branded merchandise and free samples and gifts with purchase.

However, CTP still has much more work to do. Pending regulations include outdoor advertising near schools; non-face-to-face-sale and distribution such as those done over the Internet, e-mail, and direct mail; menthol in cigarettes and other tobacco products; product standards; and deeming authority over all other tobacco products, including cigars and e-cigarettes. In FDA’s reticence in issuing these regulations, tobacco companies are taking advantage and legislation has been introduced which, if passed would renege the gains made from the Tobacco Control Act.

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| <b>American Heart Association Policy Priorities on FDA Regulation of Tobacco</b> |
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| <ul style="list-style-type: none"><li>• Oppose any legislation that would reverse provisions in the Tobacco Control Act, interfere with FDA oversight, or provide any exemptions or loopholes</li><li>• Advocate for FDA to expedite pending regulations</li><li>• Support strong deeming regulations to give FDA oversight over all tobacco products including e-cigarettes.</li><li>• Provide support for strong graphic warning labels as the FDA revisits this issue post-litigation</li><li>• Continue to monitor tobacco companies’ compliance with current law</li></ul> |
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***Advocate for strong regulations from the FDA to regulate all tobacco products, including cigars. Oppose any legislation that would promote or promulgate loopholes and exemptions for any tobacco products, including cigars.***

The FDA has announced that it intends to assert authority over all tobacco products, including cigars. No tobacco product was excluded from FDA jurisdiction under the Family Smoking Prevention and Tobacco Control Act so that FDA could evaluate the science and public health considerations of every product. However, FDA has been slow to issue this regulation and as a result, tobacco companies are taking advantage to modify products to avoid regulation. In addition, legislation has been introduced in the past few Congress that would exempt certain types of cigars.

Consumption of cigars is rising. Sales of cigars more than doubled between 2000 and 2012 from six billion cigars to more than 13 billion cigars. Cigar consumption has been increasing while cigarette consumption has declined, and much of the growth can be attributed to smaller cigars that resemble cigarettes. While cigar smoking conjures images of middle-age and older men, today's cigar smoker is more likely to be a youth or young adult, and that number is growing. Results from the 2011 Youth Risk Behavior Survey show that more than one in six (17.8 percent) high school boys currently smoke cigars.<sup>20</sup> Each day, more than 3,000 kids under 18 years old try cigar smoking for the first time.<sup>327</sup>

Disparities in regulation have created opportunities for manufacturers to make small modifications to products or their labeling so that they qualify for lower tax rates – including a recently revelation that cigar companies use kitty litter in their products to make them heavier and avoid higher taxes and regulation for lower-weighted products. They have also allowed companies to produce candy and fruit-flavored little cigars and cigarillos targeted at the growing youth cigar market.

| <b><i>American Heart Association Policy Priorities on Cigars</i></b>  |
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| <ul style="list-style-type: none"><li>• Oppose the cigar exemption bill, as well as any bill that would except any tobacco product from FDA oversight</li><li>• Advocate for FDA to stop delaying the release of deeming regulations</li><li>• Support strong deeming regulations to close the regulatory loopholes for cigars and other tobacco products</li></ul> |

### **Eliminating the Sale of Tobacco Products in Pharmacies and other Health-Related Institutions**

The association supports policies that prohibit the sale of tobacco products all health care settings, including pharmacies. It is incongruent for tobacco products to be sold in any setting that promotes health, and it is especially incongruent to place tobacco products near tobacco cessation aids. Removing tobacco products in pharmacies is another step in the association's longstanding efforts to denormalize tobacco products. This policy should be implemented in addition to other proven tobacco control policies, including increased tobacco taxes, comprehensive smoke-free indoor air laws, and full funding for tobacco prevention and cessation programs.

The prevailing consensus in the public health community is that tobacco products should not be sold in pharmacies. The California Department of Health notes that the United States is the only place in the world where tobacco products are sold in pharmacies.<sup>328</sup>

The amount of research supporting a position of banning sales in pharmacies will continue to grow as scientists study the impact of the bans in Boston and San Francisco that are currently in effect. Current studies, however, indicate that limiting access to tobacco products is a key component in denormalizing tobacco use and that such denormalization leads to fewer individuals starting to use tobacco and more individuals trying to quit.<sup>329</sup>

### American Heart Association Priority for Eliminating Tobacco Sales in Pharmacies

- The American Heart Association supports policies that prohibit the sale of tobacco products in all pharmacies

### *Air Pollution*

Air pollution is associated with a variety of negative health outcomes, including increased risk of cardiovascular disease and stroke. Pollution is comprised of a mixture of substances from sources such as vehicle and power plant emissions and the burning of fossil fuels. The Clean Air Act requires the Environmental Protection Agency (EPA) to set National Ambient Air Quality Standards (NAAQS) for six “criteria” pollutants: carbon monoxide, lead, nitrogen dioxide, ground-level ozone, particulate matter, and sulfur dioxide.<sup>330</sup> Although nationwide criteria air pollutants have declined since the NAAQS were put in place in 1990,<sup>331</sup> many states are not in compliance with EPA standards,<sup>332</sup> and pollution still poses a threat to health.

A multitude of cardiovascular outcomes have been associated with air pollution: increased hospital admissions for cardiovascular disease (CVD) and stroke; increased mortality due to CVD or stroke; increased hospitalization after a primary CVD or stroke event; and increased occurrence of out-of-hospital cardiac arrest, myocardial infarction (MI), and heart failure. Studies show that incremental increases in various criteria pollutants result in increases in occurrence of these outcomes. It should be noted, however, that few studies have shown causal pathways between air pollution and CVD/stroke, as it would not be ethical to expose study participants to levels of pollution that could potentially cause life-threatening conditions. Therefore, with the exception of a study showing changes in cardiovascular and cerebrovascular indicators after exposing healthy volunteers to low levels of pollution,<sup>333</sup> the research examines only *associations* between increases in pollutant levels and corresponding increases in cardiovascular diseases in the same geographic area. Researchers take into account the lag time between pollution exposure and disease and differentiate effects of short-term versus long-term exposure to pollution.

The effect of air pollution on health is a complex, multi-factorial process with multiple confounding factors. For example, living close to a major roadway may result in increased exposure to a variety of types of traffic-related air pollutants.<sup>334</sup> However, most of the recent research focuses on one or more specific pollutants – including particulate matter; nitrogen dioxide, sulfur dioxide, and carbon monoxide; and ground-level ozone – and their association with negative health outcomes.

**Particulate Matter.** Particulate matter is a heterogeneous mixture of acids, chemicals, metals, and other organic matter that form particles and remain suspended in air.<sup>335</sup> These particles are commonly differentiated by size: those smaller than 2.5 micrometers ( $\mu\text{m}$ ) in diameter are known as  $\text{PM}_{2.5}$  or fine particles, and particles ranging from 2.5 to 10  $\mu\text{m}$  in diameter are known as  $\text{PM}_{10}$ .<sup>336</sup> Smaller particles generally do more damage to a person’s health as they are able to circumvent defense systems and lodge themselves deep in the lungs. About 40% of  $\text{PM}_{2.5}$  emissions are a result of human activities including fuel combustion, industrial processes, and vehicle emissions.<sup>337</sup>

A comprehensive review of evidence linking particulate matter to CVD found that short-term exposure to  $\text{PM}_{2.5}$  (hours to weeks) can trigger CVD-related mortality and non-fatal events;<sup>335</sup> an estimated 10  $\mu\text{g}/\text{m}^3$  increase in average short-term  $\text{PM}_{2.5}$  exposure increased the relative risk for daily cardiovascular mortality by .4% to 1%.<sup>338</sup> The same review found that longer-term exposure to  $\text{PM}_{2.5}$  (years) increases the risk of cardiovascular mortality to an even greater extent.<sup>335,338</sup>

Studies examining particulate matter and stroke have shown that short-term<sup>339,340</sup> and long-term<sup>341</sup> increases in  $\text{PM}_{2.5}$  in the air are associated with increased hospital admissions for ischemic (but not hemorrhagic) stroke. Short-term exposure to  $\text{PM}_{2.5}$  is also associated with alterations in cerebrovascular hemodynamics that may put a person at risk for stroke,<sup>342</sup> especially among patients with pre-existing conditions such as diabetes mellitus.<sup>343</sup> Exposure to the larger particles,  $\text{PM}_{10}$ , is associated with increased risk of ischemic stroke<sup>344,345,346</sup> and stroke mortality.<sup>346,347,348</sup>

Studies examining particulate matter and cardiovascular disease have found associations between an increase in PM<sub>2.5</sub> and out-of-hospital cardiac arrest (OHCA),<sup>349,350,351,352</sup> which can be considered an indicator of cardiovascular mortality as most people do not survive OHCA.<sup>352</sup> However, when directly studying cardiovascular mortality, more evidence has been accumulated as to the negative effects of PM<sub>10</sub>.<sup>335,344,353,354,355,356</sup> Both PM<sub>10</sub> and PM<sub>2.5</sub> are associated with increases in hospital admissions for heart failure<sup>356,357, 358,359</sup> and MI.<sup>360,361</sup> Additionally, exposure to PM<sub>2.5</sub> or PM<sub>10</sub> in patients who have already suffered a first MI increases the risk of cardiovascular event recurrence<sup>362</sup> and increased risk of death in patients who have already suffered a stroke.<sup>363</sup>

**Nitrogen Dioxide, Sulfur Dioxide, and Carbon Monoxide.** Nitrogen dioxide (NO<sub>2</sub>), sulfur dioxide (SO<sub>2</sub>), and carbon monoxide (CO) are gases that pollute the air and are detrimental to health. The majority (73%) of SO<sub>2</sub> in the air is the result of fossil fuel combustion in power plants<sup>364</sup> and the majority (62% and 86%, respectively) of NO<sub>2</sub> and CO in the air is the result of transportation emissions.<sup>365,366</sup>

Studies show that exposure to NO<sub>2</sub> may contribute to the development of ischemic stroke, but not hemorrhagic stroke,<sup>344,367,368</sup> the relation between NO<sub>2</sub> exposure and ischemic stroke is particularly strong for elderly populations.<sup>369</sup> The concentration of NO<sub>2</sub> and CO in the air is positively associated with the incidence of stroke, although the association may not be significant when controlling for factors such as income.<sup>370</sup> Increases in concentrations in both SO<sub>2</sub> and NO<sub>2</sub> have been associated with increased stroke mortality.<sup>344,371</sup> Exposure to NO<sub>2</sub> is especially dangerous and potentially deadly for patients who have already suffered a stroke<sup>372</sup> or who have existing CVD.<sup>348</sup>

All three of these pollutants have also shown association with acute MI<sup>360,361</sup> and congestive heart failure (CHF).<sup>358</sup> SO<sub>2</sub> in the air is of particular concern for cardiovascular mortality.<sup>355,373,374</sup>

**Ozone.** Ground-level ozone (O<sub>3</sub>) is primarily a product of nitrogen oxides, volatile organic compounds, and heat.<sup>375</sup> Sources of these pollutants include vehicle emissions, refineries, factories, power plants, and industrial boilers.<sup>336</sup> Increases in O<sub>3</sub> in the air are associated with increased risk of OHCA,<sup>350</sup> stroke hospitalization,<sup>376</sup> and admission for CHF<sup>358</sup> on the day of exposure and recurrent ischemic cerebrovascular events three days after exposure.<sup>377</sup> O<sub>3</sub> has also been shown to cause alterations in the vascular system and heart rate that could lead to mortality,<sup>333</sup> and associations between O<sub>3</sub> and cardiovascular mortality have been shown.<sup>378</sup>

The negative effects of criteria air pollutants on cardiovascular health demonstrate the need to take advantage of opportunities to reduce air pollution. Stricter enforcement of state compliance to current NAAQS and further research determining the appropriate maximum levels of criteria air pollutants are necessary. Physicians should educate their patients regarding the harmful effects of pollution so that they may take steps to reduce their exposure. Lastly, the US should further explore opportunities for clean energy sources and energy efficient construction to reduce our reliance on energy sources that generate pollutants.

#### ***Potential American Heart Association Priorities to Address Air Pollution***

- Enact stricter EPA standards.
- Encourage kids to walk or bike to school instead of taking the bus.
- Create measures that reduce exposures to air pollution and fund more research on the impact of air pollution on the public's health.
- Encourage physicians and other health care practitioners talk to their patients about the CVD risk from exposure to polluted air and provide tips for reducing exposure, such as avoiding prolonged or heavy outdoor exertion during times when the air quality may be dangerous.
- Fully implement the Clean Air Act.
- Tighten regulations on sources of particulate matter and ozone to improve the quality of our air.
- Configure and design cities and communities to provide greater separation between residents and pollution sources such as highways and power plants.
- Invest in more research into the impacts of various types of air pollutants on health, including

those found in indoor air pollution.

- Monitor opportunities to influence legislation and regulation at the state and federal level to decrease the amount of particulate matter air pollution from various sources.
- Offer incentives to consumers and businesses to purchase energy-efficient technologies in order to reduce emissions from residential and commercial heaters, boilers, lighting, chillers, air conditioners, etc.
- Promote “green power” markets, which allow consumers to purchase electricity generated by renewable sources.
- Redesign utility rate structures to incorporate incentives for energy efficiency and clean energy.
- Set building codes for new commercial and residential construction at a minimum level of energy efficiency. Specify requirements for “thermal resistance” in the building shell and windows, minimum air leakage, and minimum heating and cooling equipment efficiencies.
- Incentivize power plants to install modern emission control systems; establish mandatory state or regional cap and trade programs which control power plant pollution by providing economic incentives for achieving reductions in the emissions of pollutants.
- Invest in clean energy development, including wind and solar energy.
- Set tougher motor vehicle standards for tailpipe emissions, enforce vehicle inspection and maintenance programs, and establish programs to help consumers purchase energy-efficient cars.
- Establish a diesel emissions reduction fund, aggressively retrofit and replace state vehicles and equipment, adopt and enforce anti-idling ordinances and legislation, mandate closed crankcase ventilation systems, and promote truck stop electrification programs.
- Promote alternative fuels for vehicles and equipment (including natural gas, propane, methanol, ethanol, electricity and biodiesel fuel) and regulate gas stations to reduce emissions.
- Establish tolls, fuel fees, carpool lanes, and other programs that reduce the number of vehicle miles travelled on roads and increase funding for public transportation.
- States can “lead by example” by developing state energy plans, mandating renewable and energy-efficient purchase commitments for state facilities, offering loan and incentive programs to increase energy efficiency in public buildings, retrofit and replace state vehicles and equipment, and implement a public communication strategy regarding the benefits of clean energy.

#### **IV. Access to Appropriate and Affordable Health Care**

*Expand and protect access to affordable, adequate, transparent insurance coverage for all*

- *Implement and Build on the Affordable Care Act*

The association’s work to implement the coverage provisions of the Affordable Care Act continues to be guided by our first principle for healthcare reform, that all residents of the United States should have meaningful, affordable healthcare coverage. The Congressional Budget Office projects that 30 million Americans will gain access to coverage once the law is fully implemented, making the ACA the most important piece of legislation for expanding access to care since Medicare and Medicaid were created. Implementation of the law will need to continue to be monitored closely and the association will need to continue working to ensure that insurance coverage is indeed available, affordable, adequate, and sufficiently understandable so that consumers can choose the plan that best meets their needs.

Even if the ACA meets the CBO’s projections for coverage, there are expected to be some 25 million people in the U.S. still without coverage after the law is fully implemented, and this number could be even higher depending on the success of education and enrollment outreach efforts, the failure of some states to expand their Medicaid programs, and other policy choices that could undermine coverage. Therefore the association will need to continue working at the federal and state levels to achieve universal health insurance coverage. Examples of the types of policies that will likely need to be supported to achieve this goal include: continuing to advocate for Medicaid

expansion in states that have not yet done so, addressing barriers to coverage for undocumented residents, and eliminating or reducing tobacco surcharges that may make coverage prohibitively expensive for tobacco users.

- ***Protect Medicare, Medicaid, and CHIP***

Medicare, Medicaid, and the Children's Health Insurance Program are important sources of insurance coverage for adults and children with or at-risk for CVD and stroke. Medicaid alone provides an important safety net for 16 million Americans with a history of heart disease, stroke or other forms of cardiovascular disease (CVD), including seniors living in nursing homes, children with congenital heart disease, and those who have been disabled by stroke, congestive heart failure or other CVD. In addition, 42 percent of Medicare beneficiaries have a heart condition and 12 percent have had a stroke. As the federal and state governments struggle with budget deficits, Medicare and Medicaid in particular are coming under increasing attention as a potential source for budget savings, even as the Baby Boomers age and more people need the coverage these programs provide. As Congress considers changes to these public programs, the association will work to:

- Protect access to Medicaid and Medicare for the millions of Americans with heart disease and stroke.
- Maintain the long-term sustainability of these two programs which are essential to our patient populations.
- Make the impact on patients, particularly those who are most vulnerable, the central focus of any dialogue on health entitlement reform.
- Ensure that entitlement reforms emphasize improvements in health care value, rather than shifting costs from the public to the private sector or from the government to beneficiaries.
- Support changes that promote prevention and coordinated care and reward higher quality as the best approaches to achieve significant cost savings and improvements in health outcomes.

- ***Access to Stroke Rehabilitation***

The association works to protect and improve stroke survivors' access to rehabilitative services in Medicare, Medicaid, and private insurance coverage. Examples of the types of policies we continue to support include:

- Actively advocating for Congress to repeal the Medicare outpatient therapy caps for physical and speech therapy and for occupational therapy or to extend the "exceptions process" that Congress has put in place to allow Medicare beneficiaries who need medically necessary therapy services to get an exception from the caps.
- Advocated for the inclusion of "rehabilitative and habilitative services and devices" as one of the 10 categories of "Essential Health Benefits" that have to be covered by all private health plans in the nongroup and small group markets and for many Medicaid beneficiaries, starting January 1, 2014. As this coverage is implemented, the association will need to continue monitoring it to ensure that access to therapy services is sufficient and that limits on therapy services are not preventing access to needed rehabilitative and habilitative care.

- ***Increase Access to Cardiac Rehabilitation***

Each year, roughly 785,000 Americans will have a heart attack and more than 60 percent will have a second and potentially fatal event.<sup>1</sup> Cardiac rehabilitation (CR) reduces the risk of a future cardiac event by stabilizing, slowing or even reversing the progression of cardio-vascular disease (CVD).<sup>3,79</sup> Patients with other cardiovascular diseases such as valve repair and heart failure also benefit from exercise rehabilitation.

Yet despite its clear benefits, CR remains underutilized, particularly among women and minorities.<sup>380,381</sup> Only 14% to 35% of eligible heart attack survivors and 31% of patients after coronary bypass surgery participate in a CR program.<sup>3,4</sup> The utilization rate for eligible Medicare beneficiaries is an even lower 12%, and evidence clearly

shows that the more sessions they attend, the better their outcomes and the lower their risk for heart attack and mortality compared with those who do not attend.<sup>382,383</sup>

Among the main reasons for low participation in CR are lack of a referral or a strong endorsement from the patient's physician; limited or no health insurance coverage; conflicts with work or home responsibilities; and lack of program availability and access.<sup>2</sup>

The wide treatment gap between the benefits obtained from CR and participation in these programs is simply unacceptable. New delivery models for health care offer opportunities to address patient barriers and lower costs. At the same time, health practitioners must fully understand and appreciate the benefits of cardiac rehabilitation for their patients.

Medicare provides reimbursement for all the recommended conditions except congestive heart failure. CR sessions are limited to a maximum of two one-hour sessions per day up to 36 sessions furnished over a period of up to 36 weeks with the option for an additional 36 sessions. Reimbursement guidelines require CR programs to include five components. These include: Physician-prescribed exercise, cardiac risk factor modification (education, counseling, and behavioral intervention, psychosocial assessment, and an individualized treatment plan.

The benefits of cardiac rehabilitation are well documented. These include:

- A 20-30% reduction in all-cause mortality rates<sup>383,384</sup>
- Decreased mortality at up to 5 years post participation<sup>385</sup>
- Reduced symptoms (angina, dyspnea, fatigue)<sup>386</sup>
- Reduction in nonfatal recurrent myocardial infarction over median follow-up of 12 months<sup>387</sup>
- Improved adherence with preventive medications<sup>12</sup>
- Increased exercise performance<sup>388</sup>
- Improved health factors like lipids and blood pressure<sup>13</sup>
- Increased knowledge about cardiac disease and its management<sup>389</sup>
- Enhanced ability to perform activities of daily living<sup>13</sup>
- Improved health-related quality of life<sup>13</sup>
- Improved psychosocial symptoms<sup>390</sup>
- Reduced hospitalizations and use of medical resources<sup>13</sup>
- Increased ability to return to work or engage in leisure activities<sup>391</sup>

Older and sicker patients, women, minority populations, patients with lower socioeconomic status or levels of education, are less likely to be referred to CR<sup>380,392</sup> and are less likely to enroll after referral.<sup>393</sup> This is particularly significant because women and minorities are far more likely to die within 5 years after a first MI compared with white male patients.<sup>2</sup>

| <b>Barriers to Cardiac Rehabilitation</b>  |
|--|
| <ul style="list-style-type: none"><li>• Lack of referral or strong encouragement to participate from physician</li><li>• Limited follow-up or facilitation of enrollment after referral</li><li>• Limited or no health care coverage (cost)</li><li>• Work or home responsibilities</li><li>• Hours of operation that conflict with work demands</li><li>• Scarcity of programs in rural areas or low-income communities</li></ul> |

- Distance to facility from patient's home
- Access to public transportation or parking issues
- Lack of perceived need for rehabilitation
- Gender-dominated programs with little racial diversity among staff
- Language problems and cultural beliefs

The American Heart Association is committed to public policies that will reduce the treatment gap for cardiac rehabilitation, with a specific focus on the most underserved populations: women, minorities, and low income individuals. These policies include:

- Expand Medicare coverage for CR to patients with congestive heart failure.
- Create and disseminate information on the benefits of CR to physicians and health plans to enhance referral, follow-up and to reduce costs.
- Provide information on CR to patient-center medical homes to facilitate coordination and follow-up with patients referred to CR.
- Support alternative models to traditional CR that address barriers associated with transportation, responsibilities at home or work.
- Monitor the inclusion of meaningful coverage for CR in state essential health benefit packages

#### ***Health Care Economics & Value-Based Care***

In response to steadily rising costs without corresponding increases in positive health outcomes, the U.S. health care system is currently undergoing dramatic transformation. The ACA and other recent efforts have helped to create a momentum of transformation within the health care system in several areas, including: investing in comparative effectiveness research; implementing patient-centered medical home models; engaging patients in health care decision-making; and utilizing value-based insurance design approaches. AHA has supported these ideas by joining other organizations to support the National Coalition on Health Care's plan for health and fiscal policy, *Curbing Costs Improving Care*.<sup>394</sup>

#### ***Investment in Comparative Effectiveness Research***

The increasing costs of health care present a significant burden to both patients and the healthcare system.<sup>395,396</sup> The economic burden of CVD is particularly worrisome: in 2010 the estimated cost of CVD was \$444 billion, with the cost of CVD treatment accounting for about \$1 of every \$6 spent on health care in the U.S.<sup>397</sup> As the population ages, the economic impact of CVD will become even more significant.<sup>398,399,400</sup> As a result, it becomes increasingly necessary to consider not just clinical effectiveness of cardiovascular treatment, but also the cost-effectiveness of – the relative *value* of – CVD interventions.

Comparative effectiveness research (CER) directly compares the effectiveness of two or more interventions to inform healthcare decisions by providing evidence on the benefits and harms of different treatment plans, medical devices, tests, surgeries, or ways to deliver health care.<sup>401</sup> The ACA establishes a mechanism for ensuring a new and stable source of funding for CER through a new private, nonprofit entity, the Patient-Centered Outcomes Research Institute (PCORI).<sup>402</sup>

Understanding the cost-effectiveness of various CVD and stroke interventions is an important step toward reducing disease burden and ensuring value for services delivered.<sup>5</sup> For example, recent evidence has shown that cardiac rehabilitation has a positive effect on survival and outcomes after hospitalization.<sup>403,404,405,406,407,408,409</sup> However, this type of intervention is currently under-utilized,<sup>410,411,412,413,414,415</sup> and there is limited data on the cost-effectiveness of this approach.<sup>416,417,418</sup> CER research may be useful for demonstrating the value of cardiac rehab to physicians, insurers, patients and other decision-makers. Imaging for CVD is another example of a service that should be reviewed for its cost-effectiveness in comparison to other methods of diagnosis.<sup>419</sup>

While it has strong potential to be an important tool to aid decision-making and practice, AHA recognizes that CER can be controversial and has addressed this by publishing principles for funding, conducting, and applying this type of research.<sup>420</sup>

### ***Delivery System Transformation: Medical Homes & Accountable Care***

The Patient Centered Medical Home (PCMH) model is emerging as a key vehicle to transforming the organization and delivery of primary care, improving health care quality, and controlling costs.<sup>421,422</sup> The PCMH is a whole-person orientation to patient care that is responsible for meeting the large majority of patients' physical and mental needs, including prevention, wellness, acute care and chronic care.<sup>423,424</sup> PCMHs emphasize integrated and coordinated care, focus on quality and safety, facilitate partnerships between patients and physicians, and empower patients with strategies for self-management.<sup>423,424,425</sup>

Evaluations of PCMHs in the private sector reveal that these models of care are meeting cost, utilization, and quality objectives by reducing hospital admissions and use of emergency department services, lowering medical and pharmacy costs, and achieving more efficient care delivery.<sup>426,427,428,429,430</sup> One recent evaluation demonstrated up to \$4.5 return on investment for every \$1 spent on developing a PCMH.<sup>427</sup> The PCMH model has also seen early success in the Medicaid program in states that have formed "Medicaid Health Homes" under the ACA: these states have already seen declines in per capita costs for patients enrolled in Medicaid.<sup>431,432</sup>

Accountable Care Organizations (ACOs) share similar basic principles to the PCMH model, but under the ACO model, provider groups assume responsibility for the quality and cost of care for the patient populations they serve, sharing in any savings generated if defined quality targets are met.<sup>433,434,435</sup> Evidence from private systems that have adopted the ACO model show the potential for substantial savings.<sup>436,437,438</sup> Building on this potential, the ACA established a voluntary ACO opportunity under Medicare – the Medicare Shared Savings Program (MSSP) – where provider groups assume responsibility for the care of a defined population of Medicare beneficiaries, sharing in Medicare savings when their ACO succeeds in delivering high-quality and lower-cost care.<sup>439,440</sup> Recent evaluation of the MSSP has had mixed results on the ability for ACO models to reduce savings for Medicare beneficiaries,<sup>441</sup> but evaluation is ongoing. The Centers for Medicare and Medicaid Innovation (CMMI), is also testing a number of medical home and ACO pilots, and evaluation of these initiatives is underway.<sup>442</sup>

Recent literature suggests that an integrated team effort is essential to providing evidence-based treatment and primary and secondary prevention of CVD.<sup>3,443,444,445</sup> While several studies demonstrate positive CVD outcomes from the PCMH model (such as reduced lipids and blood pressure levels and improved glycemic control<sup>428,446,447,448,449</sup>), there is limited research demonstrating cost-effectiveness.<sup>443,450,451</sup> Impact of the ACO model on reducing costs and improving quality of care for patients with CVD is even less well understood. One recent study showed initial promise for the ACO model in patients with depression and coronary artery disease and/or congestive heart failure.<sup>452</sup> In addition, some researchers surmise that ACOs could be designed to promote efficient care for patients who suddenly experience an unplanned critical illness, such as STEMI, stroke, or out-of-hospital cardiac arrest.<sup>453</sup> Further work must be done to define more clearly the value of PCMH and ACO approaches in the context of CVD.

### ***Patient Engagement***

Under health care reform, delivery systems are assuming increased responsibility and financial risk for patients' outcomes and costs. The concept of engaging patients in their care – educating patients about their conditions and involving them in decision-making – is an important component of this delivery system reform shift, as insurers and providers are increasingly incentivized to improve outcomes by influencing patients' behavior. "Patient engagement" refers to increasing a patient's knowledge and ability to manage his or her own health and care, combined with interventions designed to increase involvement and promote positive patient behavior.<sup>454,455</sup> Patients who are more actively involved in their care are significantly more likely to adhere to treatment regimens, demand higher-value services, seek preventive care, engage in healthy behavior, experience better health outcomes, and incur lower costs.<sup>454,455,456,457,458,459,460,461</sup>

A 2013 study found that the level of patient engagement is a significant predictor of health care costs, even after risk adjustment: here, patients who were the least active in the decision-making process about their health care incurred costs that averaged 8 to 21 percent higher than actively engaged patients.<sup>456</sup> A recent randomized trial found that increasing patient engagement improves chronic heart failure outcomes and reduces hospitalizations.<sup>462</sup> In addition, supporting patients in shared decision-making (i.e. fully informing patients about the risks and benefits of available treatments and engaging them as participants in decisions about their care) can generate health care savings. One large randomized controlled trial found that patients who received enhanced decision-making support had 12.5 percent fewer hospital admissions, 20.9 percent fewer heart surgeries and 5.3 percent lower overall medical costs.<sup>463</sup>

The ACA calls for the broader application of shared decision-making as a way to improve quality and patient experience.<sup>464,465,466</sup>

### ***Value-Based Insurance Design***

Value-based insurance design (VBID) is another tool that has emerged to reduce health care spending. VBID aims to increase health care quality and decrease costs by using financial incentives (such as reducing or eliminating co-pays) that encourage consumers to select high-quality, cost-effective health care services – those services that yield health benefits of high value relative to their costs.<sup>467,468</sup> By designing insurance packages that offer preventive care, wellness visits and certain high-value treatments (such as medications to control blood pressure) at little or no cost to consumers, health plans can promote prevention, healthy behaviors and treatment adherence among beneficiaries, all which may save money by reducing future expensive medical procedures.<sup>469,470</sup> Benefit plans may create disincentives as well, such as high cost-sharing, for health choices that may be unnecessary or repetitive, or when the same outcome can be achieved at a lower cost.

ACA emphasizes elements of VBID. For example, the ACA now requires private insurers and medical expansion plans to cover certain clinical preventive services without cost-sharing,<sup>471,472</sup> many of which are important for CVD prevention.<sup>473</sup> With careful design, implementation, and evaluation, value-based cost sharing can be an important tool for aligning patient and provider incentives to pursue high-value care. Recent research has demonstrated that reducing cost-sharing for certain drugs and treatments (such as reduced co-pays for statins and beta-blockers) has the potential to yield improved care and reduced costs for patients with CVD.<sup>469,474,475,476,477</sup> However more research is needed to better understand VBID mechanisms, particularly around cardiovascular care and stroke treatments.

### ***Expand Workforce Capacity to ensure access to care***

#### ***The Healthcare Workforce***

Meeting the demands of a rapidly aging population is a significant challenge for our healthcare workforce, especially in the context of caring for patients who have, or are at risk for, chronic diseases. The number of Americans aged 65 and older is expected to *double* by 2050.<sup>478</sup> Given that a person's chronological age is a primary risk factor for heart disease and stroke, the incidence of cardiovascular disease (CVD) is projected to significantly increase.<sup>399,400</sup> As the population ages, the need for quality CVD care – and the highly trained workforce professionals who can meet this need – will rise substantially. In addition, rising rates of obesity, diabetes, and other CVD-risk factors<sup>400</sup> compound the need for patient access to a healthcare workforce suited to prevent, diagnose, treat and manage seniors with heart disease and stroke.

***Workforce Shortages.*** The current and projected future healthcare workforce does not have the capacity to meet growing demands. The US already faces a critical physician shortage which is only becoming more severe as an estimated 25 million additional Americans gain access to health insurance through expansions under the Affordable Care Act (ACA)<sup>479</sup> and additional millions enter the Medicare system.<sup>480</sup> Current estimates by the Center for Workforce Studies of the Association of American Medical Colleges (AAMC) show a shortage of over 90,000 physicians by 2020.<sup>481</sup>

- ***Primary Care Physicians.*** By 2019, expanded coverage under ACA is predicted to increase the number of annual primary care visits by between 15.07 million and 24.26 million additional visits.<sup>482</sup> Despite the rising need for primary care services, primary care physician shortages are well-documented.<sup>483</sup> A 2012 estimate projects that the US will need to acquire nearly 52,000 additional primary care physicians by 2025 to meet care utilization needs.<sup>484</sup> As general internists, family medicine practitioners and primary care physicians serve a significant role in screening for risk-factors, diagnosing CVD, educating patients, and managing their care,<sup>485,486</sup> shortages here impact a patient's ability to get timely access to care and threaten quality of care.
- ***Nurses.*** Nurses also play an essential part in CVD prevention and treatment,<sup>487</sup> yet nursing shortages are particularly acute. Despite recent growth in the nursing workforce,<sup>488</sup> current research estimates a shortage of 260,000 registered nurses by 2025.<sup>489</sup> The magnitude of shortages projected today is twice as large as any nursing shortage experienced in this country since the mid-1960s.<sup>489,490</sup>
- ***Cardiologists.*** Recent workforce modeling predicts that the US will need to double the number of CVD specialists between 2000 and 2050 in order to meet a shortage of 16,000 cardiologists.<sup>3,400</sup> The need for additional cardiologists is driven in part by the fact CVD mortality has decreased overtime due to improved

treatments and systems of care implementation; resultantly, the number of patients with chronic CVD is increasing, and so is the need for specialists trained to address these complex care needs.<sup>491</sup>

- *Emergency Medicine.* Emergency medicine services play a critical role in the delivery of timely and quality of care for cardiovascular-related emergencies. However, too few emergency departments (EDs) meet the needs of a growing and aging population.<sup>492</sup> According to the American College of Emergency Physicians' *National Report Card on the State of Emergency Medicine*, between 1996 and 2006, the number of patients coming to EDs increased by 32%; during this same time, the number of hospital EDs dropped by nearly 7%.<sup>492</sup> The Institute of Medicine (IOM) has recognized that the supply of board-certified emergency medicine physicians in the US is insufficient to meet current demand, leading to EDs that are overburdened, under-funded, and highly fragmented.<sup>493</sup> According to the IOM, a shortage of on-call specialists and emergency room overcrowding results in long ED wait-times,<sup>493</sup> impacting timely care for patients with CVD and stroke. Two recent studies show that crowded EDs result in higher rates of adverse outcomes for patients with cardiovascular-related emergencies.<sup>494</sup>
- *An Aging Workforce.* Finally, along with the aging of the general population, the healthcare workforce itself is aging. Many registered nurses, physicians, and other health professionals are retiring, or approaching retirement age.<sup>3</sup> Nearly one-third of all physicians will retire in the next decade,<sup>481</sup> and older and middle-aged nurses represent almost three-quarters of the current nursing workforce.<sup>495</sup> About 43% of cardiologists are over 55 years old.<sup>400</sup>

### ***Specific Workforce Issues Impacting Access to Quality CVD Care.***

*Graduate Medical Education.* Over the past decade, there has been a more than 50% reduction in the number of medical school graduates selecting primary care, internal medicine or family medicine residency programs.<sup>496,497</sup> A recent survey found that only 2% of fourth-year medical students planned to engage in a career in general internal medicine.<sup>496</sup> Several studies have demonstrated that among the primary factors pushing students away from primary care and family medicine is the tremendous amount of debt facing students upon graduating and the relatively higher compensation of other specialties – on average double that of primary care physicians.<sup>498,499,500</sup> In addition, limited funding for primary care training programs, fellowships, and residency programs is a significant hurdle impacting the recruitment of primary care practitioners.<sup>501</sup> Lack of training opportunities also serves to limit growth in the field of cardiology. The size of CVD training programs for medical residents decreased by about 20% in the 1990s.<sup>491</sup> As a result, the output of cardiologists from residency programs has significantly decreased, and, today, training programs are unable to expand facing significant financial constraints.<sup>400</sup>

As for physicians specializing in emergency medicine, annually only 1,500 physicians complete emergency medicine residency programs;<sup>502</sup> this growth is insufficient to meet current demand.<sup>503</sup> Today, many hospital EDs are staffed by physicians who are not trained in emergency medicine.<sup>502</sup> A recent study from Iowa found that only 12% of emergency departments were staffed exclusively by emergency medicine residency-trained/board certified emergency physicians, and 39% of hospitals used nurse practitioners or physician assistants as sole coverage during the workweek.<sup>504</sup>

Consistent investment in primary care, cardiology training programs and emergency medicine training programs will be necessary to produce a sufficient workforce pipeline equipped to ensure access to appropriate CVD care, across the continuum of care, from prevention to diagnosis to chronic disease management.<sup>400,496,505</sup> In addition, sustained investment from CMS for graduate medical training programs is critical, along with financial and academic support for individuals pursuing primary care.<sup>500,506,507</sup>

*Medical Homes and Team-Based Care.* A growing body of evidence demonstrates that reducing CVD incidence and improving recovery from acute CVD events requires multidisciplinary, team-based, comprehensive approaches to primary and secondary prevention.<sup>443,444</sup> Offering quality primary and secondary prevention of CVD requires a spectrum of health providers – including physicians, nurses, physician assistants, pharmacists, nutritionists, social workers and family caregivers – working together to better manage patient care.<sup>3,443</sup>

While some research suggests that primary care shortages could be lessened through the effective implementation of team-based care approaches,<sup>508</sup> in general, workforce shortages greatly impact the capacity of the healthcare system to implement these models of care. The ACA promotes and incentivizes team-based care through Medicaid medical homes, Accountable Care Organizations under Medicare, and funding for testing new models through the

Innovation Center. These initiatives will help, but greater investment is needed. For example, the Association of American Medical Colleges and the Association of Academic Health Centers, among others, have advocated for changes in medical school curricula to help better train cardiologists and other specialists to work with non-physician professionals (e.g. nurses, family caregivers etc.).<sup>509,510,511</sup>

*Nursing: Scope of Practice and Training.* In many states, scope-of-practice laws limit nurse practitioners' (NP) capacity to practice to the fullest extent of their education, training, and competence.<sup>400,487,512</sup> For example, many states do not allow NPs to see patients, prescribe medications, or order and evaluate tests without physician supervision.<sup>513</sup> These laws – which often are not based on education-level or safety concerns<sup>513</sup> – set further constraints on an already stressed healthcare workforce system.

Several studies have demonstrated that NPs are capable of providing primary care services of equal or higher quality, and at lower costs as compared to physicians performing similar services.<sup>400,501,514</sup> There is also evidence that patients have comparable outcomes when care is administered by an NP.<sup>515,516,517</sup> As the delivery of health care for patients with chronic disease increasingly moves toward team-based, coordinated care models, this increases the need for nurses to be trained and empowered to meet new care challenges. Expanding and standardizing nursing scope-of-practice laws could promote more efficient and effective team-based care.<sup>506,518,519</sup> In addition, to meet growing primary care demands, nurses should be encouraged to obtain more advanced degrees and CVD and team-based leadership skill training.<sup>507,520,521</sup>

*Shortages of Healthcare Professionals in Rural and Underserved Regions.* Shortfalls in the healthcare workforce affect everyone, but the impact is most severe for vulnerable and underserved populations. Approximately 20 percent of Americans live in rural or inner-city locations designated as health professional shortage areas (HPSA).<sup>481,522</sup> HPSAs are caused in large part by the tendency of practitioners to settle in regions with an already high concentration of physicians and other healthcare professionals.<sup>523</sup> Rural and underserved areas – areas where patients have an increased risk of CVD and stroke<sup>524,525</sup> – are subsequently left without a sufficient supply of physicians, emergency medicine physicians, and cardiology specialists.<sup>526,527,528</sup> Additionally, many rural communities are at considerable distance from large medical centers or hospitals, making it difficult for these populations to obtain the specialized care necessary for quality treatment of CVD and stroke.<sup>525</sup>

Title VII health professions program and the National Health Service Corps work to distribute primary care providers to underserved areas but more policy initiatives and incentives will be necessary to meet current needs.<sup>529</sup> Additionally, increasing the supply of emergency medicine residency-trained/board-certified emergency physicians is key to ensuring rural areas are equipped to treat stroke and CVD. This requires both an increase in the number of emergency medicine residency training programs in rural areas and an increase in the number of residents who attend those training programs.<sup>502</sup>

*Family Caregivers.* Many patients suffering from heart failure, CVD, and stroke are cared for by family member caregivers.<sup>530,531</sup> Patients and family caregivers frequently cite frustration with the inadequate communication they receive from healthcare practitioners.<sup>532,533,534</sup> As family caregivers play an important role in reinforcing messages and practices recommended by providers, providers must begin to view family caregivers as part of the patient care team.<sup>509,510,511</sup> Providers should receive training on how best to educate and support family caregivers, as these caregivers require training, coaching, and open communication with providers in order to properly care for their loved ones at home.<sup>533,534,535</sup>

*Affordable Care Act (ACA).* Increasing and modernizing the health care workforce is a major goal of the ACA. ACA contains dozens of provisions related to health care workforce issues including strengthening primary care through payment reform; reducing graduate medical education caps; academic and financial assistance programs; and promoting the role of front-line health care workers like nurse practitioners who are increasingly providing primary care to medically underserved communities.<sup>507</sup> While not all of these opportunities have been subsequently funded, HHS has anticipated the need for expanded primary care capacity and has committed grant funding dollars for various health workforce development programs through the Prevention and Public Health Fund and other direct appropriations.<sup>536</sup> Sustained investment in these ACA programs is important for addressing the workforce challenges described above.

**Therefore, the AHA supports the following priorities to address the status of the nation’s healthcare workforce with the goal of ensuring and increasing access to quality care:**

- Provide sufficient public health and medical education funding and clinical training resources to improve chronic disease management, care coordination and patient-centered care support and promote the development of new models of care delivery, including those that emphasize team-based approaches using allied health professionals.
- Monitor and pursue opportunities at the state level to address workforce capacity and access.
- Support the workforce needed for both healthcare delivery and research
- Promote the growth and diversity of the healthcare workforce through a sustained and substantial national commitment to medical education and clinical training
- Support healthcare reform proposals that provide sufficient public health funding, medical education funding and clinical training resources for programs that improve chronic disease management, care coordination and patient-centered care.
- Support healthcare reform efforts that promote the development of new models of care delivery, including those that emphasize the roles of allied health professionals.
- Support efforts to produce an adequate number of well-trained cardiologists who will devote themselves to prevention, early and accurate diagnosis, and cost-effective treatment of cardiovascular diseases.
- Promote efforts to produce advanced practice providers with specific training and experience in cardiac conditions that will contribute to cost-effective care, improved staffing, and continuity of care.
- Advance evidence-based staffing models that are adaptable to the variety of clinical settings in which cardiovascular care is provided and adhere to the tenet that the availability of experienced cardiac interventionists, either as primary caregivers or as consultants, is central to the optimal delivery of advanced cardiac critical care.

***Informing USPSTF/Community Guide Recommendations***

The U.S. Preventive Services Task Force and the Community Preventive Services Task Force present two potential vehicles through which stakeholders, such as the American Heart Association, may be able to inform and positively impact federal policies that expand access to preventive services.

***United States Preventive Services Task Force (USPSTF)***

The U.S. Preventive Services Task Force (USPSTF, or “Task Force”) is an independent, volunteer panel of national experts in prevention and evidence-based medicine that reviews and analyzes existing research to make evidence-based recommendations about clinical preventive services such as screenings, counseling services, and preventive medications.<sup>537,538</sup> The Task Force assigns each recommendation a letter grade (an A, B, C, or D grade or an I statement<sup>539</sup>) based on the strength of the evidence and the balance of benefits and harms of a preventive service.<sup>540</sup> Many preventive services with an “A” (strongly recommended) or “B” (recommended) grade are important for CVD prevention, including aspirin to prevent CVD, blood pressure and cholesterol screening, obesity screening and healthy diet counseling, etc.<sup>541</sup>

Recognizing the critical importance of preventive services and care, the Affordable Care Act (ACA) strengthens the role of the USPSTF recommendations within private and public health insurance coverage:

- ***Private Plans.*** All “new” (non-grandfathered) group and individual plans, both inside and outside of state Exchanges, must cover, without cost-sharing, all A and B recommended services.<sup>542</sup>
- ***Medicaid Expansion.*** Implementing regulations make clear that where states are expanding Medicaid, the Medicaid expansion plans must cover all A and B recommended services without cost-sharing.<sup>543</sup>
- ***Traditional Medicaid.*** While preventive services for adults are considered an “optional” benefit under Medicaid,<sup>544</sup> ACA gives state Medicaid programs a financial incentive to cover preventive services for adults under the “traditional” (non-expansion) Medicaid program. ACA offers states a 1% increase in FMAP if the state Medicaid program covers *all* A or B recommended services without cost-sharing; to qualify, the state must make these services available under fee-for-service and managed care.<sup>545,546</sup>
- ***Medicare.*** Finally, ACA removes barriers to preventive care in Medicare. While Medicare does not have to cover USPSTF-recommended services, if Medicare does cover an A or B recommended preventive service, it must be fully covered by Medicare, with no beneficiary cost-sharing.<sup>547</sup>

Given the prominence of USPSTF recommendations for coverage, it is important for AHA and other stakeholders to have a voice in the USPSTF recommendation process. Review and comment by stakeholders outside the Task Force occurs at several different points during the development of evidence reports and recommendation statements: (i) during development of a research plan, USPSTF incorporates expert review and partner organization<sup>548</sup> comment on background documents to confirm that all relevant outcomes are being considered, that relevant literature has been considered, and that the evidence presented for USPSTF consideration is accurate;<sup>548</sup> (ii) once draft recommendations are developed, they are posted on the USPSTF website for public comment, and distributed to all federal and primary care partners of the USPSTF as well as appropriate clinical specialty societies for input;<sup>548</sup> and (iii) stakeholders can also nominate a topic for consideration<sup>549</sup> or request reconsideration (due to new evidence, new tests available, or status changes in the public health burden of the condition) through the Task Force’s website.<sup>550</sup>

There are also informal opportunities for review, where stakeholders can seek meetings with individual USPSTF members, partner organizations or federal partners. For example, one of the Task Force’s new duties established under the ACA is “improved integration with Federal Government health objectives.”<sup>551</sup> Consistent with this duty, stakeholders may urge certain federal agencies to request meetings with the Task Force to discuss specific federal initiatives, such as the *Million Hearts Campaign*, and how USPSTF’s work could contribute to advancing federal goals.

### **Community Preventive Services Task Force**

The ACA also codifies the Task Force on Community Preventive Services (“Community Task Force”), which presents its recommendations on community-based prevention and health promotion activities in *The Guide to Community Preventive Services* (The Community Guide).<sup>552,553</sup> The Community Task Force is an independent, nonfederal panel of public health and prevention experts that provides evidence-based findings and recommendations about community preventive services, programs, and policies to improve health. To develop its recommendations, Community Guide scientists lead or support interdisciplinary teams that carry out systematic literature reviews to identify what works to promote health and prevent disease, injury and disability.<sup>554,555</sup> Evidence compiled and recommendations developed by systematic review teams are brought to the full Community Task Force for their consideration and approval.

While there is no formal structure in place to allow for public comment or stakeholder input into the review process, systematic review teams frequently collaborate with CDC scientists and program managers, federal and non-federal liaison organizations,<sup>556</sup> and other researchers, practitioners, and policymakers.<sup>554,557</sup> AHA has collaborated with systematic review teams in the past, and, in circumstances where AHA is not a member of a given review team, it can informally collaborate with individual systematic review team members or liaison organizations to submit input.

It should be noted that while many of the Community Guide recommendations are important for CVD prevention (for example, recommendations on CVD prevention and control,<sup>558</sup> obesity prevention,<sup>559</sup> nutrition and physical activity,<sup>560</sup> and tobacco smoke<sup>561</sup>), recommendations from the Community Guide do not carry the same weight as USPSTF recommendations: there is no requirement that these recommendations become integrated in to private and public health insurance coverage. The Community Task Force operates independently of USPSTF, though ACA requires USPSTF to “take appropriate steps to coordinate its work with the Community Preventive Services Task Force...including the examination of how each task force’s recommendations interact at the nexus of clinic and community.”<sup>562</sup> Therefore, stakeholders could advocate that recommendations made by the Community Guide that touch upon clinical prevention – for example, the recommendation to reduce out-of-pocket costs for cardiovascular disease preventive services for patients with high blood pressure and high cholesterol – should be examined by the USPSTF.

The American Heart Association supports the following priorities to address the need for increased access to preventive services:

- Support health plan coverage that includes coverage of essential health care services including hospital and ambulatory care, prescription drugs, preventive services, emergency care, and rehabilitation.
- Eliminate financial barriers to preventive services in public and private health insurance plans.
- Improve the coverage of preventive services to help reduce the risk of stroke.
- Promote opportunities for states to increase coverage for evidence-based CVD preventive services with no cost-sharing through provisions that provide a 1% Medicaid FMAP increase to states that cover these services.

*Support Comprehensive, Coordinated Systems of Care (Madeleine/Jeff)*

- EMS
  - Support Strengthening 9-1-1 Systems.
  - Emergency Medical Dispatch (EMD)
  - Support the Establishment of Quality Community CPR/AED Programs
  - Support the Establishment of Quality School Based Programs Promote CPR, AED, and First Aid Credentialing for Professionals Support Strong EMS Systems

***NEMSIS***

The National Emergency Medical Services Information System (NEMSIS) was created to standardize the collection of pre-hospital patient care data by Emergency Medical Services (EMS) providers and to aggregate these data at a national level. NEMSIS is used by EMS medical directors and administrators to improve medical care provided to victims of traffic accidents and those suffering other types of injury or acute medical conditions, such as sudden cardiac arrest, heart attack and stroke. The *American Heart Association* supports federal funding to continue the implementation of NEMSIS and reduce morbidity and mortality from emergency events.

A comprehensive EMS system is essential to providing prompt, quality care to patients with acute injury and medical conditions. Recent studies have shown that effective emergency trauma care systems can improve survival from severe injuries by as much as 25 percent. (source?) The need for data systems to support a comprehensive EMS system is well established. (source?) Although many communities have these systems in place, they vary in structure and content making it difficult to compare or analyze data at the state or national level. (source?)

To address this issue, the National Association of State EMS Directors joined with its federal partners at the National Highway Traffic Safety Administration and the Health Resources and Services Administration to create a uniform national EMS data set with standard terms, definitions, and values augmented by a database that compiles select data elements from all states. Every state and territory has signed a Memorandum of Understanding acknowledging their support for NEMSIS. Over 90% of the states and territories have a NEMSIS compliant data system in place with various levels of sophistication.

NEMSIS provides many benefits to EMS providers and the communities they serve:

- The data provides feedback to medical directors that can lead to improvements in the quality of patient care through the development of evidence-based treatment protocols.
- Data on the types of calls received can help inform the content of continuing medical education programs for EMS providers.
- Information from NEMSIS can help EMS administrators reallocate resources to reduce response times, improve health outcomes, and save lives.
- Injury data can improve highway safety by identifying dangerous intersections or needed improvements in response planning which can also aid in disaster preparedness activities.
- Linkages with hospital patient outcome data can inform transport and other system-development decisions, including triage to appropriate health care facilities and the application of continuous quality improvement to assess both patient and system outcomes.
- Field and hospital data can be used to measure and improve care for patients with acute cardiovascular conditions such as heart attack and cardiac arrest across the nation.
- NEMSIS data can aid in the development of EMS outcomes measures, national fee schedules and reimbursement rates.

The American Heart Association supports additional federal funding for the following purposes:

- Increase to 50 the number of states that contribute data to the national NEMSIS database.

- Continue operation of the NEMSIS Technical Assistance Center (TAC) to expand the number of EMS response and patient outcome records housed in the national EMS database.
- Improve linkage capabilities with other health databases and state trauma registries while integrating NEMSIS with electronic health records to enhance patient care outcomes.
- The creation of regular reports providing national data for providers and policymakers.

### *Stroke and STEMI Systems of Care*

Time is of the essence in treating acute cardiovascular conditions, but in far too many cases a fragmented and disorganized delivery system prohibits patients from receiving the treatments that can improve or even save their lives. The AHA believes that leadership and resources at the federal, state, and community levels are needed to help develop and implement coordinated systems of care for acute conditions to improve patient outcomes.

Certain care processes have been demonstrated to improve patient outcomes. Systems of care seek to implement these processes so that care is coordinated and victims of heart attack receive timely and appropriate treatment.

Although the clot-dissolving drug tPA is available to treat the most common type of stroke, only 3-8.5% of eligible stroke patients receive this therapy. This thrombolytic therapy can significantly reduce disability from stroke, but should be administered as soon as possible after symptom onset and preferably within four and a half hours to be most effective. It also saves money by improving patient outcomes and reducing the need for more extensive medical care. A recent analysis of more than 2,700 stroke patients in the U.S. and Europe confirmed that greater use of tPA could save nearly \$50 million per year in the U.S. alone. Initial efforts at implementing stroke care systems have shown that they improve patient access to recommended care, including increased administration of thrombolytic therapy.

Roughly 1 out of every 4 heart attack victims each year will have the most severe type of heart attack called ST-Elevation Myocardial Infarction (STEMI). The quicker a patient with this heart attack has the completely blocked artery reopened (“reperfusion”), the better the chances are for survival and less permanent damage to the heart. Approximately one-third of STEMI patients do not receive any reperfusion therapy (including the preferred type, percutaneous coronary intervention (PCI)) to restore blood flow in the artery. Many more do not receive this treatment within the recommended 90 minutes, even though such treatment greatly reduces the risk of death or debilitation

Systems of care are tailored by states or regions and locally implemented to meet the needs and challenges of an area, but should be based on the latest scientific guidelines. The ideal system of care provides patients with seamless transitions from each stage of care to the next (EMS; acute care; subacute care secondary prevention; and rehabilitation and coverage). There are gaps and needs at each stage of this care continuum, however, that could be addressed by more coordinated care.

The American Heart Association/American Stroke Association advocates for resources and policies to help facilitate the development of coordinated systems of care in states and regions for stroke and STEMI. Key approaches include:

- Through an integrated approach with other AHA/ASA program activities, promote efforts to create inclusive and coordinated statewide systems of care to improve the treatment of the stroke patient.
- Work to ensure that the recognition, and the protection, of Primary Stroke Center, Comprehensive Stroke Center and Acute Stroke Capable Facility designation is based on Joint Commission/AHA/ASA accreditation or an equivalent accreditation process offered by a guidelines-based, nationally recognized accrediting organization.
- Utilizing current AHA/ASA guidelines for stroke care, promote within EMSS statewide standardization and implementation of stroke training, assessment, treatment, and transportation protocols.
- Support access and coverage of rehabilitation services for stroke patients.

- Through an integrated approach with the Mission: Lifeline initiative, promote efforts to coordinate systems of care to improve the treatment of heart attack and sudden cardiac arrest patients by adhering to ACC/AHA guidelines and are consistent with Mission: Lifeline recommendations for criteria for heart attack and sudden cardiac arrest systems of care.
- Work to ensure that the recognition, and the protection, of STEMI Receiving Center and STEMI Referring Center designation is based on the Society of Cardiovascular Patient Care/AHA accreditation or an equivalent accreditation process offered by a guidelines-based, nationally recognized accrediting organization.
- Support efforts that include encouraging EMS agencies to obtain or upgrade to effective 12-lead ECG field devices, including appropriations for training and equipment.
- Utilizing current ACC/AHA guidelines for heart attack and sudden cardiac arrest care, promote within EMSS statewide standardization and implementation of heart attack and sudden cardiac arrest training, assessment, treatment, and transportation protocols.

### *Systems of Care for Out-of-Hospital Cardiac Arrest*

There are almost 360,000 EMS-assessed out-of-hospital cardiac arrests (OOHCA) each year in the United States. To survive sudden cardiac arrest (SCA), victims must receive immediate cardiopulmonary resuscitation (CPR) to increase the blood flow to the heart and brain, along with an electrical shock from a defibrillator to stop the abnormal heart rhythm. Less than 10% of victims, however, who suffer a SCA outside of a hospital setting survive.<sup>1</sup> For every minute without life-saving CPR and defibrillation, chances of survival decrease 7%-10%.<sup>563</sup> CPR and defibrillation within the first three to five minutes of collapse, plus early advanced care, can result in long-term survival rates of greater than 50% for victims of SCA with witnessed ventricular fibrillation.<sup>564</sup> Survival rates in most emergency systems are lower, suggesting this optimal timeframe is not always achieved.<sup>3</sup>

CPR is critical to the survival of SCA victims. Individuals with CPR training are more likely to deliver the lifesaving intervention to SCA victims<sup>565</sup> and those with training perform higher quality CPR and increase survival rates. Unfortunately, not enough people are able to deliver effective CPR. Given that 96% of children ages 14-17 attend a public or private school,<sup>566</sup> CPR training in high schools can teach a substantial portion of the population how to deliver this lifesaving technique and help increase the likelihood that individuals suffering an SCA will receive high quality CPR. Emergency response dispatchers can also play a vital role in assisting bystanders in delivering high quality CPR while waiting for emergency personnel to arrive.

The automated external defibrillator (AED) is a simple-to-use portable device that is used to shock the heart of a person suffering a SCA to return the heart to a normal rhythm. AEDs can be found today in a variety of public settings – from schools to airports. Used by both trained and lay emergency responders, the delivers an electric shock when it detects a dangerous heart rhythm. By giving audible step-by-step instructions to the user and independently determining if a shock is needed, they are very easy for almost anyone to use.<sup>567</sup> Communities with AED programs, which include comprehensive CPR and AED training, have achieved survival rates of 40% or higher for SCA victims.<sup>2</sup> Lay responders play a crucial role in achieving high survival rates, and more AEDs and CPR training for these individuals are needed to provide this life-saving treatment.

Medical treatments for SCA also require a prompt and coordinated response. Induced therapeutic hypothermia (TH), for example, is used to improve neurological outcomes for victims of out-of hospital cardiac arrest.<sup>568</sup> It is a relatively cost effective treatment modality, but is often not readily accessible to those that need it. If TH were fully implemented in the United States, an estimated 2,298 additional out-of-hospital victims each year could be expected to survive.<sup>7</sup>

A recent AHA Scientific Statement reiterates the importance of developing regional systems of care for out-of-hospital cardiac arrest to increase survival rates. Recommendations were:<sup>569</sup>

- A community-wide plan to optimize treatment sequentially from successful out-of hospital resuscitation to hospital discharge should be implemented;
- A priori agreements between EMS and hospitals should be established with protocol-driven decisions to match patient needs with the capability of the transport-destination hospital to meet those needs. The

content and timeliness of communication from EMS to hospitals should be addressed to proactively mobilize healthcare personnel before arrival and reduce time delays to treatment;

- Regional systems may involve a town, a city, a county, a state, or another region of the country. Systems should include academic or community receiving hospitals with multidisciplinary teams, including cardiology, critical care, and neurology. The volume of patients who have restoration of circulation after cardiac arrest is not solely tied to institutions but to practitioners who practice at multiple institutions;
- Referral hospitals will continue to play a vital role in optimizing care for patients with restoration of circulation after OOHCA. Their immediate efforts, before transfer to the receiving hospital, in initiating therapeutic hypothermia early in conjunction with EMS will be important in the final outcomes of many patients. Referral hospitals should be provided with the necessary funds for equipment and education and be required to follow specific patient care and triage protocols, and they should report their experience, as has been done in selected inclusive regional trauma systems;
- As with trauma centers, burn centers, STEMI centers, and stroke centers, national criteria should be developed to enable the categorization, verification, and designation of centers for the treatment of patients with restoration of circulation after OOHCA. External credentialing should be required as opposed to self-designation to support the development and sustainability of adequate patient volumes and high-quality care. The number of level 1 cardiac resuscitation centers in a given region should be limited to maintain provider skill levels and to justify the initial costs and institutional commitment required to care for these specialized patients;
- Assessments of provider or hospital performance of acute coronary angiography should separate procedures performed in patients resuscitated from cardiac arrest from those performed in other patients to reduce potential disincentives to the performance of an intervention in these patients with high morbidity and mortality;
- Evidence-based best practices and model EMS protocols should also be developed to guide states and local EMS systems in developing inclusive regionalized approaches to post-resuscitation care.

The American Heart Association/American Stroke Association advocates for public policies and resources that support a comprehensive approach to addressing OOHCA, including:

- Greater research into its underlying causes.
- Improved data collection on out-of-hospital SCA; how SCA affects different populations; and the effectiveness of treatment methods.
- Supporting legislation and policies that encourage bystander CPR, including requiring all students to be trained in CPR and AED prior to graduating from high school;
- Championing public policy initiatives that promote the development of Medical Emergency Response Plans (MERPS) which includes placing AEDs in public places where SCA is likely to occur,
- Restoring funding for the *Rural and Community Access to Emergency Device Program* at the FY 2005 level of \$9 million annually, so that more lives can be saved each year;
- Extending Good Samaritan law coverage to all AED users and program facilitators;
- Increasing public awareness of SCA and its causes through activities such as CPR and AED Awareness Week each June.
- Implementing a community-wide plan to optimize treatment sequentially from successful out-of hospital resuscitation to hospital discharge;
- Supporting the development of a priori agreements between EMS and hospitals with protocol-driven decisions to match patient needs with the capability of the transport-destination hospital to meet those needs.
- Promote the use of and sustainable funding for nationally recognized emergency medical dispatch protocols and appropriate quality improvement programs among 9-1-1-dispatch agencies to assure that bystanders promptly receive effective CPR coaching and support efforts to train dispatch personnel to provide pre-arrival medical instructions.
- Support the establishment of quality, guidelines based, community CPR/AED programs that focus on placing AEDs in high-risk locations and training anticipated and lay rescuers in CPR and AED usage.
- Support public policy, sustainable appropriations and other initiatives that promote a strong, well trained, data driven, quality EMS system that improves collaboration, responsiveness, and effectiveness. Strengthen EMS systems by supporting efforts that will eliminate geographic, racial, ethnic, gender, and socioeconomic disparities in EMS care

- Telehealth
  - Reimbursement
  - Ease licensing/credentialing barriers

## V. Promote High Quality, High Value Health Care

In its landmark 2001 report, *Crossing the Quality Chasm*, the Institute of Medicine (IOM) declared that, “Between the health care we have and the care we could have, lays not just a gap, but a chasm.”<sup>570</sup> Shortly thereafter, McGlynn and Asch estimated that Americans only receive the recommended care approximately half of the time.<sup>571</sup> The report and this subsequent quantification served as a call to action for the healthcare community to focus its attention on improving patients’ receipt of evidence-based care. Recent policy discussions and activities, spearheaded by the passage of healthcare reform, have focused on improving healthcare quality, as one component of what has come known as the “triple aim” - better health, better health care, and care at a lower cost. Together this tripod represents a high-value healthcare system with the aim of getting the highest quality and improvement in health out of every healthcare dollar spent.

This section provides an overview of the AHA’s public policy approach to improving healthcare quality, including that which improves adherence to clinical guidelines and care protocols, promotes safe, evidence-based diagnosis and treatment of cardiovascular disease and stroke, and reduces health inequities.

### **Adherence to Clinical Guidelines and Treatment Protocols**

To improve health care quality, leading scientific organizations committed to evidence-based medicine like the American Heart Association/American Stroke Association develop clinical practice guidelines that translate clinical evidence into specific written recommendations to inform health care providers’ and patients’ decision-making. Quality improvement programs and health information technology can then be used to facilitate the application and integration of these guidelines in clinical practice.

### ***Health Information Technology***

Health information technology (HIT) includes tools, such as electronic health records (EHRs)/electronic medical records (EMRs), clinical decision support (CDS), and clinical registries, as well as many other new and emerging electronic interfaces. Well-implemented HIT has the potential to improve the quality of care and adherence to evidence-based guidelines. For example, a robust medical record that can be exchanged between a patient’s healthcare providers gives those medical professionals up-to-date, patient-specific information and medical history that can be used to inform healthcare decisions at the point of care and facilitate care coordination between physicians and across patient visits. Estimates vary of the extent of EHR adoption, but according to a Robert Wood Johnson Foundation study, 44% of hospitals and 38.2% of physicians reported having adopted at least a basic electronic health record in 2011.<sup>572</sup> While more study is needed to make and strengthen the direct link between EHRs/EMRs and improvements in quality, research and demonstration projects suggest that these tools can facilitate practitioners’ adherence to clinical practice guidelines.

According to a report from the Agency for Health Research and Quality, clinical decision support (CDS), or the provision of clinical knowledge and patient-specific information to help clinicians and patients make decisions that enhance patient care,<sup>573</sup> has the potential to improve quality and reduce costs by increasing adherence to evidence-based practices.<sup>574</sup> It does this by assessing patient-specific information and providing recommendations to the healthcare practitioner via prompts, alerts, or other electronic mechanism. By basing these tools on the latest and strongest medical evidence, they support the integration of evidence into direct patient care.

In order to support the adoption of health information technology and help healthcare practitioners incorporate it into care delivery, Congress passed the Health Information Technology Economic and Clinical Health (HITECH) Act of 2009. Otherwise known as “meaningful use,” the program establishes stages that correspond to a set of quality measures with increasing sophistication and higher thresholds of participation with each stage. Providers receive financial incentive payments for achieving meaningful use and will pay financial penalties in future years of the program.

A “clinical registry” is a database of health information on specific clinical conditions, procedures or populations. The data collected in a registry captures clinically important events relevant to a particular population or condition. Registries can be integrated with EHRs to directly support evaluation of care delivery and patient outcomes. Registries can broaden knowledge of clinical service patterns, processes and patient outcomes and capture valuable, real-time patient data that is not present in an administrative record, which typically only contains claims data or billing information. Because a registry can continuously capture data, registries have the potential to identify unnecessary or inappropriate variation and drive quality improvement by creating a continuous feedback loop to pinpoint areas of poor quality. In this way, the data collected and aggregated by the tool allows the provider or facility to identify problems with particular types of care, develop quality improvement interventions based on the identified problems, and monitor progress after implementation of a chosen intervention. As a result of the GWTG-Stroke program that uses a registry to collect and feedback information to participating hospitals, participating hospitals have shown improvement in adherence to stroke performance measures.<sup>575</sup>

Additionally, registries, as demonstrated by the experiences of the GWTG-Stroke registry can help hospitals reduce disparities in the care they deliver. While evidence suggests that not only are minorities at higher risk of suffering a stroke but they also receive lower quality of care and have worse health outcomes. Hospitals participating in GWTG-Stroke improved care for black, Hispanic, and white patients.<sup>576</sup> Clinical registries also support quality and safety evaluation by monitoring adverse events related to particular therapies, drugs, or devices<sup>577,578</sup> and examining provider adherence to safety protocols and best practice guidelines.<sup>579</sup>

Data collected via a registry can also catalyze systems changes on a regional or statewide basis to promote a more comprehensive and coordinated approach to care. Regional participation in quality improvement programs that utilize a clinical registry can help illuminate problems that exist in the system of care so that corrections and improvements can be made. For instance, data may show poor patient education about symptoms, geographical differences in the quality of care received, or problems with adherence to treatment guidelines. The data can then catalyze stakeholders to find solutions to the challenges encountered. For example, data from Maryland’s statewide stroke registry showed that some of the state’s hospitals were reluctant to give tPA – a drug used to treat thrombotic and embolic stroke – to stroke patients. Having identified this concern, stakeholders were able to investigate its cause and determined that these hospitals were wary of prepping tPA because of the drug’s cost in the event that it was ultimately not used. Consequently, they developed a system where hospitals can return unused tPA to the manufacturer; this has promoted the delivery of tPA to appropriate stroke patients.<sup>12</sup>

The increasing sophistication of these tools and the pace of advances in health information technology offer significant promise for continued improvement in and better informed clinical decision-making.

#### ***American Heart Association Advocacy Priorities around Health Information Technology***

- Support public policies that encourage the development and implementation of health information tools, such as clinical-decision-making technology that deliver clinical guidelines in real-time to clinical decision-makers.
- Promote policies that empower consumers to make informed decisions regarding the importance of owning, managing and maintaining personal health records.
- Promote legislation and regulations that encourage the development and use of HIT with appropriate patient privacy safeguards.
- Urge policy makers to create federal, state and local CVD and stroke registries in order to monitor incidence and support the development of relevant quality improvement initiatives.
- Encourage policy makers to use patient-centered, evidence-based, broadly-adopted registries like GWTG to meet many of the quality improvement and reporting requirements of federal programs and those enacted in health reform.
- Encourage use of registries as an efficient data collection tool as part of payment and delivery reform initiatives.
- Monitor meaningful use to ensure that incentives are being fully utilized to support the robust use of HIT and the specific measures included in the program are appropriate and well-tested so that unintended consequences of their use are avoided.

### ***Quality and Performance Measures***

Quality measures attempt to represent the achievement of a recommended course of treatment by a healthcare practitioner by quantifying the existence of a structural component believed to connect to high quality care, a process understood to constitute high quality care, or quantify a particular set of outcomes. Performance measures are quality measures that are applied to the performance of a clinician or group of clinicians to either benchmark care delivery or measure improvements in quality over time. Quality-of-care measures can help create learning environments for health care professionals and ensure that best practices are applied uniformly to all patients.

“Pay for performance programs” are reporting programs that link the achievement of measure to payment whether as a financial reward through additional payment or a bonus or penalties via a reimbursement withhold. More research is needed to understand the impact of these programs on patient outcomes, both intended and unintended. Evaluation, ideally using clinical rather than administrative or claims data should be a central component of any program to better understand the program’s outcomes.<sup>580</sup> Given that many programs are still in their early stages of implementation which makes systematic evaluation and understanding their long-term impact difficult. A recent study, however, based on a cluster-randomized trial and published in the Journal of the American Medical Association did show an association between pay-for-performance programs and modest improvements in cardiovascular care processes and outcomes.<sup>581</sup>

In this way, the further development of evidence-based performance measures for cardiovascular and stroke conditions and their use of in the delivery of care show promise for promoting quality.

#### ***American Heart Association Priorities on Quality and Performance Measures***

- Support public policies that encourage the health care community to report and assess quality through the development of performance measures that are integrated into quality improvement tools.
- Promote the use of risk-adjusted, standardized, evidence-based measures and the inclusion of measures of patient satisfaction, access and convenience.
- Support the evaluation of the impact of measures on quality and patient outcomes.
- Promote the use of quality measure reporting in private and public quality improvement programs.
- Ensure that payment programs that are undertaken include mechanisms for evaluating the program’s outcomes, both intended and unintended. Measure is best accomplished through the analysis clinical data as opposed to administrative or claims data and this should be encouraged as the preferred method of programmatic evaluation.
- Support financial incentives that are aligned to support systems-focused healthcare delivery.

### ***Pulse Oximetry Screening***

Often viewed as a problem of adults, cardiovascular disease also exacts a terrible toll on the young. Congenital cardiovascular defects, also known as congenital heart defects (CHD), are the most common birth defect in the U.S.<sup>582</sup> and the leading killer of infants with birth defects.<sup>583</sup> The incidence of CHD ranges between 4 and 10 per 1,000 live birth.<sup>1</sup> Tragically, more than 1,500 of them do not live to celebrate their first birthday.<sup>1</sup> Beyond the terrible death toll, physical and mental suffering, and lost potential and productivity that CHD causes, it also comes with a steep price tag. In 2004, hospital costs for all individuals with CHD totaled \$2.6 billion.<sup>584</sup>

Critical congenital heart defects (CCHD) are structural heart defects that often are associated with hypoxemia among infants during the newborn period and typically require some type of intervention – usually surgical – early in life. Without screening, some newborns with CCHDs might be missed because the signs of CCHD might not be evident before an infant is discharged from the hospital after birth. Infants with CCHDs are at risk for significant morbidity or mortality early in life because of closing of the ductus arteriosus or other physiologic changes. The targets of CCHD screening include seven primary targets ([hypoplastic left heart syndrome](#), pulmonary atresia with intact septum, [tetralogy of Fallot](#), total anomalous pulmonary venous return, [transposition of the great arteries](#), tricuspid atresia, and truncus arteriosus) and five secondary targets (coarctation of the aorta, double outlet right ventricle, Ebstein anomaly, interrupted aortic arch, and single ventricle).<sup>585</sup>

CCHDs represent about 25% of all congenital heart defects.<sup>586</sup> Using pulse oximetry to screen newborns before they are discharged from a birthing facility can help identify infants with critical congenital heart defects. Pulse oximetry is a simple test that measures the amount of oxygen in a baby's blood. Low levels of oxygen in the blood can be a sign of a CCHD or other issue that needs further attention. The test uses over the skin sensors on a baby's toe and finger, is painless and takes only a few minutes. Screening is optimally done when a baby is 24 to 48 hours of age, or as late as possible if the baby is to be discharged from the hospital before he or she is 24 hours of age.<sup>585</sup>

In September 2011, HHS Secretary Sebelius approved adding CCHD to the Recommended Uniform Screening Panel and the American Heart Association continues to advocate for policies in states across the country that will assure all babies are screened for CCHD using pulse oximetry before being discharged from a birthing facility.

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| <b><i>American Heart Association Recommendations on Pulse Oximetry Screening</i></b> |
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| <ul style="list-style-type: none"><li>• Advocate that all states require pulse oximetry screening as part of the newborn screening panel</li><li>• Assure adequate training for health professionals</li><li>• Support the development of appropriate hospital protocols</li></ul> |
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***Promote Safe, Evidence-based, Treatments for Cardiovascular Disease and Stroke Patients***

- ***Cardiovascular and Stroke Drugs, Treatments, and Devices***

The total direct and indirect cost of cardiovascular diseases and stroke in the United States is estimated to reach \$958 billion by 2020. Of these costs, \$124.6 billion in direct costs were estimated to be spent for drugs and other medical durables, second only to hospital direct costs. (cite RTI Forecasting Calculator) Cardiovascular and stroke treatments, drugs, and devices are vital in the prevention and treatment of these conditions. However, they must be safe and effective, as well as accessible and affordable, to ensure that consumers can actively engage in their healthcare and comply with the chosen course of treatment. Even when accessible and available, other factors related to healthcare utilization, such as how best to encourage patient adherence to treatment regimens, need to be understood to have maximum benefit to patients.

- ***Safety of drugs and devices***

The Association supports increased access to a broad range of heart disease and stroke drugs, treatments, and medical devices, while safeguarding patients. It is also important that diagnostic tools that identify when treatments are necessary, as well as genetic tests that help target treatments are safe, valid and of high quality, and proper safeguards are in place to protect patient information, including test results. In this way, a strong, scientifically-based FDA whose primary mission is promoting and protecting the public's health and safety, with levels of funding sufficient to support it in carrying out this critical assignment, are also necessary.

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| <b><i>American Heart Association Priorities for Safe, Evidence-based, Treatments for Cardiovascular Disease and Stroke Patients</i></b> |
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| <ul style="list-style-type: none"><li>• Promote scientific oversight and patient protections for drug, treatment and medical devices.</li><li>• Promote policies that ensure that patient information generated by diagnostics is appropriately safeguarded.</li></ul> |
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**Comparative Effectiveness Research**

In addition to ensuring the safety of drugs, devices, and treatments, evidence is needed to help determine what treatments are most effective for different patient populations. Comparative effectiveness research (CER) can provide such evidence and the Association developed a set of principles intended to guide this research so that its findings are high quality and appropriately address unmet research needs. These principles support CER based on the scientific knowledge gained from the randomized clinical trials that are typically used to assess the clinical efficacy of a new therapy. In addition, they state that it is essential for patients and healthcare providers to understand research limitations when interpreting CER findings. While comparative effectiveness research may include estimates of cost and cost-effectiveness, the principles point out that comparative effectiveness research should focus on enhancing value for patients rather than minimizing costs.<sup>420</sup>

Recent efforts underway by the Patient Centered Outcomes Research Institute (PCORI) established as part of healthcare reform<sup>587</sup> to fund patient centered research has made significant investments in this type of research on

behalf of cardiovascular disease and stroke patients. In this way, it shows great promise in expanding the evidence base in these critical areas.

***American Heart Association Priorities with Comparative Effectiveness Research***

- Promote the conduct and interpretation of comparative effectiveness research according to fundamental scientific principles.
- Encourage funding for organizations, including PCORI, that support CER that aligns with Association principles.

***Delivery System and Payment Reform***

Delivery system reforms and a focus on testing structural and organizational models of care delivery, as well as their impact on care access, utilization and effectiveness have garnered recent focus. A recent Medicare study found that the average primary care practice coordinated with 99 other physicians working across 53 different practices.<sup>588</sup> In this way, many models focus on coordinating care among these providers, supporting medical documentation that makes health information portable, and disseminating information throughout the broader system to support proactive care management. Examples of specific models include the patient centered medical home (PCMH) and accountable care organizations (ACOs).

Payment models are often used in tandem with systemic or structural changes to create financial incentives for providers, patients, and others to encourage care delivery by clinicians and adherence by patients. These payment methods can include capitation, bundled payment, or care coordination/ patient management fees. Similarly to the work that it has done on pay-for-performance programs, the AHA/ASA believes that any payment reform program must have the goal of reducing the burden of disease for patients and developed a set of principles that aim to ensure that this end goal is met and unintended consequences do not occur. (should be numbered the same as January 2006 Bufalino citation, cited above) The principles stress the importance of transparency to consumers of the existence of a payment incentive to physicians and any resulting restrictions on access to services this incentive may create; the need to allow for variation so that the unique needs of sub-populations are met, as well as existing disparities in care delivery are addressed; and the use of quality measures that are evidence-based, meaningful, and designed to ensure accountability for quality, not just cost.<sup>589</sup> Additionally, any incentive used should encourage the development of enabling structures within the healthcare system that enhance its safety, effectiveness, efficiency, equity, timeliness, and patient-centeredness.<sup>590</sup>

Further testing and evaluation of these models is needed to understand whether they are effective, as well as any unintended consequences occur that need to be avoided. The Affordable Care Act created the Center for Medicare and Medicaid Innovation (CMMI) within the Centers for Medicare and Medicaid Services (CMS) to conduct this testing and evaluation and gave it the authority to scale these models without additional Congressional action if evaluation showed they improved quality while reducing or maintaining cost.<sup>591</sup>

***American Heart Association Priorities for Delivery System and Payment Reform***

- Monitor existing demonstration models testing new delivery and payment reforms.
- Encourage adoption of evidence-based methods of care coordination.
- Encourage researchers to examine and evaluate the impact of care delivery models on cardiovascular and stroke treatment and patients, with particular attention to identifying unintended consequences as they occur.
- Evaluate the role of quality in health care payment systems.
- Support research and evaluation of mechanisms for aligning payment with healthcare improvement.

**Benefit design**

Health insurance benefit design is also increasingly being used to adjust both provider and patient behavior, making it important that public policy supports appropriate patient safeguards in the development and implementation of these designs, as well as balances the need for patient access to a wide variety of treatments with the affordability of available treatments.

The Association works with CMS, as well as other payors to evaluate the appropriateness of services and procedures, such as carotid artery stenting for stroke patients, anticoagulant home monitoring for patients with atrial fibrillation, or deep vein thrombosis, for their inclusion in benefit packages.

In order for patients to be informed consumers, benefit design must be transparent. The Association supports greater transparency as a means to empower health care consumers to better understand their share of health care costs, their current health insurance coverage and their health care coverage options. Specifically, the Association encourages public policies that would increase transparency of the costs of insurance coverage and expand consumers' health care decision-making tools.

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| <b><i>American Heart Association Priorities for Benefit Design</i></b> |
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| <ul style="list-style-type: none"><li>• Work with payors to evaluate payment policy's impact on patient care</li><li>• Ensure transparency in health insurance benefits and associated costs</li></ul> |
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### **Pharmaceutical Marketing/Advertising**

Direct-to-Consumer (DTC) advertising is the promotion of pharmaceutical products targeted at consumers, using consumer-facing channels. DTC advertising on television has been allowed since 1997 when the FDA relaxed its rules related to the broadcast advertising of drugs.

Proponents support DTC advertising as a form of patient education that creates a more informed and empowered consumer, facilitates discussions between patient and provider about the patient's health care choices, and helps avert the underuse of certain medications.<sup>592</sup> Opponents of the practice claim that it leads to the inappropriate prescribing of high cost products and interferes with the doctor-patient relationship.<sup>593</sup>

Examination of DTC advertising's impact on these factors, however, has been very limited. A systematic review of the literature that attempted to assess DTC advertising's impact on health seeking behaviors, prescribing patterns, and the direct and indirect costs of the practice only found four studies that fit its criteria. The review found that DTC advertising is associated with increased prescription of advertised products and had a substantial impact on patients' request for specific drugs as well as physicians' confidence in prescribing, while finding no additional benefits in terms of health outcomes.<sup>594</sup> The Association supports efforts to inform consumers about their health conditions and the treatments available to them. Given the minimal evidence assessing the impact of this advertising on patient outcomes, however, the Association intends to continue monitoring the issue and the evidence base as it becomes available and more robust.

### **Drug Formularies**

Policy makers are increasingly turning to drug formularies as a way to control rising healthcare costs. A compilation of drugs or drug products in a drug inventory list, formularies are created by healthcare facilities, healthcare systems, payers, and third parties in order to determine which drug products will be dispensed or covered as part of an insurance benefit. The formulary is created via a formulary system, whereby members of the particular entity work through the pharmacy and therapeutics committee to evaluate, appraise, and select from among the numerous available drug entities and drug products those that are considered most cost-effective in patient care.

Given they dictate what particular products may be dispensed or reimbursed, drug formularies guide the prescribing physician towards particular drugs or direct a pharmacist to dispense a certain drug within the class. Depending on the level of communication regarding the replacement of the prescribed drug with another is either referred to as therapeutic interchange or therapeutic substitution. A joint paper by the American Heart Association and the American College of Cardiology examines the issues associated with these processes, as they apply to cardiovascular and stroke conditions and patients.<sup>595</sup> A position statement based on this paper outlines ten recommendations to ensure that the resulting formularies balance patients' access to drugs that effectively treat their conditions with the need for payers and healthcare programs to be able to maintain general affordability of drugs across the patient population. It also lays out the requirements for communication of any changes with the prescribing physician and patient.<sup>596</sup> Most notably, it supports the use of both therapeutic interchange and generic

substitution, but opposes therapeutic substitution and supports communication of the therapeutic interchange to both provider and patient.

The Association supports policies that promote formularies that are consistent with the recommendations laid out in its position statement.

#### ***American Heart Association Priorities on Drug Formularies***

- Monitor, evaluate, and promote policies concerning drug formularies that are consistent with the AHA's Drug Formulary position statement.
- Educate lawmakers about the need to balance access and cost considerations when developing formularies for public programs, such as Medicaid and SCHIP.
- Monitor drug formulary policy

The Association supports policies that promote formularies that permit therapeutic interchange and generic substitution when necessary and in designated circumstances and do not allow for therapeutic substitution. The AHA continues to monitor, evaluate and promote proposed public policies concerning drug formularies. The Association supports increased access to a broad range of cardiovascular disease and stroke drugs, treatments and medical devices and opposes therapeutic substitution of prescription drugs within a class. Public policy should support appropriate patient safeguards in the development and implementation of formularies. Further, drugs and devices used to treat or prevent cardiovascular disease and stroke must be properly reviewed, labeled, dispensed and marketed.

#### **Medication Adherence**

Nonadherence to prescribed medications is a growing problem that has become too common; the consequences include adverse health events and added costs to the U.S. healthcare system. The New England Healthcare Institute estimates that patients who fail to adhere to their medications cost the U.S. healthcare system \$290 billion annually.<sup>597</sup> Patients with cardiovascular diseases contribute to poor adherence, raising the risk for heart disease and stroke. According to research by Vrijens and colleagues, roughly half of patients who have been prescribed high blood pressure medications stop taking them within a year.<sup>598</sup> Additional research shows that nearly one fourth of patients who have been hospitalized for an acute heart attack neglect to fill their prescriptions, only raising the risk of a subsequent heart attack.<sup>599</sup> There are many reasons why patients do not take their medications, therefore possible interventions must be multifaceted in order to improve health outcomes and reduce costs.

#### **American Heart Association Advocacy Priorities for Medication Adherence**

- Increase access to medication therapy management programs for patients with chronic conditions.
- Promote delivery and payment system reforms that incentivize medication management and emphasize care coordination.
- Support new innovative interventions that improve adherence by harnessing the power of big data and new technologies.
- Integrate the use of clinical decision making and quality improvement tools designed to improve medication adherence.

#### **Drug Shortages**

Drug shortages have been widely reported across the country and in many cases shortages in certain therapeutic classes have disrupted the delivery of evidence-based care. The problem has been particularly dire among sterile injectable drugs as those drugs are more difficult to manufacture, transport, store and administer. There is little to no literature characterizing the severity of the problem among cardiovascular care drugs and the impact on patient care. The vast majority of drugs in shortage are concentrated among five disease areas: oncology, anti-infectives, cardiovascular, central nervous system and pain management.<sup>600</sup> It is inevitable that drug shortages will continue happen as manufacturing companies face capacity issues and supplies become defective or in shortage. It is important that healthcare providers have the right tools to ensure that shortages do not impact the care received by cardiovascular care patients.

#### ***American Heart Association Advocacy Priorities for Drug Shortages***

- Support policies that foster communication between the FDA and manufacturing companies in order to prevent or mitigate drug shortages.
- Increase funding for research to better characterize cardiovascular care drug shortages and their impact on patient care.
- Educate and train healthcare providers on how to best mitigate shortages to avoid disruption in care.

#### **Personalized Medicine**

We are at the dawn of a new age, where our evolving knowledge of how genes and lifestyle combine to affect our health is transforming the practice of medicine. Genetic analysis can already identify risk factors for certain heart disorders, type 2 diabetes, and many other health conditions. Every few months, researchers are discovering more disease-related gene variants. This new information is being used to ‘personalize’ medicine according to each patient’s genetic profile. Genetic medicine can help identify disease risk as well as the likely response to certain drugs and drug doses. As scientists develop a greater understanding of the genetics of heart disease and stroke, we will move away from “one-size-fits-all” medicine to more targeted and effective prevention, treatments, and even cures.

#### **American Heart Association Advocacy Priorities for Personalized Medicine**

- Require disclosure of test validity and enact appropriate regulatory oversight for marketed tests to assure physicians and the public of test quality.
- Increase funding for research on the genetics of heart disease and the translation of new discoveries into preventive measures and treatments.
- Protect individuals undergoing genetic tests from discrimination by all forms of insurance.
- Educate and train the medical workforce to prepare for the expanded integration of genetics into healthcare practice.
- Integrate personalized healthcare with health information technology to deepen our understanding of the relationship between genetics, disease, treatments and outcomes.
- Ensure that intellectual property practices foster innovation and the development of new genetic tools.
- Educate the public about personalized medicine and encourage them to collect their family medical history.

#### **Palliative Care**

Palliative care is medical and supportive care for people with serious illness that is routinely integrated into care by all practitioners and focuses on providing patients and their families with relief from illness and suffering burden -- including symptoms, pain and stress--regardless of diagnosis<sup>601</sup>. By integrating medically appropriate care with supportive care practices, it helps patients and their families achieve goals of improved functioning and prolonging life, when possible, and with comfort and the preservation of hope at the end of life. Treatment goals are clarified and valued, care is coordinated across settings, and the patient’s practical, social, emotional, and spiritual needs are supported.

Research indicates that palliative care is beneficial for cardiovascular and stroke patients, given the symptom burden faced by these patients, the desire by many patients with serious illness to receive its services, the particular benefits of advance care planning and shared decision making for this population, and its ability to improve outcomes.

The symptoms associated with cardiovascular disease and stroke impose a significant burden on many patients and care givers. For example, end-stage heart failure is described as having “the largest effects on quality of life of any advanced disease,”<sup>602</sup> and its patients are described as a group “for whom symptoms limit daily life despite usual recommended therapies and for whom lasting remission into less symptomatic disease is unlikely.”<sup>603</sup> Stroke is one of the leading causes of death and disability in adults, making the palliative care needs of these patients and their families enormous.<sup>604</sup> While less common, children and infants also suffer from heart failure and stroke, which are often related to underlying congenital syndromes or anomalies diagnosed around the time of birth. Palliative care, with its primary focus on both expert relief of symptoms and supportive care, has the potential to alleviate patients’ and family caregiver distress, improve their overall quality of life, and foster well-being even as seriously ill patients live with illness burden and approach the end of life.

Research demonstrates that patients living with serious illness identify elements of palliative care such as pain and symptom management, avoidance of inappropriate prolongation of dying, achievement of a sense of control, and avoiding burdening others, as among their top priority needs from the healthcare system.<sup>605</sup> A majority of seriously ill patients, however, are not currently receiving palliative care.<sup>603</sup> As medical technology advances, patients are living longer and with conditions that were previously fatal, but with significant adverse implications for their quality of life and that of their families. Patients, who suffer from acute cardiovascular events or stroke when previously highly functional, also need additional support for coping and adjusting to the illness and complex decision making. Together, these factors support the need for the holistic approach taken by palliative care in helping patients and families achieve care goals. However, the “evidence suggests that these options are underused; when they are used, it is often so late in the course of illness that the potential of these options is undermined and their efficacy decreased.”<sup>602</sup>

Advance care planning discussions offer patients and families the opportunity to understand what to expect in the future, and to express their preferences and expectations for the medical care they wish to receive throughout the course of treatment for their condition, as well as near death. The process also allows patients to gain an accurate understanding of their conditions and prognosis, together with the benefits and burdens of treatment options in the context of this prognosis, so that they may meaningfully participate in decision-making. When facilitated properly, the process of advance care planning is also flexible enough to allow patients of all ages and variable levels of cognition, to participate to the level of their interest and ability. Importantly, 95% of patients with heart failure express interest in these discussions.<sup>606</sup> Given that heart failure and stroke are conditions for which the disease trajectory is often prolonged, uncertain and unpredictable,<sup>607,608</sup> it is particularly important that these individuals are given information regarding expected outcomes when life-sustaining interventions are discussed as therapeutic options and empowered to plan their preferred course of treatment according to different scenarios.

The AHA’s *Scientific Statement on Decision Making in Advanced Heart Failure* states that treatment discussions with patients “should always include specific description of alternative approaches, including continuation or withdrawal of ongoing treatments and focus on symptomatic care.” It goes on to explain that “Shared decision making incorporates the perspective of the patient, who is responsible for articulating goals, values, and preferences as they relate to his or her health care [and] incorporates the perspective of the clinician, who is responsible for narrowing the diagnostic and treatment options to those that are medically reasonable.”<sup>3</sup> Together, the physician, patient, and family work to understand how different treatments effectuate their preferences so that the plan reflects the values and goals of the patient and family. The healthcare system, however, lacks an integrated approach for discussing sudden devastating or serious illness care with patients and families, and in many cases practitioners are not adequately trained to discuss these options<sup>609,610</sup> or are not comfortable discussing them. As a result, patients and families are often insufficiently informed of all of their alternative care choices and their respective risks and benefits.

Palliative care may also improve patient outcomes. One study examined the impact of introducing palliative care early in treatment for metastatic non–small-cell lung cancer and found that patients who received early palliative care, provided at the same time as disease-focused treatment, had extended mean survival, less depression, and better quality of life as compared to patients who did not receive concurrent palliative care.<sup>611</sup> Another study that examined outcomes for patients receiving palliative care focused case management while receiving care for chronic pulmonary disease or heart failure found significantly better outcomes on self-management of illness, awareness of illness-related resources, and legal preparation for end of life, as well as patient reported lower symptom distress, greater vitality, better physical functioning and higher self-rated health than randomized controls.<sup>612</sup> While more research is needed in patients of all ages with cardiovascular disease and stroke, these data suggest that early, integrated palliative care has the potential to increase longevity and improve quality of life.

## **VI. Improved Surveillance for Heart Disease, Stroke and Related Health Factors**

In order to assess the impact of policy interventions and the success of programming on improved cardiovascular health and heart disease and stroke mortality, it is critical that the United States conduct comprehensive surveillance, monitoring, and evaluation. Larger sample sizes of children and adolescents and of minority populations, as well as state-based samples, are needed to provide adequate data for policy development and monitoring of cardiovascular health. The AHA advocates for incorporating more robust measures in current surveillance programs such as the

National Health and Nutrition Examination Survey (NHANES), Behavioral Risk Factor Surveillance System (BRFSS), Youth Risk Behavioral Surveillance System (YRBSS), School Health Policies and Programs Study (SHPPS) Surveillance food and beverage databases, pre-hospital data reporting and others, and also obtaining adequate funding for these programs.<sup>613</sup> Areas for improved surveillance or continued robust assessment would be body mass index, adiposity, physical fitness, sodium consumption patterns and sodium reduction in the food supply, trans fat, saturated fat, hypertension (prevention, prevalence, and control), tobacco use, dyslipidemia, and dietary patterns.

Clinical registries are an efficient way to collect information on healthcare trends, assess how elements of the healthcare system are functioning, and better understand the prevalence and impact of disease. Today, clinical registries are used to assess the progression of a disease, evaluate treatments utilized at various stages of disease, and observe treatment outcomes and adverse events.<sup>577,579,614,615</sup> They can also evaluate trends in healthcare usage and the provision of medically necessary care (including underuse, overuse and misuse);<sup>616</sup> monitor the impact of prevention efforts<sup>575</sup> and public health awareness campaigns;<sup>617</sup> analyze referral and diagnosis patterns;<sup>5</sup> describe patient population demographics and provider characteristics;<sup>1</sup> and track incidence of health events and recurrent events.<sup>1,618</sup> Electronic medical records also enable surveillance of trends within the healthcare system by tracking rates of admissions, readmission, and coordination of care post-discharge.<sup>4,5,8</sup>

Clinical registries also play an essential role in monitoring the healthcare needs and the services used by populations of patients that traditionally have been under-represented in epidemiological studies and clinical trials, including racial and ethnic minorities,<sup>576</sup> women,<sup>619</sup> the elderly,<sup>616</sup> individuals with multiple co-morbidities,<sup>5,620</sup> and individuals with rare diseases.<sup>578</sup> With data from a clinical registry, researchers can identify and evaluate healthcare disparities within a patient population; examine underrepresented populations and their access to healthcare services; investigate disease progression and healthcare utilization in a particular subpopulations, and the costs for treating them.

## **VII. Protect Non-Profit Sector Interests**

Nonprofit organizations are a critical component of our nation's economy and provide an invaluable public service. The AHA believes that improving the capacity of nonprofits yields significant dividends for government and society. To promote, protect and preserve the important role and contributions that voluntary health organizations, the AHA works in coalition with other non-profits, and in particular with the Independent Sector, to monitor and ensure that legislative and regulatory policies support the continued vitality of the sector.

In order to remain strong, the AHA will promote tax policy conducive to charitable organizations. The Association also believes that the nonprofit community has a vested interest and responsibility to embrace standards that hold the sector accountable for independent governance, rigorous accountability and full transparency. The AHA supports appropriate reporting requirements that are focused on preserving the public's interest and confidence in the nonprofit sector without putting unnecessary and costly burdens on charitable organizations

### ***Promote Tax Policy Conducive to Charitable Organizations***

Federal and state tax policy plays an important role in encouraging individuals who want to support charitable organizations through tax deductions. Similarly, favorable state and local income, property and other tax policy can help charitable organizations maximize their ability to preserve and direct donor dollars to mission related activities. Nonprofits were hit hard during the last economic downturn, making a favorable tax environment for charities even more crucial.

The Association supports responsible policies that encourage individual and corporate charitable giving, as well as Foundation support and preservation of operational benefits associated with tax-exempt status. In addition, the AHA supports maintaining the estate tax at levels that do not discourage or otherwise have a detrimental impact on the ability of families to leave gifts to charities of their choice through planned giving and opposes efforts to expand the applicability of the unrelated business income tax to activities that are substantially related to a nonprofit's mission.

The top areas of focus in the nonprofit sector are described below.

### ***Support the Charitable Tax Deduction***

More than 80 percent of the 46 million who itemized their tax returns in 2009 claimed the charitable deduction. These individuals are responsible for more than 76 percent of individual contributions to charitable organizations. Between 2003 and 2009, charitable organizations in the U.S. received \$281 in online donations. More than 22 percent of those donations were made on December 30 and 31 each year; underscoring the extent to which donors are aware of, and influenced by, the tax implications of their giving. An April 2011 Gallup Poll found that 62 percent of Americans who do not claim the deduction support its preservation as an incentive for giving. While some believe the charitable deduction disproportionately benefits high income taxpayers, a 2012 study by the Center on Philanthropy at Indiana University found that 79.3 percent of high-net-worth households (annual income greater than \$200,000) donated to basic needs charities in 2011.

It's important to remember that unlike incentives to save for retirement or to purchase a home, the charitable deduction encourages behavior for which a taxpayer receives no direct tangible benefit. It simply and effectively encourages taxpayers to give away a portion of their income to benefit others.

### ***Encouraging Volunteerism***

Public policy can play an important role in providing strong incentives for Americans to give their time in service to charitable organizations, including the American Heart Association. The AHA generally supports efforts to encourage people of all ages to volunteer, including maintaining an appropriate deduction for mileage expenses incurred during volunteer service. Current law allows charities to reimburse volunteers, on a nontaxable basis only, up to the charitable mileage rate of 14 cents per mile. Alternatively, volunteers are permitted to deduct their "out of pocket" expenses incurred in providing donated services — when those expenses are not reimbursed.

### ***Combined Federal Campaign***

The CFC is the largest workplace charity campaign in the United States and the only campaign authorized to solicit and collect contributions from federal employees in the workplace on behalf of charitable organizations. Pledges made by federal workers during an annual solicitation period support eligible non-profit organizations that provide health and human service benefits throughout the world.

Each campaign is managed by a volunteer group of federal employees who work with experienced nonprofit executives in their communities to generate contributions and distribute them to eligible charities. Since the inception of the CFC in 1961, federal employees have contributed almost \$7 billion. In 2011, almost 1 million employees (24% of the federal workforce) participated in the CFC, donating \$272.7 million to the work of approximately 25,000 charities.

On April 8, 2013 the Office of Personnel Management (OPM) published a proposed rule to amend Combined Federal Campaign (CFC) regulations and opened a public comment period. The proposed rule is based on recommendations made by the CFC-50 Commission, an entity created by OPM on the occasion of the 50th anniversary of the CFC in 2011 to study ways to streamline and improve the program. Many of the recommended changes are extensive and would have a marked impact on participating charities, including, the American Heart Association. These changes would have resulted in the loss of local control, the end of paper donations, and upfront application fees. Specifically, the changes impacting the nonprofit sector included:

1. The program's governance structure would change through a transition from Local Federal Coordinating Committees to a smaller number of Regional Coordinating Committees. This may mean a loss of the

feeling of local “ownership” of and engagement with the campaign, which in turn may lead to decreased participation and donations, especially for local charities.

2. The expense of the program would be shifted from the donors (via the use of a portion of donated funds) to the charities, via a non-refundable charity application fee. Participating charities would be required to pay the fee before knowing how much they would collect in donations, and even if they decided to withdraw from the campaign, would not have their fee returned.
3. OPM is proposing to eliminate the use of cash, check, and money order contributions to the Campaign, mandating electronic donations. While this might help with administrative efficiency, it could also be a barrier to donation for federal workers, many of whom still choose to donate via traditional means: the longest running and largest online campaign, the National Capital Area (NCA) campaign, has only 45% online giving participation.

The Association opposed these changes and will continue to work with various associations to preserve the current program

### ***Postal Rates for Nonprofits***

Special, preferred postage rates for nonprofits have existed since being authorized by Congress in 1951. To qualify for Nonprofit Standard Mail rates, an organization must be a nonprofit organization organized and operated for a qualifying primary purpose (religious, educational, scientific, charitable, agricultural, labor, veterans, fraternal; certain political committees may also qualify). Under current law, the nonprofit discount rate is 40 percent.

The Association would prefer to maintain the discounted nonprofit postage rates and have joined with the Independent Sector and other associations to advocates against attempts to reduce the discount that nonprofits receive on postage rates that have been included in postal reform bills introduced in the House or Senate in previous sessions of Congress. To date, postal reform legislation in both the House and Senate dropped key provisions that would have significantly reduced the nonprofit discount rate.

### ***Safeguard the Ability of Charitable Organizations to Engage in Advocacy***

While 501(c)(3) organizations are prohibited from engaging in partisan political activities, they are allowed to engage in non-partisan education and advocacy. Congress has provided very specific guidance on the types, nature and limitations of such nonpartisan activities. The AHA maintains a very robust advocacy program within these guidelines and followed similar rules and regulations at the state and local level. While the AHA supports appropriate expenditure limits for nonprofits and restrictions related to engaging in partisan activity, we vigorously preserve the ability of nonprofits to inform, influence and advocate for public policy consistent with the Association’s Mission, interest and priorities. This includes reasonable lobbying registration fees and reporting requirements.

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