



U.S. Department of Health and Human Services

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Cabinet Exit Memo | January 5, 2017

Introduction

In 1798, President John Adams signed the “Act for the Relief of Sick and Disabled Seamen,” creating a network of hospitals to care for merchant seamen and setting the foundation for what would become the United States Public Health Service Corps. In the more than 200 years since then, scientific advances and social progress have resulted in dramatic improvements in the health of the American people. Specifically, life expectancy has nearly doubled, and mortality rates from infectious disease have plummeted.

Yet in January of 2009, as President Obama took office, more than 40 million people did not have health insurance. Health care costs were growing at rates that far exceeded the growth of our economy, and our nation lagged in key measures of health care quality. Poverty was rising and, consequently, more families struggled to make ends meet. Childcare programs and Head Start, the very ladders of opportunity for children born into difficult circumstances, often failed to incorporate the latest research on early childhood development, and too many children could not access these programs. Refugees fleeing persecution and war needed assistance so they could transition to living in a new country and begin contributing to their local economy and their community. And our nation needed important investments to break new ground in medical science, innovation, and digital technologies.

Over the years, the dedicated and hardworking employees of the Department of Health and Human Services have been committed to the mission of helping Americans access the building blocks of healthy and productive lives. During the past eight years, the Department has worked tirelessly to advance this core goal and make progress on the many important issues that the Administration faced over the President’s tenure. In addition, the Department has met the challenges of new and unexpected public health issues, such as H1N1, the opioid crisis, Ebola, and Zika, that emerged during President Obama’s time in office. In this memo, I will outline some of the progress that our nation has made during the past eight years and highlight some of the steps ahead to continue to build on that progress.

Record of Progress

Access to Quality, Affordable Health Care

We have helped millions of Americans access quality, affordable health care with the Affordable Care Act (ACA), the most comprehensive reform of our health care system in a generation. The ACA expanded coverage, provided tools to control costs, and addressed gaps in coverage that persisted in some of our existing programs. We have supplemented the progress made by the ACA with further improvements in Medicare and Medicaid to provide high quality, comprehensive health care coverage for all Americans.

- **Historic reduction in the percentage of uninsured Americans.** Twenty million more Americans have health coverage because of the Medicaid expansion, the Marketplaces, and other ACA coverage provisions, such as allowing young adults to stay on their parent’s plan until they turn 26. Our uninsured rate is the lowest in our nation’s history. Today, no American can be denied health coverage because of a pre-existing condition.
- **Improved quality of health coverage no matter how you are insured.** Today, more than 138 million Americans can get immunizations, cancer screenings, and other recommended preventive services without a copayment. No insurer can impose annual or lifetime dollar limits on coverage, all plans

are required to place dollar limits on out-of-pocket costs, and women can't be charged more than men just because of their gender.

- **Improved quality of care through collaboration with health care providers and hospitals.** From 2010 through 2015, hospitals prevented an estimated 565,000 patient readmissions through changes that improve the quality of care and avoid unnecessary costs. Similarly, hospital acquired conditions such as ulcers, infections, and other avoidable traumas are down, leading to an estimated 125,000 lives saved and nearly \$28 billion in cost savings. To build on this progress and further reduce avoidable readmissions, we updated the requirements for nursing homes and other long-term care facilities that service Medicare and Medicaid beneficiaries, setting high standards for quality and safety while providing these facilities with important flexibilities to assist with the preservation of quality of life and quality of care.
- **Bending the health care cost curve.** Since 2010, health care prices across the entire health care system have grown at the slowest rate in 50 years. For the 157 million Americans who have health insurance through their employer, family premiums have grown at an average rate of 4.7 percent since 2010 – down from an average of almost 8 percent over the previous decade. The average family saved \$3,600 in premiums in 2016 compared to if trends before the ACA had continued. The life of the Medicare Trust Fund has been extended by 11 years, and Medicare spent \$473.1 billion less on personal health care expenditures between 2009 and 2014 thanks to lower rates of cost growth.
- **Reducing the cost of prescription drugs.** The ACA closed the Part D “donut hole,” helping more than 11 million people with Medicare save over \$23.5 billion on prescription drugs so far, an average of \$2,217 per beneficiary. The ACA also created a new pathway for FDA approval of biosimilars, which will increase patient access to affordable treatments.

Delivery System Reform

Since the beginning, the Administration has been driving efforts to increase access to high quality, affordable care. By combining new tools and programs provided by the ACA with existing flexibilities, and with a wide variety of business, professional, and patient stakeholders, we have charted a path to a better health care system that puts patients at the center of their care.

- **Paying for the quality of care, not the quantity of services.** The Administration has made historic progress in reforming how our health care system pays for care. For the first time in Medicare's history, we set explicit goals to move Medicare to pay for value, not volume. We proposed to tie 30 percent of Medicare payments to alternative payment models by the end of 2016, and 50 percent by the end of 2018. We reached our first goal ahead of schedule. In 2016, building on the bipartisan passage of the Medicare Access and CHIP Reauthorization Act (MACRA), our nation took another important step forward by finalizing the Quality Payment Program, a new payment system that will equip clinicians with the information, tools, and flexibility to provide high-quality, patient-centered care. A critical tool in implementing MACRA and the Quality Payment Program is the Center for Medicare and Medicaid Innovation (CMMI), which develops the innovative payment models that clinicians are encouraged to participate in under MACRA. The non-partisan Congressional Budget Office projects that successful innovations, including those that are scaled up through CMMI, will save Medicare \$34 billion

gross over 10 years. The Administration has also launched the first national quality measures in Medicare and CHIP.

- Improved care delivery by promoting care coordination, wellness, and prevention.** To improve care delivery, we are supporting providers with the tools they need to practice in the ways they think work best, like paying providers a fixed or bundled payment for all the services a patient needs to have to recover from a knee replacement or other procedure; and paying for the quality of care provided to the patient and allowing providers the flexibility to provide care in the manner they deem best. Through CMMI we also tested and expanded initiatives like the Diabetes Prevention Program, operated in YMCAs around the country. The pilot program showed that program participants diagnosed with pre-diabetes lost about five percent of their body weight, substantially reducing their risk of diabetes and saving the Medicare program an estimated \$2,650 per enrollee and helping patients live healthier lives. We provided states the option to establish Health Home entities to coordinate care for people with Medicaid who have chronic conditions and launched a CMMI model, called Comprehensive Primary Care Plus (CPC+), establishing primary care Medical Homes for Medicare beneficiaries. And in 2013, for the first time in the history of the program, the majority of Medicaid spending on long-term services and supports was for home and community-based services. More seniors and people with disabilities are able to receive long-term services and supports in their own homes instead of a nursing home, as we have worked to rebalance how Medicaid provides these important benefits.

To support state efforts to provide care delivery that is aligned across all payers, we launched the State Innovation Model. This initiative provides financial and technical assistance for the development and testing of state-led, multi-payer health care payment and service delivery models. For example, with the support of this model, Vermont has invested the past several years in establishing key building blocks for health care reform, such as engaging stakeholders, designing commercial and Medicaid Accountable Care Organization (ACO) models, and investing in health information technology. We also committed to supporting state delivery system transformation through Delivery System Reform Incentive Payment initiatives that provide states with funding that can be used to support providers in changing how they provide care to Medicaid beneficiaries.

- Making health data accessible and secure.** In order to put people at the center of their care, their doctors need to be able to get, review, use, and share copies of their health information. When patients have ownership over their own data, they are better able to monitor chronic conditions, make sure that their health information is accurate, and share their information with others, including health care providers, family, and for research. The passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009 mobilized a national effort to digitize medical information. While we know we still have important work ahead, the adoption of electronic health records has tripled in six years, allowing us to make advances in areas like e-prescribing. Our partners across industry see the value of an open and connected system. In February 2016, companies that provide 90 percent of electronic health records to U.S. hospitals publicly committed to make progress to improve the flow of health information. We also have worked to provide unprecedented access to privacy-protected data to improve the ability of consumers, providers, and payers to track performance and make informed choices.

We helped keep the American people safe from threats to their health and helped them live healthier lives.

- **Improving the health of Americans by helping to make the healthy choice the easy choice.** The Department has helped to lead the Administration-wide advancement of nutrition policy through actions such as eliminating trans fat in processed foods, updating the Dietary Guidelines for Americans, proposing major revisions to the Nutrition Facts label to provide consumers with more information to make informed choices, and ensuring that chain restaurants provide calorie information to consumers. This work helps to build on and implement the First Lady's focus on healthy lifestyles through the Let's Move initiative.
- **Fought health threats posed by H1N1, the Ebola virus and the Zika virus.**
 - *H1N1* – From 2009 to 2010, HHS and other international health organizations led the fight against the H1N1 virus. As a result of that work, we made marked improvements in vaccine development and manufacturing – developing, producing, and distributing 126.9 million doses of H1N1 vaccine in the U.S. to help 81 million people get immunized. We rapidly developed a diagnostic test for H1N1 and within weeks distributed reagents to laboratories around the world.
 - *Ebola* – In response to the outbreak of Ebola in West Africa during 2014, our Department made significant contributions to the world effort to slow the spread in West Africa, and protect Americans. We built a system that can identify passengers entering the United States who are at higher risk of having Ebola from affected countries so that at the first sign of symptoms, the health care system -- from ambulance to emergency room -- would be prepared, including monitoring 36,100 people to prevent potential spread. NIH successfully treated two patients with Ebola at its clinical center. We also established a network of 55 hospitals around the country that are Ebola treatment centers, including ten Regional Treatment Centers that are prepared to handle Ebola, and we also have enhanced capabilities to take care of new, or particularly dangerous, infectious diseases. We also made significant contributions to the development and testing of several vaccine candidates and therapeutics. We are currently working with the WHO on a pathway to licensing one of the vaccine candidates. During the 2014 outbreak, we treated 11 Ebola patients in the United States. Seven of those patients required complex medical evacuations from West Africa. One patient died. All received top-notch and sometimes groundbreaking care at one of four hospital biocontainment units across the country.
 - *Zika* – With over 38,000 cases of Zika in the United States as of December 7, 2016, with more than 32,000 in Puerto Rico alone, HHS has worked aggressively to prevent, detect, and respond to the virus. Throughout the crisis, HHS has communicated quickly and thoroughly in order to give the American people the latest information that they need to take the necessary steps to protect themselves from Zika. According to an October 2016 Kaiser Health Tracking Poll, nine in ten Americans (92 percent) said they have heard or read at least a little about the Zika virus. The NIH has taken the lead in developing a Zika vaccine and began Phase I testing of vaccine candidates *ahead of schedule*. CDC has led our efforts to work with States, Territories, and localities on strategies to detect and control mosquitoes that carry Zika, and on establishing systems to help public health officials track, monitor, and support mothers and babies affected by Zika. CMS will provide over \$66 million to affected territories

and states to support prevention activities and treatment services for health conditions related to the Zika virus. Researchers across the Department are making important breakthroughs in our understanding of the virus. The Biomedical Advanced Research and Development Authority (BARDA) is working closely with diagnostic manufacturers to facilitate the development of tests, and FDA has issued Emergency Use Authorizations for 14 tests, including 10 commercially developed tests.

- **Modernized the nation's food safety system.** The FDA took the most significant steps in decades to combat potentially deadly foodborne illness in both people and animals, finalizing seven major rules to implement the bipartisan FDA Food Safety Modernization Act (FSMA), which was signed by President Obama in 2011. The seven FSMA rules finalized in 2016 will help prevent food contamination during the food production and transportation process, enhance safety requirements for imported foods, and better protect the public health. An estimated 48 million people (1 in 6 Americans) get sick each year from foodborne diseases, according to data from the Centers for Disease Control and Prevention. Preventing foodborne illnesses through FSMA implementation will improve public health, reduce medical costs, and avoid the costly disruptions of the food system caused by illness outbreaks and large-scale recalls.
- **Launched the Global Health Security Agenda (GHSA) to better confront global epidemic threats and keep the world safe and secure.** The Global Health Security Agenda (GHSA) works to prepare countries to *prevent* and reduce the likelihood of outbreaks, *detect* threats early to save lives, and effectively *respond* to infectious disease threats. It builds upon efforts in previous Administrations to improve global preparedness and, in particular, to implement the 2005 International Health Regulations; it now includes nearly 60 countries and dozens of international organizations and non-governmental and private sector partners with representatives from across sectors. The United States government has leveraged the momentum and political support for GHSA, along with significant USG funding support to 17 partner countries and technical support to 14 others, to secure strong commitments from international partners. These commitments include G7 support, through a coordinated approach, to 76 countries to build and strengthen their health security capacities. GHSA successfully piloted global best practices for external evaluations of national health security preparedness and target-based national planning.
- **Improved antibiotic stewardship, surveillance, and research.** In the United States, over 2 million persons become ill every year with antibiotic resistant infections and over 23,000 die. In addition to the tragic toll in human lives, antibiotic resistant bacterial infections cost over \$25 billion in direct health care costs, and over \$35 billion in indirect costs due to loss of productivity. Since 2015 when the National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB) was released in response to the President's Executive Order and the report from the President's Council of Advisors on Science and Technology, the U.S. Government worked collaboratively to not only lay a strong foundation to prevent infections, improve antibiotic use, enhance surveillance and slow the emergence of resistant bacteria, but also implemented strategies to advance research and development of new antibiotics through public and private sector engagement and enhanced the global efforts to counter antibiotic resistance. Highlights include: national acute care hospitals reported reductions of 13 and 8 percent in methicillin-resistant *Staphylococcus aureus* (MRSA) and *C. difficile* infections, respectively, between 2011 and 2014, new funding was provided for more than 50 new drug candidates to treat antibiotic resistant diseases, and the percentage of U.S. hospitals reporting antibiotic stewardship programs rose by almost 10 percent.

- Protected children from the dangers of nicotine and provided adults with clearer information to help them make informed decisions about tobacco.** Through a historic rule issued as part of the implementation of the bipartisan Family Smoking Prevention and Tobacco Control Act, signed by the President in 2009, FDA extended its regulatory authority to all tobacco products – including e-cigarettes, cigars, and hookah tobacco – improving public health and protecting future generations from the dangers of tobacco use. Most notably, this rule restricts the sale of these tobacco products to minors nationwide, and helps FDA prevent misleading claims by tobacco product manufacturers, evaluate the ingredients of tobacco products and how they are made, as well as communicate their potential risks to the public. A report issued in December 2016 by the Surgeon General outlined the danger of e-cigarettes to America’s youth. The report is a call to action for our nation to continue our work to ensure a tobacco-free generation.
- Helped families and communities fight the opioid epidemic.** In helping to lead the Administration’s government-wide efforts to combat the heroin and prescription opioid epidemic, HHS is combatting the opioid crisis with an evidence-based three-part strategy, focused on improving prescriber practices, expanding access to medication-assisted treatment to help people fight addiction, and expanding the use of naloxone to save people from an overdose. The CDC released guidelines for providers prescribing opioids. In August 2016, the Surgeon General sent a letter, including the CDC opioid prescriber guideline, to 2.3 million American health professionals asking them to help lead a national movement to turn the tide on the nation’s prescription opioid epidemic. SAMHSA raised the patient limit on the number of patients to whom a qualified practitioner can prescribe buprenorphine. CMS released guidance highlighting emerging Medicaid strategies for preventing opioid-related harms and established a new approach for states to address substance use disorder. And the FDA approved several consumer-friendly naloxone products, including the first intranasal naloxone product. We also brought state leaders together in this effort – hosting two convenings so state officials could share how they are fighting the opioid epidemic and strengthen their regional work together.
- Worked to strengthen biosafety and biosecurity of laboratories in the United States.** Improving laboratory safety has been a top priority for the Department. At HHS, we have instituted reforms that promote a strong culture around laboratory safety and security; putting the right processes in place – relating to our work both as regulators and operators of labs. We have taken the following actions: HHS agencies are implementing both internal and external recommendations to continuously improve lab safety and security practices and reporting on progress in implementing these recommendations, including the establishment of an HHS Biosafety and Biosecurity Coordinating Council, which is a high-level and formal mechanism to coordinate and collaborate on biosafety and biosecurity issues across the Department.

Leading in Science and Innovation

Divisions across the Department have advanced the frontiers of medicine and research across critical priority areas. Long-term investments in NIH-supported research have generated scientific and technological innovations and breakthroughs that support the gains in our nation’s health.

- Worked with partners in Congress to pass the 21st Century Cures Act.** As an example of the progress our nation can make when we commit to finding common ground, this legislation will help end cancer as we know it, unlock cures for diseases like Alzheimer’s, and help people

seeking treatment for opioid addiction finally get the help they need. The Act also makes important updates to HHS mental health programs in key areas such as suicide-prevention, integration of primary and behavioral health care, and early intervention for serious mental illness.

- **Launched the President’s Precision Medicine Initiative, a research effort to revolutionize how we improve health and treat disease.** The President’s Precision Medicine Initiative will pioneer a new model of patient-powered research by having volunteers share their information for research to speed the time to discovery of new treatments. With bipartisan Congressional support and with our partners across the Federal government, the NIH is launching a million-person research cohort that will fuel scientific discoveries and launch a new era of health care tailored to each person. Much of this progress results from the innovative approach by FDA to the oversight of next generation sequencing, and work by OCR to clarify patients’ rights to their own health care data. We are making great strides in building the data, technology, and regulatory framework—along with private sector partnerships—to support this effort and begin recruitment of more than a million research volunteers.
- **Doubling the speed of progress in cancer research, development of treatments, and prevention through the Cancer Moonshot Initiative.** Too many American families know the devastation that cancer can bring, and its incidence is increasing worldwide. Under the leadership of Vice President Biden, this initiative is accelerating research efforts, enhancing access to data, and facilitating strategic collaborations across the public and private sector. As the Vice President has said, we are working to accomplish in five years what otherwise would take a decade.
- **Advanced our understanding of the human brain.** Despite the many advances in neuroscience research in recent years, the underlying causes of most neurological and psychiatric conditions remain largely unknown due to the vast complexity of the human brain. Since President Obama announced the BRAIN Initiative in April 2013, entities across the government, including HHS, as well as dozens of leading technology firms, academic institutions, and other partners have made significant commitments to advancing the initiative. NIH grants have facilitated the development and advancement of new tools and techniques, and FDA has worked to enhance the transparency of the regulatory landscape for neurological medical devices. For instance, BRAIN Initiative researchers at the University of California, San Francisco developed a system to rapidly analyze the genes of thousands of newborn brain cells. Using this approach they discovered clues as to how the Zika virus may adversely impact the brain.
- **Launched the first update of biotech regulations in a quarter century.** For the first time in nearly 25 years, the FDA, working closely with EPA and USDA, is reviewing and modernizing the regulatory system for biotechnology products to improve transparency and ensure continued safety in biotechnology while supporting innovation.

Giving More People the Building Blocks for Success

We have invested in Americans at every stage of life, to ensure that they have a chance to live healthy, productive lives and aspire to their full potential.

- **In the midst of the worst recession since the Great Depression, HHS helped stabilize income and health care for millions of low-income Americans.** The American Recovery and

Reinvestment Act of 2009 (ARRA) was created to jumpstart the economy, create or save millions of jobs, and put a down payment on addressing long-neglected challenges so our country can thrive in the 21st century. HHS was responsible for the implementation and management of health and human service ARRA programs. HHS awarded more than \$150 billion to help stabilize state budgets and maintain health care services for struggling families; expand child care services and Head Start, while improving quality; support state efforts that created subsidized jobs for low-income parents and disconnected youth at a time when jobs were scarce; promote the adoption of electronic health records; and advance cutting edge scientific research.

- **Improved and expanded early learning programs like Head Start.** HHS comprehensively revised the Head Start Performance Standards for the first time in 40 years to incorporate the best practices and the latest research on early childhood development and brain science, while also reducing regulatory requirements by nearly 30 percent and strengthening quality and safety. These revisions will expand the number of children attending Head Start for a full school day and year, ultimately ensuring that nearly all eligible children have access to such programs by 2021. In addition, HHS implemented the “Designation Renewal System” in Head Start to require lower-quality programs to compete for continued funding, ensuring that all Head Start programs are focused on the quality of service they provide. HHS has also implemented the landmark reauthorization of the child care program with its emphasis on improving the quality of care, including stronger health and safety requirements. The innovative Early Head Start – Child Care Partnership grants have brought together providers of both programs to expand the availability of high-quality early learning for infants and toddlers in creative ways. In collaboration with colleagues at the Department of Education, 18 states have been funded to create comprehensive and coordinated early learning systems from birth until kindergarten through the Preschool Development Grants.
- **Created the Maternal, Infant, and Early Childhood Home Visiting Program.** We know that the most important job is the job of being a parent. The Maternal, Infant, and Early Childhood Home Visiting program supports, created by the ACA and most recently extended under MACRA, supports voluntary, evidence-based home visiting services, where trained professionals meet with expectant parents and families with young children in their homes to teach them effective parenting skills and promote early learning. Home visitors can also connect families to a range of services — including health care, early education, and early intervention — to ensure that children are healthy and prepared for school, and for life. Between FY 2012 and FY 2015, the Home Visiting Program state and territory grantees provided approximately 2.3 million home visits. State Medicaid programs are also advancing this promising new model. This effort was built on research showing that home visiting programs can improve health outcomes for children.
- **Improved Mental Health and Substance Use Disorder Coverage.** Untreated mental health and substance use disorders can be debilitating and life-threatening. The ACA made mental health and substance use disorder services an essential health benefit that plans in the individual and small group markets must cover. The Obama Administration has made mental health and substance use disorder parity a priority, and because of these efforts, more than 170 million Americans will benefit from improved insurance coverage for mental health and substance use disorder care. Mental health parity eliminates restrictions on mental health and substance use coverage – like annual visit limits, higher copayments, or different rules on how care is managed

such as more frequent pre-authorization requirements or medical necessity reviews – if comparable restrictions are not placed on medical and surgical benefits.

- **Improving the child welfare system.** HHS has worked with more than half of the states to implement child welfare demonstration programs to test innovative approaches to helping children and families who are involved with the child welfare system. The waivers have been flexible enough to allow states that have seen rising need for child welfare services and foster care – including states where the increase appears to be driven in part by opioid and other drug use – respond to that increase in need. HHS also continues to promote adoption and “forever families” for children in foster care when it becomes clear they will not be reunified with birth families.
- **Caring for the caregivers of people with disabilities and older adults.** Our Department provides support to many of the caregivers nationwide who provide an estimated \$522 billion in care annually. We support about 900,000 caregivers with counseling and training services to help them, and with respite care services to provide temporary relief from caregiving responsibilities. Research has found that caregiver stress is an important predictor of nursing home entry for those they are helping, which is both expensive and often where people receiving care do not prefer to be. Data from the Administration for Community Living’s (ACL’s) Family Caregiver program found that nearly half the caregivers of nursing home eligible care recipients indicated that the care recipient would be unable to remain at home without support services. In addition, through the ACA, Medicaid has significantly expanded the options available to states to provide caregiving services that support older Americans remaining in their homes as they age.
- **Helped reduce homelessness with new resources and interagency partners.** Since 2010, HHS has helped contribute to reducing homelessness by 11 percent nationwide. In 2010 the Administration laid out bold goals in “Opening Doors,” the first federal strategic plan to prevent and end homelessness. Since then, unsheltered homelessness has been reduced by almost 26 percent, including a reduction in unsheltered families with children of 60 percent. Veteran homelessness has been reduced by 47 percent, including a 56 percent reduction in the estimated number of Veterans experiencing unsheltered homelessness. An impressive 33 communities and three states have ended homelessness among Veterans. Chronic homelessness has been reduced by 22 percent, including a 13 percent reduction in unsheltered chronic homelessness. HHS contributed to these reductions both through our homelessness-specific programs, such as ACF’s Runaway and Homeless Youth program and HRSA’s Health Care for the Homelessness program, as well as through support from our mainstream programs, such as Medicaid and Temporary Assistance for Needy Families.
- **Enhanced funding and initiatives to promote the health of the American Indian and Alaska Native population.** Throughout this Administration, HHS has substantially increased funding to the Indian Health Service (IHS) to support direct health care services, construction projects, and tribal partnerships. Funding for the IHS has increased by 43 percent under President Obama through FY 2016. In addition, ACA included a permanent reauthorization of the Indian Health Care Improvement Act. As part of the President’s Generation Indigenous initiative to help Native youth, HHS has expanded resources for behavioral health support and suicide prevention, such as through SAMHSA’s Native Connections grants. More recently, HHS has focused on improving the quality of care at IHS hospitals, including a Quality Innovation Network Quality Improvement Organization grant from CMS to support best health care practices at IHS hospitals

participating in the Medicare program. The Secretary's Tribal Advisory Committee (STAC) was the first-ever such body at the Cabinet level, established by Secretary Sebelius in 2010. The STAC signals a new level of attention to Government-to-Government relationship between HHS and Indian Tribal Governments, providing a platform for Tribes to elevate their concerns to the highest levels through quarterly meetings with the Secretary and senior leadership from across HHS. As a result of this increased engagement, HHS has accomplished several tribal priorities that will benefit people in tribal communities, such as expanding full federal reimbursement for more services to Medicaid-eligible American Indians and Alaska Natives, raising the profile of their issues within the Administration for Children and Families that funds many tribal social service programs, and creating the Tribal Behavioral Health Agenda to lay the groundwork for strengthening help that American Indians and Alaska Natives can receive for substance use and mental health issues.

- **For the first time in history, individuals are broadly protected from discrimination in health care on the basis of sex.** Thanks to the ACA individuals can no longer be denied health care or health coverage based on their sex; individuals must be treated consistent with their gender identity; and explicit categorical exclusions in coverage for all health care services related to gender transition are considered discriminatory.

Leaving the Department Stronger

Advancing innovation, strengthening program integrity and supporting and developing human resources have been a commitment for this organization.

- **Strengthened programs and protected taxpayer dollars by eliminating fraud, waste, and abuse.** Through partnerships with other federal agencies, states, and private businesses, we have used new, innovative tools to recover billions of dollars for American taxpayers and take hundreds of criminal and civil actions against people engaged in crimes against our programs. In particular, we've enhanced our fight against health care fraud – in part through \$350 million in new ACA funds. In FY 2015, DOJ and HHS recovered \$6.10 for every dollar spent on fighting health care fraud. Using enhanced data analysis capabilities, we've also been able to boost fraud prevention. Since 2011, CMS has used its Fraud Prevention System to review more than 4.5 million pre-paid claims a day for fraudulent activity, resulting in more than \$1 billion in savings, with an \$11.50 return on investment for each federal dollar spent in 2015.
- **Opening Data to the Public.** We've supported innovation across the industry, in both technology and operations, by opening more of our data to the public, elevating innovative staff-level initiatives, and focusing on public-private partnerships. Through the IDEA (Innovation, Design, Entrepreneurship and Action) Lab, we have equipped and empowered employees and members of the public to improve agency performance by experimenting with new approaches and led a series of agency-wide innovation initiatives. In 2010, we launched the Health Data Initiative to make health data more openly available so that public and private sector institutions could find innovative ways to improve health, health care, and the delivery of human services. In 2012, the FDA launched the Kidney Health Initiative with the American Society of Nephrology to combat the unmet clinical need in kidney disease, a disease which affects more than 20 million Americans at a huge cost to the American taxpayer. More than 2,000 data sets are now available on healthdata.gov, many in machine-readable form, so that companies can easily create new products and tools. ONC has galvanized the Blue Button initiative, a coalition of public and

private organizations committed to giving patients access to their digital health data. As part of these efforts, CMS launched Medicare Blue Button, which lets Medicare beneficiaries download their CMS claims history via the MyMedicare.gov portal in an easy-to-read document. HHS has recognized and cultivated over 500 staff-driven innovations like the 100K Genome Project and the NIH 3D Print Exchange. Over 200 employee innovators have been trained in design, entrepreneurship, and business methodologies.

- **Promoting Innovation through Partnerships with the Private Sector.** HHS has increased the number of public competitions held to address challenges our nation faces. For example, the FDA Food Safety Challenge sought solutions that will directly impact how the FDA performs its regulatory duties. NIH launched the Antimicrobial Resistance Diagnostic Challenge, to develop new diagnostic tests that health care providers can use to quickly identify antibiotic-resistant bacteria, and distinguish between viral and bacterial infections. Finally, the agency's Digital Services is guiding projects to improve efficiencies and customer satisfaction, including the new Quality Payment Program, which is the most integrated and technology enabled program yet, with the goal of easy interactions and providing valuable information back to physicians from across several programs.
- **Built a foundation for a health care system that's ready to fight cyber threats.** We took significant steps to improve the safety of Americans' health data and the security of life-saving medical devices across our health care system. We brought together a cross-sector partnership to identify gaps and risks and share best practices in cybersecurity, and funded the first-ever information sharing and analysis organization for the health care and public health sector. We have also deployed state-of-the-art tools and strategies to protect HHS data and assets from cyber events so that when threats occur, we can immediately detect and respond.
- **Improving Service Delivery.** This Department learned several lessons about improving service delivery from its management of HealthCare.gov – lessons that are important for any organization directing large and complex projects. First, we learned the importance of leadership and accountability, and putting in place a management structure that sets up our teams to succeed. Second, the need for constant prioritization in terms of tasks and projects in order to ensure projects are launched and completed in a way that is efficient and effective. Third, the need for a nimble and adaptive IT strategy. Above all, we continue to work every day to put the consumer at the center through steps that make enrollment quicker and smoother, and through efforts to meet consumers where they are.

Vision for the Future

We believe that this record of progress sets a strong foundation on which to build. We believe these accomplishments chart the path toward a better health care system, a strong and united front to support prevention, promote public health and combat public health threats, and a society that invests in the children and families that represent its hope for the future.

For decades, patients and health care providers operated in a system that rewarded the volume of care over the value of that care. It was a system that left tens of millions without coverage, pushed health care costs to grow far faster than our economy, and resulted in thousands of lives lost from avoidable errors.

But today, doctors, nurses, hospitals, payers and patients, along with private-sector partners, are coming together to build a better system, powered by the tools and provisions of the Affordable Care Act.

This better system is one where providers are paid based on outcomes. It's a system in which health care is integrated, with a focus on prevention. It's a system where patients are at the center of their care.

In the health care system of the future, providers work together to create a coherent care experience; they have easy and secure access to electronic records and other technology tools that can inform treatment and reveal patterns in health; and they are compensated in ways that give them the flexibility to innovate. We reward them for providing the best care for their patients.

In this system, people are the most important part of their own care. They can access their medical records and use them as they need. They can easily make appointments and read medical bills. They understand how they can best use their benefits, and they have the support they need to manage their care.

The Department's experience throughout this Administration proves that by improving access and investing in quality care, we can have a stronger health care system that also lifts the burden of costs for families, businesses, and government alike.

A stronger health care system also contributes to our defense against future threats to public health. Health threats do not operate on a predictable timeline, nor do they recognize borders, which is why rapid action and international coordination is so important.

Our partners overseas and across borders are the other key element of a strong defense, and we must all work together to build a world where all of our partners are able to prevent, detect and respond to future health threats. This means improving and working closely through existing entities like the World Health Organization and the United Nations. It also means working with new entities like the Global Health Security Agenda, and regional groups like the Pan American Health Organization.

Policymakers here in the United States should have funds readily available to respond to health threats as they arise and protect the American people. Our vision for the future is one where fighting a new health threat does not force us to divert funds from other vital health priorities.

By empowering policymakers to respond quickly to public health threats, and working in concert with partners around the globe, not only can we ensure a safer future for millions of Americans, but we can improve the health and well-being of people from every nation.

We have also fought public health threats at home, like the epidemic of opioid abuse and overdose. By working closely with both public health professionals and law enforcement, we have been able to treat this epidemic in multiple ways to ensure people escape addiction and get the treatment they need.

At the Department of Health and Human Services, we also have the chance to improve the health and well-being of our fellow Americans by investing in the success of children and families at every stage of life. Any vision for the future of our nation has to focus on how well our nation's children and families are thriving today.

I envision a future where every child growing up in America has access to the building blocks of a healthy and productive life – no matter who she is, what kind of neighborhood she grows up in or the color of her skin. It is a future where every family has an open door to quality, affordable health care – physical, mental, and behavioral. It is a future that invests in stronger families and communities – giving every person the opportunity to reach for the American dream.

Actions Needed

Health Care

As the President has said, we still have work to do to make the health care system work better for everyone. There are important steps that policymakers can take to build on this progress.

- **Continue progress under the Affordable Care Act to expand access and improve coverage quality.** The first opportunity for the new Administration will be concluding a strong fourth Open Enrollment, which ends on January 31. There is also more work to be done at HHS to strengthen the Marketplaces, including by strengthening stabilization programs, facilitating issuer entry, and taking steps to broaden the risk pool. HHS also plays a key role in working with insurers to share best practices as they continue to find better ways to provide affordable care. Congress can consider legislation on recommendations that President Obama laid out in the August 2016 article in the *Journal of the American Medical Association*, including enhancing financial assistance, creating a fallback public option to ensure strong competition in insurance markets around the country, and giving the federal government the authority to negotiate prices for certain high-priced drugs. These and other changes would build on the progress that our nation has made rather than rolling it back or starting from scratch. Repealing the ACA, as some have suggested, risks eliminating consumer protections – like making it illegal to discriminate against those with pre-existing conditions and protecting benefits – for Americans who get health insurance through the Marketplace, Medicare, Medicaid or through their job. A recent study shows that under one version of repeal without a replacement, nearly 30 million Americans would lose their coverage altogether. We can work together to make our health care system even better, but we should build on the progress we've made, not go backwards. Finally, the remaining 19 states that have not yet expanded Medicaid have the opportunity to provide coverage to 4 million of their citizens, while strengthening their economies and their health care systems.
- **Improve health care affordability and quality through delivery system reform.** When this Administration set payment goals for the Medicare program, it catalyzed action among stakeholders across the health care system, and it brought together powerful collaborative efforts to improve the way we pay for health care. The work of CMMI is crucial to this progress. Innovative CMMI alternative payment models have already improved care quality for many Medicare and Medicaid beneficiaries, and continuing to pursue these goals will ensure that these benefits are felt both within Medicare and the broader health care system. Building on the successful models developed during this Administration, while seeking out opportunities to extend value-based payment to an even broader range of providers and health care services, including high-cost drugs, not only benefits patients but allows clinicians the flexibility to practice medicine in the way that best meets the needs of their patients. The passage of MACRA was a monumental step forward in the effort to reward

quality and value in physician payments; however, additional federal legislation should be considered that would use payment incentives to drive the delivery of value-based health care throughout the entire health care system, improve the interoperability of data, and integrate care.

- **Sustain a focus on improving the quality of services provided by the Indian Health Service.** It is important to continue the historic level of additional investment in IHS, which has long been under-resourced. While more funding is necessary, it is not sufficient. The next Administration should build on the work we have done to deploy assets (i.e., new policies, detailing personnel that are experts in operations and other needed areas to IHS, convening HHS quality experts to work specifically on the hospital quality/safety issues) from across HHS to make as many meaningful changes as we can to shore up IHS and its hospitals. It should also look to ensure attention to quality of care on a system-wide basis, something that had become too decentralized, leading to serious issues at critical facilities such as Rosebud and Pine Ridge in South Dakota. The problems are complex and require longer term solutions (e.g., strengthening the health care workforce pipeline by attracting and supporting American Indian students pursuing health careers). While we're also working on initiating long-term solutions, work will need to continue beyond the end of this Administration.

Public Health

As we have outlined in our Budget, we need to continue to take steps to protect our nation from public health threats and invest in a public health infrastructure that keeps our people healthy.

- **Continue this Administration's efforts to fight the opioid epidemic.** This includes aggressive implementation of the Comprehensive Addiction and Recovery Act and 21st Century Cures legislation, which fulfills the President's request for \$1 billion to fight the opioid epidemic.
- **Combat the threat of infectious diseases through the Global Health Security Agenda.** Continued high level U.S. leadership will be critical to maintain momentum and further institutionalize the gains that have been made, including through support to WHO and partners for external evaluations and country planning. U.S. leadership should include working with partners to follow through on their commitments, emphasizing the importance of country preparedness as a national priority, and highlighting the need for sectors beyond health, including the animal health, development, security, technology, and foreign affairs sectors, to support this work. Strengthening the multi-sectoral approach will create stronger and more resilient health systems with the ability to respond effectively to outbreaks.
- **Invest in efforts to combat antimicrobial resistance.** Although we have made great progress in implementing actions in the National Action Plan for CARB, we must remain vigilant to see this critical work through. This will require additional resources for USDA and FDA to enhance surveillance work and to protect our food supply.
- **Establish a Public Health Emergency Fund.** The federal government needs a new process to rapidly respond to urgent health threats. While a reserve fund may not fully eliminate the need for additional funding in response to a large outbreak or for unexpected threats, a ready supply of financial resources is necessary for rapid response to emerging public health

threats and would save lives, save money, and protect America's health security. The fund should come with appropriate triggers, guidelines, and reporting requirements set by Congress.

- **Protect more Americans from Tobacco and Nicotine.** Despite decades of efforts to reduce tobacco use, it continues to be the leading cause of preventable disease and death in the United States. Protecting America's youth from the harmful effects of tobacco products, such as e-cigarettes and flavored cigars, should continue to be a top priority for the federal government. The federal government should continue to conduct research on the harms associated with the use of tobacco products as well as prevention techniques that focus on at-risk populations.
- **Empower families with information about the foods and beverages they consume.** Under the leadership of First Lady, Michelle Obama, and her Let's Move! initiative, we have made great strides in making sure consumers have the tools they need to enjoy a healthy diet. In 2015, HHS and USDA worked together to update the Dietary Guidelines for Americans, which provides critical information about a healthy diet. The FDA modernized the Nutrition Facts label, which will make it easier for consumers to see essential information at a glance, including calories and information about serving sizes and servings per container. The updated label also includes information about added sugars for the first time, so consumers have complete information about the amount of sugar contained in the products they buy. The FDA also published draft, voluntary targets for industry to reduce sodium in various foods. The link between sodium consumption and blood pressure is strong and well documented. High blood pressure is a key risk factor for heart disease and stroke. Continuing the work of the First Lady and the Let's Move! Initiative should remain a top priority for improving the nation's public health, especially working with industry to finalize and implement FDA's voluntary sodium reduction targets.
- **Continue to Invest in FDA for the Future.** As medical technology continues to evolve and the global marketplace continues to expand, we must make sure the FDA is fully equipped to carry out its mission in the 21st century. While FDA continues to be a global leader in first-to-market medical products, greater investment in the FDA, including improving regulatory science, will help ensure the agency can help advance emerging technologies while continuing to protect the public health. A robust FDA will also help improve competition in the marketplace, especially the pharmaceutical marketplace where health care consumers want access to safe and affordable options.

Human Services

To promote the well-being of our nation's children and youth and help seniors and people with disabilities live as independently as possible, we need to continue to invest in key HHS priorities.

- **Invest in Children and Families.**
 - Expanding access to high quality early childhood education is among the smartest investments that our nation can make. The President's vision is that all children should have safe, high-quality early care and education from birth through age four that nurture their healthy development to help them grow, thrive, be successful in school, and even find better jobs and earn more as adults. This support will also help

their parents succeed in the workforce, strengthening our economy. While the goal will take some time to achieve, important steps on the way include additional funding for Head Start to ensure that nearly all children in the program can benefit from a full-day/full-year schedule as well as further investment in child care to reach more working low-wage families that need assistance and to fully realize the quality improvements called for in the 2014 law. Implementation of the “Designated Renewal System” in Head Start has been a fundamental change to the program; the next Administration should ensure that the focus on quality in brings continues, even while considering whether any operational adjustments are needed.

- In child welfare, the next Administration should build on the work that has been done to build an infrastructure of evidence-based prevention efforts that would keep children from being abused or neglected and needing foster care. While legislation to reform the child welfare system to focus more on up-front prevention did not pass in 2016, it had strong bipartisan support, passing the House of Representatives on a voice vote. Bipartisan support for increasing the focus on prevention is clear. The current opioid crisis is a reminder that effective substance use disorder treatment can be a prevention effort in child welfare, where too many children are taken into foster care due to parental substance use issues. Stronger families are better for children – and can be cost-effective, in light of the expense involved in providing foster care.
- Finally, it is clear that the TANF program does not address the needs of families in poverty, especially deep poverty, as well as it could. We need to do more to help families in crisis and those struggling to get a foothold in the economy. The FY 2017 Budget proposed giving states more ability to test innovative and individualized approaches to helping families get jobs, sustain employment, and make progress in the labor force, while emphasizing the need for outcomes accountability and taking steps to help more families facing emergencies. While these have not moved forward, the next Administration should focus on improving TANF to make it a less bureaucratic program that does more to help families and is less about whether states comply with detailed federal rules that have little to do with what families need to succeed.
- **Responsibly manage the Unaccompanied Children program.** HHS has the legal obligation to care for children who are apprehended by immigration authorities without a parent or guardian. HHS cares for these children until they can be safely placed with a sponsor, typically a family member, while their immigration cases proceed. In recent years, the number of children referred to HHS has varied, but has been significantly higher than earlier in the decade, creating challenges both for HHS as well as for other parts of the federal government. HHS has been able to expand its shelter capacity to care for a larger number of children. Going forward, it is important that the federal government continues to have a coordinated, comprehensive effort to address migration, including the root issues facing Central America – the region of origin for most children referred to HHS care – that lead children to undertake this dangerous journey.

Conclusion

A little more than four decades ago, a young girl took a seat in a classroom in a small town in West Virginia for a new program called Head Start. In that room, she would make lifelong friends and spark a love of learning that she would carry with her into a career of public service, and eventually the chance to serve as Secretary of the Department of Health and Human Services.

My path to serve this Department and the American people was made possible by generations before me—generations of men and women who knew that the role of public service is to lift up families and empower communities.

I have been lucky to visit many of those communities during my tenure as Secretary. I have met Americans wrestling with questions about health coverage and health care, concerns about new health threats, and thoughts about how to give their children the best chance to succeed. In all of these cases, families across our country are facing real choices and challenges: What kind of health coverage is best for my family and me? What steps do I need to take to keep my pregnant wife safe from the Zika virus? What resources can help my cousin get the treatment he needs to fight his addiction? How can I afford high quality preschool for my child?

Our Department shines the brightest when we connect those Americans with the realities of the challenges and opportunities ahead. We fulfill our mission every time we help the American people have real conversations about the real choices they face. Whenever we put the American people at the center of their decisions and empower them, our nation grows stronger. That has been our goal at the Department of Health and Human Services throughout President Obama's Administration, and I hope it continues to be the legacy of this Department well into the future. It has been a privilege to serve with this team.