U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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2019

Annual Report

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Introduction

THE MEN AND WOMEN of the Department of Health and Human Services (HHS) can be proud of all they achieved in 2019. This past year was marked by exceptional progress in accomplishing our mission: to enhance and protect the health and well-being of all Americans.

We're a big department, but we're united by one strategic vision: a country where our HHS programs, and America's healthcare, human services, public health, and biomedical science institutions, work better for the people we serve. Our work is organized around the five goals laid out in our strategic plan:

1. Reform, strengthen, and modernize the nation's healthcare system.

2. Protect the health of Americans where they live, learn, work, and play.

3. Strengthen the economic and social well-being of Americans across the lifespan.

4. Foster sound, sustained advances in the sciences.

5. Promote effective and efficient management and stewardship.

There are three themes I've emphasized that encompass the work we do to deliver on these goals: First, we facilitate patient-centered markets for healthcare; second, we protect life and lives; and third, we promote Americans' independence.

In 2019, we laid out a vision for what a patient-centered, market driven healthcare system looks like: a system that's affordable, personalized, puts you in control, and treats you like a person, not a number. We're already

delivering results. Thanks to actions we took this past year, patients are gaining unprecedented control over the information they need to make decisions about their care. Retail prescription drug prices dropped in 2018 for the first time in more than 40 years, while Medicare Advantage and Part D premiums dropped to the lowest levels in years.

This past year, we protected life both here in the U.S. and abroad. HHS played a crucial role in responding to the ongoing outbreak of Ebola in the eastern Democratic Republic of the Congo, as well as the response to South America's refugee crisis. We took an aggressive approach to impactable health challenges here at home, with the launch of our historic initiative to end the HIV epidemic in America, and significant increases in access to addiction treatment that contributed to the first decline in drug overdose deaths in more than two decades.

We promoted independence by promoting adoption, with historically high levels of youth being placed out of foster care. We've expanded access to truly evidence-based treatment for people with serious mental illness, and provided new support for older Americans to remain in their homes and communities.

As we begin 2020, we have many results to be proud of, but also many challenges on the horizon. It has been and will be an honor to continue leading the HHS team, which I have great confidence will continue delivering historic results for the Americans we serve.

Alex M. Azar II
Secretary of Health and Human Services

Executive Summary

THIS ANNUAL REPORT is organized into five sections corresponding to the HHS department strategic goals, as laid out in our 2018–2022 strategic plan.

Goal 1: Reform, Strengthen, and Modernize the Nation's Health Care System

HHS aims to improve the quality and reduce the cost of healthcare Americans receive by facilitating patient-centered markets and advancing the direct care provided in our programs. Accomplishments in this section include:

- A decline in the retail prices of prescription drugs, as measured by National Health Expenditure Data, in 2018 for the first time in more than 40 years.
- The first-ever FDA plan for safe importation of prescription drugs from foreign countries, including Canada, to reduce drug costs.
- A record number of generic drug approvals from FDA for the third straight year, with a record number of first generics and record number of biosimilars approved.
- A decrease in average premiums for a benchmark plan on HealthCare.gov, for the second consecutive year since the establishment of the insurance exchanges.
- Protecting and strengthening Medicare, delivering $2.65 billion in savings and more benefits and options to beneficiaries over the last three years.
- The introduction of historic value-based payment models to change how the government pays for emergency services, kidney health, radiation oncology, and primary care.
- Redesigning the ACO program and doubling

the number of ACOs taking on downside risk, accelerating Medicare payments tied to value.
- A new requirement that hospitals disclose their standard charges (including gross charges, discounted cash prices, and payer-specific negotiated price) and a proposed rule to provide consumers with anticipated out-of-pocket costs.
- Proposal of historic reforms to Stark Law and Anti-Kickback Statute regulations that may impede value-based and coordinated care arrangements.
- A new proposed rule to give patients access to their electronic health information at no cost, including via smartphone applications.

Goal 2: Protect the Health and Well-Being of Americans Where They Live, Learn, Work, and Play

Our work to protect the health of Americans extends from addressing particular impactable health challenges here in the United States, including the opioid crisis, HIV, and other infectious diseases, all the way to protecting lives around the world from health threats. Covered in this section are accomplishments including:

- Efforts to combat the opioid crisis that led to a 4.1 percent decrease in drug overdose deaths in 2018, the first such decrease in more than two decades.
- Launching the HEALing Communities Initiative to reduce drug overdose mortality by 40 percent in communities in four states, through awarding $350 million to pursue a whole-of-society approach.
- Initiating the President's historic initiative to end the HIV epidemic in the U.S. by 2030.

- Kicking off the Advancing American Kidney Health Initiative to help prevent kidney disease and deliver better health outcomes for kidney patients.
- The first-ever Medicaid demonstrations to expand inpatient treatment options for serious mental illness.
- Deploying U.S. Public Health Commissioned Corps officers to support 32 missions responding to national emergencies, natural disasters, and other public health crises.
- Working at home and abroad to increase vaccine confidence and responded to measles outbreaks in the U.S., maintaining our country's elimination status.
- Engaging across HHS in a historic response to the Ebola outbreak in the Democratic Republic of the Congo, including the first approval of a vaccine for Ebola and conducting a clinical trial for therapeutics in a war zone.

Goal 3: Strengthen the Economic and Social Well-Being of Americans across the Lifespan

HHS plays a vital role in supporting independence for all Americans at all stages of life—whether new mothers, youth in foster care, Americans with disabilities, and older Americans. This section covers items such as:

- An initiative launched to improve availability and quality of treatment and support services for children and families impacted by neonatal abstinence syndrome.
- A nationwide listening tour to develop solutions for expanding access to affordable, high quality child care for working families.
- A record number of foster care adoptions in the U.S. in 2019.
- A new challenge for employers to design models to expand job opportunities for Americans with disabilities, especially intellectual and developmental disabilities.
- Protecting conscience in the foster care space and proposing a rule to protect religious freedom in HHS grants.

Goal 4: Foster Sound, Sustained Advances in the Sciences

HHS works to advance biomedical science to improve the health and well-being of Americans, and everyone around the world, through directly supporting research and working with the private sector to advance promising innovations. This section covers examples of our work at the frontiers of science, including:

- Continued progress of the All of Us long-term research study at the National Institutes of Health with more than 300,000 people enrolled across all 50 states.
- Initiating an effort to provide $500 million over the next decade to improve pediatric cancer research.
- The Cancer Moonshot Initiative that funded over 200 high-impact projects in FY 2019 seeking to advance critical research areas.
- A clinical trial that is testing a promising novel gene replacement therapy in patients with sickle cell disease.
- Issuing a six-year, $226 million contract to retain and increase capacity to produce recombinant influenza vaccine in the United States.

Goal 5: Promote Effective and Efficient Management and Stewardship

In 2019, HHS took major steps forward to be good stewards of taxpayer resources, provide quality customer service to employees and stakeholders, and modernize departmental operations. Included in this section:

- Ending a healthcare fraud scheme that had billed a record $1.3 billion to Medicare and Medicaid in fraudulent claims.
- A decrease in the 2019 Medicare fee-for-service estimated improper payment rate below the threshold for compliance established by law for the third consecutive year.
- HHS ranking as the best place to work among cabinet-level departments for the third straight year.
- Increased participation of staff in the Federal Employee Viewpoint Survey to 71.9 percent, far exceeding the goal set of 60 percent.
- Modernizing and coordinating communications across HHS through a comprehensive digital communications strategy.

Reform, Strengthen, and Modernize the Nation's Healthcare System

IN 2019, THE DEPARTMENT OF HEALTH and Human Services (HHS) delivered on President Trump's promise to protect what works and fix what's broken in our healthcare system. That included delivering on President Trump's vision for a personalized, affordable, patient-centric healthcare system that has you in the center, puts you in control, and treats you, the patient, like a human being, not a number.

HHS' work delivering on this vision focused on facilitating patient-centered markets in healthcare, especially through 1) reforms to how HHS finances care—through protecting and improving Medicare and Medicaid and expanding options in the individual health insurance market and 2) efforts to deliver better value in healthcare through equipping patients with price and quality transparency, providing patients with control of their health records, unleashing data, removing regulatory burdens, paying for outcomes, lowering drug prices, and accelerating drug and device approval and reimbursement.

Protecting and Strengthening Medicare

Executive Order on Protecting and Improving Medicare for Our Nation's Seniors: In October 2019, President Trump signed an executive order directing HHS to take steps to deliver more options and benefits and lower costs for beneficiaries, including to:

- Open up new options for plans within Medicare Advantage and test out new benefits.
- Accelerate Medicare's ability to pay for the latest medical technology.

- Pay doctors for the time they spend with patients, rather than procedures or paperwork.
- Cut waste, fraud, and abuse in Medicare that undermines the program.
- Help healthcare professionals like nurses practice to the top of their license.

New, lower-cost settings of care: As part of responding to the Executive Order, the Centers for Medicare & Medicaid Services (CMS) has given Medicare beneficiaries more choices on where to obtain care, improved access and convenience, and lowered out-of-pocket expenses, by adding 20 new procedures payable when furnished in either the ambulatory surgery centers or outpatient hospital departments.

Supporting access to the latest technology for Medicare beneficiaries: CMS streamlined the process for supporting innovative treatments by providing an alternative new technology add-on payment pathway in which Breakthrough Devices are no longer required to demonstrate evidence of "substantial clinical improvement" to qualify for new technology add-on payments. This will provide additional Medicare payment for these technologies while real-world evidence is emerging, giving Medicare beneficiaries timely access to the latest innovations in treatment. In addition, CMS increased the maximum new technology add-on payment from 50 percent of the cost of the new technology to 65 percent.

New Medicare Advantage supplemental benefits: CMS delivered modifications designed to help keep seniors safe in their homes and to provide respite care for caregivers, non-opioid pain management alternatives like therapeutic massages, and transportation, as well as more in-home support services and assistance.

HHS Secretary Alex Azar, CMS Administrator Seema Verma, and others look on as President Trump signs an Executive Order on Protecting and Improving Medicare for Our Nation's Seniors

New virtual care coverage: In Medicare and Medicare Advantage, doctors can now receive compensation for a much broader range of services delivered virtually, like phone or video check-ins.

Lowering Medicare Advantage premiums: Through strengthening negotiation and maximizing competition, CMS delivered lower average Medicare Advantage premiums and increased plan choices for beneficiaries in 2019 and 2020.

· This work has helped lower Medicare Advantage premiums by 23 percent and added 1,200 plan options since 2018.
· For 2020, the average MA premium is $23 a month – the lowest in 13 years.

Paying for time with patients rather than paperwork: Starting in 2021, CMS will place more emphasis in calculating compensation based on the time healthcare providers spend treating the growing number of patients with greater needs and multiple medical conditions, through increasing the value of evaluation and management (E/M) codes for office/outpatient visits and providing enhanced payments for certain types of visits.

Coverage for CAR T-cell therapy: CMS began covering the first FDA-approved Chimeric Antigen Receptor T-cell, or "CAR T-cell," cancer therapy, which uses a patient's own genetically modified immune cells to treat some people with specific types of cancer.

Lowering Prescription Drug Costs

Historic price decrease: CMS National Health Expenditure data released in 2019 showed that, for the first time in more than forty years, the retail price of prescription drugs fell in 2018.

First-Ever safe drug importation action plan: For the first time ever, the FDA issued a proposed rule that, if finalized, would allow states to submit plans for the importation of certain prescription drugs from Canada in order to lower Americans' drug costs, and also issued draft guidance for industry to facilitate importation of prescription drugs, including biological products, that are manufactured abroad, authorized for sale in a foreign country, and originally intended for sale in that foreign country, which could give drug companies new flexibility to lower drug prices.

Lowering Part D premiums: For the third year in a row, the average basic premium for Medicare Part D prescription drug plans is projected to decline. Over the past three years, average Part D basic premiums have decreased by 13.5 percent, from $34.70 in 2017 to a projected $30 in 2020, saving beneficiaries about $1.9 billion in premium costs over that time.

Real-Time Pharmacy Benefit Tool: Starting in 2020, Part D plan sponsors will be required to make available a real-time benefit tool that

provides prescribers with information about what drugs are covered by a patient's insurance coverage, what cost-sharing may be, and other information.

Historic generic drug approvals: For the third year in a row, the FDA approved a record number of generic drugs in FY 2019, approving or tentatively approving a record 1,171 generic drugs, including 125 applications for first generics of medicines that had no generic competition.

Historic biosimilar approvals: While implementing several facets of its Biosimilars Action Plan (BAP), the FDA approved 10 biosimilar products in calendar year 2019, an increase from seven in 2018 and five in 2017. FDA also witnessed an increase in the number of biosimilars marketed to consumers, including products for treating cancer, neutropenia, Crohn's disease and arthritis.

Draft Guidance to advance insulin competition: To inform product developers who intend to seek FDA approval of proposed insulin products that are biosimilar to, or interchangeable with, an approved insulin product, FDA issued a draft guidance to clarify what data and information may or may not be needed to demonstrate biosimilarity or interchangeability.

Increasing Options and Lowering Costs for Health Insurance

Lower premiums, more options on HealthCare.gov: For the second year in a row, average benchmark premiums for plans offered on HealthCare.gov dropped, declining by 4 percent from 2019 to 2020, while the number of issuers participating in the Exchanges increased by 20, giving consumers more coverage choices.

Improving the enrollment experience: In 2018, CMS developed a new enhanced direct enrollment pathway for consumers to enroll in an Exchange plan directly through an approved issuer or web-broker, without the need to be redirected to HealthCare.gov or to contact the Exchange Call Center. In 2019, for the first time, Enhanced Direct Enrollment was made available through the entire Open Enrollment period. In addition, for the first time, consumers were able to "window shop" and preview plan options ahead of the Open Enrollment period.

Health Reimbursement Arrangements: With the Departments of Labor and Treasury, HHS issued

FOR THE SECOND YEAR IN A ROW, AVERAGE BENCHMARK PREMIUMS FOR PLANS OFFERED ON HEALTHCARE.GOV DROPPED, DECLINING BY 4 PERCENT FROM 2019 TO 2020

a rule that will expand the use of two new types of Health Reimbursement Arrangements beginning January 2020, giving millions of American workers more options for health insurance coverage.

Providing state flexibility: Since 2017, HHS and the Department of the Treasury approved twelve Section 1332 waivers authorizing state reinsurance programs to lower premiums, ranging from an estimated 6 percent reduction in Rhode Island to a 30 percent reduction in Maryland. Hawaii was also issued a waiver in 2016 to avoid having to establish a Small Business Health Insurance Program (SHOP) as part of its Exchange.

Transforming Medicaid and Making It Sustainable

Reducing potential for improper payments: CMS continued its work to ensure sound fiscal stewardship and oversight of the Medicaid program by proposing a comprehensive update to Medicaid's regulations that ensure the program operates in a sound fiscal manner, consistent with statutory requirements. This proposal would clamp down on abusive financing arrangements by reducing the potential for inappropriate payments so that federal Medicaid dollars are being spent on Medicaid beneficiaries, not state projects that do not benefit Medicaid beneficiaries, or to supplement or supplant the state's required share of Medicaid financing.

Protecting the integrity of Medicaid and CHIP: CMS issued a new proposed rule to ensure the integrity of the Medicaid and the Children's Health Insurance Program (CHIP) eligibility and

Secretary Alex Azar speaks at a press conference announcing the Emergency Triage, Treat, and Transport (ET3) Model

enrollment process by aiming to improve the accuracy and consistency of eligibility determinations across states.

Supporting research on improving Medicaid: For the first time, CMS released a robust repository of research-ready Transformed Medicaid Statistical Information System (T-MSIS) data files. Researchers and others can now use this data to answer questions about Medicaid and CHIP enrollment, services and payment.

Updated Medicaid scorecards: CMS released an updated Medicaid and CHIP Scorecard, an innovative public-facing federal dashboard that includes additional data points, measures, and enhanced functionality.

Substance Use Data Book: CMS produced the first ever Substance Use Data Book, with information about diagnosis and treatment. These and other efforts helped to ensure that states have the flexibility to best serve their residents.

Paying for Outcomes

New models that pay for value: HHS continued to work to realign incentives in how we pay for healthcare, and developed over a dozen new innovative payment models that allow reimbursement to be tied to value, rather than merely volume of services.

- ***Kidney care:*** As part of the President's *Advancing American Kidney Health* Initiative,

the Kidney Care Choices Models and the proposed ESRD Treatment Choices Model add financial incentives for providers and suppliers to better manage care for Medicare beneficiaries to delay the onset of kidney disease and incentivize kidney transplantation and home dialysis.

- ***CMS Primary Cares Initiative:*** The Direct Contracting and Primary Care First models are the next step in transforming how Medicare pays primary care providers. These models align up to a quarter of Medicare beneficiaries to primary care entities participating in payment arrangements based on outcomes rather than volume.

- ***Emergency Triage, Treat and Transport (ET3) model:*** Traditionally, Medicare has paid for patients who call 911 and are picked up by emergency medical services to go to the hospital, which can be unnecessary and expensive. The ET3 model will allow ambulance suppliers and providers to partner with qualified health care practitioners to deliver treatment at the site of a medical emergency (either on-the-scene or through telehealth) and to bring patients to alternative destination sites (such as primary care doctors' offices or urgent-care clinics) that may represent lower cost, more appropriate options than a hospital.

- ***More Accountable Care Organizations taking on risk:*** CMS revamped the Medicare Shared Savings Program in the Pathways to Success final rule to put ACOs on a quicker path to

taking on real risk. By January 2020, almost 37 percent of ACOs will be on the path to take on risk—doubling the number of ACOs taking on downside risk.

Delivering Transparency around Price and Quality

Delivering on President Trump's Executive Order on Improving Price and Quality Transparency in Healthcare:

- Finalized a rule so that, starting January 2021, hospitals will have to disclose publicly their negotiated rates for services and the discounted cash price they're willing to take.
- Proposed a rule to require that most health insurance insurers provide patients, upon request, cost-sharing data, similar to an advance explanation of benefits, delivering transparency around all healthcare prices.
- Launched the HHS Quality Summit to convene federal and private stakeholders to produce a health quality roadmap that will align quality measures across federal departments.

Modernized and redesigned Medicare Plan Finder: For the first time in a decade, CMS launched a modernized and redesigned Medicare Plan Finder, which provides users with a mobile friendly and easy-to-read design.

First official Medicare app: CMS launched its first app, "What's Covered," that delivers accurate cost and coverage information on mobile devices so users can quickly see whether Medicare covers an item or service.

Qualified Health Plan Five-Star ratings: For the first time, CMS is requiring the display of the Five-Star Quality Rating System nationwide for qualified health plans offered through Exchanges, to offer consumers more information to help them compare plans.

Provide Patient Control of Health IT and Unleash Data

Proposed historic interoperability rule: CMS and the Office of the National Coordinator for Health Information Technology (ONC) proposed rules on interoperability to help allow individuals to quickly and easily access their health information electronically. ONC'S proposed rule requires the healthcare industry to adopt standardized application programming interfaces (APIs) to help patients securely and easily access their electronic health information using smartphones and other mobile devices.

Blue Button 2.0: Through Blue Button 2.0, Medicare beneficiaries can now securely connect their data to apps and other tools developed by innovative companies. The apps can help them organize and share their claims data,

Dr. Rick Schultz speaks in the Roosevelt Room with President Trump at an event on honesty and transparency in healthcare prices

find health plans, make care appointments, and check symptoms. As of December 2019, 54 applications are in production and over 2,400 developers from 1,456 organizations are working on development of applications.

Helping clinicians access claims data: The "Data At the Point of Care" API Pilot is making a patient's Medicare A, B, and/or D claims data available to the clinician directly in their workflow to support treatment decisions.

Removing Regulatory Burdens

Freeing clinicians to spend more time with patients: In 2019, CMS eliminated reams of overly burdensome and unnecessary regulations and sub-regulatory guidance, to allow clinicians and providers to focus on their primary mission — improving their patients' health. These efforts are estimated to save $6.6 billion through 2021—with a reduction of 42 million burden hours, giving that time back to clinicians and providers to spend with their patients and not on needless paperwork.

Simplifying Participation in Pay-for-Performance Program: CMS established an approach for simplifying ways for clinicians to participate in the pay-for-performance program Merit-Based Incentive Payment System (MIPS) called the MIPS Value Pathways (MVPs).

Regulatory Sprint to Coordinated Care: HHS continued work under the direction of Deputy Secretary Eric Hargan on the Regulatory Sprint to Coordinated Care to benefit patients and providers through regulatory reforms that allow for commonsense, value-based, patient-centered innovations.

- *Anti-Kickback Statute:* The HHS Office of Inspector General (OIG) proposed a rule that, if finalized, would remove unnecessary regulatory obstacles to value-based healthcare arrangements, giving more options for providers to work together in innovative ways to better coordinate care, while maintaining strong safeguards to protect patients and programs from fraud or abuse. For instance, under the proposed rule, a doctor could provide a patient who's taking a large number of medications with a free smart pillbox to help him or her keep medications organized and alert the physician of any missed doses.

- *42 CFR Part 2:* SAMHSA proposed reforms for 42 CFR Part 2 to decrease burden for

EFFORTS TO ELIMINATE OVERLY BURDENSOME AND UNNECESSARY REGULATIONS AND GUIDANCE ARE ESTIMATED TO REDUCE BURDEN HOURS FOR CLINICIANS AND PROVIDERS BY 42 MILLION, FREEING THEM TO SPEND MORE TIME WITH PATIENTS

practitioners and ultimately increase access to care for those with substance use disorders.

- *Stark Law:* CMS proposed to modernize and clarify the regulations that interpret the Medicare physician self-referral law, also called the "Stark Law," to open additional avenues for physicians and other healthcare providers to coordinate the care of the patients they serve. As one example, under the proposal, a hospital could donate cybersecurity software to physicians who refer patients to it, ensuring security of patient records sent between the hospital and doctors' offices without encouraging consolidation of providers.

- In December 2018, the Office for Civil Rights published a Request for Information seeking input from the public on how the HIPAA Rules could be modified to further Secretary Azar's goal of promoting coordinated, value-based healthcare. OCR reviewed the comments and developed a proposed rule which will be issued in the coming months.

Deputy Secretary's Innovation's and Investment Summit (DSIIS): HHS Deputy Secretary Hargan convened four meetings with healthcare leaders focused on innovation and investment, identifying and discussing critical issues that affect innovation in healthcare This was the first department-wide effort of its kind that HHS had ever undertaken to understand and accelerate innovation in healthcare. The ideas, insights and information gathered from DSIIS helped to ensure that HHS understands the perspective of those focused on innovation.

Rear Admiral Michael Weahkee, Principal Deputy Director of the Indian Health Service, attends the National American Indian and Alaska Native Heritage Month celebration at HHS

Committing to High-Quality Care in the Indian Health Service

Establishing an IHS Office of Quality: The Indian Health Service formally established the IHS Office of Quality in 2019, to provide national leadership and promote consistency in health care quality across the agency. The IHS has made significant strides in addressing priority areas for quality improvement, including implementing credentialing and privileging software agency-wide; hiring an IHS credentialing program manager at headquarters; and awarding a new contract for an adverse events reporting and tracking system.

New steps toward tribal self-governance: In 2019, the Ak-Chin Indian Community in Arizona, the Rolling Hills Clinic of the Paskenta Band of Nomlaki Indians in California, and the Iowa Tribe of Kansas and Nebraska entered into self-governance compacts and funding agreements. The IHS has now entered into a total of 104 compacts and 130 funding agreements with the participation of over 370 federally recognized tribes and tribal organizations.

Supporting ambulatory facilities in Indian Country: IHS awarded $15 million for eight tribal health facilities to eight tribes and tribal organizations as part of the competitive Small Ambulatory Program to fund construction, expansion or modernization of small ambulatory health care facilities, which are an important part of the

Indian health system and can expand access to various outpatient services.

Delivering results through the Special Diabetes Program for Indians: The Assistant Secretary for Planning and Evaluation published an Issue Brief, *The Special Diabetes Program for Indians: Estimates of Medicare Savings.* The Issue Brief reported that a 54 percent decrease in the incidence of diabetes-related end-stage renal disease in American Indian and Alaska Native populations from 1996 (the year before the Special Diabetes Program began) through 2013, likely resulting in thousands of fewer cases and hundreds of millions of dollars in savings to Medicare. Improvements in related outcomes in this population far surpass those observed in other races.

Protect the Health of Americans Where They Live, Learn, Work, and Play

PROTECTING AMERICANS' HEALTH is a vital piece of HHS's work, ranging from combating health emergencies and promoting proven prevention efforts like vaccination to tackling longstanding public health problems, such as the HIV epidemic. HHS leadership has identified in particular a number of specific health challenges where a focused approach can and has begun to make a real impact, such as America's crisis of opioid addiction and overdose.

Around the world in 2019, HHS played a key role in keeping Americans safe and healthy by responding to health emergencies, especially the refugee crisis in South America and the Ebola outbreak in the Democratic Republic of the Congo.

Combating the Opioid and Drug Overdose Crisis

In 2017, HHS formulated a five-point strategy for combating the opioid crisis, and President Trump made it one of his administration's top priorities. By 2019, key data points showed that the dedication of HHS and communities across America is bearing fruit:

- In 2018, drug overdose deaths declined by 4.1 percent, the first decline in more than two decades.
- According to HHS estimates, the number of Americans now receiving medication assisted treatment (MAT) has increased by 39 percent since 2016, with more than 1.28 million individuals receiving MAT.
- From January 2017 through October 2019, the estimated total amount of opioids prescribed declined by 32 percent.
- The number of Americans misusing prescription pain relievers has declined significantly, from 12.5 million in 2015 to 9.9 million in 2018.
- The number of young adults with a heroin-use disorder significantly decreased from 165,000 in 2017 to 101,000 in 2018.

Following are some of the many actions taken across HHS to combat the opioid crisis, divided into the five points of the HHS strategy, during 2019.

Better Access to Treatment, prevention, and recovery services

Continuing the State Opioid Response program: SAMHSA implemented the State Opioid Response (SOR) grant program, providing $1.4 billion in grants to states, continuing the program launched in 2018 with a special focus on boosting access to MAT. As of 2019 mid-year reporting, thanks to states' use of SOR funds, 46,681 clients were served, 271,550 naloxone kits were distributed, and 14,433 overdoses were reversed.

SAMHSA block grants going to support MAT: From 2016 to 2018, utilization of MAT supported by SAMHSA's Substance Abuse Prevention and Treatment Block Grant increased by approximately 100 percent, from 58,000 to 110,000 service recipients.

Historic numbers of Medicaid Substance Use Disorder treatment demonstrations: By the end of 2019, CMS had approved 27 state Medicaid demonstrations to improve access to substance use disorder (SUD) treatment, which includes opioid use disorder treatment, with new flexibility to cover inpatient and residential treatment.

New payment models: CMS announced cooperative agreements and funding awards with states for the implementation of the Integrated Care for Kids (InCK) and the Maternal Opioids Misuse (MoM) payment models, which focus on coordinating and increasing access to treatment for children and pregnant women, including for the treatment and prevention of substance abuse and other mental health challenges.

Supporting state Medicaid programs in fighting the crisis: CMS made $47.5 million in planning grants to 15 states through $47.5 million to help increase the capacity of Medicaid providers to deliver substance use disorder treatment and recovery services.

Covering MAT in Medicare: CMS finalized an expansion of Medicare coverage to include opioid treatment programs that deliver MAT, effective January 1, 2020.

Expanding access to treatment in health centers: HRSA awarded $200 million to 1,208 Health Center Program grantees to establish and expand access to SUD and mental health services. Compared with the prior year, health centers saw a 33 percent increase in SUD patients, a 46 percent increase in patients receiving MAT, and a 65 percent increase in the number of providers eligible to prescribe MAT when compared to last year.

Improving early interventions for neonatal abstinence syndrome: In 2019, ACL launched a three-year, $1.3 million cooperative agreement with the University of Wyoming to improve availability and quality of treatment and support services for children and families affected by neonatal abstinence syndrome. It is estimated that a baby experiencing opioid withdrawal is born every 15 minutes, and research suggests they are at risk for poorer developmental outcomes.

Laying the foundation for a stronger behavioral health workforce: The National Health Service Corps established the Substance Use Disorder Workforce Loan Repayment Program, which added new provider types and made approximately 1,100 awards. In addition, HRSA delivered two new Opioid Workforce Expansion Programs, which are slated to train and add 2,700 behavioral health professionals and 4,300 new paraprofessionals to the workforce.

Combating the opioid crisis in rural America: HRSA awarded $135 million to 216 rural organizations across 47 states to establish partnerships to develop and implement plans for addressing the treatment and recovery needs in their communities and support MAT in rural hospitals, health clinics, or tribal organizations. HRSA also awarded grants to establish three Centers of Excellence on Substance Use Disorders to identify, translate, and disseminate evidence-based practices, at the University of Kentucky, the University of Rochester, and the University of Vermont.

Office on Women's Health support for screening and treating women and girls: The Office on Women's

Assistant Secretary Brett Giroir speaks at a press conference at HHS

National Institute on Drug Abuse Director Nora Volkow speaks at a press conference at HHS

Health supported the work of 20 grantees in training more than 500 primary care and OB-GYN health providers to use the evidence-based screening, brief intervention, and referral to treatment services (SBIRT) approach to support patient care.

Addressing the opioid crisis among racial/ethnic minority and disadvantaged populations: The Office of Minority Health supported the work of 12 grantees to prevent opioid abuse, increase access to opioid treatment and recovery services, and reduce the health consequences of opioid abuse in racial/ethnic minority and disadvantaged communities disproportionately affected by the opioid crisis.

Establishing a national Opioid Response Network: Through the Opioid Response Network, SAMHSA made teams of local experts are available in every state across the country to support responses to the opioid crisis. These teams have responded to over 1,000 requests and provided training to individuals who collectively serve more than 1 million Americans.

New waivers for MAT prescribing: SAMHSA approved 23,049 waivers to prescribe opioid-addiction medication in FY 2019, allowing new practitioners to undertake office-based opioid treatment, bringing the total number of waivered providers to more than 73,000.

A new easy-to-use treatment finder: SAMHSA launched FindTreatment.gov, a newly designed website that helps connect Americans looking for substance abuse treatment with approximately 13,000 locations across the United States.

Launching Opioid Rapid Response Teams: CDC and the U.S. Public Health Service Commissioned Corps launched the first Opioid Rapid Response Teams, which are available on short notice worked to support state and local governments when there is a spike in opioid-related overdoses or closure of a clinic where patients are prescribed opioid therapy.

Helping primary care providers implement MAT in their practices: AHRQ developed and posted the MAT Playbook, an online interactive guide to support primary care practices through the process of offering MAT to their patients. The Playbook is accompanied by a searchable database of over 400 tools and resources.

Addressing the rise in opioid related harms in older adults: AHRQ launched an integrated set of projects, including an evidence review, a quality improvement pilot, and a funding opportunity announcement to address the rise in opioid related hospitalizations and emergency department visits in older adults by improving management of pain, opioid use, and OUD in this population.

Partnering with faith-based organizations: The Center for Faith and Opportunity Initiatives (the Partnership Center) worked to convene and educate faith-based organizations and other partners regarding the opioid crisis, including:

- Co-hosting, with the National League of Cities, more than 60 faith and community-based organizations, entrepreneurs, social service, and public health agencies for a national meeting, "Partners in Hope: Strengthening Recovery with Community-based Workforce Development Efforts."

- Producing the "Faith & Community Roadmap to Recovery Support: Getting Back to Work," a roadmap to help congregations and communities support people in recovery seeking to find employment

- Hosting national webinars for faith and community leaders related to opioid addiction and related issues, on topics including the CDC's "Evidence-based Strategies for Preventing Opioid Overdose," addictions and trauma-informed care for veterans, and bereavement services to cope with traumatic loss.

Better data on the epidemic

Supporting state and local health department prevention efforts and reporting: In September, CDC made more than $300 million in awards to launch three-year cooperative agreements under the Overdose Data to Action Initiative, which will support state, territorial, county, and city health departments in obtaining high quality, more comprehensive, and more timely data on overdose morbidity and mortality and using those data to inform prevention and response efforts.

Google Maps featuring drug disposal sites: Based on technology developed during the HHS Opioid Code-A-Thon in 2018, the HHS Office of the Chief Technology Officer (CTO) worked with Google to launch a drug disposal site locator on Google Maps, which draws on over 70 datasets from HHS and other federal agencies, and covers over 7,000 safe disposal sites across 17 participating states.

Launching a new national awareness network: SAMHSA successfully launched the Drug Abuse Warning Network (DAWN) program, using data from more than 35 hospitals in rural, suburban and urban communities. SAMHSA will be able to quickly identify trends in substance use and identify emerging issues across the country.

Updating the National Survey on Drug Use and Health: SAMHSA successfully updated the National Survey on Drug Use and Health by adding questions related to the use of MAT for opioid use disorder as well as the use of kratom.

IN 2018, DRUG OVERDOSE DEATHS DECLINED BY 4 PERCENT, THE FIRST DECLINE IN MORE THAN TWO DECADES

Tracking Neonatal Abstinence Syndrome (NAS) trends: Using Hospital Cost and Utilization Project (HCUP) data, AHRQ developed a series of quarterly reports and an online interactive map to help policy makers track the rate of NAS-related newborn hospitalizations over time by state, patient characteristics such as sex, expected payer, and measures such as cost and length of stay.

Better targeting of overdose reversing drugs

Developing a new overdose-reversing drug: To help save lives in the current opioid epidemic or following a deliberate attack using fentanyl, ASPR issued a contract between BARDA and a pharmaceutical company to help develop a product that, if approved by FDA, would be a fast-acting, long-lasting, intranasal, potentially improved form of an opioid overdose drug. The life-saving drug naloxone, while effective, often must be given multiple times to completely reverse the effects of an opioid in someone exposed to high doses, and longer lasting drugs can reduce the need for repeat dosing.

Equipping first responders with overdose-reversing tools: SAMHSA awarded an additional 28 First Responder – Comprehensive Addiction Recovery Act grants, which over the life of the program has led to the distribution of 69,677 naloxone kits, 18,909 naloxone administrations, and 7,056 overdose reversals reported.

Better pain management

Protecting Part D beneficiaries from opioid misuse: CMS introduced new Medicare Part D opioid safety policies to reduce prescription opioid misuse while preserving medically necessary access to these medications. The new opioid

THE NUMBER OF AMERICANS NOW RECEIVING MEDICATION ASSISTED TREATMENT (MAT) IS ESTIMATED TO BE 1.28 MILLION, AN INCREASE OF 39 PERCENT SINCE 2016

policies include improved safety alerts at the pharmacy for Part D beneficiaries who are filling their initial opioid prescription or who are receiving high doses of prescription opioids.

New guide for safe reduction in opioid prescribing: In October, the Assistant Secretary for Health published a new *Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics – PDF*, which provides advice to clinicians who are contemplating or initiating a change in opioid dosage, helping clinicians to conduct a thorough, deliberative case review and discussion with the patient and avoid any harm to the patient through a reduced dosage.

A final report on pain management best practices: In May, the Pain Management Best Practices Inter-Agency Task Force issued its final report, which lays out the need for an individualized, multimodal, multidisciplinary approach to pain management, and provides recommendations for clinicians centers on five major treatment approaches.

A new digital tool for pain management: Surveys have found that almost 20 million Americans suffer from pain that interferes with their daily lives. In response, AHRQ released an interoperable digital tool that helps clinicians find pain-related information about specific patients and consolidates that information into a single dashboard. The dashboard helps clinicians quickly access vital information, such as patients' pertinent medical history, pain assessments, previous treatments, and potential risks, all to identify options and assist in shared decision making between clinicians and patients.

Using data to take down pill mills: OIG used advanced data analytics to assess broad usage patterns and target pill mills with increasing sophistication. One OIG take-down in a single state netted 50 individuals, including medical providers, diverting prescription opioids through pill mill clinics. Losses to public and private payers in this single operation came to $66 million and involved 6.2 million diverted pills.

Combating unsafe corporate marketing: OIG investigations resulted in a pharmaceutical company paying $700 million to settle allegations that it illegally marketed and promoted the opioid treatment drug suboxone. Allegations included the knowing promotion to physicians prescribing in an unsafe manner, and making false and misleading claims to the Food and Drug Administration, state Medicaid agencies, and physicians.

Record-breaking prescription takeback operations: HHS leadership promoted and educated the public about safe removal of unused opioid medications from homes. This included promotion of two National Take Back Days, in April and October, covering more than 6,000 collection sites and working with nearly 5,000 law enforcement partners, which resulted in the collection of more than 1.8 million pounds worth of prescription drugs.

Better research on pain and addiction

Historic new levels of support for research on pain and addiction: NIH used $945 million in total FY 2019 funding to award over 375 projects, involving both researchers and private biotech firms, across 41 states through the NIH HEAL Initiative, a trans-agency effort aimed at accelerating scientific solutions to stem the national opioid public health crisis and offer new hope for individuals, families, and communities affected by the devastating crisis. Research supported through HEAL is working to discover safer treatment options for pain management and expedite the development of therapies to treat OUD and reverse overdose.

Launching the HEALing Communities Study: As part of the HEAL Initiative, NIDA and SAMHSA have launched the HEALing Communities Study in Ohio, Kentucky, New York and Massachusetts, with more than $350 million in NIH funding, which aims to reduce opioid fatalities by at least 40 percent in participating communities over three years with a whole-of-society approach to combating the crisis.

Ending the HIV Epidemic

In the State of the Union Address on February 5, President Trump announced the historic goal of ending the HIV epidemic in the United States by 2030. The *Ending the HIV Epidemic: A Plan for America* initiative will leverage the powerful data and tools currently available to reduce new HIV infections in the United States by 75 percent in five years and by 90 percent by 2030. HHS immediately began work on the President's initiative.

Planning grants to key jurisdictions: The initiative identified 48 counties which account for more than 50 percent of the new HIV diagnosis and seven states with a disproportionate rural occurrence of HIV. CDC awarded all of these jurisdictions funds to conduct state and local planning as part of the new initiative.

Jumpstart grants to four jurisdictions: HHS kicked off the implementation phase of the initiative by announcing awards of $1.5 million each to three jurisdictions—DeKalb County, Ga.; Baltimore City, Md.; and East Baton Rouge, La.—to jumpstart activities on reducing the number of new HIV transmissions. In addition, the Indian Health Service awarded $1.5 million to the Cherokee Nation to begin implementation work.

Unprecedented expansion of access to preventive medication: HHS secured from Gilead Sciences, Inc., a historic donation of medication for pre-exposure prophylaxis (PrEP), taken daily to prevent HIV, for up to 200,000 uninsured, at-risk Americans for up to ten years, at no cost to the individuals. In December, OASH launched Ready, Set, PrEP, a national program that will make these medications available in pharmacies, including with donated dispensing and promotion services from a number of corporations.

Securing Year One funding: The President's FY 2020 Budget requested $291 million to fund the first year of Ending the HIV Epidemic, a request that was fully funded in the appropriations bill passed in December 2019.

Conducting deep community outreach: CDC leadership, in coordination with Secretary Azar, OASH, HRSA, and the Indian Health Service, visited 38 of the prioritized jurisdictions identified by the initiative. HHS leadership met with community leaders on the ground, including state, tribal, local, and territorial leaders, governors, members of Congress and staff, community-based organizations, and people living with HIV, with a goal of learning from the perspective

PRESIDENT TRUMP ANNOUNCED ON FEBRUARY 5, 2019, THE HISTORIC GOAL OF ENDING THE HIV EPIDEMIC IN THE UNITED STATES BY 2030

of communities hardest hit by HIV, including black and Hispanic Americans, American Indians and Alaska Natives, and gay men.

USPSTF recommendation on PrEP: AHRQ commissioned a review of the existing evidence on the benefits and harms of pre-exposure prophylaxis (PrEP) in high-risk populations, which has been shown to reduce the risk of acquiring HIV by up to 97 percent. AHRQ's review led to a new clinical practice recommendation from the U.S. Preventive Services Task Force encouraging clinicians to offer PrEP to people at high risk of acquiring HIV.

Using Title X as an avenue for PrEP: The Office of Population Affairs published resources for Title X family planning sites to help guide them through ways to add PrEP services for their clients, including how to prepare clinicians and staff for PrEP implementation, how to approach clients about PrEP, and other lessons learned.

Advancing epidemiology in Indian Country: IHS provided $2.4 million to enable Tribal Epidemiology Centers to strengthen public health capacity of tribal, urban Indian organizations, and intertribal consortia in developing or accelerating Native-specific community plans to end the HIV epidemic in Indian Country.

The first-ever HHS Global-Domestic HIV Meeting: In June, the Office of Global Affairs and the Office of Infectious Disease and HIV/AIDS Policy, hosted the first-ever HHS-wide meeting on combining the lessons of domestic and global HIV efforts, including data use, prevention, treatment, finding and testing, and adherence to treatment, bringing together HHS employees working on HIV-related programs globally and domestically, from CDC, HRSA, SAMHSA, NIH, FDA, IHS, OASH, and the Office of the Secretary.
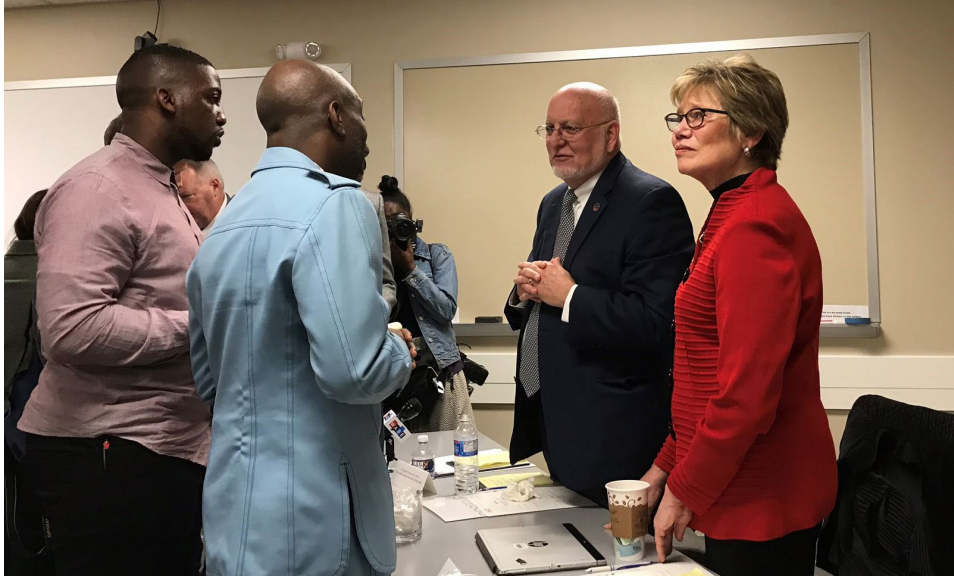
CDC Director Robert Redfield speaks to community members on an *Ending the HIV Epidemic* initiative visit

Record results for the Ryan White HIV/AIDS Program: In December, HRSA announced that clients of the Ryan White HIV/AIDS Program had reached a new record high for viral suppression, at 87 percent of clients, compared with 63 percent of the general population diagnosed with HIV. Viral suppression among people with HIV ensures longer, healthier lives, and also prevents further transmission of the virus, playing an essential role in helping to end the HIV epidemic.

New tool to help identify the right HIV treatments: FDA authorized marketing of the first next-generation sequencing test for detecting HIV-1 drug resistant mutations, which offers healthcare professionals a new tool in helping to select treatment options for their patients, as the right combination of antivirals can lower viral loads and help keep patients with HIV healthy for many years.

Approved new HIV Prevention and Treatment Drugs: In 2019, the FDA approved two new important products for the prevention and treatment of HIV: a new pre-exposure prophylaxis drug to prevent HIV infection, and a new two-drug regimen for HIV-infected patients who have never received antiretroviral treatment. The new two-pill regimen replaces a predecessor three-pill regimen, representing a new benefit to patients who may have issues taking multiple medications over a long period of time.

Advancing American Kidney Health

In July, President Trump signed an executive order to launch Advancing American Kidney Health, a bold new initiative to improve the lives of Americans suffering from kidney disease, expand options for American patients, and reduce healthcare costs.

A vision for better kidney health: The Office of the Assistant Secretary for Planning and Evaluation, in partnership with experts from across HHS, published a paper laying out the initiative's vision, including specific solutions to deliver on three specific goals: fewer patients developing kidney failure, fewer Americans receiving dialysis in dialysis centers, and more kidneys available for transplant.

Value-Based Payment Models for Kidney Care: In July, the Center for Medicare and Medicaid Innovation (the Innovation Center) announced the Kidney Care Choices Model, which adds financial incentives for providers to manage care for Medicare beneficiaries to delay the onset of kidney disease, increases the array of options for dialysis, and incentivizes kidney transplantation. Also in July, the Innovation Center proposed the End-Stage Renal Disease (ESRD) Treatment Choices Model, which would create financial incentives for clinicians and ESRD facilities to increase rates of home dialysis and kidney transplants. In October, the

Innovation Center began accepting applications for Kidney Care Choices, which is expected to include more than 200,000 Medicare beneficiaries.

Preparing an Educational Campaign: More than 30 million Americans have some stage of kidney disease, and most are not aware of it. As called for in the President's executive order, in October, HHS signed a memorandum of understanding with the American Society of Nephrology and the National Kidney Foundation to partner on an educational campaign to increase awareness of the signs and risks of kidney disease.

Proposing new accountability to increase the organ supply: Each year, more than 8,000 Americans die waiting for an organ transplant. Life-saving organs such as kidneys are obtained from deceased donors by organ procurement organizations (OPOs), private entities that are regulated by CMS. Longstanding concerns have existed about OPOs' varying performance, particularly because they are allowed to essentially self-report on their own work—allowing them to exclude difficult-to-procure or -transplant organs and potentially leading thousands of viable organs to be unused. In December, CMS issued a proposed rule to reform the way OPOs are held accountable, a proposal that attracted broad bipartisan support and support from former Obama Administration officials. Administration estimates suggest that the proposed rule could result in 5,000 more organs procured per year.

A proposal to expand support for generous living donors: HRSA issued a proposed rule to remove financial barriers to organ donation by expanding the scope of reimbursable expenses incurred by living organ donors to include lost wages and child-care and elder-care expenses incurred by a primary care giver.

New prizes from KidneyX: The novel public-private partnership, run out of the CTO's office, continues to advance innovation in the prevention, diagnosis, and treatment of kidney disease. Through 2019, KidneyX has awarded $1,000,000 in prizes to over 15 teams to advance testing of artificial kidneys, launched prize competitions to unlock ideas from those living with kidney disease, prototype redesigned dialysis, and issued a Request for Information to help shape a moonshot Artificial Kidney Prize.

Improving Maternal and Women's Health

Nearly 1 million home visits: HRSA announced $351 million in funding to 56 states, territories, and nonprofit organizations through its Maternal, Infant, and Early Childhood Home Visiting Program. Awardees showed improvement in 18 of 19 performance measures, providing voluntary, evidence-based home visiting for at-risk pregnant women and parents with children up to kindergarten, with 930,000 visits provided in 2019.

Ms. Tunisia Bullock speaks at a press conference at which President Trump signed an Executive Order on Advancing American Kidney Health

Testing new models to improve rural maternal health and obstetric care: In September, HRSA awarded nearly $9 million to launch the Rural Maternity and Obstetrics Management Strategies (RMOMS) program with partners in Missouri, New Mexico and Texas, to pilot, test, and develop models that improve access to and continuity of maternal obstetrics care in rural communities.

Supporting better data on maternal health: To better identify and characterize maternal deaths and identify prevention opportunities, CDC supported 25 states for the Enhancing Reviews and Surveillance to Eliminate Maternal Mortality (ERASE MM) program. This program coordinates and manages Maternal Mortality Review Committees that support CDC Perinatal Quality Collaboratives, which are networks to improve quality of care for mothers and babies.

A landmark year for promoting women's health at FDA: In the year that FDA's Office of Women's Health (OWH) marked its 20th anniversary, the FDA took significant steps to improve the health of American women:

OWH funded research projects on pulmonary embolism, which is the blockage of blood flow to the lungs by blood clots, and a leading cause of maternal death, and the development of an artificially intelligent virtual pregnant woman modeling suite to support regulatory decisions.

- Funding was allocated to evaluate the labeling compliance of dietary supplements targeted specifically to women, as well as evaluation of potential contamination of products that contain live microbes, with special emphasis on pregnant women and lactating women, and infants.
- FDA approved a variety of new therapies to help advance women's health, including:
  - a new targeted therapy for patients with a certain type of metastatic breast cancer;
  - a new biologic drug to treat osteoporosis in certain postmenopausal women at high risk of breaking a bone;
  - a new drug to treat premenopausal women with acquired, generalized hypoactive sexual desire disorder (low sexual desire); and
  - the first FDA-approved drug specifically for the treatment of women with postpartum depression (based on research from the National Institute of Mental Health)

GRANTEES IN HRSA'S TELEHEALTH NETWORK PROGRAMS REPORTED SAVING 3.1 MILLION MILES ANNUALLY FOR PATIENTS NOT DRIVING TO DISTANT PROVIDERS.

- In September, FDA's Center for Devices and Radiological Health unveiled a new Health of Women Program Strategic Plan, seeking input from stakeholders to help shape its implementation and aiming to work towards a better understanding of how medical devices perform in women and exploring unique issues in the regulation of medical devices related to the health of women.

Rural Health

Covering virtual check-ins: Starting in 2019, Medicare began to pay for "virtual check-ins," allowing a patient to check in with their clinician by phone or other telecommunication system and send videos or images their clinician and helping the clinician decide whether the patient needs to make a trip to be seen in-person.

Addressing wage index disparities for rural areas: CMS made changes to the hospital wage index in inpatient and outpatient settings that help address Medicare wage index disparities between high wage index and low wage index hospitals, which have been seen as disproportionately burdening rural hospitals.

New flexibilities for rural hospitals: CMS made it easier for hospitals to provide outpatient services under general supervision, which does not require a physician to be present for actual procedure, as opposed to the prior rule of direct supervision, relaxing a burden that can be a particular impediment for Critical Access Hospitals and hospitals in rural areas with limited access to providers.

Expanding access to telehealth in health centers: HRSA added standard language encouraging

telehealth to its funding opportunities, resulting in a 30 percent increase in awards that incorporate telehealth. Grantees in HRSA's Telehealth Network Programs reported saving 3.1 million miles annually for patients not driving to distant providers.

Commissioned Corps officers providing no-cost medical care to the vulnerable: The U.S. Public Health Commissioned Corps continued its partnership with Remote Area Medical, to provide no-cost medical, vision, and dental services to individuals in underserved and underinsured rural communities, with almost 600 Commissioned Corps officers deploying to nine mobile clinics across the country.

Protecting the Health of American Youth

A historic Surgeon General's advisory on marijuana: In August, the Surgeon General released an Advisory on Marijuana Use and the Developing Brain, which emphasizes the importance of protecting young Americans and pregnant women from the risks that marijuana poses to healthy brain development in adolescence and during pregnancy. Thanks to President Trump's donation of his paycheck from the second quarter of 2019, the Office of the Surgeon General released a digital ad campaign across Facebook, Instagram, Twitter, and Google Search targeted towards pregnant women and parents

of adolescents. The campaign, which ran seven weeks, resulted in 6,831,681 impressions, 344,030 clicks and 17,081 social engagements, with 158,350 visits to the advisory itself.

The first-ever blueprint for increasing youth sports participation: The Office of the Assistant Secretary for Health released the National Youth Sports Strategy, the first federal roadmap that outlines steps that communities, state and local governments, businesses, and other stakeholders can take to ensure that all youth have the opportunity, motivation, and access to play sports—regardless of their race, ethnicity, sex, ability or ZIP code. The strategy was announced by Secretary Azar, Surgeon General Adams, and Advisor to the President Ivanka Trump at an event at the Washington Nationals Youth Baseball Academy and Fort Dupont Ice Arena.

Supporting community collaboration for youth sports: As part of the Youth Engagement in Sports Initiative, the Office of Minority Health and Office on Women's Health co-funded 18 grantees with the aim of identifying characteristics of effective collaborations that improve physical activity and nutrition via increased sports participation, especially for disadvantaged youth or those in communities with no or few sports programs.

Members of the President's Council on Sports, Fitness, and Nutrition join Ivanka Trump, Advisor to the President, and HHS Secretary Alex Azar at an event launching the first National Youth Sports Strategy

Promoting Global Health and Global Health Security

Fulfilling the National Biodefense Strategy: In the first year following the release of the National Biodefense Strategy, HHS stood up and led the interagency Biodefense Coordination Team, issuing a data call on biodefense programs across the federal government, soliciting input from non-governmental stakeholders, and working to develop a comprehensive assessment of the U.S. biodefense enterprise. The process will culminate in a public report describing actions taken to reduce the risk of biological threat to the American people, to be released in 2020.

New health policy dialogues with key regional partners: Through the Office of Global Affairs, HHS convened two first-ever policy dialogues in 2019, one with Brazil and the other with Canada, to strengthen bilateral cooperation on a range of shared priorities, such as strengthening immunization rates, tackling the challenge of influenza preparedness, reducing rates of vaping in youth, combating the opioid epidemic, collaborating more closely on preventing anti-microbial resistance, and cooperation in multilateral fora. These meetings were the first of what are expected to become annual events to strengthen global health security in the Americas.

Protecting life and sovereignty around the world: Across the United Nations system and beyond—such as the United Nations General Assembly, the World Health Organization, and the Pan American Health Organization—HHS worked actively to support the sovereign right of nations to make their own laws on abortion, in the face of intense intimidation from U.N. agencies and other nations. As President Trump said at the 2019 U.N. General Assembly: "We are aware that many United Nations projects have attempted to assert a global right to taxpayer funded abortion on demand, right up until the moment of delivery. Global bureaucrats have absolutely no business attacking the sovereignty of nations that wish to protect innocent life." As part of an effort dubbed "Protecting Life on Global Health Policy," the Unted States government worked with countries to produce and present joint statements, with 8 countries at the World Health Assembly in May, 20 countries at UNGA in September, and with 10 countries at the Nairobi ICPD+25 in November, underscoring a joint commitment to protecting national sovereignty in matters that pertain to life and the

255,000 PEOPLE HAVE RECEIVED A VACCINATION FOR EBOLA VIRUS DISEASE

family. To secure these commitments, in July, Secretary Azar sent a letter with Secretary of State Mike Pompeo to urge countries to partner with the U.S., and HHS officials visited Hungary, Poland, Canada, St. Lucia, and Brazil to educate leaders on the initiative. In total, countries joining the initiative represented more than 1 billion people.

Boosting global health through FDA approvals: FDA approved the first live, non-replicating vaccine to prevent smallpox and monkeypox, authorized marketing of the first diagnostic for detecting Zika virus, and approved the first vaccine for the prevention of dengue disease.

Advancing Sickle Cell Disease treatment and cures globally: At the World Health Assembly in May, HHS held a side event on sickle cell in Sub-Saharan Africa, convening seven African delegations, Ministers of Health, the WHO, and professional societies, enabling the identification of major gaps in treatment and care. In August, HHS co-sponsored a side event on the same topic at the WHO Africa Regional Committee Meeting, alongside the First Lady of the Republic of Congo, Antoinette Sassou Nguesso. These meetings, combined with ongoing contacts with key bilateral and multilateral stakeholders in the region, are building efforts toward the development of an Africa-based Sickle-Cell-Disease initiative.

The Ebola Outbreak

In 2019, the outbreak of Ebola that began in August 2018 in the eastern Democratic Republic of the Congo (DRC) continued, but significant efforts by the United States have helped contain its spread and save lives.

Seeing the situation on the ground: In September, Secretary Azar, CDC Director Robert Redfield, and NIAID Director Tony Fauci, Admiral Tim Ziemer of the U.S. Agency for International Development, alongside officials from the

Members of the U.S. delegation to the Democratic Republic of the Congo speak with a boy who had just been told he no longer had Ebola in Butembo, Democratic Republic of the Congo

National Security Council, led a delegation to the DRC, Uganda, and Rwanda to see the situation on the ground and communicate the Trump Administration's commitment to bringing the outbreak to an end. Dr. Redfield had previously visited the region during the outbreak.

Running a historic clinical trial in a war zone: NIH advanced several promising agents for treating Ebola, including supporting the Pamoja Tulinde Maisha (PALM) clinical trial of four investigational agents for the treatment of patients with Ebola. Preliminary results indicated that individuals with Ebola receiving two of the treatments had a greater chance of survival, leading patients to now be randomized among the two more successful treatments.

A first-ever FDA-approved vaccine: The FDA approved a BARDA-supported vaccine for the prevention of Ebola virus disease, which, as part of an expanded access protocol, has been administrated to more than 255,000 people, including first responders, healthcare workers, burial providers, and contacts of Ebola cases. The research approach used to study the effectiveness and safety of this vaccine was precedent-setting during a public health emergency. The FDA granted the vaccine's application Priority Review, a Tropical Disease Priority Review Voucher, and a Breakthrough Therapy designation. Because of the public health importance of the vaccine, the FDA worked closely with the company to demonstrate safety and effectiveness of the vaccine in less than six months.

CDC continues large-scale deployments and technical assistance: As of December 13, 2019, CDC staff have conducted 573 deployments to the DRC, neighboring countries, and WHO headquarters to respond to the Ebola outbreak, complementing CDC permanent staff in the three high-risk countries bordering the outbreak—South Sudan, Rwanda, and Uganda—as well as the DRC. CDC's border health technical assistance has been used to improve the public health screening of more than 75 million travelers at 80 checkpoints in the DRC since the outbreak began. Swift efforts by CDC and international partners in Goma and Uganda extinguished transmission when cases emerged.

Fostering relationships to combat the outbreak: In April, Secretary Azar hosted a meeting with then recently elected DRC President Tshisekedi to discuss response efforts, as well as other key health issues in the country, and in September, Secretary Azar co-hosted a meeting with regional leaders, including President Tshisekedi, at the U.N. General Assembly on the same topic.

The South American Refugee Crisis

Addressing regional health crises and security: In response to the humanitarian and refugee crisis created by the failure of the illegitimate Maduro regime in Venezuela—the largest humanitarian crisis the Americas have ever seen—Secretary Azar continued a series of Americas Health Ministerial meetings to focus attention on and

discuss needs and solutions to the regional health crisis, with Ministerial meetings occurring in Peru and Colombia in 2019.

Delivering tangible victories to protect the health of refugees: HHS helped deliver a number of tangible accomplishments to promote refugee health, including the development of a Unified Vaccination Card for the region, a mental health training for healthcare workers to better assist traumatized refugees, and a continuing coordination mechanism that allows technical experts from the region to share information and make decisions.

Supporting the deployment of the USNS Comfort: The Commissioned Corps helped respond to the crisis by contributing staff to the USNS Comfort, a U.S. Navy hospital ship, as it sailed through Latin America, to provide medical assistance, with a total of 893 days deployed, as part of the inter-service humanitarian mission.

Fighting the Flu

New presidential leadership on the influenza: Each year, seasonal influenza sickens millions of Americans, hospitalizes hundreds of thousands, and kills tens of thousands, while an influenza pandemic is widely acknowledged to be the single greatest potential health threat. In 2019, President Trump signed an executive order to modernize flu manufacturing and protect Americans from the flu, and HHS took a number of steps as part of this work.

Increasing advanced flu vaccine manufacturing capacity: ASPR issued a six-year, $226 million contract to retain and increase capacity to produce recombinant flu vaccine, a more modern and efficient form of flu vaccine manufacturing. When the project is completed, it will double the awardee's recombinant protein-based flu vaccine manufacturing capacity in the United States.

Novel antivirals for flu infection: ASPR currently is supporting two novel antivirals for the treatment of hospitalized flu-infected patients, increasing America's capacity to treat people who become infected and prepare for a future flu pandemic.

Supporting better flu diagnostics: Through BARDA, ASPR continued pursuing better diagnostics for the flu that are closer to the patient supporting the development of two in home diagnostic tests and six wearable biometric sensors to inform and empower individuals to take action early.

A new ventilator for vulnerable populations: ASPR supported the development of a portable ventilator capable of providing mechanical respiratory support for critical care of newborn babies, adults and elderly patients. The Philips ventilator was cleared by FDA earlier this year for use in institutional, home, and field settings by minimally trained operators and is now stockpiled in the Strategic National Stockpile for immediate distribution when needed.

Secretary Alex Azar speaks with U.S. Public Health Service Commissioned Corps officers at an event launching the USNS *Comfort* mission to Latin America

NIH continues work toward a universal flu vaccine: NIH-supported research for "universal" influenza vaccines capable of generating protection against multiple seasonal and pandemic influenza strains continued in 2019, with the NIH establishing the Collaborative Influenza Vaccine Innovation Centers (CIVICs), a multidisciplinary program to support research and development of promising new influenza vaccine candidates. NIH also announced multi-year studies to examine how initial and repeated exposures to influenza viruses in childhood shape immune response to future influenza exposures and vaccines. In addition, the NIH Clinical Center launched a clinical phase I trial of an NIH-developed universal influenza vaccine candidate.

CDC support for flu testing and vaccine manufacturing: CDC developed and characterized more than 50 candidate vaccine viruses for vaccine manufacturers and characterized more than 10,000 influenza viruses with next-generation genetic testing, providing valuable information for vaccine improvement and drug development to increase uptake and reduce vaccine hesitancy.

Boosting Vaccine Confidence

A new push to promote infant immunization: To mark National Infant Immunization Week in 2019, leaders from across HHS—including Secretary Azar, Assistant Secretary for Health Brett Giroir, CDC Director Robert Redfield, NIH's Tony Fauci, and other officials from CMS and elsewhere—undertook a major media push, participated in TV and radio interviews, social media conversations, and other activities, generating tens of millions of impressions.

Global efforts to promote vaccine confidence: Together with Canada, the European Union, Romania, Ukraine, and Brazil, the U.S. hosted one of the largest side events of the World Health Assembly, entitled Promoting Vaccine Confidence: Enhancing Global Immunization Efforts to Protect the Health of All Generations, which galvanized support for increased global action on vaccine confidence. Following the side event, the United States began work on an immunization resolution for the 2020 World Health Assembly.

A new charge for the National Vaccine Advisory Committee (NVAC): Assistant Secretary for Health Brett P. Giroir charged the NVAC with developing a report that summarizes the

ASPR ISSUED A SIX-YEAR, $226 MILLION CONTRACT TO RETAIN AND INCREASE CAPACITY TO PRODUCE RECOMBINANT FLU VACCINE, A MORE MODERN AND EFFICIENT FORM OF FLU VACCINE MANUFACTURING

evidence and research in vaccine confidence and provides recommendations on strategies to improve vaccine confidence across the lifespan. This report will be submitted for vote during the September 2020 NVAC meeting.

Responding to Health Threats at Home

Real-Time Data on Disease Threats: CDC expanded the ability to investigate disease threats and share information through its National Syndromic Surveillance Program BioSense Platform. Data from 58 sites, representing 4,478 facilities, like emergency departments, can now be used as a real-time data source for healthcare providers to use in making quicker data-driven decisions to satisfy individual patient needs.

Investigating lung injury associated with use of e-cigarette, or vaping, products: CDC and FDA actively investigated the outbreak of e-cigarette, or vaping, product use–associated lung injury (EVALI), together with state and local health departments and clinicians. In a breakthrough, CDC laboratories detected vitamin E acetate in the lungs of lung injury patients, consistent with findings from FDA testing of products used by patients. These data, together with epidemiologic data showing most cases reported using THC-containing e-cigarette, or vaping, products from informal sources, provide direct evidence that vitamin E acetate is strongly linked to EVALI. At the time of publishing of this report, evidence is insufficient to rule out the contribution of other chemicals of concern in some of the reported EVALI cases.

FDA LAUNCHED "THE REAL COST" YOUTH E-CIGARETTE PREVENTION CAMPAIGN, A COMPREHENSIVE EFFORT TARGETING NEARLY 10.7 MILLION YOUTH, AGED 12-17, WHO HAVE USED E-CIGARETTES OR ARE OPEN TO TRYING THEM

Public health response to largest measles outbreak in decades: CDC led a major public health response to the largest measles outbreak since 1992, which threatened the nation's elimination status. More than 1,200 measles cases occurred in close-knit communities and were linked to travelers from other countries with large measles outbreaks like Israel, Ukraine, and Philippines. CDC assets were deployed alongside state and local health workers to stop the spread of the outbreak, successfully preserving the nation's measles elimination status.

Combating hepatitis A: CDC led an investigation into nearly 24,000 hepatitis A cases that were part of the widespread outbreaks affecting more than 29 states. Sixty percent of cases have resulted in hospitalization, and 236 people have died. CDC has helped every affected state in its outbreak response efforts.

Combating Nicotine Addiction and Tobacco Use

Tackling the surge in youth e-cigarette use: The 2019 National Youth Tobacco Survey, fielded by CDC and FDA, showed a continued increase in youth use of e-cigarettes, while the 2019 Monitoring the Future Survey, fielded by NIDA, showed that youth who primarily used a commonly sold cartridge-based brand of e-cigarettes, overwhelmingly used fruit, mango, mint, and other flavors. In response to these data, the FDA and leaders from across HHS developed a targeted approach to protecting youth from nicotine addiction, leading to the January 2020 announcement that FDA would prioritize

enforcement against illegally marketed cartridge-based Electronic Nicotine Delivery Systems (ENDS) of all flavors, excluding tobacco and menthol, while also prioritizing enforcement against any ENDS product that is targeted to minors or whose marketing is likely to promote use of ENDS by minors, and against all other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access.

Continuing CDC commitment to tobacco control: CDC provided funding and technical support to health departments through its National Tobacco Control Program, the only nationwide investment that supports all 50 states, the District of Columbia, eight U.S. Territories, and multiple American Indians/Alaska Natives tribes for comprehensive tobacco control efforts. In 2019, these entities prepared health advisories; collected state-level data on youth use of tobacco products, including e-cigarettes; and created and disseminated evidence-based educational materials about youth use of tobacco products, including e-cigarettes, to the public through social media and other mechanisms.

Educating youth about the dangers of e-cigarette use: FDA launched "The Real Cost" Youth E-Cigarette Prevention Campaign, a comprehensive effort targeting nearly 10.7 million youth, aged 12-17, who have used e-cigarettes or are open to trying them. The campaign features hard-hitting advertising on TV, digital and social media sites popular among teens, as well as posters with e-cigarette prevention messages in high schools across the nation.

Providing educational resources for teachers and administrators: FDA joined forces with Scholastic to develop educational resources about the use of e-cigarettes for high school teachers and administrators, distributed to more than 700,000 high school educators.

Surgeons general statement on tobacco product use in the uniformed services: Vice Admiral Jerome Adams, Surgeon General of the U.S. Public Health Service Commissioned Corps, joined with the Surgeons General of the Air Force, Army, and Navy to pen the first-ever joint letter on the impact of tobacco product use on force readiness in July 2019 and summarized resources available for service members to help them quit. In 2019, the Commissioned Corps remained the only tobacco-free uniformed service.

Responding to Natural Disasters

Protecting health and saving lives in disasters: In 2019, ASPR led the federal government's public health and medical response to seven hurricanes, two earthquakes, California wildfires, and five National Special Security Events. More than 2,120 federal disaster responders were deployed to help lead the response, along with 214 tons of medical equipment and supplies. ASPR also deployed 1,804 recovery specialists who dedicated more than 220,900 hours to rebuilding the capacity for health and social services in Puerto Rico, Florida, U.S. Virgin Islands, and California.

Training for first responders: Through HHS's Counter-Narcotics and Terrorism Operational Medical Support program, ASPR provided tactical medical training to 716 EMTs, paramedics, physicians, first responders and law enforcement officers in 2019. This nationally recognized training furthers the medical and public health response to terrorism and other incidents of national significance, including active shooter situations.

New steps for regional preparedness: ASPR continued to expand and demonstrate the effectiveness and viability of its Regional Disaster Health Response System pilot projects, which aim to improve the local, state, and regional situational awareness, integration, and coordination of medical response activities to a large-scale incident. The system builds on the success of ASPR's Hospital Preparedness Program, which in 2019 grew to include 32,000 health care coalition partners, including pharmacies, blood blanks, long-term care organizations, clinical labs, outpatient care centers, and medical supply chain organizations.

Preparing for medical countermeasure distribution: Through the Last Mile Pilot Program, ASPR collaborated with seven major U.S. cities to identify gaps and possible solutions for distributing and dispensing medical countermeasures during a public health emergency.

An unprecedented pandemic exercise: ASPR also led Crimson Contagion, the largest-ever exercise involving twelve federal departments/agencies, twelve states, 96 local jurisdictions, 24 native American Tribes, 87 hospitals, and more than 100 private sector partners.

A new opportunity for disaster-related healthcare innovations: ASPR released a new broad agency announcement—the equivalent of a request for proposals, with more flexibility to support innovators—called "ASPR Next," inviting proposals for next generation solutions such as cutting-edge technologies that transform drinking water to water for sterile injection/infusion or ensure hemodialysis in disaster settings.

Ongoing responses from a ready Commissioned Corps: In part using deployment teams that are

Secretary Alex Azar receives a briefing from Assistant Secretary for Preparedness and Response Robert Kadlec in the Secretary's Operations Center at HHS

At the United Nations General Assembly, Secretary Alex Azar joins representatives from other countries issuing a joint statement coalescing on the principle that there is no international right to abortion

ready to deploy within eight hours—as part of a force that stands at over 95 percent readiness—Commissioned Corps officers responded to 32 disaster responses, planned events, and community health and services mission, representing 12,372 days deployed.

Combating Anti-Microbial Resistance (AMR)

A new clarion call from the CDC: CDC published the second Antibiotic Resistance (AR) Threats Report, showing that antibiotic-resistant infections cause more than 35,000 deaths each year in the United States. This report, a follow-up to CDC's first AR Threats Report in 2013, which sounded the alarm about AMR and drove initial action by highlighting the 18 most dangerous bacteria and fungi that cause resistant infections in the United States. There was good news in the new report —an overall 18 percent reduction in deaths from antibiotic-resistant infections since the 2013 report, and a nearly 30 percent reduction in hospital deaths—but the new report found emerging threats and the need for new levels of cooperation and action.

Collecting an unprecedented set of government and private-sector commitments: In September, CDC marked the close of the AMR Challenge, a year-long global call to accelerate progress in the fight against AMR. In response to the challenge, governments from around the globe, NGOs, pharmaceutical and biotech companies, and

other private-sector businesses made nearly 350 commitments to fight AMR, such as commitments to reduce antibiotic use in animals.

Addressing the economic challenges for antibiotic development: CMS finalized an alternative, expanded pathway for a New Technology Add-On Payment for drugs designated by the FDA as Qualified Infectious Disease Products—for which new antimicrobials can qualify—and increased the potential add-on payment from 50 percent to 75 percent. CMS also finalized a change to inpatient payments that recognizes the added clinical complexity and cost of treating patients with drug resistance, to ensure that hospitals are not financially disadvantaged by using the most appropriate antimicrobial drug.

CDC testing to support healthcare providers: CDC tested more than 46,000 isolates for containment through the AR Laboratory Network, which aims to detect new and emerging drug resistance. CDC supported more than 360 responses to contain the spread of resistant pathogens.

Generating new knowledge for combating AMR: In 2019, AHRQ provided $10.6 million of funding for new and continuing investigator-initiated research grants to develop improved methods for combating antibiotic-resistant infections and improving antibiotic use.

Leading nations to fight AMR globally: During the World Health Assembly, the United States

sponsored and led a resolution, calling for WHO to take action on combating AMR, asking WHO to strengthen the One-Health Tripartite partnership—including WHO, the Food and Agriculture Organization, and the World Organization for Animal Health (OIE)—and providing for continued member state input on the implementation of WHO programs and activities. The resolution was adopted by all member states, with more than 40 co-sponsors across all WHO regions.

Working with India to combat AMR: HHS's Office of Global Affairs worked with counterparts from India to combat AMR by strengthen surveillance systems for AMR and Hospital Acquired Infections, facilitating a new Memorandum of Understanding between the HHS-funded CARB-X initiative and the Indian Department of Biotechnology to develop new antimicrobials, and engaging with Indian stakeholders on regulatory pathways for new antimicrobials.

Tackling Mental Health, Serious Mental Illness, and Suicide

Supporting inpatient treatment for serious mental illness: CMS approved the two first-ever demonstration approvals—for Vermont and Washington, D.C.—to support comprehensive mental health treatment by providing flexibility around Medicaid's bar on payment for treatment in institutes for medical diseases.

New resources from HRSA to help respond to mental health crises: In July 2019, HRSA launched a new ***Critical Crossroads:*** Pediatric Mental Health Care in the Emergency Department Toolkit to provide hospital emergency departments with resources to better manage and coordinate care for children and adolescents in mental health crisis.

Providing support for mental health services and schools: Through the Mental Health Technology Transfer Centers, SAMHSA under took new efforts to provide school-based mental health training and education, providing training to more than 10,500 school personnel, state officials, local officials and mental health practitioners.

Working with state governments: SAMHSA launched the SAMHSA/VA Governor's Challenge to Prevent Suicide among Service Members, Veterans and their Families, with the first cohort of seven states, focused on working to identify and support at-risk veterans and their families not in VA care. So far, examples of progress include training of military cultural competency for hundreds of providers in Virginia, expansion of screening for veteran status and suicide risk within healthcare systems in New Hampshire, and implementation of lethal means education and programming with gun shops in Colorado.

Working toward an improved suicide hotline: SAMHSA submitted the National Suicide

Assistant Secretary Elinore McCance-Katz speaks at the SAMHSA Prevention Day event

Hotline Improvement Act Report to the Federal Communication Commission (FCC), leading to the FCC recommendation that 988 be assigned as the nation's national suicide prevention hotline number. SAMHSA continued to support its suicide helpline, which fielded 2.1 million calls in FY 2019.

Training faith-based partners about mental illness: The Partnership Center worked to establish a two-way street of collaboration between faith communities and mental health professionals to help combat serious mental illness, including:

- Conducting six "Mental Illness 101" webinars, educating close to 9,000 registrants on different mental health disorders and ways in which faith and community leaders can better support individuals and their families experiencing these disorders.

- Convening more than 50 faith leaders for a national meeting — Small Acts of Great Love: Building a Framework for Faith Communities to Respond to Mental Illness — where leaders advised the Partnership Center on how to better engage faith leaders.

- Continued technical assistance to a learning collaborative of organizations and leaders working at the intersection of mental illness and faith communities, to discuss strategies for peer engagement, models for faith engagement in addressing mental illness, and best practices for applying for funding from SAMHSA.

- Hosting an expert panel meeting, in partnership with SAMHSA, to encourage mental health professionals to be more competent about religion and spirituality, and develop more understanding of how it can improve outcomes for clients.

Modernizing Food Safety and Oversight

Starting up routine inspections under the Produce Safety Rule: As part of implementing the Food Safety Modernization Act (FSMA), FDA initiated routine inspections of large farms for produce safety (other than sprouts operations), working under cooperative agreements with state regulatory partners to conduct 1,000 large farm inspections.

Tracking FSMA progress: In September, the FDA launched a Food Safety Dashboard designed to track the impact of the FSMA rules, measure their progress, and help the FDA continue to refine its implementation.

Using new technology to improve food safety: The FDA announced its intent to develop a new approach to food safety to leverage technology in creating a more digital, traceable, and safer food system, including the use of blockchain, sensor technology, the Internet of Things, and artificial intelligence. In October, the FDA held a public meeting and opened a Federal Register docket to hear from a broad cross-section of stakeholders on what concepts should be incorporated in the new initiative in order to strengthen the safety of the food supply.

Launching a historic modernization of dietary supplement regulation: The FDA announced a new plan for implementing one of the most significant modernizations of dietary supplement regulation and oversight in more than 25 years, which will include: the Dietary Supplement Ingredient Advisory List, a rapid-response tool to communicate more quickly when there are concerns about unlawful ingredients; a flexible regulatory framework; and new partnerships to protect public health. As one example, partnerships would include the creation of the Botanical Safety Consortium, a public-private enterprise that allows scientists from industry, academia, and government to explore and promote scientific advances in evaluating the safety of botanical ingredients and mixtures in dietary supplements.

STRATEGIC GOAL 3

Strengthen the Economic and Social Well-Being of Americans Across the Lifespan

Supporting and Protecting the Vulnerable

Enrolling the homeless in Head Start: In 2019, ACF's Office of Head Start launched the #HomeAtHeadStart campaign that focused on the enrollment of families experiencing homelessness into the Head Start program. Data showed six percent (approximately 60,000 families) enrollment of families experiencing homelessness; of these families, approximately 30 percent acquired housing while enrolled in Head Start.

Developing recommendations for family and youth homelessness: In 2019, ACF planned and hosted ten regional listening sessions on family and youth homelessness, allowing ACF leaders to learn about trends, barriers, and local innovative responses from a diverse group of more than 600 stakeholders. With this information, ACF is developing a summary report with recommendations that will empower families and youth to self-sufficiency.

Improving response to survivors of domestic violence: In 2019, SAMHSA and ACF issued a joint Information Memorandum calling for increased collaboration between domestic violence, mental health, and substance use disorder treatment service providers and systems, which highlights the prevalence of domestic violence among individuals receiving services in mental health and substance use disorder treatment settings and offers information about training, resources and strategies for improved collaboration between systems.

Caring for an unprecedented influx of Unaccompanied Alien Children: ACF cared for an unprecedented number of Unaccompanied Alien Children (UAC), while HHS secured emergency funding from Congress. ACF worked to maintain consistent, high-quality care and safely unify children with sponsors and identified legislative flexibilities to help to procure facilities for care of UAC that can be more appropriately scaled to meet the needs of the program. ACF was able to expand capacity to care for 69,440 children referred from the Department of Homeland Security in FY 2019, the highest in the program's history, and lay a foundation for a more flexible, sustainable system to care for children in the future.

Boosting Health, Work, and Upward Mobility

Laying the groundwork for better access to child care: In 2019, ACF's Office of Child Care facilitated partnerships across HHS, ACF and the White House to plan and implement ten regional roundtables on access to child care, involving more than 900 participants and culminating in a summit at the White House in December, at which the White House released a comprehensive set of child care principles to spur action in the administration, in Congress, and at the state and local level.

Launched public-private partnership on economic mobility: In 2019, ACF started a public-private partnership to advance economic mobility, garnering the support of six New England state agencies and legislatures, and the Federal Reserve Banks of Boston and Atlanta. The partnership's work resulted in 17 new state policies and legislation introduced, and adoption by the National Conference of State Legislatures of a national resolution to address benefits cliffs and work disincentives.

Assessing the state of human services: In 2019, ACF produced the first-ever report on state and

Assistant Secretary Lynn Johnson, Governor Mike Parson, Advisor to the President Ivanka Trump, Secretary Alex Azar, and Senator Roy Blunt visit a Guadalupe Centers classroom

county human services leadership data and recommendations on moving toward an out-comes-based, person-centered human services delivery system that streamlines federal bureaucracy and cuts red-tape. ACF presented these findings to member agencies of the newly established U.S. Interagency Council on Economic Mobility, chaired by Secretary Azar.

A challenge to expand hiring of Americans with disabilities: The Administration for Community Living (ACL) issued a challenge to businesses to develop recruiting and retention programs to better include workers with disabilities—par-ticularly people with intellectual and develop-mental disabilities—and to display leadership in addressing this critical economic issue. The initiative aims to identify models that can be shared to help businesses across the country reach a wider talent pool and to create more opportunities for employment for people with disabilities. Funds will be awarded in 2020 to help winners test and implement programs.

Supporting Independence of Older Adults and People with Disabilities

Helping older adults live independently: The Home and Community-Based Supportive Services program funds a combination of sup-ports tailored to the individual that help older

adults remain in their own homes and communities rather than entering nursing homes or other types of institutional care. In 2019, these programs provided an estimated 22 million rides to doctor's offices, grocery stores, pharmacies, senior centers, meal sites, and other critical daily activities, more than 40 million hours of personal care, homemaker, and chore services, and more than 10 million hours of adult day services.

Making Medicare and Medicaid work for the elderly: CMS modernized the Programs of All-Inclusive Care for the Elderly (PACE) with a fully integrated model of managed care service delivery for the frail elderly, most of whom are "dual-eligible beneficiaries" on both Medicare and Medicaid, by providing more opportunities for states to test approaches to serving these individuals. CMS also improved quality of care for dual eligibles through the 2020 Medicare Advantage rule, which requires plans to integrate benefits for beneficiaries enrolled in Dual Eligible Special Needs Plans and to make it easier for enrollees in these plans to navigate their coverage.

Advancing person-centered planning and improving quality: In January, ACL and CMS launched the National Center on Advancing Person-Centered Practices and Systems to help systems serving people with disabilities and older adults to embrace, adopt, and implement person-centered principles. The National Quality Forum launched a project to develop a national

consensus on person-centered planning and provide a preliminary recommendation to HHS on the development of standards and quality measures for person-centered planning.

Addressing health disparities for people with disabilities: In October, ACL awarded a new grant totaling $1.5 million over three years to establish the Center for Dignity in Healthcare for People with Disabilities at the University of Cincinnati Center for Excellence in Developmental Disabilities. This center is a first-of-its-kind investment aimed at educating medical professionals about the civil rights and support needs of Americans with disabilities as they access routine and lifesaving care from the beginning of life until its natural end. It will develop resources for reporting healthcare discrimination and advocating for people with intellectual and developmental disabilities in partnership with them and their families.

Widespread adoption of innovative technology for those with disabilities: "Visual scene displays" (VSD) are an alternative method of presenting information, using visual scenes rather than written or spoken text, that can be used to present information to people with speech or language problems. VSDs were developed with funding from ACL's National Institute on Disability, Independent Living and Rehabilitation Research, and have been shown to be effective in helping adults with severe chronic aphasia, primary progressive aphasia, dementia, and other conditions. 2019 saw

technology adopted by all manufacturers and app developers who serve these populations, providing speech language clinicians and practitioners effective and easier-to-use options to help the people they serve.

Supporting Family, Foster, and Adoptive Caregivers

Working to reduce number of children in foster care: A 2019 report, developed with Adoption and Foster Care Analysis and Reporting System (AFCARS) data, shows that the number of children in foster care decreased at the end of FY 2018 for the first time since 2011, while the number of children entering care dropped. ACF continued its work to focus on prevention and support children and families to help keep children from needing to enter foster care. In September 2019, the Children's Bureau within ACF announced the first year of a five-year award of nearly $25 million to nine community-based projects to help prevent child maltreatment, reduce entries into foster care, and meet the needs of families before a crisis occurs.

Record number of adoptions: The number of adoptions with U.S. child welfare agency involvement increased to over 63,100 in FY 2018, the largest number of adoptions reported by AFCARS since AFCARS data collection began in FY 1995.

Assistant Secretary Lynn Johnson speaks at the 2019 National Adoption Day Celebration at HHS

Assistant Secretary Lance Robertson and Deputy Secretary Eric Hargan speak with a Walter Reed Community and Senior Center client

Working toward a national family caregiver strategy: In 2019, ACL hosted the inaugural meetings of the two advisory councils established by the RAISE Family Caregivers Act and the Supporting Grandparents Raising Grandchildren Act: the RAISE Family Caregiving Advisory Council and the Supporting Grandparents Advisory Council. The year closed with both councils seeking public input to inform the development of strategies to guide their ongoing work.

Advancing Tribal Programs and the Government-to-Government Relationship

Task Force on Missing and Murdered American Indians and Alaska Natives: In 2019, President Trump signed an Executive Order Establishing the Task Force on Missing and Murdered American Indians and Alaska Natives. ACF's Commissioner of the Administration for Native Americans (ANA), Jeannie Hovland, was named as one of the task force members. The task force will lead in developing and publishing best-practices guidance for use by federal, state, local and tribal law enforcement in cases involving missing and murdered American Indians and Alaska Natives.

Creation of Stop, Observe, Ask, and Respond (SOAR) Network: In 2019, ACF's Office on Trafficking in Persons, in partnership with ANA and IHS,

created the Stop, Observe, Ask, and Respond (SOAR) for Native Communities, a free online training that will help those serving indigenous populations better understand human trafficking and its impact on Native peoples.

Implementing NIH strategic plan for tribal health research: The NIH Tribal Health Research Office (THRO) implemented NIH's first strategic plan for Tribal health research and facilitated the first-ever Tribal data-sharing and use agreement between the Environmental influences on Child Health Outcomes (ECHO) research program grantees and the Navajo Nation, who will share participant data on a nationwide platform to ultimately improve the health of Navajo mothers and children. This data-sharing agreement could be used as a blueprint for data-sharing agreements with other Tribes.

Integrating traditional medicine as part of comprehensive care: In collaboration with NIH and CDC, the THRO coordinated the largest Native-led traditional medicine summit ever held, bringing together traditional healers and allopathic practitioners to discuss the sustainability and culturally respectful integration of traditional healing practices to manage pain and provide comprehensive health care to Tribal patients.

Tackling suicide in Indian Country: In 2019, IHS launched the Ask Suicide-Screening Questionnaire pilot project, in collaboration with the National Institute of Mental Health, to initiate universal suicide screening in the

American Indian and Alaska Native population. The pilot project will provide universal screening for all patients in the two selected IHS emergency departments, capturing patient-related data and initiating a suicide risk assessment protocol to ensure quality care.

Protecting Life & Conscience

Title X Final Regulation: In March 2019, HHS finalized a new Title X regulation that ensures compliance with the law as passed by Congress, including the statutory prohibition on funding programs where abortion is a method of family planning. The rule provides for physical and financial separation between Title X–funded family planning services and abortion-related activities. Rather than comply with the Title X final rule, certain former grantees relinquished their grants. The HHS Office of Population Affairs awarded the relinquished funds (more than $33.6 million) to 50 of the remaining grantees. These funds will be used to expand services in unserved or underserved areas.

Enforcing conscience rights: In January, the HHS Office for Civil Rights (OCR) notified the State of California that its law requiring pro-life pregnancy resource centers to refer clients for abortions, by posting notices about free or low-cost family planning services and abortion, violated the Weldon and Coats-Snowe Amendments. This is the first time that any state has been found in violation of these laws, reflecting HHS's heightened commitment to enforcing conscience protection statutes.

The Affordable Care Act and abortion: In December, CMS issued a final rule to require issuers of Qualified Health Plans—individual market insurance plans sold through Exchanges under the Affordable Care Act (ACA)—to bill and send separate invoices for insurance coverage of abortions that cannot receive government funding under the Hyde Amendment (i.e., not in cases of rape, incest, or threatening the life of the mother). CMS also provided enforcement discretion for issuers to allow an enrollee who fails to pay the premiums for such abortion coverage, including for reasons of conscience, to continue only their health coverage without being terminated for failure to pay the abortion premium.

Protecting religious freedom and avoiding undue burden in HHS grants: In November 2019, HHS issued a proposed rule that would revise certain regulatory provisions adopted by the previous administration that concerned faith-based organizations, and foster care and potential adoptive families and children. At the same time, HHS issued a notice of nonenforcement of these and other regulatory provisions adopted by the previous administration because of concerns that the prior regulations had not gone through the proper review under the Regulatory Flexibility Act.

Commissioner of the Administration for Native Americans Jeannie Hovland shakes hands with President Donald Trump after the signing of an Executive Order Establishing the Task Force on Missing and Murdered American Indians and Alaska Natives

Addressing funding of research involving human fetal tissue from elective abortions: In June 2019, HHS announced an administration policy with respect to the use of human fetal tissue from elective abortions in HHS-conducted or -funded research: Intramural NIH research that requires acquisition of human fetal tissue from elective abortions will not be conducted, and new extramural grant applications, or current research grants in the competitive renewal process, that propose to use fetal tissue from elective abortions and that are recommended for potential funding through NIH's two-level external scientific review process will be reviewed by an ethics advisory board which would recommend whether, in light of ethical considerations, NIH should fund the research project.

Protecting conscience in foster care and adoption: In January 2019, HHS issued an exemption from certain regulatory requirements to help protect the right of various faith-based non-profits in South Carolina to retain their religious character while partnering with the state in providing foster care services.

Safeguarding Patients' Rights

Ensuring the right of patients to timely access to their health information: In February 2019, OCR announced the HIPAA Right of Access Initiative, which aimed to vigorously enforce the right of individuals to get access to their health records promptly, without being overcharged, and in the readily producible format of their choice. OCR initiated investigations throughout the country, and completed two settlements with covered entities that failed to provide individuals their medical records.

Impactful agreement to improve processes for investigating and resolving Title IX and Section 1557 complaints: In August 2019, OCR secured an agreement with Michigan State University to resolve an investigation into sexual abuse by Larry Nassar. In October, OCR also kicked off a new Sex Discrimination Initiative at the ESPNW Summit.

Protecting parents with disabilities from discrimination: In December, OCR announced a voluntary resolution agreement and ensured that Child Welfare Programs in the Oregon Department of Human Services protect parents with disabilities from discrimination. OCR had initiated a compliance review of the department following news reports and a complaint from an advocate alleging that Oregon had removed two infant children from a mother and father with disabilities and denied the parents effective and meaningful opportunities to reunite with their children due in significant part to their allegedly having IQ scores that were too low.

Advancing regulatory reform efforts to revise ACA: In May, OCR proposed to revise ACA Section 1557 Nondiscrimination Rule, to follow the law as passed by Congress and eliminate billions in unnecessary costs.

Ensuring access to transplants for Americans with disabilities: In February, OCR resolved a complaint involving the refusal to place a person with disabilities on an organ transplant list, a discriminatory and potentially life-threatening issue for the patient with disabilities.

Taking action to stop discrimination against patients with HIV: In October, OCR secured corrective action and ensured that a Florida orthopedic practice protects patients with HIV from discrimination. The enforcement action included having the provider amend its nondiscrimination policies and revise its procedures for dismissing any patient from the practice. The provider also agreed to provide staff with multiple trainings on HIV, federal non-discrimination laws, grievance procedures, and the requirement to refrain from retaliatory actions.

Foster Sound, Sustained Advances in the Sciences

Supporting Priority and Breakthrough Research at NIH

Accelerating diagnosis of genetic diseases in newborns: Researchers supported by NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development combined whole genome sequencing with artificial intelligence to speed diagnosis of genetic diseases in newborn infants. Their approach diagnosed a typical case in 20 hours, compared with 16 days for traditional sequencing, which could one day help diagnose rare genetic disorders more quickly, providing much-needed time for care and treatment.

Making inroads toward a cure for sickle cell disease: In August, the latest findings from an NIH-supported clinical trial for a novel gene replacement therapy in patients with severe sickle cell disease indicated that the therapy has succeeded in 17 patients, with no clinical complications. The new gene produces normal red blood cells and healthy hemoglobin, and it seems to alleviate the painful crisis that mark this life-threatening condition. One of the patients who has experienced a successful recovery was featured on *60 Minutes* in March.

Unprecedented study on type 2 diabetes: Researchers from the National Human Genome Research Institute published the largest genomic study of type 2 diabetes in sub-Saharan Africans, with data from more than 5,000 individuals from Nigeria, Ghana, and Kenya. Researchers confirmed known genomic variants and identified a novel gene ZRANB3, which may influence susceptibility to the disease in sub-Saharan African populations and could influence the development of the disease in other populations, which may yield a simple,

yet vastly effective way of treating it in a personalized manner.

Taking steps on Alzheimer's disease-related dementias: To spur innovation in meeting the challenges of complex care management for people with dementia—and the most common dementia diagnosis, Alzheimer's disease—NIH funded a new effort, the Imbedded Pragmatic AD/ADRD Clinical Trials (IMPACT) Collaboratory. NIH's National Institute on Aging established the IMPACT Collaboratory to meet the urgent public health need to deliver high quality, evidence-based care to people living with dementia and their caregivers within the healthcare systems that serve them. NIA also awarded three prizes as a part of its Eureka prize competition to develop new technology applications to improve dementia care coordination and/or care navigation. Several NIH-supported research advances in the field were also made, including the identification of a protein that might act as a protective factor, slowing down the rate of cognitive decline in Alzheimer's patients, and identification of five new AD risk genes, as a result of large-scale data sharing across several data centers in the largest-ever Alzheimer's gene study.

Partnering with the Private Sector

BARDA hits 50 FDA approvals as part of accelerating medical countermeasures: Through BARDA and other avenues, in 2019, ASPR and its partners:

- Earned the 53rd FDA medical countermeasure approval/clearance, with 12 of those occurring in the 2019 alone, including:
  - the first treatment for blister injuries caused by sulfur mustard;

NIH Director Francis Collins and *All of Us* Chief Engagement Officer Dara Richardson-Heron take part in a live stream about the research program

- – a one-size fits all ventilator that is portable, easier to use, and less costly to maintain;
  - – three Zika diagnostic tests; and
  - – the first rapid diagnostic test for detecting Ebola virus antigens.
- · Advanced the development of:
  - – the first Marburg and Sudan Ebola virus vaccines;
  - – a next-generation burn imaging device; and
  - – technology that, for the first time, could produce blood platelets outside the human body.
- · Transitioned the first antimicrobial product, a diagnostic, from CARB-X to BARDA. The graduation from CARB-X early development to BARDA's advanced clinical development marks an important milestone toward the goal of approval for use with hospitalized patients.

Over the last 15 years, ASPR has supported 27 medical countermeasures using Project BioShield authorities and funding, and added 16 products to the Strategic National Stockpile (of which 13 have achieved FDA approval or clearance, with the others potentially available under Emergency Use Authorization).

Advancing plant and animal biotechnology innovation: In FY 2019, the FDA published the Plant and Animal Biotechnology Innovation Action Plan, providing an overview of priorities the FDA will pursue to support innovation in American agriculture and food technology, while advancing the agency's public health mission.

Using public-private partnerships to tackle tick-borne diseases: Led by the CTO's office, institutions participLed by the Office of the Chief Technology Officer, institutions participating in a public-private partnership published the first-ever Lyme Innovation Roundtable Summary Report, and developed four new digital tools including symptom-tracking technologies, gamification of tick-prevention education, and interactive heat-maps in a "TickTracker" free app to report ticks in real time, to help people stay safe from tick bites.

Adapting and expanding NIH's study of Parkinson's Disease: As part of the Accelerating Medicines Partnership (AMP), NIH and partners launched AMP Parkinson's Disease, to focus on identifying and validating promising markers of the disease to track progression and eventually develop biological targets for discovery of new drugs. In November, the AMP PD partnership announced the opening of its Knowledge Portal to the research community. The portal, including de-identified clinical, genomic, and transcriptomic information from nearly 4,300 Parkinson's disease patients and healthy controls. It allows researchers to study complex data sets and perform genome-wide analyses at a scale previously impossible.

Tackling a shockingly common killer, sepsis: One in three Americans who die in a hospital die of sepsis, a condition that affects more than 1.7 million Americans each year and represents not only an every-day threat, but a deadly challenge in the event of a mass casualty attack or natural disaster as well. As part of its Solving Sepsis program, ASPR awarded 10 contracts valued at $35.6 million to improve awareness, prediction, diagnosis, prognosis, treatment, and recovery of sepsis, aiming to reduce the incidence, morbidity, mortality, and cost of sepsis by investing in these six key strategic areas.

Harnessing Real World Evidence

Launch of an All of Us Research data browser: The All of Us Research Program is an ambitious effort, launched by NIH in 2018, to partner with 1 million or more people from diverse backgrounds to share information with the goal of advancing precision medicine research. In May 2019—just one year after its national launch—the Program released its interactive Data Browser, providing participants and researchers their first look at the expansive and most diverse data resource ever compiled. So far more than 300,000 people have enrolled from all 50 states, including more than 236,000 participants who have completed all of the initial steps of the program. Of these participants, 80 percent represent communities that are historically underrepresented in research, including 51 percent from racial and ethnic minority groups.

Sharing data to improve tribal health outcomes: In May, the Deputy Secretary oversaw the first tribal data-sharing agreement for a nationwide research consortium creating a large-scale database, facilitated by NIH, between the Navajo Nation and NIH grantees of the Environmental influences on Child Health Outcomes Program, which studies the effects of a broad range of early environmental influences on child health and development.

Making Strides in the War on Cancer

Kicking off the Childhood Cancer Data Initiative: In the 2019 State of the Union, President Trump announced that NIH would be launching the Childhood Cancer Data Initiative, and putting $500 million in new funding over 10 years towards childhood cancer research at the National Cancer Institute. Later in the year, as part of the FY 2020 spending bills, Congress appropriated of the first year of these funds, $50 million.

New research on childhood brain cancers: Robotics-enabled, high-throughput screening technologies at NIH enabled researchers to identify a drug pair that shows promise for treating a group of deadly childhood brain cancers collectively called diffuse midline gliomas. The studies, published in November, also uncovered a previously unrecognized vulnerability in the cancer cells that scientists may be

Assistant Secretary Robert Kadlec speaks at the 2019 ASPR Award Ceremony at HHS

National Institute of Allergy and Infectious Diseases (NIAID) Director Anthony Fauci and NIAID Deputy Director for Clinical Research and Special Projects H. Clifford Lance speak with colleagues at NIH

able to exploit to develop new strategies against the cancer and related diseases, and planning is now underway for a clinical trial of the drug combination once dose assessment is complete for each drug.

Awards through the Cancer Moonshot^SM Initiative: As of FY19, NIH's Cancer Moonshot initiative funded over 150 high impact projects, in a diverse array of research areas including advancing immunotherapy, understanding drug resistance, improving the implementation of proven prevention strategies, focusing on pediatric cancer, and sharing big data to identify commonalities across cancer types and, with enough data, across individual cancer cases.

Advancing personalized cancer treatment: The I–PREDICT clinical trial, which was conducted by an NIH-funded investigator team people with advanced cancer whose disease had progressed despite previous therapy, successfully implemented molecular profiling approach to combination therapy. The study demonstrated the feasibility of using tumor DNA sequencing to match patients with individualization combination therapy —in many cases involving immunotherapy. The study reported promising outcomes for patients with a higher number of matched genetic alterations. If confirmed, this result will advance the use of molecular profiling in clinical practice.

Promote Effective and Efficient Management and Stewardship

Stopping Healthcare Fraud

*Fighting improper payments in Medicare: T*he estimated improper payment rate in Medicare decreased from 8.12 percent in 2018 to 7.25 percent in 2019, the third consecutive year the rate has been below the 10 percent threshold for compliance established by Congress in 2010. In addition, through the Medicare Address Validation project, CMS prevented between $5 and $23 billion in fraud in 2019.

Taking down largest healthcare fraud scheme ever charged: Two Florida residents were convicted in the largest healthcare fraud scheme ever charged by federal authorities, in which the scheme's leader bribed doctors into admitting patients into his care facilities. In addition to billing Medicare and Medicaid a record $1.3 billion in fraudulent claims, the facilities provided inadequate care.

Protecting taxpayer funds: In 2019, the Office of Inspector General returned some $5.9 billion in taxpayer funds (overwhelmingly related to Medicare and Medicaid), excluded 2,640 bad actors from billing HHS programs, and brought more than 1,400 civil and criminal actions against wrong doers.

Regulatory Reform and Simplification

Top federal agency in reducing regulatory burden: For the second year in a row, HHS ranked first overall among all federal agencies in reducing the present-value economic burden of its regulations by $11.4 billion. From FY 2017 to 2019, HHS achieved a total reduction in economic burden of $25.7 billion in present-value savings, with 46 deregulatory actions compared with just 18 regulatory actions—approximately a 2.5:1 ratio

Reducing burdens on providers to allow more time to be spent on care: As part of the Meaningful Measures Initiative, CMS eliminated 79 measures across quality payment programs that resulted in projected savings of $128 million across provider settings. Through the Omnibus Burden Reduction Rule, CMS implemented changes to save providers an estimated 4.4 million hours of time previously spent on paperwork with an overall projected savings to providers of $800 million annually. Additionally, the Office of the National Coordinator for Health Information Technology (ONC) and CMS jointly published a draft *Strategy on Reducing Regulatory and Administrative Burdens Relating to the Use of Health IT and EHRs* for public comment.

Fixing Federal Register mistakes and inconsistencies through AI: The Deputy Secretary's office initiated an experimental AI-enabled review of all HHS regulations that identified hundreds of technical errors and over 50 opportunities to remove paperwork submission requirements—especially outdated requirements like faxes. This effort was featured in September at the White House AI in Government Summit, and is now being implemented through a coordinated effort across the department to issue new rules corrections that will clean up HHS regulations and rescind unnecessary and outdated requirements.

Achieving Results with ReImagine HHS

Coordinated through the Deputy Secretary's office, *ReImagine HHS* involves ten ongoing initiatives that are empowering career civil servants to fulfill the department's mission more effectively. Accomplishments from 2019 include:

FOR THE SECOND YEAR IN A ROW, HHS RANKED FIRST OVERALL AMONG ALL FEDERAL AGENCIES IN REDUCING THE PRESENT-VALUE ECONOMIC BURDEN OF ITS REGULATIONS BY $11.4 BILLION IN FY 2019

Moving to a 21st century workforce: Under the "Maximize Talent" initiative, HHS's Office of Human Resources implemented a reform pilot in the Washington D.C. area HR Center to include shared certificates, which expedited the recruitment and hiring process by allowing multiple managers to select from the same candidate pool. An average of 73 percent of candidates selected during the pilot (Q1-Q3) were from simplified recruitments (either shared certificates or other express hires) resulting in a 168 percent increase in the number of new hires scheduled to enter on duty.

Improving NIH operations: The "Optimize NIH" initiative launched the FOIAXpress platform and public request portal in the second quarter of FY 2019, allowing NIH to increase the number of processed FOIA requests by 126 percent and decreased its FOIA backlog by 24 percent.

Reforming acquisitions: The "Buy Smarter" initiative has used blockchain technology, artificial intelligence, and machine learning to identify opportunities to achieve over $720 million in annual cost avoidance and savings on goods and services, once fully operational. By the end of FY 2020, HHS anticipates realizing between $6 and $9.5 million in cost avoidance and savings related to these efforts.

Accelerating clinical innovation: The "Accelerate Clinical Innovation" initiative established a partnership with FasterCures to engage public and private partners in shared efforts to further map, accelerate, and measure the innovation ecosystem at HHS.

Making HHS more innovative and responsive:

Under the "Optimizing Regional Performance" initiative, HHS developed a Regional Facilities Utilization Model that has identified $150 million in potential savings at four regional offices and a 62 percent reduction in footprint within ten years. At the same time, three divisions have realigned their regional offices, eight offices have created optimization plans, and the role of HHS's Regional Directors has been strengthened to maximize collaboration across the regions and within HHS and provide increased authority and oversight.

Building Budgetary and Operational Excellence

Enterprise Infrastructure Solutions: HHS began implementing its new Enterprise Infrastructure Solutions contract, which includes high-speed circuits to support the HHS network, audio conferencing, voice-over internet protocol, and cloud services that will yield a cost savings of at least $111 million over the life of the 13-year contract period. Establishing a single program office for the contract, HHS will net an additional $86 million in cost avoidance.

Upgrading human capital management: In May, the Office of the Assistant Secretary for Administration (ASA) successfully upgraded HHS's central enterprise human capital management system, representing the culmination of more than 9 months of focused effort to create a lasting baseline and single cloud-based solution for managing HHS personnel transaction and reporting. In less than two months, the team trained more than 3,500 users and implemented a retroactive pay raise resulting in more than 90,000 pay adjustments in the middle of the transition to the new system, while keeping the project $12 million under budget.

Faster processing of FEVS results: In 2019, HHS adopted an Employee Viewpoint Survey Analysis and Results Tool (EVS ART), an innovative, no-cost tool developed by the NIH's National Institute of Diabetes and Digestive and Kidney Diseases to automate analysis of the Federal Employee Viewpoint Survey, reducing agency processing time from weeks to minutes. The tool has now been provided as a resource to every executive department as a way to help agencies identify the lowest scoring 20 percent of work units and set goals for improvement under the President's Management Agenda.

Bolstering OMHA workforce: In 2019, the Office of Medicare Hearings and Appeals (OMHA) took important steps to bolster its workforce and enhance efficiency, enabling it to beat a target for reducing the appeals backlog. OMHA:

· Hired 51 new Administrative Law Judges (ALJs) and 14 transferring ALJs from other agencies by the end of FY 2019.

· Successfully added four new field offices and a new satellite office in 2019, increasing adjudication capacity by almost 80 ALJs and 700 essential adjudicatory and support staff positions.

· In total, nearly doubled the size of its workforce by the end of FY 2019.

· Slashed the appeals backlog by approximately 30 percent in FY 2019, surpassing the reduction target that was mandated for the Department in *American Hospital Association vs. Alex Azar.*

Moving to more electronic appeals processing: In 2019, the Departmental Appeals Board (DAB) continued with the Medicare Operations Division's Digital Transformation Initiative, by enhancing the division's electronic case management system to permit direct upload of work product and related documents. This has allowed the DAB to coordinate with CMS to implement the electronic upload of claim files directly from CMS contractors to the Medicare divisions case processing system—saving time, minimizing the amount of paper changing hands, and eliminating the need for physical mailing.

Developing and implementing digital communication strategy: Across HHS, operating and staff divisions are working with the Assistant Secretary for Public Affairs on the development and implementation of an HHS Digital Communications Strategy to modernize communications work across the department and improve the Department's ability to communicate effectively with the people it serves. A key driver of the strategy development is the 21st Century Integrated Digital Experience Act ("IDEA") that requires agencies to modernize to meet current communication expectations of the American public for both external and internal digital communications products.

Making HHS a Better Place to Work

Best cabinet-level agency at which to work: HHS was ranked the best cabinet-level agency to work at in the Federal Government for the third year in a row, according to the 2019 Federal Employee Viewpoint Survey (FEVS) results. To drive increased FEVS participation and engagement, ASA developed and executed an eight-week enterprise communications campaign that included department-wide e-blasts, senior leader video messages, and promotional marquees on the HHS Intranet and HHS TV monitors, contributing to an HHS Employee

Deputy Secretary Eric Hargan presents Gears of Government Awards to HHS employees

Secretary Alex Azar and HHS employees participate in Public Service Recognition Week activities at HHS

Engagement Index increase of 0.7 percentage points in 2019, to 73.5, which is 5 points higher than the overall government-wide average.

Modernizing and simplifying hiring at SROC: HHS's central Staffing, Recruitment, and Operations Center (SROC) created three hiring options—Standard, Complex, and Express—with approximately 80 percent of hiring actions now done utilizing the Express method. This enabled shifting SROC's workload from low-value, high-volume transactional work to high-value, customer-focused work. In addition, twelve Op Divs and Staff Divs serviced by SROC began an Enterprise Shared Certificates Program Pilot, the first of its kind in the federal government, leading to an increase of its hires by more than 200 percent since implementation.

Improving SES oversight, performance, and position management: ASA developed a new Charter to establish the Executive Resource Board (ERB), chaired by the Deputy Secretary, to provide senior leader oversight and accountability throughout the HHS SES Corps, leading to the creation of a new program to establish defined criteria for performance award and performance pay adjustments for SES staff.

Maximizing the Promise of Data

Using emerging technologies to identify savings: The Office of the Chief Information Officer (OCIO) established a recurrent neural network that identified more than $110 million in budgetary savings in the Office of the Secretary alone. OCIO also stood up a neural network for cybersecurity at no additional cost and reduced the time required to analyze security data from four days to minutes.

Laying the foundation for an HHS data hub: The Office of the CTO published a report with the future roadmap for integrating HHS data and awarded a contract to build the first-ever, enterprise-wide Data Sharing Hub and governance model, including the development of standardized inter-agency data use agreements.

Enabling consumer access to immunization records: CTO partnered with CDC and states to accelerate consumer access to online immunization records, with 60,000 accounts created to help patients receive vaccinations in a timely manner.

Harnessing AI to help patients: CTO and Presidential Innovation Fellows led short-term technology sprints with industry to build digital tools—using federal data and emerging technologies like AI—to improve clinical trials, experimental therapies, and data-driven solutions for complex challenges from cancer to Lyme and tick-borne diseases. In 2019, using "big data" sets from the National Cancer Institute, seven industry teamscreated AI-driven solutions to match patients with clinical trials.

Advancing interoperability: The HL7 Fast Healthcare Interoperability Resource (FHIR)®, the adoption of which has been supported in

part by ONC, became the basis for the Apple "Health Records" app, using the standard to create a foundation for convenient access to electronic health information for more than 100 million American iPhone users. Recently, the University of California San Francisco and Cornell University Tech announced an initiative called "CommonHealth" to bring medical records to Android-based smart phones using the same FHIR standard.

Moving toward a trusted health IT framework: ONC awarded a cooperative agreement to The Sequoia Project to serve as the Recognized Coordinating Entity to help develop, update, implement, and maintain the Trusted Exchange Framework and Common Agreement, which will create the baseline requirements for health information networks to share electronic health information. ONC also released the first draft of the Qualified Health Information Network Technical Framework, which describes technical and functional requirements for exchange among Qualified Health Information Networks.

Using technology to help with training to combat trafficking: In 2019, ACF's Office of Trafficking in Persons expanded their training abilities through technology and strategic partnerships to have the ability to train more than two million individuals to recognize and identify human trafficking.

Using PulseNet to detect foodborne illness outbreaks: CDC completed the transition to whole genome sequencing in PulseNet, the national laboratory network that connects foodborne illness cases in order to detect outbreaks. The technique, for example, has been successfully used to detect and investigate *Listeria* outbreaks, yielding a threefold increase in the number of *Listeria* outbreaks solved and decreasing the overall size of these outbreaks. Following the switch to the new sequencing technique in July, the PulseNet system received and evaluated more than 24,500 whole genome sequences and investigated more than 160 clusters of foodborne outbreaks.

Bolstering the Security and Efficiency of the Biomedical Research Enterprise

Using the cloud to advance biomedical research: NIH's STRIDES Initiative provides NIH intramural researchers and NIH-funded researchers at more than 2,500 research and academic institutions with cost-effective access to industry-leading cloud environments, tools, and services. Since its launch in 2018, the initiative has moved over 30 petabytes of biomedical research data into the cloud, including many of NIH's high-value datasets, such as the National Cancer Institute's Genomic Data Commons, the Framingham Heart Study, the Gabriella Miller Kids First Pediatric Research Program, and NIH's largest dataset, the Sequence Read Archive (SRA). As a result of the STRIDES Initiative, NIH-funded research programs are benefitting from $4.7 million in annualized cost savings.

Protecting the security of our biomedical enterprise: Through the Office of National Security, HHS expanded its partnerships with the national security community, and higher education partners, to respond to threats to the U.S. research enterprise. HHS worked across the whole of government to address the importance of balancing the need for scientific advancement while protecting data and intellectual property.