



2020 Annual Report



Introduction from Secretary Azar

2020 was one of the most challenging years in the history of our country and in the history of the Department of Health and Human Services. The unprecedented challenge of the COVID-19 pandemic has forced us not only into an emergency footing for all of the past year, but impacted just about every program HHS runs.

As a nation, we mourn the more than 400,000 Americans we have lost to COVID-19. As a department, we especially grieve for those members of the HHS family who have died from the virus, often having put their lives on the line to fight the virus. They are, and will always be remembered as, American heroes.

There is an end to the pandemic in sight, with the delivery of safe and effective vaccines through Operation Warp Speed. The success of Operation Warp Speed's partnership across the government and with the private sector builds on the remarkable efforts of this past year: unprecedented amounts of funding delivered to healthcare and human services providers, historic regulatory flexibilities to adapt to the pandemic, and dedicated work of our scientists and public health experts in guiding the pandemic response.

Even as we have focused on combating COVID-19, our department has still charged ahead on other priorities. In 2020, we delivered major achievements on the vision I set out for value-based healthcare back in 2018, and we finalized changes with the potential to transform the prescription drug marketplace forever. We made progress against public health challenges like the epidemic of youth use of e-cigarettes, and we redoubled our commitment to battling our country's crisis of opioid addiction and overdose through access to medication-assisted treatment. The department also made major advances in management, earning recognition across the federal government for improving our business processes.

This report provides just a sampling of the many achievements on these efforts and the COVID-19 response, organized around the response and HHS's five strategic goals. Battling COVID-19 will not only continue to be a focus for HHS for months to come; it will also have lasting lessons for how we battle health challenges and perform much of our work. When we defeat the pandemic, this

department will emerge stronger than ever before, justly proud of the work that every member of the HHS family has done.

It has been the honor of a lifetime to serve as HHS Secretary, and I could not be prouder to have led this remarkable team over the last three years. The dedication and ambition that the HHS team has shown over the past year is a strong foundation for more success in the years to come.

Alex M. Azar II

Secretary of Health and Human Services



Vaccines

A record time to humans: On January 7, 2020, even before the viral sequence had been shared by researchers in China, researchers at the National Institutes of Health (NIH) reached out to Moderna to begin designing a vaccine using mRNA technology that NIH and the Biomedical Advanced Research and Development Authority (BARDA), within the Office of the Assistant Secretary for Preparedness and Response (ASPR), had worked on to speed potential vaccine development and manufacturing. On January 11, the morning after the sequence was shared, NIH researchers began work on the vaccine. By March 16, the first dose was administered to a human in Phase 1 trials—a record time for a vaccine trial. On December 18, the Food and Drug Administration (FDA) granted an emergency use authorization (EUA) for the Moderna/NIH vaccine, and on December 21, distribution of doses supported and purchased by Operation Warp Speed (OWS) began.

Designing Operation Warp Speed: An unprecedented partnership between HHS and the Department of Defense (DoD), Operation Warp Speed aimed to deliver substantial quantities of safe and effective COVID-19 vaccines by the end of 2020, without cutting any corners, by building a broad portfolio of vaccines to mitigate risk, running steps of development and manufacturing concurrently to the extent possible, and providing comprehensive support for development, manufacturing, and distribution. OWS and its precursors began examining more than 100 vaccine candidates that were in various stages of development in May 2020, a portfolio development process eventually led by chief scientific advisor Moncef Slaoui. From these candidates, 14 promising products were chosen, from which more than \$11 billion in support was eventually provided for six candidates, from Moderna, Pfizer/BioNTech, Sanofi/GSK, Johnson & Johnson, Novavax, and AstraZeneca. As of January 2021, two of these vaccines have been authorized and three others are in Phase 3 clinical trials. Operation Warp Speed, through BARDA and NIH, provided support for the end-to-end advanced development of five investigational COVID-19 vaccines, including manufacturing development and scale-up, Phase 1 through Phase 3 clinical trials, non-clinical, and regulatory efforts.

Sustaining manufacturing through OWS: Scaling production of biological products such as vaccines can be a major cause of delay or failure in development and manufacturing processes. With logistical expertise and manpower brought on from the DoD, BARDA, and the leadership of manufacturing head Carlo de Notarestefani, OWS supported manufacturing of vaccines at every step of the way, through the Defense Production Act (DPA) and other informal actions to prioritize supplies. At one point, for instance, an OWS partner had ordered a particular kind of pump that it needed to make vaccines, but found out that the train that was shipping the pump had broken down and wouldn't arrive on time. OWS staff found the train, searched it, and put the pump on a plane to the manufacturing plant it needed to reach.

A rigorous, transparent FDA process: Authorization of OWS vaccines followed an open and transparent review process, which included publicly available guidance on standards for authorization, input from independent scientific and public health experts through the FDA's Vaccines and Related Biological Products Advisory Committee, and a thorough evaluation by the agency's career scientists to ensure these vaccine met FDA's rigorous, scientific standards for safety, effectiveness, and manufacturing quality needed to support emergency use authorization.

Preparing for mass vaccinations: Under the auspices of OWS, BARDA and DoD used private-public partnerships to expand the supplies of specialized materials and resources, such as cold-chain storage, manufacturing consumables, glass vials, needles, syringes, and other materials, that are required for the production and distribution of vaccines and other medical countermeasures. Forward thinking by ASPR and DoD led to partnerships with ApiJect, Retractable Technologies, Becton Dickinson, Smith's Medical, SiO2 Materials Science, Corning, as well as others, which are ensuring sufficient supplies to produce COVID-19 vaccines and other medical countermeasures. On behalf of the Strategic National Stockpile (SNS), ASPR contracted with McKesson Corporation to produce, store, and distribute more than 6 million COVID-19 vaccine ancillary supply and mixing kits, enough to support vaccination of every American. The kits are being distributed in amounts to match vaccine orders and are provided at no cost to enrolled COVID-19 vaccination providers.

A plan for vaccine distribution and administration: Enlisting the operational expertise of the Department of Defense, under the leadership of General Gustave Perna, OWS began developing plans in conjunction with the Centers for Disease Control and Prevention (CDC) in the middle of 2020 for an unprecedented vaccination campaign. In September, CDC published an interim playbook for states and other public health jurisdictions with which it works on vaccination programs, and worked with states on their plans for vaccine distribution and administration nearly every day throughout the fall and early winter of 2020. OWS and CDC also reached agreements with CVS and Walgreens to provide a turnkey solution for vaccination of residents of long-term-care facilities, as well as agreements to enroll members of 19 chain pharmacies and pharmacy associations as vaccination sites.

Supporting clinical trials: Two parallel and complementary efforts supported the clinical trials for COVID-19 vaccines. BARDA worked with the sponsors to support their clinical research

organization partners to enroll at least half, and often more than half, of the participants in the Phase 3 trials. NIH utilized existing infrastructure from other biomedical research initiatives to establish the COVID-19 Prevention Network (CoVPN), which merged four existing clinical trials networks and pivoted their research focus, enabling OWS vaccine candidates to have much larger clinical trials than many other vaccine trials, to deliver results faster, and to reach minority populations to ensure a representative trial. Together, these efforts supported the large Phase 3 trials, generating safety and efficacy data to be considered for potential EUAs. To facilitate the clinical evaluation and safe conduct of ongoing COVID-19 vaccine and therapeutic clinical trials, ASPR's SNS supplied personal protective equipment (PPE) and diagnostic tests to numerous clinical trial sites across the United States.

Ensuring no American faces a cost for vaccination: OWS, the Centers for Medicare & Medicaid Services (CMS), and the Health Resources and Administration (HRSA) laid the groundwork to ensure that every American who wants a vaccine can receive one without any out-of-pocket costs. CMS, along with the Departments of Labor and the Treasury, ensured immediate coverage and payment for COVID-19 vaccinations for individuals covered by group health plans and health insurance issuers. CMS announced that any vaccine that receives FDA authorization, either through an EUA or licensed under a Biologics License Application (BLA), would be covered under Medicare as a preventive vaccine at no cost to beneficiaries, and released new Medicare payment rates for COVID-19 vaccine administration, recognizing the potentially increased costs involved. In addition, HRSA is establishing the COVID-19 Vaccine Administration Assistance Fund to provide reimbursement to providers for vaccine administration services provided to beneficiaries who have a non-qualified health plan that either does not include COVID-19 vaccination as a covered benefit or provides only partial reimbursement for this benefit. The program will reimburse providers for COVID-19 vaccine administration fees, as well as any applicable co-pays, deductibles, co-insurance and out-of-network fees, for these patients.

Boosting the vaccine effort through partnerships: HHS's Office of Intergovernmental and External Affairs convened two Vaccine Consultation Panel groups, one with intergovernmental partners and another with external groups, to communicate with key partners about OWS, including to drive clinical trial recruitment and address vaccine hesitancy, and to discuss messaging best practices around a successful vaccination campaign.

Developing a strategy for supporting global vaccine access: HHS's Office of Global Affairs (OGA) led the development of an interagency strategy, coordinated through the National Security Council, to provide international access to COVID-19 vaccines once domestic needs are met.

Supporting international vaccine partnerships: OGA facilitated discussions on COVID-19 vaccine development between HHS/OWS leadership, and senior leaders from critical international partners involved in vaccine development and deployment, including G7 countries and key international organizations, such as Gavi, The Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations (CEPI), UNICEF, and The Access to COVID-19 Tools (ACT)

Accelerator. OGA also led bi-weekly calls between the U.S. and the United Kingdom on both vaccines and therapeutics, supported regular calls between U.S. and Canadian health leadership, and led weekly Vaccine Confidence Coordination & Communication calls among the Five Eyes nations.

Therapeutics

The first authorized and approved therapeutic: On February 25, NIH began a clinical trial of Gilead's candidate drug remdesivir for COVID-19, which announced positive results on April 29. On May 1, remdesivir received an EUA and on October 22 the drug received full FDA approval. In May and June, HHS allocated more than 150,000 donated courses of remdesivir, and then secured more than 500,000 treatment courses of remdesivir for American hospitals through September, representing more than 90 percent of the world's supply through September, after which point it was no longer a scarce commodity. On May 8, NIH began clinical trial testing of the antiviral remdesivir plus the anti-inflammatory drug baricitinib for COVID-19, and the combination received an EUA on November 19.

Wide access to convalescent plasma: FDA, BARDA, and other partners facilitated an expanded access program for COVID-19 convalescent plasma, a promising treatment that uses infusions of plasma with antibodies from patients who have recovered from the virus, reaching more than 70,000 Americans through the expanded access protocol. On August 23, FDA issued an EUA for convalescent plasma, expanding access further to this promising treatment. Through direct funding and media campaign efforts, BARDA's plasma team increased COVID-19 plasma collection from 5,000 units per week in early April to over 20,000 units collected per week in December 2020. Throughout 2020, over 520,460 units of convalescent plasma have been collected and the vast majority have been used locally. NIH is now supporting multiple randomized controlled trials on convalescent plasma in cooperation with academic medical centers.

Two authorized monoclonal antibody treatments: Beginning with funding awards in early February by BARDA, HHS and OWS supported development of Regeneron's monoclonal antibody cocktail casirivimab/imdevimab for treatment of COVID-19. Under OWS, funding was provided to purchase Regeneron's product as well as Eli Lilly's bamlanivimab, both of which received EUAs in November 2020 for use by patients at risk for severe COVID-19 in order to avoid hospitalization. BARDA has now acquired up to 1.5 million treatment courses of casirivimab/imdevimab and approximately 950,000 treatment courses of bamlanivimab; as of early January 2021, more than 641,000 courses of these two products had been allocated to states and more than 414,000 courses have been delivered to administration sites. ASPR has now also supported the opening of several federally supported infusion sites to promote use of these treatments.

Purchases of potential future treatments: OWS has also purchased through BARDA and DoD two products in advance of authorization: AstraZeneca's monoclonal antibody cocktail AZD7742, for post-exposure prophylaxis, and Merck's MK-7110, to treat hospitalized patients with COVID-19.

Accelerating therapeutic development: In April, FDA rapidly developed a Coronavirus Treatment Acceleration Program, a special emergency program to expedite development of potential treatments for COVID-19. As of December 31, 2020, there were over 590 COVID-19 drug development programs in the planning stages, over 400 trials reviewed by FDA, eight COVID-19 treatments had received EUAs and one (remdesivir) had received FDA approval.

An unprecedented adaptive trial through public-private partnership: NIH designed a large, adaptive clinical trial protocol to test various promising avenues of treatments, known as the [ACTIV Public-Private Partnership](#). This work enabled rapid design, implementation, and completion of clinical trials, with the first definitive trial, for remdesivir, completed and published within weeks of the onset of the pandemic, an unprecedented feat.

Ensuring payments for COVID-19 therapeutics: CMS established additional Medicare hospital payment to support Medicare patients' access to potentially life-saving COVID-19 therapies and made changes to reimbursement for outpatient hospital services to ensure payment for certain innovative treatments for COVID-19 occur outside of bundled arrangements and are paid separately.

Testing and Diagnostics

Broad access to COVID-19 testing for all patients: While most European nations require a patient to present with symptoms in order to receive a test provided by the public sector, HHS and the states have supported broad availability of testing, through both private and public channels, for people with or without symptoms and with or without known exposure. For testing people with symptoms and other key categories, the United States has invested in, developed, and has now provided broader access to rapid antigen tests than any other large country on the planet.

Support for innovative diagnostic options: NIH's RADx initiative, the diagnostics arm of Operation Warp Speed, has supported a combined portfolio of 22 companies with innovative diagnostic options for a total of \$476.4 million in manufacturing expansion contracts, helping to accelerate the eventual production of these products. RADx products include Ellume's test that received an EUA from FDA in December, the first over-the-counter fully at-home test for COVID-19. BARDA has supported the development of 39 COVID-19 diagnostic tests, of which 19 have received EUAs, with over 82 million BARDA-supported tests shipped to healthcare providers across the country. BARDA funding has also been invested to increase the domestic diagnostic manufacturing capacity at three diagnostic test manufacturers, with the eventual goal of producing an additional 15 million or more tests per month.

Ever-expanding testing options: As of the end of 2020, 309 tests and sample collection devices were authorized by the FDA under EUAs for COVID-19, including 235 molecular tests and sample collection devices, 63 antibody tests, and 11 antigen tests. There are 32 molecular authorizations that can be used with home-collected samples. EUAs have been granted for one molecular prescription at-home test, one antigen prescription at-home test, and one over-the-counter at-home antigen test.

Community Based Testing Sites partnership: Starting in April, the Testing and Diagnostics Working Group, led by the Office of the Assistant Secretary for Health spearheaded the Community Based Testing Site program, which has now performed more than 5 million tests at retail and pharmacy sites in more than 3,200 locations in every state and the District of Columbia, with more than 2,700 sites remaining active, the majority in socially vulnerable areas. CVS, Walgreens, and other pharmacies have opened more than 5,000 testing locations made possible by this federal model and regulatory flexibilities that HHS provided.

More options for RT-PCR testing: Under the auspices of Admiral Brett Giroir’s testing and diagnostics working group, HHS supported the validation of multiple different types of material and methods—like nasal swabbing instead of nasopharyngeal swabbing—to dramatically increase the availability of supplies and spare desperately needed PPE. FDA provided regulatory flexibility around things like storage media for samples, and HHS worked with academic medical centers and private industry to validate pooled sampling, a method used around the world that could dramatically increase labs’ throughput capacity, to facilitate regulatory authorization.

Strategically distributing rapid tests: As soon as the first rapid test was authorized by FDA, the Abbott ID Now product, the federal government bought up 40 percent of the world’s supply, and allocated it to those who needed it most and could use it best: state public health departments, nursing homes, ultra-critical infrastructure, the Indian Health Service, and other partners. With the next wave of rapid tests, which use instrument readers to automatically provide a result, HHS used the DPA to prioritize federal orders and sent them to every nursing home in America by mid-September. Finally, in the fall, HHS coordinated the distribution of 150 million BinaxNOW antigen tests, to states, long-term-care facilities, historically black colleges and universities, and Tribes.

Producing and procuring testing supplies: HHS and FEMA performed more than 40 Air Bridge flights to bring testing supplies like swabs and pipette tips to the United States during a time of global scarce supply. At the end of April, under the DPA and other authorities, HHS and DOD awarded several contracts to a company in Maine, Puritan, to double their swab production from 20 million to 40 million swabs a month. In total, HHS has used the DPA 13 separate times to speed production and allocation of supplies necessary for testing production.

HHS-led surge testing: Surge testing conducted under the auspices of the testing and diagnostics working group has been established in 23 states and at over 630 sites, resulting in more than 760,000 tests conducted, with turnaround times for testing sites averaging less than 2 days.

Expanding the testing workforce: The Office of the Assistant Secretary for Health (OASH) issued guidance under the Public Readiness and Emergency Preparedness (PREP) Act that authorizes licensed pharmacists to order and administer FDA-authorized COVID-19 tests and extended coverage to licensed health-care practitioners prescribing or administering point-of-care COVID-19 tests for screening in congregate facilities.

Intra-departmental scientific collaboration on serology tests: To support the availability of accurate serology tests, NIH's National Cancer Institute began an interagency collaboration with FDA to evaluate commercially developed tests. Serology tests are vital for determining the efficacy of promising therapeutic or vaccine candidates and for studies of disease prevalence.

Ensuring payment for COVID-19 testing: CMS quickly implemented regulations and statutory provisions that removed barriers to COVID-19 testing in Medicare, Medicaid, CHIP, and private insurance. This included ensuring Medicare, Medicaid, and CHIP beneficiaries can receive COVID-19 tests without cost sharing; clarifying that Medicare, Medicaid, and CHIP coverage of COVID-19 tests includes serology or antibody tests; and allowing Medicaid and Medicare to pay for certain COVID-19 tests without a physician order.

Speeding tests through smart payment policies: CMS nearly doubled payment in Medicare for certain lab tests using high-throughput technologies that can process more than 200 specimens a day to appropriately pay laboratories to rapidly diagnose large numbers of COVID-19 tests and began paying for COVID-19 testing based on turn-around time.

Flexibilities to support testing: CMS extended Medicare payment to laboratories to collect COVID-19 lab specimens from certain people at home or in other community settings in certain circumstances, and gave states greater flexibility to cover COVID-19 tests administered in alternate locations and paid for through Medicaid. CMS also expedited reviews of applications for lab certification, ensuring that labs are able to begin testing as quickly as possible to meet consumer needs.

Requiring enhanced testing for nursing homes: CMS required that all nursing homes in states with a 5 percent positivity rate or greater test all nursing home staff each week, enhancing efforts to keep the virus from entering and spreading through nursing homes by identifying asymptomatic carriers. CMS also revised infection-control regulations for long-term care facilities to require nursing homes to test their staff for COVID-19 and required nursing homes to offer COVID-19 tests to residents when there is an outbreak, or when residents show symptoms.

National Leadership and Scientific Guidance

Providing operational coordination and support to the field: In May 2020, in consideration of the need to reduce FEMA's responsibilities in anticipation of what turned out to be an unprecedented hurricane and wildfire season, the Secretary established a Joint Coordination Cell (JCC) within the Immediate Office of the Secretary. Led by Vice Admiral Dan Abel of the U.S. Coast Guard, the JCC fostered intra-HHS unity of effort and harmonized activities of federal departments, agencies, and working groups to advance the national strategy determined by the Unified Coordination Group (UCG) comprised of HHS Secretary Azar, FEMA Pete Administrator Gaynor, White House Task Force Coronavirus Response Coordinator Deborah Birx. The JCC evolved federal actions toward longer-term sustainment by leading multi-agency working groups that provided direct assistance and technical advice to federal and state, local, tribal, and territorial

governments (SLTT) governments. The Testing and Diagnostics Working Group under the leadership of Admiral Giroir, monitored and ensured the stability and capacity of the diagnostics supply chain to support national testing needs, coordinated national testing policies and guidance, and coordinated the Community-Based Testing and surge testing programs. The Healthcare Resilience Working Group provides technical advice to the national healthcare system including workforce, facilities, supplies, and processes at all points in the healthcare system including Project ECHO calls to directly reach providers in the field via mass webinars and video conferencing to provide direct advice on all aspects of healthcare resilience from PPE preservation to practitioner mental health. The Mitigation and Risk Working Group, heavily coordinated with the CDC and staffed by CDC in Atlanta, implemented effective community mitigation strategies to prevent or slow COVID-19 transmission, including through advice to the multi-agency COVID-19 Response Assistance Field Teams (CRAFT) deployed to advise states on surge responses. The Data Strategy and Execution Working Group, drawing on expertise from ASPR, CDC, the Office of Management and Budget, OMB, HHS CIO, U.S. Digital Service, the Department of Labor, the John Hopkins Applied Physics Labs, and other partners has created an unprecedented common operating picture for the pandemic response at all levels. Supply Chain Next Generation Strategic National Stockpile, started with ASPR and Rear Admiral John Palowczyk, works to bring full visibility into the U.S. PPE supply chain, as described below, to best apply the DPA and DPA-like HHS authorities, and to improve the domestic manufacturing and delivery of PPE.

Scientific leadership through MMWRs: CDC's *Mortality and Morbidity Weekly Report* (MMWR) has published 186 studies on COVID-19 as of early January 2021. Among many other topics, these reports provided information and analysis on the risk of transmission at large gatherings, choir practices, and congregate living situations like prisons, meat processing plants, and nursing homes, as well as the disparate impact of COVID-19 in racial and ethnic minorities and identified the elevated risk of severe outcomes for older adults and people with underlying conditions.

Comprehensive scientific guidance: Beginning with the first guidance published on January 17, about recommendations for handling samples of SARS-CoV-2, CDC has published 4,523 documents providing information and guidance for government agencies, businesses, and the public about how to handle challenges arising from COVID-19.

Answering queries from all quarters: CDC has fielded more than 723,000-plus calls and emails to CDC-INFO, the agency's national call center for the public and for clinicians, and 48,000-plus inquiries from doctors, nurses, or other clinical staff and health departments received by CDC.

Formulating treatment guidelines: Beginning in mid May, as knowledge developed around potentially promising treatments for COVID-19, NIH worked with federal scientists and clinicians and a panel of outside experts to begin publishing treatment guidelines for COVID-19 that provide overviews of the evidence on various potential treatments, following a practice pursued by NIH during the early days of the HIV/AIDS epidemic. When the United Kingdom announced promising

results on June 16 from a randomized controlled trial on the use of the steroid dexamethasone, it was added to the guideline on June 25.

Bringing new skills to support nursing homes: AHRQ established a new [National Nursing Home COVID-19 Action Network](#), which connects academic medical centers and nursing homes, through Project ECHO, to provide free training and local mentorship to accelerate the implementation of evidence-based infection and safety practices. One hundred training centers are now providing support to over 7,000 nursing homes in every state and the District of Columbia, helping protect both nursing home residents and staff.

Research on pregnant mothers and COVID-19: NIH leveraged existing research to initiate large-scale studies on the effects of COVID-19 on maternal and fetal health during pregnancy, to improve understanding of SARS-CoV-2 infection impacts and to ensure COVID-19-related treatments are adequately formulated and tested for their specific needs.

Bringing added public health expertise to Indian Country: IHS coordinated with CDC to hold tele-Infection Control Assessment and Response (ICAR) sessions for federal and tribal facilities. The tele-ICARs assess infection prevention practices and guide quality improvement activities and have been an invaluable addition to IHS prevention efforts during the COVID-19 response.

Rapid research commenced on healthcare delivery lessons: AHRQ invested in health services research to understand how healthcare delivery systems were innovating to improve patient care, awarding \$15 million in 29 rapid-cycle grants to allow teams already in the field to expand their work and for new teams to study how health systems were protecting patient safety, expanding access to care, implementing telehealth, and addressing healthcare disparities. These grants will produce early findings in the spring of 2021.

Providing infection control recommendations, guidance, and training for nursing homes: CMS released a toolkit with recommendations and best practices to states that address the specific challenges facing nursing homes as they combat COVID-19, which is now updated regularly, in addition to weekly calls with nursing homes, state nursing home associations, and other stakeholders. CMS launched an unprecedented, scenario-based, national training curriculum featuring the most recent lessons learned and best practices to equip both frontline caregivers and their management with the knowledge they need to stop the spread of COVID-19 in their nursing homes.

Guidance around nursing home visits: CMS issued visitation and holiday visitation guidance on limiting visitors and nonessential healthcare personnel at nursing homes, except in compassionate care and end of life situations, to prevent transmission of the virus.

An independent nursing home commission: CMS made public the [Independent Nursing Home COVID-19 Commission Findings](#), which validate the unprecedented federal response to COVID-19 to date, on new website devoted to all nursing home guidance. Combined

efforts from across the federal government helped drive significant reductions in the incidence of COVID-19 cases and deaths, as well as lower death rates from cases, in nursing homes in the summer of 2020.

Providing nursing home oversight: CMS conducted more than 55,000 investigations of patient health and safety in nursing homes nationwide since March, prioritizing infection control and situations in which residents are at risk for serious injury or death. All 15,417 Medicare and Medicaid nursing homes were required to report cases of COVID-19 to all residents, their families, and the CDC.

Shielding Americans from COVID-19-related fraud: As of December 17, 2020, the FDA had identified more than 1,240 fraudulent and unproven medical products related to COVID-19. To proactively identify and neutralize threats to consumers, the FDA launched Operation Quack Hack in March 2020. The Operation Quack Hack team has reviewed thousands of websites, social media posts, and online marketplace listings, resulting in over 150 warning letters to sellers, more than 275 reports sent to online marketplaces, and more than 275 abuse complaints sent to domain registrars to date.

[Advancing Data Capabilities](#)

Expanding syndromic surveillance: CDC expanded its ability to investigate and monitor the spread of the COVID-19 outbreak through its National Syndromic Surveillance Program (NSSP) BioSense Platform (syndromic surveillance monitors symptoms and other health data among patients not known to have a given virus). NSSP helped state health officials understand and monitor the spread of the COVID-19 outbreak throughout the general population. In 2020, 59 sites representing 5,041 facilities, including 3,310 emergency departments, contributed data to the platform. This platform's syndromic data were also essential to 2020 efforts to understand opioid overdoses and the national outbreak of a new syndrome, e-cigarette or vaping-associated lung injury (EVALI).

An unprecedented data hub: HHS's Office of the Chief Information Officer (OCIO) and other HHS and federal partners created HHS Protect, an unprecedented system and set of capabilities, powered by various private sector technologies, for sharing, parsing, housing, and accessing more than 200 sets of COVID-19 data, in less than 10 days. HHS Protect makes these diverse data sources securely and conveniently available not just across the federal government—to thousands of authorized and vetted users across HHS agencies alone—but to SLTT governments too, including state public health officials and COVID-19 support staff for governors. Through a new contractor collection system instituted in 2020, HHS Protect now receives daily data from 100 percent of American hospitals on COVID-19 patients, ICU capacity, PPE supplies, and many other measures.

Making more data and analysis readily available to leaders and the public: As part of the Data Strategy and Execution Workgroup (DSEW) in the Joint Coordination Cell, ASPR and CDC played in developing the daily Senior Leader Brief which is used as the primary source of response

information throughout the federal government. The DSEW team developed a number of key information products, including the COVID-19 Community Profile Report, used daily by Response leaders and then made public via HealthData.gov on December 18. More recently, the DSEW team developed Project Greenlight, which allows near real time information flow to federal and SLTT governments on hospitalizations, ICU bed capacity, staffing, and PPE availability down to the facility level nationwide, with similar data available for long-term-care facilities.

Levering health records to support the COVID-19 fight: In September, the Office of the National Coordinator for Health IT (ONC) released five cooperative agreements to health information exchange organizations (HIEs) to help support state and local public health agencies in their efforts to respond to public health emergencies, including disasters and pandemics such as COVID-19. Each of the five recipients will work to improve HIE services so that public health agencies can better access, share, and use health information during public health emergencies. These efforts will also support communities that are disproportionately impacted by COVID-19.

Providing public health insights through de-identified health records: ONC, in cooperation with HHS Protect, initiated a new effort called HHS Connect, which seeks to use and scale the unique abilities and characteristics of health information exchanges to facilitate and expand the secure, electronic movement and use of de-identified health information. This effort is expected to answer key public health questions for HHS using comprehensive data feeds from 12 states.

Making nursing home data available: CMS published data on a new website devoted to nursing home guidance showing the incidence of COVID-19 in nursing homes, as well as the results of the agency's targeted infection control inspections, including individual facility survey results.

Strategic and timely data analysis: The Office of the Assistant Secretary for Planning and Evaluation (ASPE) developed hospital level estimates of ventilators and ICU beds at the request of ASPR that were used by ASPR and FEMA in resource allocation decisions and provided the estimates to state data partners to support their resource allocation decisions. At the request of CIO and NIH, ASPE developed risk scores to inform selection of clinical trial participants as they test vaccines. To support human services efforts, ASPE also estimated need for nutrition services for older Americans and Americans with disabilities for use by ASPR/FEMA and shared the results with FEMA food security stakeholders.

[Deploying Personnel to the Frontlines](#)

Deploying the Commissioned Corps: Due to the rapid escalation of the COVID-19 pandemic, the U.S. Public Health Service Commissioned Corps deployment expanded rapidly from 38 officers on February 1, 2020 to over 4,366 officers in support of the pandemic response. The Public Health Service has supported more than 50 missions for a total of 571,855 deployment days, including: supporting the evacuation and return of American citizens from China and Japan; assisting CDC with airport screenings to monitor the health of travelers; assisting with infection control screening at the border; operating community based testing sites; and supporting the remdesivir

compassionate use trial in Japan. The Public Health Service also assembled multidisciplinary COVID-19 clinical strike teams, which have been deployed to supplement local and regional healthcare providers at medical facilities in areas of greatest need.

Putting CDC experts on the ground: 1,509 CDC staff have conducted 2,870 deployments to 254 cities across the United States and abroad and more than 60 countries to respond to COVID-19. This included support for epidemiologic surveillance, infection prevention and control, worker safety and health, health communications, contact tracing, repatriation, and quarantine stations.

Calling up the NDMS: ASPR deployed Disaster Medical Assistance Teams of the National Disaster Medical System (NDMS) deployed to New York City, the epicenter of the first and largest COVID-19 outbreak in the United States. In collaboration with the DoD, NDMS staffed the nation's first field hospital at the Javits Center in New York City (NYC). Additional personnel from NDMS's Disaster Mortuary Operational Response Team deployed in support of the NYC Medical Examiner's Office. As the disease continued to spread rapidly throughout the United States, NDMS teams were called into action. As of December 1, more than 2,500 response personnel deployed to areas experiencing the greatest need, from Guam to Alaska, from New York to California and everywhere in between, including to support the Navajo Nation. Many of these personnel deploy more than once; some as many as eight or nine times. To protect the physical and mental health of response personnel, ASPR recruited, trained, and deployed a team of mental health specialists to support the behavioral health needs of personnel deployed for disaster response. These professionals deployed with ASPR-directed teams or served as part of a call center to reach back to providers who had returned home following a COVID-19 deployment.

Providing a public health strike force: When new "hot spots" emerged around the country in June 2020, the UCG directed the JCC to deliver resources to SLTT jurisdictions to reduce the spread of the virus and "flatten the curve" in those locations. In response, the JCC and ASPR/DoD planners developed an innovative, multidisciplinary, interagency program called the COVID-19 Field Assistance Response Teams (CRAFT). The JCC led the rapid-response teams of the CRAFT, comprised of more than 340 personnel from the Public Health Service, CDC, FEMA, ASPR, HRSA, CMS, and other agencies, while coordinating with other governmental partners. In all, the CRAFTs conducted more than 650 engagements in 33 states over 14 weeks. The CRAFT mission later matured into a CDC-managed and ongoing technical assistance mission, the COVID-19 Outreach, Response, and Engagement (CORE), which has provided a combination of in person, virtual and online engagements to over 35 states and territories.

Forming the HHS Emergency Response Force: Recognizing the need for long-term sustainment of HHS COVID-19 response operations, the JCC, in coordination with the Assistant Secretary for Administration (ASA) developed the HHS Emergency Response Force program, to organize a cadre of HHS staff volunteers who desire to support COVID-19 response operations by serving as a member of a working group for up to 120 days. This JCC/ASA managed program coordinates human resource actions with the HR managers from each of the HHS divisions. To

date, over 200 HHS personnel have volunteered, with nearly 100 HHS volunteers deployed to serve either within the JCC, the ASPR-managed Secretary's Operation Center, or on one of the working groups.

Using the Medical Reserve Corps: More than 400 Medical Reserve Corp units in all 10 regions across the country contributed more than 700,000 volunteer hours in the fight against COVID-19. Units assisted with call center operations; community education and outreach; PPE inventorying and distribution; patient case and contact investigations; patient monitoring; community screening and testing operations; surge support at long-term-care facilities and healthcare facilities, and alternate care sites; and vaccine administration.

Providing on-the-ground quality assistance: CMS deployed Quality Improvement Organizations (QIOs) to provide immediate assistance to 1,152 nursing homes in hotspot areas, and deployed QIOs to an additional 2,073 nursing homes for intensive technical assistance, training, and infection prevention assistance. CMS also deployed Federal Task Force Strike Teams to provide onsite technical assistance and education to nursing homes experiencing outbreaks in an effort to help reduce transmission and the risk of COVID-19 spread among residents.

Sending IHS health responders into the field: The Indian Health Service (IHS) coordinated contact tracing efforts to increase detection capability of new cases and target resources to address clusters and established Critical Care Response Teams (CCRT) to be deployed to IHS and tribal sites to provide clinical guidance and support during the pandemic. During FY 2020, CCRTs visited 6 individual sites, conducting 16 separate hands-on training sessions for over 230 staff.

[Producing and Distributing PPE](#)

Early efforts to boost PPE supplies: On January 24, ASPR formed three government-wide task forces—on healthcare system capacity and resilience; development of medical countermeasures like diagnostics, therapeutics, and vaccines; and on supply chains, including personal protective equipment (PPE). The same week, ASPR leaders and others began conversations with manufacturers of N95 respirators in the United States, leading U.S.-based production on N95s to rise from about 250 million annually in January to about 640 million annually by March. In February, the department began examining DPA authorities to help mobilize American industry and prevent the movement of critical supplies out of the United States. On March 2, after several weeks' worth of collaborative work between FDA and CDC, FDA received and quickly responded to a CDC request to authorize industrial N95 respirators for use in healthcare settings, creating the potential to use millions of additional N95s in new settings where they were badly needed. On March 4, the Strategic National Stockpile (SNS) published a notice of intent to purchase 500 million N95s for the SNS, helping to drive more manufacturing investments and expansion—at a time when there were still just about 100 COVID-19 cases confirmed in the United States and before Congress had provided a supplemental appropriation (an effort which HHS had been working toward since January).

Deploying SNS assets: While the SNS was not designed to support a nationwide pandemic response, the bulk of its supplies were rapidly deployed, in just six weeks in early 2020, to support the response. Ninety percent of the SNS's existing inventory of PPE was distributed to frontline U.S. healthcare workers caring for patients with COVID-19; recipients included all 50 states and 8 territories. During this same timeframe, the SNS also deployed all 42 of its Federal Medical Stations, which included 8,500 beds and emergency medical equipment and supplies, to support the nation's COVID-19 response efforts.

Visibility into supply chains: Beginning in March, HHS secured agreements with the vast majority of major medical distributors, in part by invoking a provision in the DPA, to reach an agreement that the distributors would provide HHS with real-time data about where their product was going. This allowed the federal government to understand where needs were greatest and route product to meet needs.

Enlisting FEMA and the military to launch Operation Airbridge: In February, HHS reached out to the Department of Defense to secure logistical expertise to support PPE supply chains. The head of logistics for the Joint Chiefs, Rear Admiral John Polowczyk, began work at HHS on March 9, and together, HHS, FEMA, and DOD launched Operation Airbridge, to charter aircraft that would bring desperately needed PPE from factories abroad, where it could not quickly reach the United States, to where it needed to go. By getting these supplies here and marrying that up to the data HHS was collecting, the operation was able to send supplies where they were needed most. On June 30, the final Airbridge flight landed in Columbus, Ohio. A total of 249 flights delivered the following supplies into private sector supply chains through Project Airbridge: nearly 6.3 million N95 respirators; 937.0 million gloves, 125.4 million surgical masks, and 66.8 million surgical gowns. Beyond Project Airbridge, as of January 8, 2021, HHS, FEMA, and the private sector combined have coordinated the delivery of 425 million N95 masks, 1.7 billion surgical masks, 41 billion pairs of gloves, and more.

Building a next-generation SNS: Over the course of 2020, the federal government invested nearly \$10 billion in reimagining and expanding the SNS, creating an "SNS 2.0," to include a broader array of medical products, deeper reserves, more domestic manufacturing, and full visibility into private sector supply chains. As of December 18, 2020, the SNS held more than 150,000 ventilators, 9 times more than it did in January 2020, and 190 million N95 respirators, 15 times more than January 2020. Replenishment of PPE will continue through 2021. The SNS also expanded the pharmaceuticals it stockpiles for emergencies, awarding seven contracts to pharmaceutical vendors to supply intravenous drugs used in intensive care units. In July, ASPR awarded a contract to support the opening of a medical glove manufacturer in New Hampshire. Prior to the COVID-19 pandemic, medical gloves were not made in the United States.

Expanding the SNS footprint: To accommodate a rapidly increasing inventory in response to COVID-19, ASPR expanded SNS warehouse operations to include three new facilities strategically

located across the nation, broadening storage capacity by 150,000 pallets of lifesaving medical countermeasures and supplies.

Quick work with the private sector to make face mask alternatives: Beginning with work in February to have American clothing companies retool production lines to make masks, ASPR purchased and coordinated the distribution of more than 650 million reusable cotton face coverings to support critical infrastructure areas across the country, including long-term care facilities and schools.

Distributing masks to faith and community organizations: HHS's Center for Faith and Opportunity Initiatives (The Partnership Center) partnered with ASPR and FEMA to distribute 42.5 million cloth face coverings to faith- and community-based stakeholders, who, in turn, distributed them to their community members, including many of the nation's most under-resourced individuals and their families.

Repatriation, Quarantine, and Travel

Unprecedented travel restrictions to slow the spread and save lives: On January 31, Secretary Azar and HHS public health leaders presented the case to the President that aggressive restrictions on travel would help slow the spread of the virus to the United States, departing from decades of traditional resistance to such measures. That evening, in conjunction with the declaration of a public health emergency, when there were still just 125 confirmed cases worldwide outside of China, the Secretary announced the unprecedented restrictions on travel from China, later followed by restrictions on travel from Brazil, Iran, the United Kingdom, the Republic of Ireland, and the Schengen Area of Europe.

Updating travel restrictions and measures: HHS and leaders from CDC made the case for and maintained aggressive restrictions on cruise ship travel, including an unprecedented "no-sail order," through October 31. In later December, the United States began requiring a negative COVID-19 test for passengers from the United Kingdom, due to the discovery of a more transmissible strain of SARS-CoV-2 in that country. In early January 2021, the testing requirement was extended to all international air travelers coming to the United States, effective January 26.

A historic repatriation and quarantine operation: ASPR, in collaboration with the Department of State, facilitated and staffed one of the largest repatriation and quarantine efforts in history, bringing home more than 3,000 individuals, mostly U.S. citizens and their immediate family members, whom the U.S. government evacuated from Wuhan, China, or had been passengers on the Diamond Princess or the Grand Princess Cruise ships. Thousands of response personnel from the NDMS, CDC, Public Health Service, and the Administration for Children and Families (ACF) assisted with the repatriation and quarantine missions. As part of the repatriation mission, ASPR deployed for the first time its newly formed NDMS Aeromedical Evacuation Teams, helping to safely move thousands of passengers on 20 flights to federal quarantine sites. While quarantined, these response personnel worked 24/7 to provide basic medical care, COVID-19 screening and

testing, and wrap around services (housing, meals, linen and laundry services, and trash removal), as well as communication updates to both the travelers and to the surrounding communities.

Providing human services to repatriated Americans: ACF's Office of Regional Operations supported the repatriation of American citizens and collaborated with Office of Management Budget (OMB) staff to craft and enact a proposal to lift the statutory limitation on support for repatriating U.S. citizens from abroad in an emergency from \$1 million to \$10 million.

Delivering Emergency Funding

Unprecedented levels of emergency funding: In total, in FY 2020 2020, HHS managed \$250 billion in emergency supplemental appropriations for COVID-19, the largest discretionary emergency funding increase in the department's history, and the Office of the Assistant Secretary for Financial Resources (ASFR) worked to ensure that funds across operation and staff divisions were quickly apportioned and available through grants and contracts while ensuring appropriate oversight and financial controls, with technical assistance and status updates regularly provided to Congress.

Early action to free up funding: On January 22, the day after the first U.S. case was confirmed, Secretary Azar signed a memorandum from CDC to send a request to the Office of Management and Budget to notify Congress that HHS needed to access \$105 million from the Infectious Disease Rapid Response Reserve Fund. On January 30, HHS began conversations with OMB about the need for a supplemental appropriation to continue this work on PPE, therapeutics, diagnostics, vaccines, and federal and state response efforts. On February 2, HHS notified Congress of the intent to use the Secretary's transfer authority to repurpose flexible funds for the response. Conversations with OMB on funding needs continued, on an essentially daily basis, throughout February, eventually resulting in the March 6 signing of a supplemental funding bill.

Administering the Provider Relief Fund: The CARES Act and the Paycheck Protection Program and Health Care Enhancement Act provided \$175 billion for a Provider Relief Fund to prevent, prepare for, and respond to COVID-19, domestically or internationally, for necessary expenses to reimburse eligible health care providers for health care related expenses or lost revenues that are attributable to the virus. On April 1, the Office of the Secretary designated HRSA to administer the fund. Within three weeks of the passage of the CARES Act, HRSA had distributed more than \$30 billion in payments to offer immediate relief to nearly 320,000 providers across the nation. In 2020, the Provider Relief Fund has made almost \$117 billion in payments to approximately 428,000 unique healthcare providers, including hospitals in areas especially hard hit by the virus, safety-net hospitals, rural health clinics and Critical Access Hospitals, nursing homes and other residential care facilities, and more. In late December an additional \$3 billion was appropriated for the Provider Relief Fund through Coronavirus Response and Relief Supplemental Appropriations Act.

Leveraging the Provider Relief Fund to boost nursing home quality and safety: HHS designated \$2.75 billion of the Provider Relief Fund, out of the \$10 billion allocated to skilled nursing facilities and nursing homes, in an upfront payment to support increased testing, staffing,

and PPE needs in nursing homes. Then, another \$2.25 billion is being made in quality incentive payments linked to nursing home performance in slowing the spread of the virus. Between September and October, 86 percent of 14,334 eligible nursing homes met the incentive program's infection control criteria in either September or October, resulting in over 6,375 combined fewer infections relative to the rates seen in the communities where they exist.

Rapid funding for and consultation with tribal communities: IHS expedited the distribution of \$1.9 billion of emergency funding, including, once funding was announced, coordinating and conducting statutorily required tribal consultation and urban confer in an extremely short timeframe. With a concentrated effort on alerting tribes and urban Indian organizations of funding opportunities, the average turnaround time from enacted bill to consultation and confer was 5 days. After consultation and confer occurred, funding was distributed within 8 days on average. IHS allocated \$700 million to support IHS federal and tribally operated health programs and urban Indian organizations, \$819 million for COVID-19 testing, \$114 million for medical supplies, \$95 million for telehealth, and \$188 million for other COVID-19 support activities.

CDC support for state, tribal, local, and territorial public health work: CDC supported state, tribal, local, and territorial critical COVID-19 response activities using multiple mechanisms to award more than \$12 billion directly to jurisdictions, with the largest awards going out less than 30 days after CDC received funds. Such support has helped cover expenses for laboratory equipment, reagents, and other specialized materials needed for lab processing and testing of COVID-19 samples, contact tracing, personal protective equipment purchases and fit testing, and quarantine and housing needs for persons under investigation for COVID-19.

Advanced funds for healthcare providers: Over the first three weeks of April, CMS expanded an existing, little used program called Advances and Accelerated Payments, to give about 50,500 Medicare providers over \$100 billion in advance funding in anticipation of future claims activity. CMS had made about 100 such advances in the previous five years.

Emergency funding for health centers: In just six weeks (from March 24 to May 7, 2020), HRSA delivered nearly \$2 billion in supplemental funding to health centers through over 4,100 COVID-19 grant awards, reducing the amount of time usually required to issue grant awards by 93 percent. Health centers are using these funds to provide COVID-19 testing and immunizations, treat patients with COVID-19 symptoms to alleviate burden on the nation's emergency rooms and hospitals, and provide essential primary care services to patients with ongoing primary care and mental health care needs, including continuing essential services needed to manage conditions that put patients at increased risk for COVID-19 complications.

Supporting the Ryan White HIV/AIDS Program: Within just 15 days, HRSA made \$90 million in immediate COVID-19 relief available through grants to 560 of its Ryan White HIV/AIDS program recipients.

Aid for Rural Health Clinics: HRSA led efforts to respond to the COVID-19 pandemic in rural communities, deploying \$225 million to support testing in over 4,500 Rural Health Clinics.

Support for rural hospitals: HRSA awarded \$150 million to support nearly 1,800 small rural hospitals as they prepare, prevent, and respond to COVID-19. The funds allow hospitals maximum flexibility in how they respond to COVID-19, including the provision of testing and laboratory services as well as the purchase of PPE.

Comprehensive investments in telehealth expansion: HRSA awarded a variety of grants to support expanded access to telehealth: over \$11 million to support 14 Telehealth Resource Centers (TRCs) to provide expertise and customized telehealth technical assistance; \$5 million to two recipients through the Licensure Portability Grant Program to assist telehealth clinicians nationally on licensure and credentialing and work with licensing boards and national compacts to streamline licensing; \$15 million to four recipients to support telehealth work on pediatric care, maternal health care, state public health systems and family engagement for children with special health care needs during the pandemic; and \$15 million to 159 organizations across five health workforce programs to provide telehealth training to students, physicians, nurses, physician assistants, allied health and other high-demand professionals.

Reaching Americans with new funding for aging and disability networks: After the passage of emergency funding legislation, ACL began the process of awarding \$1.2 billion in grants to support aging and disability networks that serve older Americans and Americans with disabilities, with distribution of the funds proceeding within 48 hours of appropriation. The supplemental funds included in the two major funding bills passed by Congress in early 2020 represented a 55 percent increase in ACL's annual grant budget and distribution of the funds provided critical services to older adults and people with disabilities. Using these funds, the aging and disability network converted congregate meals to home-delivered meals; PPE was procured to help the network professionals who provide in-home care; and respite care and other support was provided to caregivers. ACL also distributed \$85 million to 284 Centers for Independent Living across the United States to respond to the COVID-19 pandemic, which were utilized to address the surge in needs of individuals with disabilities to access or reconnect them with the services and supports needed to remain safely in their communities. These centers quickly pivoted their processes to deliver virtual services and supports, formed partnerships in their communities to distribute personal protective equipment, food and nutrition services, and continuity in personal care services.

Meeting emergency mental health needs: The Substance Abuse and Mental Health Services Administration provided \$425 million to states and communities to address the mental health and substance use disorder effects of COVID-19 in record time. Funds have gone to support, among other needs, Certified Community Behavioral Health Clinics; tribal health programs, and the Suicide Lifeline/Disaster Distress Helpline and its follow-up programs as well as other suicide prevention efforts.

Addressing Mental Health During COVID-19

Ensuring access to medication-assisted treatment: The Substance Abuse and Mental Health Services Administration (SAMHSA) provided increased flexibilities to opioid treatment programs using medication-assisted treatment (MAT) by allowing states to request blanket exceptions that allow stable patients to receive 28 days of take-home doses of medication and up to 14 days of take-home medication for those patients less stable.

MAT and naloxone via telehealth: SAMHSA worked in concert with the Drug Enforcement Administration to waive the in-person physical exam for those receiving buprenorphine while also permitting the use of telehealth for established patients with opioid use disorder. These provisions balanced patient and community safety.

Engaging the faith community: The Partnership Center hosted a webinar series that engaged 9,767 faith and community Leaders in efforts to equip them for the anticipated surge in COVID-19-related mental health challenges.

Historic Regulatory Flexibility

Flexibility for nursing homes to combat the virus: CMS allowed facilities to transfer or discharge residents in order to group residents based on their COVID-19 status, and also made it easier for nursing homes to staff up by extending training requirement deadlines.

Helping healthcare workers practice to the top of their license: CMS expanded the capacity of the healthcare workforce by removing barriers for physicians, nurses, and other clinicians to be quickly hired from the local community or other states, and by cutting red tape so that health professionals can practice at the top of their license. That includes, for instance, temporarily waiving Medicare supervision requirements for non-physician clinicians; allowing nurse practitioners, physician assistants, and nurse anesthetists to practice at the top of their licenses and across state lines; and permitting wider use of verbal orders rather than written orders so clinicians can focus more of their time taking care of patients instead of on paperwork.

Meeting the needs of healthcare workers: CMS waived regulations under the Stark Law so that hospitals can now support their medical staff during this national emergency by providing benefits like daily meals, laundry services, or childcare services while they are on duty.

Reducing regulatory and reporting requirements to support a focus on patient care: CMS made comprehensive efforts to reduce paperwork and regulatory burdens on healthcare providers during the crisis, from temporarily eliminating certain paperwork requirements and adjusting audit schedules to extending providers' certifications to bill Medicare and Medicaid. CMS also lifted or delayed a huge share of quality reporting programs.

Expanding hospital capacity through flexibility: CMS enhanced hospital capacity to manage

COVID-19 surges by allowing hospitals to temporarily expand capacity to alternative care sites (known as the CMS Hospitals Without Walls initiative), such as ambulatory surgery centers, inpatient rehabilitation hospitals, converted hotels, and dormitories. Among other actions, CMS also allowed non-skilled nursing facility (SNF) buildings that are state-approved to be temporarily certified as and available for use by a SNF in the event nursing homes need to isolate COVID-19 positive residents.

Expanding available health workforce through flexibilities: HRSA introduced a variety of flexibilities for the National Health Service Corps and Nurse Corps, allowing members to serve where they are most needed without having to worry about whether they are in compliance with their service requirements. HRSA also helped expand the health workforce by waiving fees associated with querying the National Practitioner Data Bank, making it easier for providers to make expedited credentialing, hiring, privileging, and licensing decisions.

Expanding Healthcare Capacity and Access to Care

Covering care for the uninsured: To ensure that uninsured Americans have access to care and testing for COVID-19, HHS used appropriations from the Provider Relief Fund and other dedicated appropriations to reimburse, through HRSA, providers who deliver COVID-19 testing, treatment, and vaccinations for the uninsured. Healthcare entities that conduct COVID-19 testing of uninsured individuals, provide treatment to uninsured individuals with a COVID-19 primary diagnosis, or administer a COVID-19 vaccine to uninsured individuals request claims reimbursement through the HRSA program electronically and will be reimbursed generally at Medicare rates, subject to available funding. In 2020, more than \$2.7 billion had been paid out in testing and treatment claims to over 29,000 providers. HHS also protected uninsured individuals coping with COVID-19 by prohibiting providers receiving reimbursement through the HRSA COVID-19 Uninsured Program from balance-billing these patients.

Expanding access to treatments and countermeasures: FDA developed and posted more than 65 drug development related guidances to provide information to industry in response to various aspects of the COVID-19 pandemic including those related to hand-sanitizer, clinical trials, inspections, post-market safety, vaccine development, and compounding of drugs. To increase patient access to critically needed medications in shortage, or prevent potential shortages, FDA expedited review and approved more than 25 original Abbreviated New Drug Applications (ANDAs) for the treatment of patients with COVID-19 and more than 300 ANDA supplements under the agency's COVID-19 prioritization programs.

Advancing innovative countermeasures: BARDA supported 17 lifesaving medical countermeasures of various kinds to combat COVID-19, such as wearable vital-sign sensors and patient monitoring systems, needle-free vaccine administration technologies, and machine-learning-based sepsis detection algorithms. For example, a project with 98point6, a low-cost, telehealth primary care service, aims to assess, triage, diagnose, report and track patients with COVID-19, generating a national hotspot map. This program has completed 38,000 virtual visits with 5,700

suspected COVID-19 cases. Discussions are underway to potentially expand to other government agencies such as Indian Health Services and the Veteran's Administration.

A dramatic expansion of telehealth coverage and access: Actions taken by HHS spurred a dramatic rise in the use and availability of telehealth during COVID-19: Since mid-March, an average of 1.1 million Medicare beneficiaries have used telemedicine services each week, over 65 times higher than the pre-pandemic weekly average of 17,000 beneficiaries. In total, over 13.9 million beneficiaries have used telemedicine services during the pandemic. Steps included expanded Medicare telehealth coverage to people in all areas of the country, rather than just rural areas; expanded Medicare payment for telehealth services to allow routine office visits, preventive health screenings, mental health counseling, and care that ordinarily would require a trip to an outpatient clinic or hospital emergency room; allowing both patients and providers to carry out telehealth visits from their homes, rather than doctor's offices, and expanding the types of healthcare providers and settings of care that can provide telehealth, to include home health, hospice, rural health clinics, physical and occupational therapists, and others. CMS also updated the State Medicaid & CHIP Telehealth Toolkit to help states partner with providers to better understand telehealth coverage and payment, and a snapshot showed that more than 34.5 million telehealth services had been delivered to Medicaid and CHIP beneficiaries during the public health emergency.

Allowing easy-to-use technologies for telehealth: The HHS Office for Civil Rights (OCR) issued a [Notification of Enforcement Discretion](#) to empower covered healthcare providers to use widely available communications applications without the risk of penalties imposed by OCR for violations of HIPAA rules for the good faith provision of telehealth services. Providers can therefore use services like Skype and Facetime that ordinarily may not be HIPAA-compliant.

Protecting patients with kidney disease: In October, OASH's InnovationX launched the \$300,000 KidneyX [COVID-19 Kidney Care](#) challenge for front-line solutions that reduce the transmission of coronavirus among people living with kidney disease and/or reduce the risk of kidney damage among people who contract the virus. CMS worked with the dialysis community, the Kidney Care Emergency Response team, and ASPR to collect data to ensure the wellbeing of the 528,252 patients with end stage renal disease. Technical assistance was provided to 6825 dialysis facilities related to isolation, cohorting, testing and infection control and prevention.

Telehealth in Indian Country: Prior to the COVID-19 pandemic, many IHS providers did not offer remote healthcare visits to their patients. In FY2020, HIS was able to expand telehealth visits eleven-fold, from roughly 75 to 907 telehealth visits per week on average—in addition to many other telehealth modalities used, such as care provided over the telephone, which is common in the bandwidth-constrained environments of Indian Country.

Allowing copay waivers to support telehealth: OIG issued guidance to support providers in delivering needed patient care during the public health emergency, including regarding the ability of healthcare providers to reduce or waive amounts owed by Medicare and Medicaid beneficiaries for

telehealth services during COVID-19. OIG also issued guidance around the Anti-Kickback Statute intended to support access to care.

Providing states flexibility to adapt Medicaid and CHIP: CMS rapidly approved more than 530 waivers and flexibilities for states and territories to address their local needs for the pandemic. In the second quarter of 2020, median processing time was 17 days for disaster relief State Plan Amendments and 7 days for Social Security Act section 1915 waivers; significantly faster than the processing time for non-COVID actions, which was 64 days and 43 days, respectively. State Medicaid programs were permitted to enroll eligible beneficiaries more quickly in programs that care for the elderly and people with disabilities, and to make changes to state rules to enhance access and delivery of services for vulnerable populations in home and community-based settings. CMS fostered acceleration of broader telehealth coverage policies and payment by issuing new guidance on telehealth opportunities, outlining ways that states can remove barriers to telehealth, and rapidly approving state requests for emergency waivers and funding.

Mental health via telehealth: Using existing resources, SAMHSA mobilized its network of training and technical assistance providers to help train behavioral health providers on the use of telehealth, with SAMHSA courses reaching capacity within minutes of being announced and over 300,000 providers taking advantage of information, training and resources from SAMHSA TTC network.

[Combating COVID-19 Disparities](#)

Data on disparities: CDC published regularly updated data on disparate rates of infection, hospitalization, and mortality across racial and ethnic demographics: As of January 2021, American Indians, Alaska Natives, and Hispanic Americans are 3.3 times more likely to be hospitalized than non-Hispanic white Americans, while Black Americans are 3 times more likely to be hospitalized. AHRQ researchers showed that [disproportionate rates of COVID-19 illness and death](#) among racial and ethnic minorities were likely linked to higher probabilities of exposure at work and at home.

A research coalition to combat disparities: NIH launched the [Community Engagement Alliance \(CEAL\) Against COVID-19 Disparities](#), which focuses on addressing misinformation around COVID-19, engaging trusted partners and messengers in the delivery of accurate information and educating communities on the importance of inclusion in clinical research to overcome COVID-19 and health disparities generally. CEAL research teams are also conducting research on the most effective strategies for ensuring inclusion and for engaging, educating and increasing awareness within these groups about vaccine and treatment clinical trials to prevent and treat the disease.

Reaching vulnerable communities with strategic partnerships: The Office of Minority Health (OMH) within OASH developed a new \$40 million initiative to fight COVID-19 in racial and ethnic minority, rural and socially vulnerable communities. The project involves a cooperative agreement with the Morehouse School of Medicine to lead the initiative to coordinate a strategic network of

national, state, territorial, tribal and local organizations to deliver COVID-19-related information to communities hardest hit by the pandemic.

Supporting testing at community health centers: In May, HRSA awarded \$583 million to support COVID-19 testing in 1,385 HRSA-funded community health centers nationwide, many of which are located in medically underserved communities and are often the main source of affordable and accessible healthcare in those communities. More than 98 percent of community health centers, as of January 2021, offer COVID-19 testing. Over 91 percent of health center patients are at or below 200 percent of the Federal Poverty Level, 63 percent are racial or ethnic minorities, and nearly 23 percent are uninsured. As of early January, health centers have provided nearly 8 million COVID-19 tests.

Delivering multilingual COVID-19 information: In addition to efforts by CDC to make public health information available in both English and Spanish, FDA's official COVID-19 [webpage](#) has been translated into [Spanish](#) and includes the FDA COVID-19 Frequently Asked Questions (available in [English](#) and [Spanish](#)). The FDA has also created a COVID-19 [Multilingual Resources webpage](#) that features a growing collection of educational materials in Spanish, Simplified Chinese, Korean, Vietnamese, Tagalog, among other languages.

Protecting Rights

Protecting civil rights in triage practices: Based on a series of complaints against states for discriminatory policies in triaging guidelines when hospital systems face capacity constraints, OCR developed model best practices that protect civil rights, including early case resolutions with four states under which states at the fastest rate in OCR's history, under which states agreed to adopt such best practices and agreed to change policies that would/could have resulted in categorically exclusions of individuals because of their disability in violation of federal civil rights laws.

Supporting access to clergy and protecting religious freedom during the pandemic: Through extensive technical assistance, OCR worked with key players, such as CDC and CMS, to ensure that needed public health response measures treated religiously-motivated conduct on an equal basis with secular conduct. For example, in partnership with CMS, OCR provided technical assistance to a state university medical system which adopted new policies ensuring clergy access to patients for religious purposes and ensuring nondiscrimination on the basis of disability during the COVID-19 pandemic, a practice that has now been incorporated in other health systems. OCR facilitated the resolution of a complaint against a university hospital to provide accommodation to the religious exercise of a medical student to keep a beard according to his faith while using personal protective equipment.

Protecting Americans with disabilities during the pandemic: ACL's Protection and Advocacy Systems in five states filed complaints with OCR alleging that their state's standards discriminated against people with disabilities, resulting in updated Crisis Standards of Care guidelines.

Promoting Well-Being with Human Services

Delivering services safely to moms and children: HRSA provided guidance to its home visiting and Healthy Start grantees to help them shift to virtual care delivery for high-risk pregnant women, children, and families during these especially challenging times.

Promoting economic recovery and reentry to work: In the wake of the pandemic, ACF's Office of Regional Operations stood up the agency's first-ever cross-program policy team, producing four nationally recognized products for state and tribal cabinet-level officials to effectively respond to the pandemic's effects on economic opportunity. The state-responsive policy products included program flexibilities for states to cover costs of PPE and IT in moving to a virtual human services delivery system and how states could treat increased income from the CARES Act when determining benefits for families.

Protecting Americans from eviction: In response to an August executive order, HHS, through CDC, worked with the Departments of Housing Development and of the Treasury to implement a regulation using public health authorities to prevent Americans from being evicted from their homes.

Supporting transitions back home from the hospital: ACL created a team to address the needs of older adults and people with disabilities who needed to transition back to their community setting following hospitalization. The team responded to the states' request for technical assistance to prevent overcrowding in nursing facilities, hospitals and other congregate care settings.

Continuing child welfare work during the pandemic: In the summer of 2020, the Children's Bureau held regional roundtables with youth with experience in the child welfare system from around the country to hear of their experiences during this period of the COVID-19 pandemic, interrupted schooling, and protests for racial justice. The Children's Bureau then issued [a letter to state child welfare directors](#), with the particular point of encouraging ongoing support for young people aging out of the foster care system during COVID-19, resulting in numerous state actions to provide support for this vulnerable population.

Funding and supporting safe child care: The Office of Child Care (OCC), the Child Care and Development Fund (CCDF) program, and state, territory and tribal grantees developed flexibilities to help meet the child care needs of the nation's essential workers throughout this pandemic, while also working toward stabilizing the supply of child care providers and meeting the child care needs of working families despite widespread closures, increased costs and other disruptions caused by COVID-19. OCC awarded and administered \$3.5 billion in supplemental funding; provided guidance on available programmatic flexibilities; granted over 180 waivers to allow additional flexibility; launched technical assistance efforts; posted resources on ChildCare.gov; and partnered with the CDC on virus mitigation guidance for child care providers.

Keeping Head Start safely open: ACF's Office of Head Start provided its 1,600 grantees, who serve over 1,000,000 of the nation's most vulnerable children and their families, with ongoing support that enabled grantees to respond to the challenges of COVID-19. Support included immediate flexibilities that ensured local staff continued to receive pay and benefits, comprehensive technical assistance that reached more than 300,000 people, and constant and varied communications, all of which helped Head Start and Early Head Start programs lead the country in implementing in-person learning. Essentially all programs remained (and remain) open throughout the pandemic, with 60 percent able to provide some level of in-person learning to enrolled children. The CDC highlighted these innovations and safe work by Head Start/Early Head Start program in a December 11 MMWR publication.

Leading the Global Response

Bilateral strategic dialogues on the response: OGA leveraged existing strategic dialogues with countries including the United Kingdom, Canada, Australia, New Zealand, Brazil, Mexico, South Africa, Ukraine, Dominican Republic, Iraq, Qatar, Kuwait, Israel, Japan, India, South Korea, and the European Commission to hold discussions and reviews of country response to the COVID-19 pandemic and identified opportunities to deepen collaboration opportunities with countries around the world. These efforts both enhance the response to COVID-19 and deepen U.S. relationships with these nations for future global health and health security efforts.

Hosting regular G7 health minister calls: Starting in early February, Secretary Azar initiated a Health Track under the U.S. G7 Presidency focused on COVID-19 and commenced an unprecedented series of conference calls among G7 health ministers, hosting 22 calls throughout the year, to discuss challenges from the pandemic and possible solutions to address them. These calls provided an opportunity for health ministers to exchange timely information about COVID-19 diagnostics, vaccines, and therapeutics; PPE; WHO reform; and travel and border measures in their countries.

Pushing for transparency and cooperation from China: OGA and other HHS divisions led efforts to navigate the U.S. relationship with health authorities in China during the initial outbreak in Wuhan, including communications across the interagency. OGA's Health Attaché in China led health briefings to the U.S. Mission to Beijing during the early phase of the crisis, and facilitated high level communication between the U.S. and China, such as calls between Secretary Azar and Minister of Health Ma. After weeks of pressure by Secretary Azar and other HHS officials, WHO was finally allowed to lead a mission to China, including U.S. experts from NIH and CDC, although the scope of the mission was still strictly limited. Many US government concerns around the early stages of the outbreak and especially China's lack of transparency and WHO's inability to hold them accountable became the basis for WHO reform efforts now gaining momentum through several independent reviews of WHO's response.

Building a partnership with Taiwan over COVID-19: In August, Secretary Azar became the highest-ranking member of the executive branch to visit Taiwan since 1979, highlighting the

important contributions of Taiwan to global health as evidenced by their management of COVID-19 using transparency, technology, and science. The visit afforded the opportunity to shed light on WHO and China's pressure campaign to keep Taiwan from playing a role at WHO and sharing its expertise and successes within the region and broader global community.

Facilitating availability of samples for COVID-19 medical countermeasure development:

OGA led the U.S. Government Sample Sharing Working Group as it identified U.S. sample needs related to COVID-19, discussed priorities, and coordinated access to SARS-CoV-2 isolates and related clinical samples. The working group activated the Emergency Use Simple Letter Agreement (EUSLA), a material transfer agreement specifically developed for use during emergency situations, and HHS worked closely with other federal agencies to ensure that they use the EUSLA to obtain and share samples, resulting in government, academic, and industry partners having access to these critical SARS-CoV-2 isolates and other materials to enable the medical countermeasure research and development.

Coordinating Communications

Standing up a Joint Information Center: Within the Joint Coordination Cell, the Secretary established a Joint Information Center (JIC) to coordinate federal communications between the White House and the inter-agency to ensure that the federal government spoke with one voice regarding COVID-19 response operations. The JIC developed the Daily COVID-19 Communications Report, a one-stop shop for talking points and the latest information on pandemic response operations.

Daily media interviews: HHS public health leaders did TV, radio, and print interviews and other public engagements on a daily basis throughout the crisis, including more than 325 interviews by Secretary Azar, more than 2,500 interviews and other engagements by National Institute of Allergy and Infectious Disease Anthony Fauci, more than 225 interviews by FDA Commissioner Stephen Hahn, and hundreds of interviews by Assistant Secretary for Health Brett Giroir and CDC Director Robert Redfield.

Comprehensive, science-based briefings: Through early January 2021, CDC has held 26 telebriefings on COVID-19. During January and February 2020, Secretary Azar held regular briefings with public health officials such as Dr. Fauci, CDC Director Robert Redfield, and CDC leaders such as Dr. Ann Schuchat and Dr. Nancy Messonnier.

A regular cadence of Operation Warp Speed briefings: Starting in May, OWS held regular briefings with the media and with members of Congress and staff. Starting in December, OWS has held weekly briefings on the vaccine distribution and administration program.

Providing web tools and digital content: The Office of the Assistant Secretary for Public Affairs (ASPA) managed over 1,025 COVID-19-related updates to HHS.gov and created a COVID-19 website hub for HHS. User feedback was used to continually improve COVID-19 communications

on the web and in social media. In March, ASPA also began sending a weekly all-staff email updating HHS employees thanking them for their work on COVID-19 and recognizing the work done by various parts of the department, with URLs tracked within the messages typically generating 3–5,000 clicks through to the HHS Intranet and other sources of public health information. Similar regular emails were begun by other HHS divisions, and division leadership provided other sources of useful information, such as NIH’s five virtual Town Halls, with over 20,000 live viewers each time, featuring experts in epidemiology, infectious disease, human resources, travel, communication, research services, and acquisitions.

Aggressive outreach on the Provider Relief Fund: ASPA led the communication efforts for the unprecedented \$175 billion Provider Relief Fund Program, standing up a new public database to ensure transparency in disclosing the recipients of provider relief funding; held multiple press calls with the Secretary and senior HHS officials; issued a constant cadence of press releases with each round of new funding announcement (36 in total so far) and continues to coordinate the stewardship of the program with HRSA and others. The Office of the Assistant Secretary for Legislation (ASL) responded to more than 340 inquiries on the Provider Relief Fund, while also maintaining the Department’s program grant notification system for members of Congress, which sent 33,000 notifications in FY 2020. HRSA also amplified messages around the Provider Relief Fund across the country through their extensive networks, with HRSA’s Office of Regional Operations reaching over 30,000 stakeholders representing over 5,000 organizations.

Responding to congressional oversight: In FY 2020, ASL’s Office of Oversight and Investigation cleared over 1,457 letters and worked with the Office of the General Counsel to transmit over 465,000 pages of documents to requesting congressional committees with oversight jurisdiction.

Building stakeholder relationships: The Office of Intergovernmental and External Affairs organized and hosted three webinars with HRSA for providers, tribal, and faith communities regarding the Provider Relief Fund and created and maintained a hospitalcovid19@hhs.gov email account to respond to external questions and concerns regarding the fund, in addition to helping the HHS Executive Secretariat (Exec Sec) respond to over 400 letters from external groups regarding the fund.

HHS's Five Strategic Goals



Paying for Value

Announcing participants in Primary Care First: In November, the Center for Medicare and Medicaid Innovation (CMMI) announced 916 participants across 26 regions in the first year of Primary Care First, one of three prongs of the Primary Cares initiative to bring unprecedented levels of value-based payments to primary care in Medicare. Primary Care First offers primary care practices the opportunity to share in some upside and some downside risk of improved outcomes in their patient population.

Announcing the launch of direct contracting: In November, CMMI announced 51 participating organizations for the Direct Contracting path of the Primary Cares Initiative, which is more ambitious and aimed at larger practices, in which practices will bear the total cost of care risk for the extra health spending, not just at their own practice but throughout the system.

A new region-wide model for direct contracting: In December, CMMI announced a third prong of the Primary Cares initiative, Direct Contracting Geographic, which will test an approach to improving health outcomes and reducing the cost of care for Medicare beneficiaries in multiple regions and communities across the country. Through the model, participants will take responsibility for beneficiaries' health outcomes, giving participants a direct incentive to improve care across entire geographic regions. Within each region, organizations with experience in risk-sharing arrangements and population health will partner with healthcare providers and community organizations to better coordinate care. Beneficiaries in the model will maintain all of their existing Medicare benefits, including the ability to see any provider they choose, and may receive enhanced benefits such as additional telehealth services or easier access to home care. Participants will also have the ability to reduce beneficiary cost sharing for Medicare Part A and Part B services and offer beneficiaries a Part B premium subsidy.

Bringing value-based payments to more cancer patients: CMMI announced the new mandatory Radiation Oncology Model, a model expected to improve the quality of care for cancer patients receiving radiotherapy for 16 different types of cancer while reducing Medicare expenditures, through bundled payments that allow providers to focus on delivering high-quality treatments rather than biasing toward specific sites of care.

Expanding value-based transport payments: CMS expanded the Medicare Prior Authorization Model for Repetitive, Scheduled Non-Emergent Ambulance Transport nationwide. The model has saved Medicare about \$650 million over four years while preserving quality of care and access to essential services.

Promoting Patient and Provider Use of Data

Delivering interoperability of health records: In March, ONC and CMS published final rules to require interoperability of health information, as outlined in the 21st Century Cures Act. The ONC final rule promotes innovation in the healthcare technology ecosystem to deliver better information, more conveniently, to patients and clinicians; promotes transparency by allowing the use of computers, smartphones, and software to provide opportunities for the American public to regain visibility in the services, quality, and costs of healthcare; and defines exceptions to “information blocking” (practices that interfere with the access, exchange or use of electronic health information).

Blue Button 2.0 continues to spur innovation: Following the 2018 launch of Blue Button 2.0, which allows Medicare beneficiaries to securely connect their data to tools developed by innovative companies, over 60 apps are available to help beneficiaries manage their health, a 100 percent increase over FY2019.

Enforcing rights to health records: The Office for Civil Rights (OCR) completed a total 13 enforcement actions since the beginning of FY2020 in its Right of Access Enforcement Initiative, which aims to ensure patients can obtain their medical records as cheaply and quickly as the law requires.

Price and Quality Transparency

Historic price transparency measures: Starting on January 1, 2021, hospitals are required to make prices more transparent, by posting their standard pricing information online in a machine-readable format and making easily accessible online their standard charges for at least 300 common shoppable services, as well as their negotiated rates with insurers for those services. Starting in 2022, patients will have access to negotiated costs from their insurer as well, and then their cost-sharing information for the most common services in 2023, and for all services in 2024. The transparency rules also provide flexibility for payers to pass savings along to patients when they choose lower cost providers, without it counting against medical loss ratios. When one of the transparency rules came under fierce opposition by industry, the Office of the General Counsel (OGC) and the Department

of Justice (DOJ) successfully defended the rule in federal district and circuit court so that it could go into effect on January 1.

Transparency for patients and providers on drug pricing: Beginning in 2021, Part D plans are required to provide a real time benefit tool to clinicians with information that they can discuss with patients on out-of-pocket drug costs at the time a prescription is written. Part D plans will be required to make a real time benefit tool to their enrollees starting January 1, 2022.

A first-ever Quality Roadmap, helping to inform the COVID-19 response: HHS and other federal departments require healthcare providers to track thousands of quality measures. By some estimates, these tracking and reporting requirements cost our doctors \$16 billion annually, and it is not unusual for a small community hospital to track and report over 1,000 quality measures to over a dozen payers and regulators. In 2019 and 2020, HHS convened an 18-member private sector panel and an internal governmental panel for a series of meetings, known as the Quality Summit, that helped inform HHS's blueprint for reform, the [Health Quality Roadmap](#), which was the first-ever holistic assessment of the quality system. The roadmap proposed three major reforms: giving the private sector more input into governance of quality measures, like private, nearly universal standards used in industries like accounting; modernizing quality infrastructure and analytics, to reduce the burden of collecting quality data and increase its usefulness; and continuing to increase focus on measures that matter. The Quality Roadmap informed the nursing-home Provider Relief Fund initiative launched to respond to COVID-19, which, as part of more than \$20 billion allocated to skilled nursing facilities and assisted living facilities, provided approximately \$5 billion in funding tied to simple metrics regarding whether nursing homes were successfully protecting residents from the virus.

[Regulatory Reform to Allow Value-Based Care](#)

Removing barriers to substance abuse treatment: In July, SAMHSA successfully finalized a new rule under 42 CFR Part 2 Rule, the first area of regulation to see a final rulemaking as part of the Deputy Secretary's Regulatory Sprint to Coordinated Care. 42 CFR Part 2 was intended to protect patient records created by federally-assisted programs for the treatment of substance use disorders, but had become so burdensome as to actually pose barriers to treatment and potentially increase stigma around it. The final rule revised the Part 2 regulations to decrease burden for practitioners, increase access to comprehensive, high-quality care for those with substance use disorders, and facilitate better coordination of care while maintaining its confidentiality protections against unauthorized disclosure and use.

Permitting commonsense arrangements to deliver value and improve health: Prior to 2020, the regulations under the Stark Law and the Anti-Kickback Statute, two laws that heavily regulate how physicians are paid and how healthcare providers can work together, had never seen a major update to account for the rise of value-based care—even though the risk of certain kinds of fraud is naturally much lower when providers are being paid for outcomes rather than procedures. For this reason, these two areas were also identified as part of the Regulatory Sprint to Coordinated Care.

Historic changes to these regulations finalized in November 2020 mean that, for instance, if a patient is leaving the hospital after surgery, the hospital can provide a care coordinator to work with the post-discharge doctor to help navigate care, and the hospital can create financial incentives for the doctor to keep the patient healthy and out of the hospital.

A path forward for reforming HIPAA: As part of the Regulatory Sprint, in December 2020 OCR posted on HHS’s website a proposed rule to support care coordination and case management through reforms to HIPAA’s privacy rule, aiming to facilitate the transition to value-based healthcare by improving individuals’ access to their health information, permitting more information sharing for care coordination, and removing administrative burdens that do not meaningfully contribute to the protection of the privacy of individuals’ health information.

Strengthening Medicare

Lower costs for Medicare beneficiaries: For plan year 2021, average Medicare Advantage premiums have been reduced by an estimated 34 percent since 2017 (the lowest in 14 years), and average Part D basic premiums have been reduced by 12 percent since 2017 (some of the lowest premiums in 7 years).

Promoting convenient sites of care: CMS gave patients more choices on where to obtain care by gradually allowing, over the next three years, more than 1,700 additional services to be provided in the lower-cost hospital outpatient setting versus more expensive and potentially less convenient inpatient settings. In 2021, approximately 300 musculoskeletal services (such as certain joint replacement procedures) would be newly payable in the hospital outpatient setting. Another 270 additional procedures that are already payable when performed in the hospital outpatient setting were made eligible for Medicare reimbursement when performed at an ambulatory surgery center, giving patients more choices to get lower cost care outside of a hospital. At the Secretary’s direction, CMS also began the process of eliminating the “inpatient only” list, where Medicare will only pay for certain procedures in a typically more costly hospital inpatient setting. Existing changes to support access to services in lower-cost settings have been estimated to save beneficiaries \$150 million in lower copayments.

Faster access to the latest technology: To support the fastest possible access to innovative technology, CMS updated the way Medicare covers medical devices designated as breakthrough products by FDA, providing automatic coverage effective on the date of FDA approval or clearance for the next four years, after which Medicare can examine whether to continue coverage of the device based on evidence gathered.

New incentives for innovation: The 2020 Medicare payment rule increases the maximum possible add-on payment for new technologies from 50 percent above the cost of the existing technology to 65 percent of it, promoting innovation in areas like kidney care, and waives certain criteria for breakthrough devices to be eligible for the new technology add-on payments.

Affordability of Insurance

Maintaining stability of the ACA exchanges: Through Plan Year 2021, the average benchmark premiums for plans sold on Healthcare.gov has dropped for three consecutive years, the first decreases since its implementation, including a 2 percent decrease for the 2020 coverage year. Increased issuer participation across Healthcare.gov will reduce the percentage of people with access to just one issuer in their county to just 4 percent in 2021, a dramatic reduction from 29 percent in 2018.

Promoting state innovation: CMS approved a first-of-its-kind waiver for Georgia that will address systemic issues with the individual health insurance market in the state that is projected to produce lower premiums, greater access, and greater consumer choice in a more competitive private insurance market.

An expanded option for financing employer-based coverage: Starting January 2020, under a rule finalized by HHS, the Department of Labor, and the Department of the Treasury, employers will be allowed to offer new types of Health Reimbursement Arrangements (HRAs), where employees can receive tax-free benefits from their employer to purchase insurance on the individual market of their choosing, giving millions of American workers more options for health insurance coverage and potentially driving more competition in the individual insurance market.

Providing flexibility for lower-cost employer plans: HHS, the Department of Labor, and the Department of Treasury finalized a rule to provide more flexibility for changes in employer-based insurance plans that have grandfathered status (exempting them from some Affordable Care Act requirements), giving these plans ways to update benefits without being subjected to new costly regulations.

Lowering Drug Prices

Delivering discounts to patients at the pharmacy counter: Under the drug pricing status quo, discounts are negotiated on behalf of patients but do not have to be reflected in the prices patients pay at the pharmacy counter, with rebates in Part D alone totaling \$39.8 billion in 2019, an average discount of nearly 30 percent for brand drugs. HHS, including the Office of the Inspector General, finalized a rule this fall to end this broken system of kickbacks, and replace it with a simple, transparent system where these discounts are applied at the pharmacy counter. The rule means not only lower out-of-pocket costs for patients using the most expensive drugs, but also an end to incentives that have driven the list prices of drugs higher and higher.

Expanding access to low cost insulin and injectable epinephrine: HRSA finalized a rule to require HRSA-funded health centers to pass on discounts to medically underserved patients on insulin and injectable epinephrine that it purchases through the 340B Drug Pricing Program, which can deliver very deep discounts on these drugs for the nearly 30 million patients who use health centers each year, including more than 6.7 million uninsured Americans.

A model to change the incentives around foreign free-riding: CMS announced the Most Favored Nation drug payment model, run through the Center for Medicare and Medicaid Innovation, to lower Medicare Part B payments for certain drugs to the lowest price for similar countries and save American taxpayers and beneficiaries more than \$85 billion over seven years.

Lowering out-of-pocket costs through more accurate reimbursement: Reductions in Medicare reimbursement for certain hospital outpatient drugs obtained through the 340B drug discount program have now saved Medicare beneficiaries nearly \$1 billion on drug costs since the policy went into effect in 2018. OGC and DOJ successfully defended these policy changes in federal district and circuit court.

Updating Part D plan design: CMS announced the Part D Payment Modernization model, beginning in 2020, to test an approach to Part D in which incentives are better aligned to control costs, as well as the Part D Senior Savings Model, a voluntary model that enables participating Part D enhanced plans—more than 1,600 of which were on offer for Plan Year 2021—to lower Medicare beneficiaries’ out-of-pocket costs for insulin to a maximum \$35 copay per thirty-day supply throughout the benefit year.

Promoting value-based drug contracting with states: CMS published a final rule to support value-based contracting by states in Medicaid that codifies a broad definition of value-based purchasing, which aims to better align pricing and payment to an expected clinical outcome in a targeted population. By doing so, CMS hopes to encourage outcome-based agreements and negotiation with private payers benefiting not only people with Medicaid, but also patients covered by other types of insurance.

The first-ever paths to safe importation of drugs to lower prices: FDA issued a [final rule](#) and [guidance](#) that lay the foundation for the safe importation of certain drugs originally intended for foreign markets. The final rule implements a provision of federal law that allows FDA-authorized programs to import certain prescription drugs from Canada under specific conditions that ensure the importation poses no additional risk to the public’s health and safety while achieving a significant reduction in the cost of covered products to the American consumer. The final guidance for industry describes procedures drug manufacturers can follow to facilitate importation of prescription drugs, including biological products, that are FDA-approved, manufactured abroad, authorized for sale in any foreign country, and originally intended for sale in that foreign country.

Promoting lower costs through generic competition: In FY 2020, FDA approved or tentatively approved more than 900 ANDAs, including more than 70 first generics, and 30 generics under the Competitive Generic Therapy pathway.

[Unleashing the Telehealth Revolution](#)

Making expansions permanent: CMS took regulatory action to allow Medicare payment for more virtual check-ins and telehealth visits, including permanently expanding certain telehealth services

offered during the COVID-19 public health emergency and extending coverage for more than 60 services previously not available via telehealth after the end of the emergency.

Expanding knowledge of the telehealth experience: To better understand how patients' experiences vary across various forms of telehealth and in-person care, [AHRQ released a new patient experience survey](#) applicable to any type of ambulatory care visit, regardless of whether the care was delivered in-person, by phone, or by video call. The first-of-its-kind instrument is helping health systems and professionals learn about patients' experiences with telehealth.

Improving Quality in the Indian Health Service

Community Health Aide Program goes national: In July, Admiral Weahkee officially signed a policy that will expand the IHS's Community Health Aide Program (CHAP) on a national basis, after several decades of success by the program reaching remote communities in Alaska. CHAP provides for three types of provider extenders: Community Health Aides working under a physician or physician's assistant; Behavioral Health Aides working under a behavioral health professional; and Dental Health Aides working under a dentist. The CHAP model increases access to care by bringing healthcare closer to patients and provides a pathway for Indian community members to work toward professional degree programs in the healthcare field.

A funding boost for IHS: IHS implemented a \$243 million increase in agency funding from 2019 to 2020, including and the department proposed another \$185 million funding increase for 2021. These new investments were sufficient to fully cover staffing for new and replacement IHS facilities while also covering contract support costs so tribes can run their own facilities, as well as support for a completely new electronic health records system for IHS.

Expanding the IHS and VA Partnership: In 2020, IHS and the Veterans Affairs/Veterans Health Administration amended their national reimbursement agreement, which allows direct healthcare services to eligible American Indian and Alaska Native veterans at 74 IHS facilities. In FY 2020, \$20.49 million was reimbursed by the VA for healthcare services to the IHS and tribal health programs for more than 5,200 veterans, and nearly a million prescriptions were processed through the VA Consolidated Mail Outpatient Pharmacy for IHS-eligible veterans enrolled in the VA.

IHS improves quality and achieves vital certifications: As of August 2020, 100 percent of all IHS hospitals and Critical Access Hospitals have achieved and maintained CMS conditions of participation, and, as of the first quarter of FY 2020, 90 percent of IHS Health Centers and 46 percent of IHS hospitals with ambulatory care services have attained designation as Patient Centered Medical Homes. In FY 2020, the Pine Ridge and Rosebud Hospitals both received CMS certification and achieved full Joint Commission accreditation.

Extending care to new federally recognized tribes: IHS assisted seven tribes with receiving federal recognition in the Nashville Area and one in the Billings Area. These Area Offices worked with IHS headquarters to establish program funding levels for these tribes, successfully securing

New Tribes appropriations and establishing healthcare services for them, to expand access to quality care for IHS beneficiaries in Virginia and Montana.



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

Combating the Opioid and Addiction Crisis

According to the 2019 National Survey on Drug Use and Health, the prevalence of opioid-use disorder (OUD) decreased significantly from 2.1 million Americans in 2018 to 1.6 million in 2019. In 2018, the number of Americans dying from drug overdoses dropped for the first time in more than two decades, but overdose deaths began rising again in late 2019 and continued rising in 2020.

Better Access to Treatment, Prevention, and Recovery Services

Sustained increases in medication-assisted treatment: The number of Americans receiving medication-assisted treatment (MAT) for opioid use disorder (OUD) increased at least 38 percent from 2016 to 2020, while prescriptions of two forms of MAT—buprenorphine and naltrexone—have risen 46 and 31 percent respectively.

Grants for treatment and other services: SAMHSA disbursed \$1.5 billion through the State Opioid Response (SOR) grant program and further strengthened the language to require the use of MAT as the standard of care for the treatment of OUD.

Expanding access through Medicaid: With approvals of demonstrations in Oklahoma and Maine to provide flexibility around Medicaid's bar on paying for inpatient mental health treatment, the number of states with such waivers for substance use disorder treatment reaches 31.

More prescribers of medication-assisted treatment: In FY2020, SAMHSA increased the number of practitioners waived to prescribe buprenorphine, one form of MAT by 13,833, a nearly 18 percent increase from the end of FY2019.

Expanding access to treatment at health centers: Data released in 2020 found that, as a direct result of HRSA's investments to expand access to integrated mental health and substance abuse services, health centers saw a 46 percent increase in substance use disorder patients in 2019, a 51 percent increase in patients receiving medication-assisted treatment, and a 45 percent increase in the number of providers eligible to prescribe medication-assisted treatment, compared with 2018. In

total, the number of patients receiving MAT at community health centers has risen 264 percent since 2016.

Prevention, treatment, and recovery in rural communities: Through HRSA’s Rural Communities Opioid Response Program (RCORP) initiative, \$298 million has been invested to support substance use disorder (SUD)/opioid use disorder (OUD) services across more than 1420 counties since 2018. FY 2019 RCORP grantee performance data shows that 453,686 individuals were screened for SUD as a result of RCORP funding. Additionally, more than 12,000 individuals received MAT services through RCORP-funded programs.

Supporting the development of new MAT options: FDA issued a final guidance on clinical endpoints that are acceptable for demonstrating the effectiveness of drugs intended to treat opioid use disorder.

Covering MAT through Medicare and Medicaid: Beginning January 1, 2020, CMS expanded Medicare coverage for opioid treatment programs that deliver medication-assisted treatment (MAT) and counseling to people suffering from opioid use disorders, now ensuring some form of MAT coverage across all CMS programs.

Boosting the treatment workforce: Through its National Health Service Corps, HRSA supported more than 1,600 new substance use disorder providers serving in rural and underserved areas, increasing its behavioral health field strength by 41.7 percent above FY 2019. HRSA also developed a new Addiction Medicine Fellowship program and made 44 awards that support addiction psychiatry and addiction medicine training. Further, the number of all NHSC loan repayment awardees holding waivers to prescribe MAT rose 63 percent.

Enabling MAT expansion: AHRQ published the [Medication-Assisted Treatment \(MAT\) for Opioid Use Disorder Playbook](#), a comprehensive guide for implementing MAT in primary care and other settings, which contains the latest guidance, tools, and resources to address MAT implementation.

Better Pain Management

Youth misuse of pain relievers drops: According to the 2019 NSDUH, pain reliever misuse decreased significantly from 2018 to 2019 for those 12–17 years of age and has continued trending downward for 18–25 year olds.

More alternatives to pharmacological pain medication: CMS finalized a national coverage determination of acupuncture for the treatment of lower back pain, expanding access to this potential alternative treatment and allowing the generation of more data on its efficacy.

Promoting patient-centered prescribing: AHRQ’s new [Division of Digital Healthcare Research](#) produced an open-source, interoperable [Pain Management Dashboard](#) that provides

frontline clinicians with information about a patient’s medical history, pain assessments, historical treatments, and risk considerations, to support appropriate, evidence-based treatment of chronic pain. This advanced clinical decision support system also links to prescription drug monitoring program databases.

Better Targeting of Overdose Reversing Drugs

Naloxone prescribing continues to rise: The amount of naloxone prescriptions rose 502 percent from January 2017 through July 2020, according to prescribing databases.

SAMHSA support for naloxone: As of mid-2020 reporting, 645,000 naloxone kits had been distributed and 32,300 overdoses were reversed with support from SAMHSA’s SOR grant program.

Empowering law enforcement to prevent and respond to overdoses: CDC supported the Overdose Response Strategy with the Office of National Drug Control Policy, which is designed to enhance public health-public safety collaboration and strengthen and improve efforts to reduce drug overdoses within 21 High-Intensity Drug Trafficking Areas across 34 states.

Analysis to support better policies around naloxone: ASPE collaborated with CDC on analysis of naloxone co-prescribing laws and their impact, and published a blog post on this topic and also analyzed the impact of out-of-pocket payments on naloxone utilization.

Improving provider guidance around naloxone: As of July 2020, the FDA announced changes to the prescribing information for opioids and medications to treat opioid use disorder. These changes include recommending that as a routine part of prescribing these medications, healthcare professionals should discuss the availability of naloxone with patients and caregivers, both when beginning and renewing treatment. Additionally, they should consider prescribing naloxone based on a patient’s risk factors for overdose.

Better Data

Understanding challenging populations: ASPE analyzed electronic health records data for people experiencing homelessness with OUD, finding high rates of comorbid behavioral health conditions and low rates of treatment (especially buprenorphine and naloxone) and led a workgroup on neonatal opioid withdrawal syndrome to include prenatal exposure to other substances.

Discovering troubling trends in older adults: After a publication based on HCUP data noted that hospitalizations and emergency department visits related to opioids were rising rapidly in older adults, AHRQ consulted with other HHS agencies and awarded implementation grants that pilot the use of computer-decision support to enhance shared decision making around pain management for older adults served by HRSA-funded community health centers in Chicago, to strengthen connections with community and tribal resources in Oklahoma, and to develop care pathways and data driven quality improvement protocols among primary care clinics in rural Michigan and Ohio.

Better Research

Continuing the HEAL Initiative: Since its launch in 2018, the NIH HEAL Initiative, a comprehensive, inter-agency effort to provide scientific solutions to the opioid crisis, has awarded over \$1.8 billion in over 500 research teams across all 50 states to study opioid use and pain.

Supporting CDC opioid-prescribing guidelines: [Seven comprehensive reports](#) developed by AHRQ's Evidence-Based Practice Center Program were used by the CDC to update its national opioid-prescribing guidelines.

Expanding and Improving Treatment for People with Mental Illness

New waivers for states to support treatment: As of the end of 2020, seven states have Medicaid demonstration projects approved to support access to inpatient treatment and community-based services for serious mental illness, all seven approved since CMS published historic guidance to support these efforts in 2018.

Supporting decision-making on serious mental illness: A joint initiative between ACL's National Institute on Disability, Independent Living, and Rehabilitation Research; SAMHSA; and the American Psychiatric Association developed an app, the SMI Adviser, that provides an easy step-by-step process for individuals to create and share a psychiatric advance directive (PAD, a legal document that includes a list of instructions and preferences that the individual wishes to be followed in case of a mental health crisis when the individual may not be able to make decisions for him or herself.

Bold support for new treatments for SMI: NIH launched an arm of the Accelerating Medicines Partnership (AMP) to meet the urgent need for early therapeutic interventions for people at risk of developing schizophrenia, following AMP launches for Alzheimer's and autoimmune diseases.

Enlisting the faith community on mental illness: The Partnership Center joined with Columbia University's Spirituality Mind Body Institute (SMBI) to cohost a [six-part webinar series on Spirituality and Mental Health](#), with more than 10,500 registrants, promoting understanding of how spirituality has a positive impact when incorporated into treatment and services for those with mental illness.

Expanding treatment support to incarcerated Americans: SAMHSA Assistant Secretary Elinore McCance-Katz issued a letter to states and territories in February 2020 allowing the use of Community Mental Health Services Block Grant (MHBG) funds to serve individuals with SMI who are incarcerated. SAMHSA had historically not allowed for the provision of services while an individual is incarcerated, and supporting access for the incarcerated will ideally help individuals have more healthy re-entries to society from criminal justice institutions.

Advancing American Kidney Health

Supporting heroic organ living donors: HRSA issued a new rule that removed disincentives for living organ donor transplantation, by expanding support for a broader set of donation expenses like lost wages, child care, and elder care, to help address the current demand for kidney transplants. Living organ donation is an important option for thousands of men, women, and children on the national transplant waiting list, and transplants using organs from living organ donors accounted for 19 percent of the nearly 40,000 transplants performed in 2019.

Portable dialysis machines deployed for the first time: In May, the Strategic National Stockpile deployed 50 portable kidney dialysis machines and supplies to New York City and Long Island Intensive Care Units to provide surge capacity for facilities caring for patients with COVID-19, which has caused acute kidney injury and therefore required dialysis in a share of ICU cases. The new dialysis technology uses tap water to make the solution necessary for dialysis on demand, helping to reduce demand for dialysis supplies, and may hold promise for improved care for patients in other challenging circumstances in the future.

A new mandatory model in Medicare to reward more convenient dialysis and transplants: In September, CMS finalized a mandatory model, the End-Stage Renal Disease Treatment Choices Model, which will enroll about one-third of traditional Medicare beneficiaries with ESRD, about 120,000 patients, in a system that rewards more convenient, comfortable options like home dialysis and incentivizes, rather than discourages, transplants.

Expanding the supply of donated organs by holding organ procurement organizations accountable: CMS finalized a rule designed to tackle longstanding problems in the organ transplant system, by requiring that the organizations responsible for organ procurement be transparent in their performance; highlighting the best and worst performers; and requiring organizations to compete on their ability to successfully facilitate transplants. CMS estimated that if all OPOs were to meet both the donation and transplantation rate measures, the number of annual transplants would increase from about 32,000 to 37,000 by 2026, for a total of almost 15,000 additional transplants in that time.

Driving kidney innovation through prizes: The KidneyX Innovation Accelerator awarded \$3 million in prizes to six winners of [Redesign Dialysis Phase 2](#), in which winners built and tested prototype solutions, or components of solutions, that can replicate normal kidney functions or improve dialysis access. In October, InnovationX launched the \$2.5 million [Artificial Kidney Prize](#) challenge, a competition to accelerate the development of continuous kidney replacement therapies that provide transformational treatment options beyond current dialysis methods.

Expanding access to organs through updated science: CDC and the U.S. Public Health Service published an updated [solid organ transplant guideline](#) for assessing organ donors and monitoring transplant recipients for human immunodeficiency virus (HIV), hepatitis B virus, and hepatitis C

virus infections, which reflects advances in transplant technology and safety that can increase the utilization of organs available for transplants.

Transforming Rural Health

A rural action plan for all of HHS: HRSA and HHS's rural health task force developed and supported the HHS Rural Action Plan, the first HHS-wide assessment of rural healthcare and human services efforts in more than 18 years. The action plan provides a roadmap for HHS to strengthen departmental coordination to better serve the millions of Americans who live in rural communities. Eighteen HHS agencies and offices took part in developing the plan, which includes 71 new or expanded activities for FY 2020 and beyond.

A payment model to support rural transformation: In September, CMMI announced the notice of funding opportunity for the Community Health Access and Rural Transformation (CHART) Model, which aims to transform rural healthcare delivery and enable local community collaboration by providing upfront seed money to redesign systems of care and align across providers and payers based on their unique needs.

Interagency partnership to advance rural broadband access: HHS reached a memorandum of understanding with the Federal Communications Commission and the Department of Agriculture to promote rural access to telehealth via broadband. In January 2021, HRSA awarded \$8 million to fund the Telehealth Broadband Pilot program, which will support providers in four states in assessing the broadband capacity available to rural healthcare providers and patient communities to improve their access to telehealth services.

Providing new supplies to support rural care: ASPR and HRSA partnered to supply more than 900 rural hospitals across the United States with approximately 1,750 ventilators from the SNS. These devices will be provided at no cost to improve patient access to lifesaving respiratory care services in rural areas. The ventilators with kitted accessories and consumables will be delivered from the federal government directly to hospitals.

Disaster Response

Coordinating disaster response across the nation and around the world: While simultaneously responding to state, local, territorial, and tribal requests for assistance in the COVID-19 response, ASPR led the federal government's public health and medical response for nine hurricanes: Zeta, Delta, Sally, Marco, Laura, Isaias, Hanna, Cristobal, and Douglas; the Puerto Rico earthquake, the Oregon and California wildfires; the Beirut explosion; and seven National Special Security Events. Hundreds of federal disaster responders were deployed to help lead the response along with 108 tons of medical equipment and supplies to support field operations. ASPR also deployed 55 recovery specialists to help rebuild the capacity for health and social services in California, Louisiana, Oregon, and Puerto Rico.

Launching the Ready Reserve: The CARES Act made several technical fixes that will allow for the implementation of the Ready Reserve Corps as part of the U.S. Public Health Service Commissioned Corps, a long-planned augmentation of the service. The Ready Reserve Corps is a cornerstone of the Modernization Plan established by the Assistant Secretary for Health and will greatly expand the Commissioned Corps' capabilities by having officers available on short notice (similar to the other uniformed services' reserve programs) to assist the active duty component with both routine public health needs and a growing number of emergency response missions.

New countermeasures for health emergencies: Within ASPR, BARDA developed a robust portfolio of second-generation blood products to improve the safety, availability and usability of blood products. Several of the products will be targeted for use in the pre-hospital environment, which would provide new capabilities for emergency medicine in regional localities and rural communities. For example, BARDA is supporting development of Velico's spray dried plasma and Cellphire's thrombosomes which would enable emergency vehicles and remote locations to store spray dried plasma (Velico) and platelet-derived product (Cellphire) on the shelf for potentially up to three years—vastly improving current capabilities for resuscitation and treating traumatic injuries.

Food Safety

Building an international coalition for better food safety: OGA, working closely with the EU, Japan, Canada, Australia, Mexico, and Member States of the Africa Group, proposed an agenda item for the 2020 World Health Organization Executive Board meeting that built on past food safety efforts to increase discussion and consultation with Member States on actionable items for addressing food safety, integrating science and technology into needed public health solutions. In advocating for the resolution, the United States stressed the need for additional work at the local, national, regional and global levels to strengthen national food safety systems, including through better surveillance and coordinated food safety emergency response, as well as the important role of CODEX.

Saving money through better lab detection: CDC continued to enhance PulseNet, a national laboratory network that connects foodborne illness investigations, preventing approximately 270,000 illnesses and saving at least half a billion dollars in medical costs and lost productivity annually. It's estimated that, for every \$1 invested in PulseNet, \$70 is saved.

A modern, digital food safety system: In July, FDA released the New Era of Smarter Food Safety Blueprint, outlining plans over the next decade to harness new and emerging technological tools and approaches to create a more digital, traceable, and safer food system. FDA issued a proposed rule in September to standardize the information firms must maintain to facilitate rapid and accurate traceability.

Broadening genomic sequencing for foodborne illness: FDA's genomic epidemiology program for foodborne pathogens expanded significantly in 2020 to serve a greater number of national and international stakeholders. Early economic estimates suggest that the implementation of genomic

epidemiology networks like FDA's GenomeTrakr have a significant impact on reducing the burden of foodborne illness on public health, including a \$1.8 billion reduction in the cost of the burden of *Salmonella* annually.

Combating Anti-Microbial Resistance

Supporting new antibiotic tools: With support from BARDA, three innovative, cutting-edge investigational drugs to treat antibiotic-resistant infections will move into advanced stages of development: one treats bloodstream infections caused by *Staphylococcus aureus* bacteria, one restores the body's natural balance of bacteria to prevent *Clostridioides difficile* infections, and the third drug candidate uses bacteriophage to kill E. coli bacteria that cause drug-resistant urinary tract infections. The funding will support Phase 2 and/or Phase 3 clinical trials and other activities required to seek approval from the FDA. These innovative antibacterial candidates have the potential to be not only tools to address drug-resistant bacterial infections but are essential in contributing to national health security preparedness by providing new capabilities to respond to secondary bacterial infections that may follow public health emergencies and mass casualty events.

A new federal antibiotic purchase: ASPR entered into its first Project BioShield contract for the advanced clinical development, procurement and stockpiling of an antibiotic, NUZYRA from Paratek Pharmaceuticals, to expand national preparedness for biological threats and drug-resistant secondary bacterial infections that can complicate public health emergency response.

Expanding CARB-X: BARDA continued its support of the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), an international public-private effort to spur antibiotic development and combat anti-microbial resistance (AMR), enabling the expansion of this portfolio to 66 active projects. 2020 saw a second company conclude development of a product under CARB-X and begin receiving continued support from BARDA's Advanced Research and Development antibiotic program.

Updated National Action Plan for CARB: Building on successful implementation of the original Plan, HHS led the U.S. government in developing an updated National Action Plan for [Combating Antibiotic-Resistant Bacteria \(CARB\)](#), to cover 2020 through 2025. The 2020 Plan sets ambitious new targets aimed at achieving the five goals of the National Strategy for CARB, which focus on infection prevention and antibiotic stewardship, surveillance, diagnostic testing, innovative treatments, and international coordination.

Improving Antibiotic Use in Long-Term Care: The AHRQ Safety Program for Improving Antibiotic Use achieved a significant reduction in antibiotic starts in over 400 long-term care facilities. The Program adapts principles of AHRQ's Comprehensive Unit-based Safety Program to improve antibiotic prescribing, engaging bedside clinicians through the use of the Four Moments of Antibiotic Decision Making, which is an innovative approach to antibiotic stewardship that enables clinicians to be stewards of their own antibiotic prescribing.

Building a coalition to fight AMR globally: The United States co-chairs the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR), an HHS-wide effort led by OGA, with its Secretariat housed at CDC, to ensure broad U.S. government participation in its activities. Over the past five years, TATFAR achieved the goals set in its 2015-2019 work plan and is developing the next iteration of the work plan.

Improving stewardship of antibiotics globally: Recognizing the importance of strengthening efforts to prevent the development of antibiotic resistance, BARDA and OGA led and recommended HHS endorsement of the Stewardship & Access Plan developed by CARB-X, requiring all CARB-X funded product developers to have measures in place to support sound stewardship of antimicrobials once their product enters pivotal clinical trials.

Fighting the Flu

Promoting the flu shot during COVID-19: By working with manufacturers of the flu vaccine, CDC was able to project that between 194 million and 198 million doses would be made available for the 2020–2021 flu season, up from 178 million the previous year. CDC purchased an additional 2 million doses of pediatric and 9.3 million doses of adult flu vaccines this year for public vaccination programs and [made available guidance](#) for healthcare providers on how to offer vaccinations safely during the pandemic, including at walk-through or drive-through vaccination clinics.

Improving flu preparedness through better vaccine manufacturing: To support President Trump’s executive order on modernizing influenza vaccines, ASPR, in collaboration with the National Influenza Vaccine Modernization Task Force, released the [National Influenza Vaccine Modernization Strategy 2020-2030](#) outlining the federal government’s plans to support the next generation of influenza vaccines by focusing on three overarching strategic objectives: strengthen and diversify influenza vaccine development, manufacturing, and supply chain; promote innovative approaches and use of the new technologies to detect, prevent, and respond to influenza; and increase influenza vaccine access and coverage across all populations. As a first step to strengthening our manufacturing capabilities, BARDA funded the retrofitting of a U.S.-based recombinant influenza manufacturing facility. A strong domestic manufacturing capability remains critical for national security and response to seasonal or pandemic flu. BARDA also modified a Broad Agency Announcement it uses to express interest in project areas, seeking proposals for mRNA-based vaccine platforms to address both pandemic and seasonal influenza.

A new test for flu and SARS-CoV-2: CDC developed a new laboratory test that simultaneously identifies two types of influenza viruses (influenza A and influenza B) and SARS-CoV-2, for which FDA issued an EUA on July 2.

Keeping global flu preparedness aligned: OGA led negotiations on a decision point cosponsored by Brazil and adopted at the 73rd World Health Assembly to maintain prioritization of global pandemic and seasonal influenza preparedness and align planning efforts with WHO’s Global

Influenza Strategy 2019-2030. The decision point supported the Global Influenza Surveillance and Response System (GISRS) and the Pandemic Influenza Preparedness (PIP) Framework, encouraged updated national influenza plans, promoted rapid and timely sample sharing, and called for renewed action on global influenza vaccine manufacturing. This decision point builds on previous U.S.-funded global influenza preparedness work at WHO and supports the goals of the National Influenza Vaccine Modernization Strategy.

Combating Infectious Threats around the World

Ending two Ebola outbreaks in the DRC: The 10th outbreak of Ebola in the Democratic Republic of the Congo (DRC), which began in August 2018 in the North Kivu province of the DRC, officially ended on June 25, 2020. The 11th Ebola outbreak, which began in early June 2020 in the Equateur Province, ended on November 18, 2020. U.S. leadership played a crucial role in bringing an end to the North Kivu outbreak, the second deadliest Ebola outbreak in history: Meetings by Secretary Azar, CDC Director Robert Redfield, NIAID Director Anthony Fauci, and U.S. Ambassador to the DRC Mike Hammer led the DRC government to establish an Incident Management System that significantly improved coordination between the national government and WHO, other U.N. agencies, and NGOs. Working with Merck, BARDA and NIH helped develop a safe and highly effective vaccine, which became the first FDA-approved Ebola vaccine, delivered to more than 200,000 people in the region, and HHS provided crucial assistance to clinical trials in the DRC for two therapeutics, which became the first-ever FDA-approved Ebola therapeutics. To combat the North Kivu outbreak, CDC deployed 404 staff in 676 deployments for preparedness and response efforts.

New tools to defeat infectious disease threats: BARDA-funded partnerships resulted in the FDA approval/licensure/clearance of four medical countermeasure products in 2020, including the two therapeutics to treat Ebola, one a cocktail of monoclonal antibodies and one a single monoclonal product. BARDA also supported the development of the first-ever adjuvant, cell-based influenza vaccine designed to protect against influenza A (H5N1) and a new diagnostic test for Zika.

Promoting Vaccine Confidence and Access

Improving systems to address drops in childhood vaccinations: When orders for routine pediatric vaccines dropped following the declaration of the COVID-19 national health emergency, CDC reacted by developing a new vaccine ordering analysis tool that monitors routine immunization ordering; launching county-level vaccine ordering maps and analyses; and working to reverse decreased pediatric immunizations during the pandemic.

Combating vaccine hesitancy globally: OGA leads a group of the Five Eyes countries (U.K., Canada, Australia, New Zealand and the United States) on vaccine confidence, aligning our nations' efforts and sharing best practices to enhance vaccine confidence messaging globally. Following a U.S.-led vaccine confidence side event at the 2019 World Health Assembly, the United States led an Immunization Resolution adopted by Member States during the 73rd World Health Assembly.

Expanding providers of childhood vaccines: HHS issued an amendment to the Declaration under the PREP Act to expand access to childhood vaccines during the COVID-19 pandemic that authorized state-licensed pharmacists to order and administer vaccines to persons ages three through 18 years.

Advancing immunization record system: Partnering with CDC and jurisdictional immunization registries, OASH's InnovationX effort accelerated capabilities for large national provider organizations to report and query immunization records across 44 jurisdictions in the United States. This work enabled 13 immunization information systems so far to share immunization records, addressing gaps in reporting when residents cross jurisdictional boundaries for care.

Strengthening Health Cooperation and U.S. Humanitarian Leadership

Combating malign influences in the Americas: OGA used diplomatic relations in the Americas region to mitigate efforts by states, including Cuba, Venezuela, and Russia, who are working to increase their influence in the region to the detriment of US safety and security. OGA coordinated with other U.S. government agencies to strengthen diplomatic ties and offer technical and humanitarian assistance to dissuade countries in the region from accepting aid from these ill-intentioned states. Examples include using OGA's Health Attaché office to persuade Brazil to reject the Russian COVID-19 vaccine, and offering CDC technical assistance in lieu of Panama accepting an offer of Cuban doctors.

A first-ever South America regional office: At the end of October, CDC opened its new South America regional office in Brasilia, Brazil, which will strengthen CDC's ability to protect Americans by responding more rapidly to health threats wherever they occur and building key relationships to tackle shared health priorities.

Opening Bolivia to health diplomacy: After decades of silence between the U.S. and Bolivia, OGA re-established health diplomatic relations with the Ministry of Health of Bolivia following national elections. Re-engaging allows the U.S. to strengthen ties in the region, which is important for influence in regional and multilateral fora, including the Pan American Health Organization. Improving relations and technical collaboration is also important to U.S. health security and increasing Bolivia's capacity to prevent, detect, and respond to outbreaks.

Combating Infectious Threats at Home

Responding to the epidemic of sexually transmitted infections: As the rate of sexually transmitted infections rises in the United States (e.g., chlamydia with a 19 percent increase since 2014, gonorrhea with a 63 percent increase since 2014) OASH's Office of Infectious Disease and HIV/AIDS Policy led development of the first-ever Sexually Transmitted Infections Federal Action Plan.

The first major Lyme public-private partnership: HHS announced a [\\$25 million LymeX Innovation Accelerator public-private partnership](#) with the Steven and Alexandra Cohen Foundation for [Lyme innovation](#) and competition prize awards, the largest-ever public-private partnership to combat Lyme disease through support for diagnosis, treatment, and prevention options. As part of this effort, OASH's InnovationX launched the [Health+](#) patient-centered innovation cycle, obligating nearly \$1.8 million in government funds to engage stakeholders as part of the LymeX partnership. Reflecting the importance of patient advocates and voices in combating Lyme disease, [LymeX.Crowdicity.com](#) was set up, an idea management platform enabling participants with lived experiences to vote on the top 10 Lyme disease research priorities, engage with the site's core values, and sign up to be considered for an interview.

Combating Hepatitis A: CDC led an investigation into nearly 34,200 hepatitis A cases that were part of widespread outbreaks affecting 33 states, as of September 25, 2020. CDC has helped every affected state in their outbreak response efforts. States have administered more than 4.3 million hepatitis A vaccine doses to adults since the outbreaks began; nearly 1.3 million of those doses have been distributed by CDC, a more than 4-fold increase from pre-outbreak years.

[Combating Tobacco and E-Cigarette Use](#)

Bold action drives reduction in youth e-cigarette use: In 2013, FDA and CDC's National Youth Tobacco Survey (NYTS) found that less than 5 percent of American high schoolers reported using e-cigarettes; by 2019, 30 percent of high schoolers were using them—a more rapid rise in use than had been observed by modern surveys of any substance. In September 2019, FDA announced that it planned to prioritize enforcement against certain illegally marketed e-cigarettes that are most appealing to youth, and companies soon pulled these products from the market. In January 2020, finalization of the policy outlined FDA's prioritized enforcement of flavored (other than tobacco and menthol), cartridge-based e-cigarettes, which are especially appealing to youth. According to the NYTS, the number of youth using any tobacco product dropped from 6.2 million in 2019 to about 4.5 million in 2020—down about 28 percent, a remarkable one-year drop.

Effectively encouraging smokers to quit: CDC aired a new round of 'Tips from Former Smokers' hard-hitting ads focused on raising awareness about heart disease, cancer, chronic obstructive pulmonary disease, and Buerger's disease. In 2020 alone, more than 182,000 total calls to 1-800-QUIT-NOW were received through the first 18 weeks of the campaign. Findings from a 2020 CDC study found that the Tips campaign has led more than 1 million U.S. adults to quit smoking and an estimated 16.4 million U.S. adults to attempt to quit smoking during 2012–2018.

Updating cigarette package warnings: FDA issued a final rule to require new health warnings on cigarette packages and in cigarette advertisements, the most significant change to cigarette labels in more than 35 years, which aims to increase public awareness of lesser-known, but serious negative health consequences of cigarette smoking.

Understanding e-cigarette use-related lung injury: In the spring of 2019, several users of e-

cigarettes were diagnosed with lung injury related to their product use. This illness was named E-cigarette or Vaping Associated Lung Injury (EVALI). As of February 18, 2020, nearly 3,000 individuals were hospitalized with EVALI and 68 EVALI-related deaths were confirmed. In addition to close monitoring and investigation of the situation by CDC, in order to better understand the causes, mechanisms, and long term effects of EVALI and e-cigarette use, NIH and FDA contributed over \$14 million to fund 41 small short-term projects on the issue in 2020.

[Ending the HIV Epidemic in America](#)

First implementation grants for the Ending the HIV Epidemic initiative: In 2019, HHS announced Ending the HIV Epidemic: A Plan for America (EHE), which aims to end the HIV epidemic in America by 2030. In 2020, CDC awarded \$109 million to 32 state and local health departments that represent the 57 EHE Phase 1 jurisdictions. The funding was awarded through CDC’s “Integrated HIV Program for Health Departments to Support Ending the HIV Epidemic in the United States” cooperative agreement and is part of a five-year funding program. Communities will use the funding to customize and implement high-impact HIV diagnosis, treatment, prevention, and response strategies, and to reduce local barriers to HIV prevention and care.

Leveraging health centers and the Ryan White HIV/AIDS Program for EHE: HRSA awarded nearly \$54 million to 195 health centers with service delivery sites in geographic locations identified by the EHE initiative, emphasizing outreach, HIV testing, partnerships, and workforce expansion to increase access to and use of PrEP, as well as linking individuals who test positive for HIV to treatment. HRSA also awarded approximately \$63 million to 60 Ryan White HIV/AIDS Program recipients to link people with HIV to essential HIV care and treatment and support services, as well as to provide workforce training and technical assistance. This includes more than \$55 million to 39 metropolitan areas and eight states that are Ryan White HIV/AIDS Program Parts A and B jurisdictions to enable recipients to implement strategies, interventions, approaches, and core medical and support services to reduce new HIV infections in the U.S.

Expanding prevention access through Ready, Set, PrEP: OASH announced that, beginning April 1, 2020, patients enrolled in the Ready, Set, PrEP program to cover PrEP medications for uninsured people at risk for HIV will fill their prescriptions for PrEP medication at no cost at their choice of Avita Pharmacy, CVS Health, Health Mart, Longs Pharmacy Solutions, Rite Aid, and Walgreens locations or by using one of these pharmacies’ mail order solutions. This represents about a third of all the pharmacies in the country, providing a valuable service to those using PrEP and resulting in substantial cost savings to the federal government. In June, Albertsons Companies and Walmart donated their pharmacy dispensing services to the Ready, Set, PrEP program, increasing the number of pharmacies participating in the program to expand access to HIV prevention medications.

Supporting science on effective HIV program design: NIH awarded approximately \$10 million to support implementation science research to advance the goals of the EHE initiative. All of the

funded projects involve close collaboration between NIH investigators and local implementing partners and community groups in EHE Phase I priority areas.

A dashboard for the initiative: OASH launched the America's HIV Epidemic Analysis Dashboard (AHEAD), the first national HIV dashboard, which provides up-to-date information about EHE progress.

A new record for the Ryan White HIV/AIDS Program: Exceeding its own goal, HRSA continued to increase access to quality healthcare, improve health equity, and reduce transmission by increasing viral suppression for 88 percent of its Ryan White HIV/AIDS clients in medical care, compared with 64.7 percent viral suppression among all people diagnosed with HIV. As a result of expanded HIV prevention services, the number of people receiving HIV tests in HRSA-funded health centers grew by 9.7 percent, to more than 2.2 million.

Combating discrimination against HIV patients: OCR took corrective action against a facility that banned a patient from its practice after the patient filed an OCR discrimination complaint for the facility's refusal to perform surgery because of the patient's HIV+ status.

Promise of a long-acting preventive regimen: In 2020, two large NIAID-sponsored clinical trials found that a PrEP regimen containing an investigational long-acting form of an HIV drug injected once every eight weeks was safe and more effective than daily oral PrEP at preventing HIV acquisition.

[Addressing Costly Chronic Conditions](#)

Launching Healthy People 2030: OASH's Office of Disease Prevention and Health Promotion released Healthy People 2030, the nation's 10-year plan for addressing our most critical public health priorities, which lays out a more focused set of objectives than past Healthy People plans. In December, OASH released 23 Leading Health Indicators, representing the highest priority objectives for Healthy People 2030, and 8 Overall Measures of Health and Well-Being to assess the impact of Healthy People 2030 on life satisfaction, life expectancy, and mortality and health.

Raising awareness of hypertension: The Surgeon General issued a *Call to Action* urging Americans to recognize and address hypertension control as a national, public health priority, providing strategies for those on the frontlines of healthcare and public health to address this costly, dangerous and far too common chronic health condition.

A new set of dietary guidelines for Americans: In partnership with the U.S. Department of Agriculture, OASH's Office of Disease Prevention and Health Promotion released the 2020–2025 Dietary Guidelines for Americans in December, with comprehensive guidance for women who are pregnant and breastfeeding, infants, toddlers, and older adults. The 2020–2025 Dietary Guidelines includes recommendations for infants and toddlers for the first time. In response to a congressionally mandated report from the National Academies of Science, Engineering and

Medicine, USDA and HHS implemented new measures to increase transparency for the development process of this edition that resulted in over 100,000 public comments, demonstrating increased public engagement over previous editions.

Building on the first-ever National Youth Sports Strategy: Using the 2019 National Youth Sports Strategy as a roadmap, OASH developed an implementation plan for the strategy in 2020 and met with youth sports organizations across the country through a series of workshops. The organizations helped better understand the impact of COVID-19 and how to encourage participation in youth sports in the wake of the pandemic. OASH used knowledge gained during the workshops to launch the NYSS Champions, a youth sports partnership coalition with over 100 members serving over 10 million youth and representing nearly 14 million volunteer hours.

Continuing the implementation of the COPD National Action Plan: NIH's National Heart, Lung, and Blood Institute, through the [Learn More Breathe BetterSM Community Subcontract Program](#), provided funding to organizations around the country to implement innovative health education initiatives aimed at increasing awareness about chronic obstructive pulmonary disease (COPD) and supporting the goals of the COPD National Action Plan.

Promoting Women's Health

A new plan for addressing maternal mortality and morbidity: In December, HHS released a departmental [Action Plan](#) and announced a partnership to reduce maternal deaths and disparities that put women at risk prior to, during, and following pregnancy. The Surgeon General issued a complementary [Call to Action to Improve Maternal Health](#) outlining the critical roles everyone can play to improve maternal health.

Expanding the reach of National Women's Health Week: During the 2020 observance of National Women's Health Week, the Office of Women's Health strengthened partner and ambassador engagement, increasing number of federal and non-federal partners by 18 percent and 56 percent, respectively. With support from partners and ambassadors, NWHW content and tools were shared a record 140,677,963 times and reached 34,058,492 people across social media.

Addressing high blood pressure in women: The Office on Women's Health created a new initiative to address blood pressure disparities among women of reproductive age (18-39) and the first national observance focusing solely on hypertension awareness in women of reproductive age to educate women ages 18-44. With the goal of achieving blood pressure control in 80 percent of reproductive-age women with hypertension by 2025, OWH issued a hypertension challenge to ensure women with hypertension during pregnancy and/or postpartum receive appropriate monitoring and follow-up. OWH will award prizes for up to 20 programs with proven track records of helping individuals monitor and control high blood pressure.

Supporting families through Home Visiting and Addressing Maternal Mortality and Morbidity: In September 2020, HRSA awarded approximately \$341 million in funding to 55 states,

territories and nonprofit organizations through the Maternal, Infant and Early Childhood Home Visiting (MIECHV) Program and approximately \$16 million in funding to nine states through the State Maternal Health Innovation (State MHI) Program to improve maternal health outcomes. The MIECHV program supports communities to provide voluntary, evidence-based home visiting services to pregnant women and parents with young children up to kindergarten entry. The State MHI Program helps states address high rates and disparities in maternal mortality and morbidity through innovation in maternal health service delivery, such as expanding telehealth services to improve access to care.

Battling Sickle Cell Disease

New leadership on sickle cell disease: OMH developed multiple efforts to improve the lives of those living with Sickle Cell Disease (SCD), including commissioning a National Academies of Sciences, Engineering, and Medicine Strategic Plan and Blueprint for addressing SCD in the U.S. and organizing a White House SCD Roundtable hosted by First Lady Melania Trump.

Strategic grants to improve SCD treatment: OMH awarded two grants totaling \$2.25 million designed to help improve the lives of those affected by SCD, to develop and implement a national SCD clinical data collection platform and to determine the feasibility and effectiveness of providing financial incentives to providers to improve the quality of life for children with SCD through increased prescription rates of hydroxyurea. In addition, OMH provided \$500,000 to support HRSA's SCD Treatment Demonstration program (TDP) to deliver SCD-specific education to primary care providers and other health professionals using Project ECHO. HRSA's two SCD programs (TDP and the SCD Newborn Screening Follow up Program) work together to increase the number of healthcare providers knowledgeable about SCD evidence-based treatment guidelines and link individuals and families to education, support, and evidence-based care.

Tackling SCD globally: OGA and OASH jointly developed an initiative to combat SCD globally, centered on evidence-based practices that are highly cost-effective, feasible, and tailored to the specific needs and resources of individual countries, tied into efforts toward the expansion of primary healthcare as a mechanism to achieve universal health coverage. HHS also co-hosted the World Bank's first convening of the Global Coalition for Sickle Cell Disease in February 2020, bringing together key public and private stakeholders in a new unprecedented global enterprise to significantly reduce the morbidity and mortality of SCD in Sub-Saharan Africa.



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

Boosting Adoption and Strengthening Child Welfare Systems

Unprecedented progress on adoption from foster care: ACF's Children's Bureau and Assistant Secretary Lynn Johnson continued to lead the [All-In campaign](#) with governors and states on adoption, putting a greater focus on adoption from foster care. ACF's [most recent data](#) showed a record high level of adoptions and a steady decrease in foster care numbers.

Strengthening prevention: As of the end of FY2020, the Children's Bureau has established 13 demonstration projects across the country that are co-designed with families and communities with an explicit focus on strengthening families through primary prevention. Strategies incorporate a continuum of collaborative services and supports from community-based partnerships to strengthen and preserve families by meeting their needs prior to formal involvement in the child welfare system. Despite the challenges of COVID-19, grantees have utilized creative ways to meet the needs of their community and to continue implementation efforts through the use of various virtual platforms.

Improving child welfare infrastructure: The Children's Bureau [published](#) several draft technical assistance self-assessment tools to support states and tribes developing comprehensive child welfare information systems. The Children's Bureau worked closely with title IV-E agencies to refine the tools and ensure they reflect child welfare program needs as well as modern technologies. The distribution of these technical assistance self-assessment tools helps promote the economical, effective and efficient design, development, implementation and management of child welfare information systems.

Prohibiting discrimination against individuals with disabilities and limited English proficiency: OCR took enforcement actions to protect the rights of parents and family members with disabilities and limited English proficiency (LEP) from discrimination in the child welfare system. OCR reached statewide settlements with the States of [Massachusetts](#), [New Jersey](#), [West Virginia](#), and [Oregon](#) to protect the rights of persons with disabilities to be free from discrimination in state child welfare programs.

Protecting Life at all Stages

Protecting life in global health assistance: HHS worked with the Department of State and U.S. Agency for International Development to implement President Trump’s restored and expanded Mexico City Policy, known as “Protecting Life in Global Health Assistance,” to ensure that, consistent with applicable law, global health assistance administered by HHS is not provided to foreign non-governmental organizations that provide or promote abortion as a method of family planning.

Building a coalition to protect life in global fora: Secretary Azar, along with Hungarian Minister for Family Affairs Katalin Novak and Brazilian Deputy Chief of Mission Fernando Pimentel, hosted 30 Ambassadors from likeminded countries at the Blair House in January 2020 to further strengthen collaborative efforts among nations with regard to the four pillars of HHS’s Protecting Life in Global Health Policy: promoting a positive vision for women’s health, protecting the lives of the most vulnerable, defending the important role of the family, and encouraging respect for national sovereignty in multilateral fora.

Signing of the Geneva Consensus Declaration: Culminating work on PLGHP was the October 22, 2020 ceremonial signing of the Geneva Consensus Declaration (GCD), cohosted by Secretary Azar and Secretary Pompeo and five other co-sponsoring nations – Brazil, Egypt, Hungary, Indonesia, and Uganda. So far, the Geneva Consensus Declaration has been signed by 35 nations representing over 1.6 billion people from every region of the world. Secretary Azar called this historic achievement “without contest the most significant international commitment made in the history of the prolife movement.”

Holding the U.N. and WHO accountable on abortion during the pandemic: The U.N. and WHO increasingly promote abortion as health policy guidance, but in 2020, also began using the COVID pandemic to export abortion around the world by declaring it essential to the COVID-19 response, including in countries where abortion is illegal or restricted. OGA’s PLGHP initiative undertook efforts to hold these multilateral organizations accountable by drafting three research documents exposing U.N. and WHO efforts to manipulate pandemic response to garner funding for abortion. This research resulted in USAID Acting Administrator John Barsa’s letter to the Secretary General, calling on the U.N. stick to its mandate and to halt its promotion of and funding for abortion during the COVID-19 pandemic.

Permitting states to exclude abortion providers from Medicaid Family Planning: In January 2020, CMS approved Texas’s Healthy Texas women family planning demonstration waiver to provide meaningful family planning and health services while fostering a culture of life and excluding abortion providers. Earlier, CMS had rescinded a State Medicaid Director letter, which had the result of providing State Medicaid Programs with more flexibility to set qualification standards for Medicaid providers, including requirement that may exclude abortion providers from the Medicaid program.

Convening an Ethics Advisory Board on research involving human fetal tissue: Pursuant to the Administration’s June 2019 policy statement on funding for research involving human fetal tissue from elective abortions, in 2020, the Secretary convened the first-ever ethics advisory board to advise on whether, in light of the ethical considerations, the Secretary should withhold funding for certain grant applications that proposed research involving the use of human fetal tissue from elective abortion. Subsequently, HHS published a proposed rule to strengthen safeguards and program integrity requirements applicable to such research.

Promoting Healthy Family Planning and Sexual Behavior

Promoting healthy family planning: OASH’s Office of Population Affairs (OPA) operated 75 Title X family planning service delivery grants, including five new grants serving three states without current Title X services. Title X grantees provided free or low-cost quality family planning and related preventive services to over 3.1 million clients. OPA supported nine Title X continuation research grants to test innovative approaches to improving family planning service delivery and linking family planning services and substance use disorder screening and treatment.

Testing new teen pregnancy prevention approaches: OPA funded 17 new TPP demonstration grantees to develop and test new and innovative interventions, including 13 new innovative and impact network grants to develop interventions in seven key priority areas, and four new grants to rigorously evaluate innovative interventions. OPA also awarded four TPP research grants and one research-to-practice center grant to promote health and positive assets to reduce teen pregnancy.

Supporting the success sequence: In October, ACF’s Family and Youth Services Bureau awarded 79 organizations—including faith-based and community organizations—approximately \$31 million in grants for fiscal years 2020 through 2022 to educate youth on sexual risk avoidance, implementing the Positive Youth Development framework which teaches participants how to voluntarily refrain from sexual activity and the benefits of success sequencing for poverty prevention.

Expanding support for healthy fatherhood: ACF’s Office of Family Assistance made a total of 113 grant awards to 100 organizations across 30 states to promote healthy marriage and responsible fatherhood, a 33 percent increase in the number of grants in operation throughout the 2015-2020 cohort. The grant awards will help individuals, couples, fathers and youth build strong relationships to support families and communities.

Improving Human Services in Indian Country

Playing a part in Operation Lady Justice: As part of the administration-wide Operation Lady Justice effort to address the crisis of missing and murdered Native Americans, the Administration for Native Americans (ANA) produced “[Missing and Murdered Native Americans: A Public Health Framework for Action for ACF and the Communities It Serves](#)”. The framework takes a public health prevention approach to this issue and will change the way ACF works in partnership with tribes and Native American populations on this issue. The framework provides a pathway for ACF

program offices to take action together through four pillars (culture, language, traditional practices; economic mobility; prevention; and the social determinants of health) and five protective factors.

New thinking on tribal early childhood programs: ANA, in partnership with the ACF Office of Early Childhood and the Federal Reserve Bank of San Francisco, developed a blueprint for action to identify ways to support tribal early childhood coordination. The blueprint was created through a tribal early childhood working group that involved multiple federal agencies as well as tribal leaders and tribal early childhood stakeholders. Increasing both access to and quality of tribal early childhood services promote economic mobility and can help prevent of adverse childhood experiences.

Supporting tribal capacity for participating in federal grants: ANA awarded \$1.4 million under a new initiative: Social and Economic Development Strategies for Growing Organizations (SEDS-GO). The SEDS-GO program strengthens internal governance structures and capacity so tribes and native organizations run more efficiently and effectively to better serve Native American communities. The SEDS-GO program contributes to ANA's commitment to help tribes and Native organizations strengthen their competitiveness for federal and private sector grants and develop sound financial and programmatic management systems.

[Integrating Health and Human Services to Address Social Determinants of Health](#)

Bringing together health and human services stakeholders: More than 20,000 community based organizations are supported through federal grants administered by ACL to provide services like nutrition support, managing chronic disease, falls protection, reducing social isolation, meeting transportation needs, supporting employment, ensuring economic independence, and addressing other non-medical risk factors. These types of supports have been shown to [improve health outcomes and reduce the cost of care](#) for older adults and people with disabilities, but there has been a long-standing chasm between healthcare and social services. To help bridge the gap, ACL hosted the first-ever National Summit on Health Care and Social Service Integration, bringing more than 500 healthcare and social services leaders in-person or virtually to discuss the development of a framework that will jumpstart healthcare and social services collaborations on a local, regional and national scale. In August, ACL followed up on the Summit with the landmark publication of the draft document: [Strategic Framework for Action: State Opportunities to Integrate Services and Improve Outcomes for Older Adults and People with Disabilities](#). This document has already catalyzed health and human services integration efforts in at least a dozen states during 2020.

Better data on social determinants: CDC expanded the U.S. Diabetes Surveillance System with a new social determinants of health module to help identify under-resourced areas of the United States and assess the potential impact of health disparities on diabetes burden and risk factors, giving public health professionals and researchers a more complete look at factors potentially impacting people's ability to successfully manage diabetes and prevent type 2 diabetes around the U.S. HRSA developed and implemented greater reporting capabilities in the Uniform Data System used by

health centers to provide greater information on the prevalence of social determinants of health data collection efforts in health centers, which will support and advance research to better understand the causes of poor health outcomes such as diabetes and maternal mortality. HRSA has developed and is implementing new social determinants of health measures for CY 2020 UDS reporting on the number of patients that screen positive for food insecurity, housing insecurity, financial strain, and lack of transportation/access to public transportation. This will provide the first national dataset on social risk factors among health center patients which will be used to inform Health Center Program development and value-based care delivery.

Using data analytics to meet social need: AHRQ's used a \$6 million grant initiative to support the integration of data on chronic disease, social determinants of health, and community services to create actionable dashboards to support better chronic disease management and prevention of high-risk individuals and populations in primary care. Dashboards will allow practices serving high risk patients and communities, including those with multiple chronic conditions and people with substance use disorder, to risk stratify and identify patients with social needs, such as food insecurity and inadequate housing, and connect them to community services.

New strategies to support caregivers: ACL led HHS implementation of the [RAISE Family Caregivers Act](#) and the [Supporting Grandparents Raising Grandchildren Act](#), which established two councils tasked with producing reports for Congress on supporting family caregivers and supporting grandparents raising grandchildren respectively. At its November meeting, the RAISE council adopted 26 recommendations for their report to Congress; during its October meeting, the Advisory Council to Support Grandparents Raising Grandchildren finalized 22 recommendations to advance change and improve supports to Kinship Families and Grandfamilies. These efforts have been coordinated across 14 federal agencies, more than 30 external groups, and thousands of caregivers and other stakeholders.

Using social determinants data to inform health systems research: AHRQ compiled and released [a new database on SDoH](#) variables that provides easy to use, linkable social-determinants-focused data to increase the efficiency and accuracy of health systems and other research. The database is informing research and cutting-edge approaches to addressing emerging health issues, and ultimately will contribute to improved health outcomes and the reduction of health disparities.

Promoting state innovation around social determinants: CMS released a State Health Official letter to describe opportunities under Medicaid and CHIP to better address social determinants of health in order to support states when designing programs, benefits, and services that can more effectively improve population health and lower overall healthcare costs in the Medicaid and CHIP programs by addressing these factors.

Incorporating social determinants into health records: ONC is piloting ways to encode social determinants of health data such as housing, transportation, food security, and income captured in an assessment tool used by health providers, helping to standardize the collection, exchange, and integration of patient reported outcome data in EHR systems to support the electronic sharing of

this information. ONC also issued a funding opportunity to address well-documented challenges, including registry infrastructure of APIs; health IT tools to scale research; and integrating healthcare and human services data to support improved outcomes.

[Helping Americans with Disabilities Live and Thrive in the Community](#)

Marking 30 years of the Americans with Disabilities Act: To commemorate the 30th anniversary of the passage of the Americans with Disabilities Act (ADA), ACL and OCR held a virtual event and launched a microsite, [ACL.gov/ADA](https://acl.gov/ada), to mark the 30th anniversary and serve as an ongoing resource on the importance of inclusion and integration.

Expanding the workforce to support Americans with intellectual and developmental disabilities: “Direct service providers” (DSPs) deliver vital services that ensure Americans with intellectual and developmental disabilities (I/DD) have the support they need to live independently in the community. Demand for these essential professionals is at an all-time high and growing, partially as a result of more people being able to live in the community, but turnover is high and there are significant challenges to recruiting and retaining DSPs. To address the lack of stability of the DSP workforce, ACL established a prize challenge in November that seeks innovative business models to increase the size and capability of the DSP workforce, soliciting proposals that address these supply challenges and provide a more sustainable potential business model.

Addressing health gaps for the I/DD population: Research found that people with developmental disabilities were over three times more likely to die from COVID-19 compared to people who do not have these disabilities, reinforcing the stubborn health disparities that affect Americans with I/DD. During 2020, ACL awarded a \$1.75 million grant to Rush University School of Nursing to establish the Partnering to Transform Health Outcomes with Persons with Intellectual Disabilities and Developmental Disabilities (PATH-PWIDD). Working with a national cross-sector consortium, their networks, and committees, PATH-PWIDD will address the lack of educational content about individuals with intellectual and developmental disabilities in current health education training programs. This effort will reach 30 medical education programs and impact more than 15,000 healthcare students during the five-year project.

Protecting parenting rights of Americans with disabilities: As mentioned above, OCR reached statewide settlements with [Massachusetts](#), [New Jersey](#), [West Virginia](#), and [Oregon](#) to protect the rights of persons with disabilities, including people in long-term recovery and treatment for opioid use disorder, to be free from discrimination in state child welfare programs.

Continued efforts to support employment for Americans with disabilities: As of early 2020, seventy-four percent of working-age adults without disabilities are employed, while only 30 percent of people with disabilities are working. Throughout 2020, ACL continued to lead the Multi-Agency Task Force to Increase Employment Opportunities for People with Disabilities, which improved coordination and reduced duplication of effort of 11 executive branch departments. Because of the Task Force’s accomplishments, the National Council on Disability recommended

that the President retain it going forward. In conjunction with the Task Force, ACL created an Inclusive Pipeline Challenge competition that received proposals from more than 50 American businesses, ACL awarded cash prizes to five finalists for proposals that demonstrated innovative approaches to recruiting, retaining, and advancing employees with disabilities. These finalists are now refining their models and competing for the \$60,000 phase two prizes and the \$100,000 grand prize.

Technical assistance to support employment of people with disabilities: In August, ACL established the Disability Employment Technical Assistance Center focused exclusively on increasing competitive, integrated employment of people with disabilities. To help mark the celebration of the 100th Anniversary of the formation of the Vocational Rehabilitation program and the 30th anniversary of the ADA, ACL formalized a partnership called *Pathways to Partnership* with the Office of Special Education and Rehabilitative Services at the Department of Education to improve federal agency coordination to increase competitive integrated employment for students and youth with disabilities. ACL also funded a new Center for Knowledge Translation in Employment Research to help vocational rehabilitation agencies and businesses find, understand and use research related to employing people with disabilities.

Studying disability discrimination in healthcare and child welfare: OCR issued a request for information on disability discrimination in healthcare and child welfare contexts in preparation for updating its existing disability nondiscrimination regulations. OCR sought information concerning discrimination with respect to organ transplantation, life-saving or life-sustaining care or denials of care based on medical futility determinations, suicide prevention and treatment programs, crisis standards of care, healthcare value assessment methodologies, child welfare, and availability of auxiliary aids and accessible medical equipment.

Protecting infants and others with disabilities: OCR issued a proposed rule promoting the fundamental human dignity of individuals with disabilities in healthcare and protecting the rights of parents seeking treatment for infants with disabilities. The proposed rule would update and clarify existing Departmental regulations on disability nondiscrimination, EMTALA, and Medicare and Medicaid Conditions of Participation.

Promoting Independence and Work

Unprecedented partnership on promoting work across agencies: ACF's Office of Family Assistance launched a multi-agency initiative to leverage three major workforce development programs (HHS's Temporary Assistance for Needy Families, the Department of Labor's Workforce and Innovation Opportunity Act (WIOA) program, and the Department of Agriculture's SNAP Employment and Training program) to address the labor force issues of those previously disconnected from the workforce and also impacted by the pandemic in getting into sustainable employment. Eleven states have agreed to partner with the three federal agencies to leverage the same programs and state leadership in furtherance of integrating these large and complex programs that have not historically coordinated effectively across agencies.

Leveraging child support to promote work and mobility: The Office of Child Support Enforcement provided technical assistance and trainings to state child support programs in implementing or enhancing noncustodial parent employment programs. Providing noncustodial parent employment services can help increase participation in the workforce, improve compliance with court-ordered child support payments, and provide low-income Americans with a path out of poverty to self-sufficiency.

New evidence around how to promote work: In 2020, ACF launched the [Pathways to Work Evidence Clearinghouse](#), which identifies and provides accessible information about evidence-based interventions designed to improve employment outcomes, reduce employment challenges, and support self-sufficiency for people with low incomes.

Empowering states to innovate on supporting work: ACF's Office of Regional Operations built a multi-million-dollar, multi-year, multi-funder public-private partnership to advance economic recovery for low-income families. As a result, ORO produced four national and regional reports on states' recommendations on flexibilities, waivers and statutory changes to better respond to the pandemic and improve human services delivery.

Protecting Conscience and Religious Freedom

Promoting equal treatment for faith-based organizations: In coordination with eight other Departments and agencies, HHS issued a final rule, published in December 2020, that ensures that faith-based organizations can participate in federal programs on an equal playing field with secular organizations and are not required to provide notices and referrals that secular organizations are not required to provide.

Aligning grants regulation with federal nondiscrimination statutes: HHS continued work toward a final rule, published in January 2021, that requires grantees to comply with applicable nondiscrimination statutes, including those protecting religious liberty. The final rule revises certain regulatory provisions in the HHS grants regulation that were amended in 2016 to condition funding for grant recipients, including adoption and foster care service providers, in a way that burdened faith-based providers.

A major court victory for religious freedom: In November 2018, HHS and the Departments of Labor and of the Treasury issued two final rules to provide regulatory relief to American employers, including organizations like the Little Sisters of the Poor, that have religious or moral objections to providing coverage for contraceptives, including those they view as abortifacient, in their health insurance plans. In 2020, the Administration triumphed 7–2 in defending these rules at the Supreme Court.

Taking action on conscience protections: In December, after OCR had found that the state of California imposed universal abortion coverage mandates on health insurance in the state, in violation of federal conscience laws, and the state refused to come into compliance, HHS

announced plans plan to withhold \$200 million in federal Medicaid funds from the state in the first quarter of 2021 and to seek to withhold an additional \$200 million every quarter until California complies.

Protecting conscience rights of healthcare workers: In December, DOJ filed a lawsuit on HHS's behalf against the University of Vermont Medical Center. OCR determined that the medical center violated the Church Amendments, which protect the conscience rights of healthcare workers, when it required a nurse to assist in an abortion against her conscience-based objections in 2018, and the medical center repeatedly refused to cooperate with OCR or conform its policies to what the law requires. The lawsuit seeks a court order that they comply.



Supporting Lifesaving Science

A new treatment for children’s tumors: An NIH-funded clinical trial led to FDA approval of a new treatment for children with a tumor disorder that affects the brain, spinal cord, and nerves throughout the body.

Immunotherapy breakthrough on leukemia: A NIH-sponsored clinical trial demonstrated that treatment with an immunotherapy drug is superior to standard chemotherapy for children and young adults with relapsed leukemia. These patients, whose survival has not substantially improved for decades, now have a new and better standard of care.

Tackling Alzheimer’s Disease: NIH continued to make important progress on Alzheimer’s disease and related dementias (ADRD), part of implementing the National Alzheimer’s Project Act. As of early January, of the many candidates in NIH-supported ADRD drug development programs, ten have moved through the pipeline, from basic discovery through preclinical development, to reach the human testing phase. NIH currently supports more than 40 trials testing drug candidates targeting different aspects of the disease.

A biomarker for concussion recovery: A collaborative study conducted by scientists from the National Institutes of Health, Department of Defense (DOD), and multiple academic institutions, including with support from the NCAA, identified blood biomarkers that could help to predict which athletes need additional time to recover from a sports related concussion.

Progress toward an artificial pancreas: An NIH-supported clinical trial at four pediatric diabetes centers found that a new artificial pancreas system — which automatically monitors and regulates blood glucose levels — is safe and effective at managing blood glucose levels in children as young as age six with type 1 diabetes.

Understanding breast cancer treatment better: A study supported by NCI found that postmenopausal women with HR-positive, HER2-negative breast cancer that has spread to a limited number of lymph nodes, and whose recurrence risk is low based on genomic profile, do not benefit

from chemotherapy when it is added to hormone therapy, potentially saving tens of thousands of postmenopausal women each year the time, money, and harmful side effects that come with chemotherapy infusions.

Advancing the science of pest control: CDC registered a new active ingredient, discovered and developed CDC scientists, with the Environmental Protection Agency for use in insecticides and insect repellents. The new ingredient, nootkatone, repels and kill ticks, mosquitoes, and a wide variety of other biting pests. Nootkatone is responsible for the characteristic smell and taste of grapefruit and is widely used in the fragrance industry to make perfumes and colognes. CDC's licensed partner, Evolva, is in advanced discussions with leading pest control companies for possible commercial partnerships.

Boosting research through health records: ONC pilot-tested and refined the FHIR Clinical Genomics standard, which will advance approaches to exchanging and integrating genomic data into electronic health record systems for clinical care and research.

[Supporting Research to Empower Americans with Disabilities](#)

A model for helping Americans with I/DD live in the community: An ACL/NIDILRR grantee at Syracuse University developed and refined a research-based model for supporting adults with intellectual disabilities who live in the community. [Supported Decision-Making](#) is an alternative to more restrictive guardianship models that limit decision-making and independent living options among people with disabilities. This intervention has been cited as a service delivery model in multiple states and localities, including [Delaware](#) and [Utah](#).

New technology for people who are blind: ACL/NIDILRR's [Rehabilitation Engineering Research Center on Universal Design and the Built Environment](#) developed a new “talking tactile display” technology for people who are blind. This technology, developed in partnership with NIDILRR grantee Touch Graphics, allows people who are blind to better understand and navigate complex built environments and to interact with multimedia museum exhibits. Following full development and commercial availability, multiple stakeholders have purchased and applied the technology, including [Amazon](#) and the [Smithsonian](#).

[Driving the Biomedical Industry through Public-Private Partnerships](#)

Fully launching BARDA DRIVE: BARDA issued a solicitation to support DRIVE Venters, which will fulfill the authority provided to BARDA under the 21st Cures Act to support a Medical Countermeasure Innovation Partner using innovative venture capital practices to support development of new solutions for health threats.

Bringing pharmaceutical manufacturing back to America: BARDA began working with a team of private industry partners led by Phlow Corporation to expand pharmaceutical manufacturing in the United States for use in producing medicines needed during the COVID-19 response and future

public health emergencies. The new partnership will provide immediate, U.S.-based capacity to produce the active pharmaceutical ingredients (APIs) and the chemical compounds for those ingredients to make critical medicines to help alleviate or prevent drug shortages, particularly during the COVID-19 pandemic. Currently, a majority of APIs or their precursor chemical ingredients for critical medicines are manufactured outside the United States.



Goal 5: Promote Effective and Efficient Management and Stewardship

Delivering Regulatory Reform

Reducing burdens to put patients first: CMS's Patients over Paperwork effort has generated cumulative savings to the medical community of an estimated \$6.6 billion since 2017, with a reduction of 42 million burden hours for providers through 2021.

Expanding the healthcare workforce: CMS reformed and removed numerous regulations so that healthcare professionals can practice at the top of their license, including making permanent several flexibilities provided during the COVID-19 PHE that allow non-physician practitioners to provide the care they were trained and licensed to give, without imposing additional restrictions.

New transparency around guidance documents: Under Executive Order (EO) 13891, Promoting the Rule of Law through Improved Agency Guidance Documents, HHS, like all government agencies, was required to publish all guidance documents online in a single, searchable, indexed repository within 120 days of issuance. At the time of the issuance of the EO, FDA was the only agency with an existing guidance repository that met the requirements of the EO. ASPA Digital collaborated with Exec Sec and built the database. The site launched publicly in June, and as of September contains over 29,000 documents. Rather than having each division create and maintain multiple costly websites, which was estimated as potentially costing tens of millions of dollars, ASPA was able to stand up an online guidance repository for just over \$2 million.

Improving Data Stewardship

Training HHS staff to get better insights from data: OASH relaunched the department's flagship data analytics training and internal innovation acceleration program, in partnership with the Office of the Assistant Secretary for Administration's Office of Business Management and Transformation. Demand grew more than 300 percent within one year to nearly 800 applications for 30 seats, and this scalable program model is now in consideration for use by the White House, CMS, and other federal agencies and HHS Operating Divisions.

A first-ever synthetic database for health claims: AHRQ started a project to produce a first-of-its-kind “synthetic database,” a resource that contains all the detail of claims data and comprehensive information on patients’ socioeconomic and demographic characteristics, ensuring the privacy of the data while creating new opportunities for insights.

Reducing data costs through an enterprise-wide data strategy: Work by the Office of the Chief Technology Officer (CTO) and *ReImagine HHS* to establish the Department’s first enterprise-wide data sharing platform is now estimated to reduce costs associated with data sharing and analysis by \$64 million over ten years. To support HHS’s growing need for data scientists, CTO also trained and graduated 100 HHS data analysts.

Granular data on health challenges in every community in America: CDC announced the expansion of the 500 Cities Project, a 2016 initiative to provide city- and neighborhood-level health estimates for a large portion of the nation’s population. The project was renamed PLACES, and now provides **P**opulation **L**evel **A**nalysis and **C**ommunity **E**stimates to the entire United States to show the prevalence of chronic diseases and the health impacts on underserved communities. PLACES can help local and state health departments and community organizations decide where best to target resources to address these health challenges. PLACES is the first-of-its-kind effort to release local area health information covering the entire United States, and provides data estimates for 27 health measures for four U.S. geographic levels—counties, incorporated and census-designated places, census tracts, and zip codes—many of which were previously unavailable.

Protecting and Preserving Taxpayer Dollars

Improper payments continue to drop: CMS work resulted in an estimated \$12.17 billion reduction in improper payments for CMS programs since 2016, with Medicare improper payments decreased by 11 percent from 2018 to 2019. In FY 2020, CMS is reporting the lowest improper payment rate in 12 years for the Medicare Fee for Service program.

Reducing costs through bundled acquisitions: ASA, using principles developed through the *ReImagine HHS* Buy Smarter initiative, consolidated eleven different telecommunications services contracts from the Operating and Staff Divisions, with projected savings of \$700 million over the next 12 years and creating a model for federal acquisition consolidation.

Promoting research funding integrity: In 2020, OASH’s Office of Research Integrity (ORI) made findings of research misconduct against 10 researchers who had received or collaborated on PHS grants totaling over \$64 million, dating back to 1997. In addition, ORI alerted NIH to concerns about seven other researchers whose practices raised questions about stewardship of almost \$42 million in PHS funds.

Largest healthcare fraud takedown in history: In September 2020, even amidst the pandemic, OIG and DOJ carried out the largest healthcare fraud takedown in history, across 51 judicial districts. The national takedown resulted in charges against 345 individuals for submitting more than

\$6 billion in false and fraudulent claims to federal healthcare programs and private insurers, including more than \$4.5 billion connected to prescribing or ordering unnecessary medical items or services by leveraging aggressive marketing tactics and so-called telehealth services, more than \$845 million connected to substance abuse treatment facilities, and more than \$806 million connected to other healthcare fraud and illegal opioid distribution schemes across the country.

A major False Claims Act settlement against a pharmaceutical industry: In July, Novartis Pharmaceuticals Corporation entered into two settlements totaling \$642 million to resolve allegations that it had violated the False Claims Act. The first settlement addressed the company's alleged illegal use of three foundations as conduits to pay the copayments of Medicare patients taking two of Novartis's drugs. The second settlement resolves claims arising from the company's alleged payments of kickbacks to doctors. Novartis entered into a 5-year corporate integrity agreement with OIG as part of this settlement.

Continued excellence in financial reporting: ASFR's Office of Finance published HHS's Agency Financial Report, which received its seventh consecutive "Certificate of Excellence in Accountability Reporting" and received its fifth "Best-in-Class" award for an exemplary section of the report

Continuing Business Process Improvements

Setting the standard for grants management: HHS developed the first government-wide grants management long-term strategic vision and roadmap as the government-wide designated Quality Service Management Office (QSMO), a designation finalized in January 2021. Based on recipient pain points and over a dozen engagement sessions with federal agencies representing 90-plus percent of annual government-wide grant award dollars and volume, this vision is the foundation for a 5-year plan submitted as part of HHS's designation as the Grants QSMO.

Simplifying the grants experience for grant-makers: After incorporating the *ReImagine HHS* Reinventing Grants Management Initiative, ASFR developed a Grant-Recipient Digital Dossier (GDD) system, which will help simplify the user experience for all-grant related activities across HHS and reduce HHS review time from 4 hours to 15 minutes.

Reducing the grants backlog: Addressing a long-standing management challenge, ASFR led a cross-department effort to reduce the backlog of open but expired grants by over 24,000 grant documents (a 75 percent reduction) and is positioned to eliminate the backlog in FY21.

Sustaining Grants.gov performance: ASFR managed Grants.gov system operations and maintained same-day response for partners and customers even with the dramatic increase in COVID-19 funding, which drove a 94 percent increase in user registration and 1,000 percent increase in applicant activity.

Improving processes at NIH: The *Optimize NIH* initiative formed under *ReImagine HHS* undertook a number of operational improvements: replacing paper-based processes with online

capabilities reducing administrative burden; creating public and internal portals improving accountability and minimizing risks; launching dashboards for data-driven decisions; upgrading and integrating existing enterprise systems to reduce redundant reporting, and automating workflows for streamlined processing.

Faster processing of correspondence: Exec Sec improved the time it took to triage official correspondence from 35 minutes in FY 2019 to 20 minutes in FY 2020. In all, 5,570 letters were triaged in FY 2020, compared with 3,270 letters in FY 2019. In addition, over the past year Exec Sec managed to reduce the average number of days to prepare a letter for Secretary signature from a high of 65 days to a low of 35 days at the end of FY 2020.

Centralizing and improving HR processes: ASA worked to move to the cloud the new Administrative Data Hub, which connects human resources, travel, and facilities data to save money and time with improved analysis. The move allows more efficient and lower cost access as well as integration of additional administrative data sources.

Creating a rapid hiring option: ASA launched HireNow, which provides easy access to tens of thousands of qualified resumes from shared certificates across HHS. The system reduces average time to hire by 75 days, and hiring managers filled dozens of positions with the system in 2020.

Bringing AI to HR: ASA deployed 13 robotic process automations, or bots, to perform HR tasks previously performed by staff, freeing HR staff to focus on higher value assignments. Through FY 2020, the bots saved HHS 14,272 hours of manual work, equivalent to seven full-time staff, avoiding more than half a million dollars in costs.

[Advancing Department Appeals Processes](#)

Reducing the Medicare backlog: The Office of Medicare Hearings and Appeals (OMHA) reduced its appeals backlog by approximately 61 percent by the end of FY 2020 off of 2018 levels. This percentage reduction surpassed the end of FY 2020 target reduction of 49 percent that was mandated for the Department by the mandamus order in *American Hospital Association v. Azar*.

Going electronic with Medicare appeals: OMHA completed implementation of its Electronic Case Adjudication and Processing Environment, transitioning to a fully electronic, paperless adjudication system that was the critical element that allowed maximum telework and continued productivity and hearings during the COVID-19 pandemic. Beginning in October, OMHA successfully launched its internal preparation and quality control process for high-reliability document scanning of the deferred Medicare appeals workload in order to capture, manage, store, and preserve paper files in electronic formats. These electronic files are uploaded to ECAPE in a

more efficient and effective manner. OMHA estimates that it is digitizing 85,000 images per month with this new electronic process.

Adapting to maximize the rate of departmental appeals: Through a reimbursable interagency agreement, Administrative Law Judges in the Civil Remedies Division of the Departmental Appeals Board (DAB) hear and decide appeals of tobacco enforcement actions brought by the FDA, which include civil monetary penalty determinations and No Tobacco Sale Orders. Following FDA's pause in inspections of tobacco retailers to the COVID-19 public health emergency, the number of new and closed cases filed in the division dropped dramatically, so attorneys began drafting decisions relating to appeals from Medicare providers or suppliers and nursing home civil monetary penalty cases, helping to address DAB's Medicare appeals backlog.

[Adapting to Telework and Virtual Services](#)

Going virtual with Medicare hearings: OMHA developed new policies to encourage remote adjudication of appeals and reduce the burden on on-site teams, such as electronic adjudication of paper appeals, issuing emails for dispositions rather than physical mailings, and remote print and mail to supplement in-office activity. OMHA also developed six minimal presence case processing protocols to further define the procedures for case processing.

Supporting and encouraging staff: During the maximum telework posture caused by COVID-19, many HHS divisions, including ASFR, ASA, ONC, FDA, NIH, and others, began producing new regular newsletters or messages to staff to fill a void of in-person engagement experienced with maximum telework. Many other divisions, including IHS, HRSA, AHRQ, and NIH, also began or increased the frequency of all-staff calls to provide opportunities for two-way feedback with team members. Divisions also developed comprehensive virtual preparedness documents, including guidance on virtual meeting and collaboration tools, to help staff quickly and efficiently move to a maximum telework environment, and then created comprehensive guidance on safe return to the office for some employees.

[Protecting National Security](#)

Maintaining the security of the biomedical research enterprise: NIH has played a leading role in addressing threats posed by foreign talent recruitment programs. Working in close coordination with other agencies, NIH queries have led to dozens of legal and compliance actions to enhance the security and integrity of federally supported research.

Monitoring emerging threats: The HHS Office of National Security, now the most active non-Title 50 agency on national security matters, produced intelligence reports on emerging threats and briefings for Department leadership, with over 707 intelligence products in FY 2020.

Defending against cyber attacks: ASA successfully defended the department against the largest distributed denial-of-service (DDOS) cyberattack ever experienced by any federal agency, without

disrupting services, while 95 percent of HHS's workforce was teleworking. The department subsequently defeated seven more nation-state-led cyberattacks, including defending against more than 1.8 billion events during an 18-hour period.