U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

2017: A Year of Accomplishment

2017 Accomplishments Under President Trump

In the first year of the Trump Administration, the Department of Health and Human Services led the effort to support healthier people, stronger communities, and a safer country.

HHS engaged with healthcare professionals and providers of all kinds to identify federal regulatory burdens that hurt patients, as well as ways to lower high prescription drug costs. This resulted in a net decrease in the burden imposed by HHS regulations as well as positive reforms in a range of Medicare payment rules, actions from the Food and Drug Administration, and ongoing reviews of further areas for action.

Reflecting the priority President Trump placed on fighting America's opioid crisis, the department aggressively implemented its five-point strategy for the issue, including expanding access to prevention, treatment and recovery services; targeting the availability and distribution of overdose reversing drugs; strengthening public-health reporting and data; supporting cutting edge research on pain and addiction; and advancing pain management.

The department led a round-the-clock, weeks-long public health response to Hurricanes Harvey, Irma, and Maria, deploying thousands of personnel and collaborating with local officials to inform disaster response, ensure continuity of medical care, and provide emergency services. The department continues to work in affected areas to restore medical services.

HHS's participation in top-level international health meetings helped advance President Trump's firm commitment to global health security and preparedness for a range of cross-border infectious threats.

The department began to implement a process called *ReImagine HHS*, pursuant to the Office of Management and Budget's request that each agency come up with a plan for reforming its functions. HHS, through deep consultation with the department's employees, coalesced around six strategic shifts for the department, and then announced ten different initiatives under these shifts.

Contents

Advancing Patient-Centered Healthcare and Healthcare Reform

- HHS helped lead and coordinate the effort to make American healthcare more affordable, providing critical support to the Administration's efforts to pursue both legislative and administrative approaches to reform. The efforts culminated in the December repeal of the Affordable Care Act's individual mandate tax on working families.
- Ending in December, the Centers for Medicare & Medicaid Services (CMS) conducted a successful, consumer-friendly open enrollment period at significantly lower cost than in previous years, attracting similar levels of enrollment with more focused investments in marketing.
- In February, CMS announced that millions of Americans – including entrepreneurs, early retirees, and employees of small businesses – who are currently enrolled in pre-Obamacare plans are able to remain in those plans, if they so choose.
- In April, the department finalized the Market Stabilization Rule, first released in draft less than a month after President Trump's inauguration, to boost competition in insurance markets, ensure Americans see the lowest premiums possible under current law, and increase choices for patients.
- In response to President Trump's October executive order aimed at more affordable healthcare, the department began to examine the potential for expanding the use of short-term limited-duration insurance plans, which are free from costly Affordable Care Act mandates, and worked with the Departments of Labor and Treasury to consider approaches to expanding the use of association health plans and health reimbursement arrangements.

- CMS provided health insurance issuers with additional time to file qualified health plan submissions for calendar year 2018.
- In October, CMS announced a revised process for Section 1115 Medicaid waivers, underscoring the department's commitment to working with states to give them flexibility and timely responses to waiver requests.
- In November, CMS released a draft Plan Year 2019 Payment Notice for Affordable Care Act plans, which proposes a range of new flexibilities to bring down costs for consumers, including more flexibility for states to set essential health benefit benchmarks.

- The Assistant Secretary for Planning and Evaluation (ASPE) published two analyses documenting how the Affordable Care Act has:
    - Increased premiums and federal subsidies, more than doubling premiums from 2013 to 2017; and
    - Seen decreased insurer participation in the exchanges, leading to reduced choice and competition in the individual market.
- In November, CMS Administrator Seema Verma announced that, for the first time in the history of the Medicaid program, the department would be considering the inclusion of community engagement and work requirements for certain program populations.
- The November announcement followed up on a March letter from Secretary Tom Price and Administrator Verma to all state governors stating their commitment to work with them to improve the Medicaid program and usher in a new era of flexibility, giving states more freedom to design programs that meet the needs of their citizens.
- In November, CMS issued a Medicare Part C / Part D proposed rule to update Medicare Advantage (MA) and the prescription drug benefit program (Part D) that would promote innovation and empower MA and Part D sponsors to improve quality of care and provide more plan choices for MA and Part D enrollees. Benefits included:
    - Proposals for the treatment of biosimilars and generics within Part D would result in an estimated $195 million in savings a year for the Medicare program from 2019 through 2023, some of which may passed onto beneficiaries in the form of lower premiums or better benefits;
    - Proposals to lift Part C and D provider enrollment burdens for occasional prescribers such as dentists;
    - Proposals to empower beneficiaries to access their prescription drugs at the pharmacy they prefer, by revising the pharmacy participation rules in Part D, promoting greater participation of local pharmacies and expanding beneficiary access to all types of pharmacy delivery services, including mail-order; and
    - A Request for Information on ensuring that discounts drug companies provide in the pharmaceutical supply chain get passed on to seniors at the pharmacy counter.
- In the 2017 Physician Fee Schedule, CMS expanded rural access to care through telehealth by finalizing the addition of several codes to the list of telehealth services to better serve rural practice areas.
- CMS reduced the number of individual clinicians and groups who must participate in the MIPS quality payment system to exclude clinicians or groups with under$90,000 in Part B allowed charges or under 200 Part B beneficiaries, in order to reduce burden for those who still find it challenging to participate and need more time to prepare.
- CMS removed procedures from the inpatient-only list (in the Outpatient Prospective Payment System Rule, or OPPS), giving patients greater choice to decide which site of

service is right for them for six procedures, including total knee replacements, one of the most common and costly procedures. Medicare beneficiaries will now have the option to seek care in a lower cost setting of care (i.e., an outpatient setting rather than a more expensive inpatient setting).

- The Food and Drug Administration (FDA) took key actions to advance innovations on behalf of patients to improve their health and well-being by approving:
    - New drugs to treat multiple sclerosis, Parkinson's Disease, and Duchenne muscular dystrophy;
    - The first two biosimilars for the treatment of cancer, one for the treatment of HER2+ breast and stomach cancers and one for the treatment of certain colorectal, lung, brain, kidney and cervical cancers
    - The first short-acting follow-on insulin product
    - The first drug in the U.S. with a digital ingestion tracking system, embedded with an ingestible sensor that interfaces with technology to record when the pill was taken
    - Multiple new drugs to treat Hepatitis C
    - A drug to reduce the likelihood of a particular type of breast cancer recurring after treatment
    - A new use for a drug to treat certain mutations of cystic fibrosis
    - New versions of opioids with abuse deterrent properties; and
    - The first sickle cell treatment in 20 years.
- In November, FDA announced a comprehensive policy framework and issued a suite of guidance documents for the development and oversight of regenerative medicine products, including cellular therapies, delivering on key provisions of the 21st Century Cures Act.
- FDA announced a Digital Health Innovation Plan to promote and oversee innovation within digital medical devices.
- The Office of the Assistant Secretary for Health (OASH) Liaison to Veterans Affairs, the Administration for Community Living (ACL), and the VA worked together to strengthen the Veteran-Directed Home and Community Based Services Program by increasing the number of veterans who are able to receive quality care in their homes and communities.

- HHS's Office of Civil Rights (OCR) continued to ensure that healthcare entities do not discriminate on the basis of disability. For instance, on July 27, 2017, OCR entered into a resolution agreement with an Oklahoma nursing home that discharged a patient because the patient had HIV/AIDS, in violation of federal civil rights laws protecting

people with disabilities. Under the agreement, the nursing home will take steps to ensure its practices and procedures do not discriminate on the basis of disability.

- As part of its ongoing commitment to training health professionals, the Health Resources and Services Administration (HRSA) supported 9,200 National Health Service Corps primary care clinicians who served nearly 10 million people in high-need rural and underserved communities. HRSA also supported the training of more than half of new pediatricians in the U.S. through the Children's Hospital Graduate Medical Education payment program, including more than 11,000 pediatric specialty and sub-specialty residents. More than 60 percent of these hospitals are disproportionate share hospitals serving children from rural and underserved communities.

Rolling Back Burdensome Regulations

- Through the end of Fiscal Year (FY) 2017, for the first time in many years, the net regulatory burden imposed on the economy by HHS rules went down.
- HHS initiated an ongoing review of rules, regulations, and guidance promulgated by the previous administration under the Affordable Care Act, and has so far taken 39 separate actions to bring down costs as part of this effort.
- HHS undertook a major review of regulations that affect the provision of care and the doctor-patient relationship, consulting with provider groups to determine what is raising the cost of care, lowering the quality of care, burdening their practices, or interfering with their relationships with their patients. So far, that process has included:
    - Withdrawing 70 of the previous Administration's regulatory actions;
    - Taking 68 deregulatory actions and only including 27 regulatory ones in the Fall 2017 Unified Agenda; and
    - Initiating reviews of more than 20 percent of FDA's total regulations as part of an ongoing review of the entirety of the agency's regulations; and
    - Holding secretarial roundtables and more than 200 meetings involving senior HHS staff and more than 30 organizations representing over 1 million medical practitioners.

- CMS launched its "Patients Over Paperwork" initiative, highlighting its efforts to reduce regulatory burden. As a part of this initiative, Administrator Verma traveled to eleven cities in nine states to host listening sessions on the impact that regulatory burden has on providers, doctors, and clinicians.

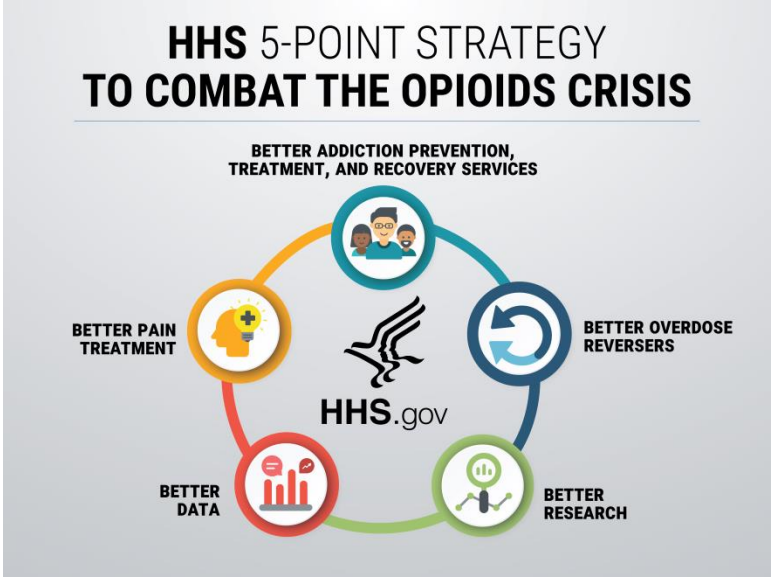
- CMS announced a three-year delay for certain provisions in the final Home and Community Based Services Settings rule, and continued to collaborate with state partners on ways to minimize disruption in services for beneficiaries and reduce administrative burden for states and providers.
- CMS's finalized OPPS rule includes a provision that would alleviate burdens rural hospitals experience in recruiting physicians by placing a two-year moratorium on the direct supervision requirement currently in place at rural hospitals and critical access hospitals.
- CMS proposed and finalized a rule to update 2018 Medicare payment and policies when patients are admitted into hospitals, with numerous actions to support the patient-doctor relationship in healthcare; reduce regulatory burdens on providers; and promote transparency, flexibility, and innovation in the delivery of care. As one example, the rule reduced the number of electronic clinical quality reporting measures from eight to four.
- CMS approved 26 state demonstration waiver actions for state Medicaid programs in 2017. These include two new demonstration programs, eight extensions, and 16 amendments across the following states: Alabama (3), California (2), Delaware, Florida (2), Iowa (2), Massachusetts, Mississippi, Missouri, Montana (2), New Jersey (2), Oklahoma, Pennsylvania, Texas (2), Utah (2), Virginia, West Virginia, and Wisconsin.
- CMS approved the first ever 10-year Medicaid waiver, building on the Administration's commitment to reduce administrative burdens and partner with states to improve the Medicaid program and the people it serves.
- CMS proposed a one-year regulatory moratorium on the payment policy threshold for patient admissions in long-term care hospitals while the agency continues to evaluate long-term care hospital policies.
- CMS's final rule for the Quality Payment Program (QPP), the new program for paying clinicians that CMS is required to implement, included a number of policies to ease the transition for clinicians. CMS decreased the number of clinicians required to participate and added an option to help small, rural practices join together to share the responsibility of complying.
- CMS released an RFI to welcome continued feedback on Medicare Advantage and Part D, soliciting ideas for regulatory, sub-regulatory, policy, practice, and procedural changes to better accomplish transparency, flexibility, simplification and innovation in the programs.
- CMS released an RFI regarding the Affordable Care Act's restrictions on physician-owned hospitals and what the role for these facilities ought to be in the health system.
- In June, CMS released an RFI to solicit public comments on how to create a more flexible, streamlined approach to the regulatory structure of the individual and small group insurance markets.
- The Reagan-Udall Foundation, which supports FDA, launched the Expanded Access Navigator, to provide patients with life-threatening illnesses or diseases with access to

unapproved drugs under FDA's expanded access program (also known as "compassionate use").

Combating the Opioid Crisis and Drug Abuse

- In April, HHS laid out a five-point strategy for the department's efforts to address the opioid epidemic, focused on empowering local communities:

    1. *Better treatment, prevention, and recovery services:* Improving access to treatment, prevention, and recovery services, including the full range of medication-assisted treatment;
    2. *Better targeting of overdose reversing drugs:* Targeting availability and distribution of overdose-reversing drugs;
    3. *Better research:* Supporting cutting-edge research on pain and addiction;
    4. *Better data:* Strengthening public health surveillance;
    5. *Better pain management*: Advancing the practice of pain management



- In October, at President Trump's direction, Acting Secretary Eric Hargan declared an unprecedented nationwide public health emergency regarding the opioid crisis.
- Acting Secretary Hargan and other top HHS officials engaged in fact-finding trips to learn from those on the front lines of the response to the opioids epidemic, including people in recovery, service providers, families of victims lost to overdose, first responders, law enforcement, public health authorities, and others.
- In September, the Centers for Disease Control and Prevention (CDC) fully launched the Rx Awareness Campaign, a large, extensively tested multimedia campaign to increase awareness and knowledge about the risks associated with prescription opioids and to prevent their misuse.
- The department began work with the White House to develop a larger public-awareness campaign surrounding the risks of opioid addiction.
- The Center for Faith-Based and Neighborhood Partnerships held five webinars that brought HHS's top experts to thousands of Americans in communities looking to learn more about how to tackle the crisis.

- Surgeon General Jerome Adams traveled to hear the many stories of Americans — police, business owners, doctors, teachers, faith leaders, parents, sons, and daughters — who have been touched by the opioid epidemic.

Better Prevention, Treatment, and Recovery Services

- In April, HHS awarded $485 million in grants to states and territories to help combat opioid addiction. The Opioid State Targeted Response Grants, through the Substance Abuse and Mental Health Services Administration (SAMHSA), went to all 50 states, the District of Columbia, and 6 territories. The program supplements activities to support a comprehensive array of prevention, treatment, and recovery services pertaining to opioids.
- In September, SAMHSA awarded $144 million in grants to support opioid and other substance abuse efforts in clinics across the country, with grant locations shown in the graphic to the right. Funding included:
    - $49 million for Residential Treatment of Pregnant and Postpartum Women;
    - $35 million for the Medication Assisted Treatment Prescription Drug and Opioid Addiction Targeted Capacity Expansion grants;
    - $9.8 million for State Pilot Grants for the Treatment of Pregnant and Postpartum Women;
    - $4.6 million for Building Communities of Recovery to increase the availability of long-term recovery support services; and
    - $1 million for Improving Access to Overdose Treatment to expand access to FDA-approved products to reverse opioid overdoses.

- In October, CMS announced a bold new waiver/demonstration policy that increases the flexibility for states to apply for new funding/expenditure authority to address one of the biggest barriers to treatment: the decades old statutory requirement that prohibits Medicaid from paying for inpatient or residential addiction treatment at facilities with more than 16 treatment slots. Under CMS's new policy, states can more quickly gain approval to use Medicaid funding to provide residential treatment at these facilities while they are building their broader treatment capacity (rather than having to build it first, and then apply for the waiver, as under the previous administration). Two states have already received approvals under the new policy (New Jersey and Utah) and several more applications have come in for review.
- In October, OCR published guidance to ensure that healthcare providers understand their broad ability to share information with patients' family members during crisis situations, such as drug overdoses, without violating HIPAA.

- As a part of the Hurricane Harvey response, SAMHSA announced that, when no other funds are available, affected states would be authorized to reallocate previously awarded formula and discretionary grants to help those unable to pay for medications for the treatment of opioid use disorder.
- HRSA awarded nearly $4.2 million to 34 rural health organizations to increase access to treatment and recovery services for opioid abuse in rural communities.
- HRSA released a best practices guide for rural grantees regarding opioid overdose reversals, summarizing the lessons learned from grant recipients, and a "Rural Prevention and Treatment of Substance Abuse Toolkit," containing model programs and program sustainability strategies.
- In November, FDA issued a final guidance on developing generic abuse-deterrent opioids to encourage industry to move away from opioid formulations that can more easily be manipulated or abused.
- In November, FDA announced approval of the first once-monthly formulation of buprenorphine, further expanding the medication-assisted treatment options available to patients with opioid use disorder.
- The Administration for Children and Families (ACF) awarded a $7.8 million contract for a new project to evaluate and support states in implementing promising initiatives assisting members of families receiving Temporary Assistance for Needy Families (TANF) in overcoming opioid use disorder, other substance use disorders, or serious mental illness, so that they are able to enter the workforce and ultimately achieve self-sufficiency.
- In July, the Office on Women's Health (OWH) awarded 20 cooperative agreement grants totaling $2 million to public and private nonprofit entities across 15 states to address the primary and/or secondary prevention of prescription and illegal opioid misuse by women across the lifespan.
- In September, a new contract for the National Center on Substance Abuse and Child Welfare was awarded, co-funded between SAMHSA and ACF's Children's Bureau, to provide training and technical assistance to improve family recovery, safety and stability by advancing practices and collaboration among agencies, organizations, and courts working with families affected by substance use and co-occurring mental health disorders and child abuse and neglect.
- OASH's Regional Health Administrators began collaboration with local officials for cooperation on treatment, recovery, and prevention, including partnerships with schools, faith-based organizations, and more.
- The Center for Faith-Based and Neighborhood Partnerships created a "toolkit" designed to equip local communities—lay persons, faith groups, non-profits, and health care providers—with practical steps they can take to bring hope and healing to the millions suffering the consequences of opioid abuse.

Better Targeting of Overdose-Reversing Drugs

- In May, SAMHSA announced $1 million in OD Treatment Access grants to expand the availability to overdose reversal medications in healthcare settings and to establish protocols to connect patients who have experienced a drug overdose with appropriate and timely treatment.
- In September, SAMHSA announced $44.7 million in grants to help local communities equip first responders with overdose-reversing drugs.

Better Data

- In August, CDC began calculating monthly provisional data on counts of drug overdose deaths as a rapid response to this public health crisis, in order to provide a more accurate, closer to "real-time" look at what is occurring both nationally and at the state level.
- In August, CDC released the first "Annual Surveillance Report of Drug-Related Risks and Outcomes – United States," covering the latest data available on rates of opioid prescribing, substance use disorder, nonfatal hospitalizations and emergency department visits, and overdose deaths.
- In September, CDC awarded more than $28.6 million in additional funding to 44 states and the District of Columbia to support their responses to the opioid overdose epidemic. The funds, provided in the 2017 Consolidated Appropriations Act bill signed by President Trump, expanded programs to strengthen prevention efforts and better track opioid-related overdoses, known as "Enhanced State Surveillance of Opioid-Involved Morbidity and Mortality" and "Prescription Drug Overdose: Prevention for States." This built upon the July 2017 announcement that CDC was providing $12 million to states to support overdose prevention activities.
- In June, the Agency for Health Research and Quality (AHRQ) released its report on "Patient Characteristics of Opioid-Related Inpatient Stays and Emergency Department Visits Nationally and by State," showing a sharp rise among women for opioid-related hospital stays.
- In July, OIG released a report about opioids within the Medicare Part D prescription drug program that found:
    1. One in three Medicare Part D beneficiaries received a prescription opioid in 2016,
    2. About 500,000 beneficiaries received high amounts of opioids,
    3. Almost 90,000 beneficiaries are at serious risk, and
    4. About 400 prescribers had questionable opioid prescribing patterns for beneficiaries at serious risk.
- In July, CDC released a "Vital Signs" report finding that opioid prescribing declined nationally from 2010 to 2015, but remains three times as high as in 1999.

- In December, CDC's National Center for Health Statistics released 2016 mortality data, finding that American life expectancy had dropped for the second consecutive year, in part due to rising rates of drug overdoses. Opioid overdoses rose from approximately 33,000 in 2015 to approximately 42,000 in 2016, up 27 percent in the largest percentage increase on record.
- On October 1, SAMHSA's revised "Mandatory Guidelines for Federal Workplace Drug Testing Using Urine" went into effect, updated to include the authority to test for four semi-synthetic opioids: oxycodone, oxymorphone, hydrocodone, and hydromorphone.
- In October, AHRQ published a report that describes the essential features of successful models of medication-assisted treatment for primary care and examines factors that may limit access to treatment for opioid use disorder in rural primary care settings. The report also includes links and descriptions to nearly 250 tools and resources to support the delivery of medication-assisted treatment in rural primary care settings.
- In December, as part of a department reorganization initiative called "Get Better Insights from Better Data," the HHS Office of the Chief Technology Officer (CTO) held an unprecedented national opioids code-a-thon, bringing together 50 teams of data experts and computer scientists to derive insights and solutions for the epidemic from HHS data sets, some brought together for the very first time.

- CMS released an updated version of the Medicare opioid prescription mapping tool. The tool is an interactive, web-based resource that visually presents opioid prescribing rates within Medicare Part D by geography. Communities can use the tool to help understand regional variation, target resources, and develop solutions for the opioid crisis.
- Using data from the Healthcare Cost and Utilization Project, AHRQ added 2017 data to its interactive query tool known as "Fast Stats," including inpatient data for 44 states and emergency department data for 30 states. AHRQ also created a new interactive map showing trends in opioid-related hospitalizations, allowing state-by-state comparisons.

Better Research

- Throughout the year, NIH held three major conferences on the opioid crisis covering 1) medication development for opioid use disorder and overdose prevention and reversal;

2) the development of safe, effective, non-addictive pain treatments; and 3) understanding the neurobiological mechanisms of pain.

- NIH Director Francis Collins and National Institutes for Drug Abuse (NIDA) Director Nora Volkow published a *New England Journal of Medicine* article announcing a public-private partnership at NIH to advance science of pain and addiction and bring new treatments to patients.
- NIH supported a research study finding that two commonly used medications for the treatment of opioid use disorder, buprenorphine and naltrexone, are comparable in effectiveness once treatment has been initiated.
- NIH launched a new study called "Advancing Clinical Trials in Neonatal Opioid Withdrawal Syndrome," to evaluate treatment options and improve clinical care of infants with neonatal abstinence syndrome, or NAS. The study will include sites located in rural and medically underserved communities, to better understand current approaches to managing NAS cases (including non-pharmacological approaches), and develop protocols for conducting large scale studies across the country to inform clinical care for affected infants.
- CDC released its final strategy for the Protecting Our Infants Act, addressing gaps, overlap, and duplication with regard to federal efforts on NAS.
- OWH issued a final report on opioid use, misuse, and overdose in women, which examined the impact of the opioid epidemic on women and highlighted promising practices that address their specific needs.
- In conjunction with the opioid code-a-thon, the Office of the Chief Technology Officer hosted an opioid symposium that brought together policy makers, researchers, advocates, and others on the front lines of the opioid epidemic to promote innovative ways that technology and data can be used to address the national crisis.

Better Pain Management

- FDA announced an Opioid Policy Steering Committee weeks after Commissioner Gottlieb took office.
- In June, FDA recommended that Opana ER, an opioid, be withdrawn from the market because of the drug's risks outweighing its benefit. In July, the drug's sponsor announced it was withdrawing the drug.
- FDA undertook an assessment of risks and benefits of opioids within its risk evaluation framework, asking for public comment on draft revisions to prescriber education on risks of opioids, and held a public meeting in May on how to enhance training for prescribers on opioids.
- The Indian Health Service (IHS) established a national committee on Heroin, Opioid, and Pain Efforts (HOPE) that will work to provide safe and effective pain management and prevent opioid misuse.

- In October, OASH solicited nominations for the Pain Management Best Practices Inter-Agency Workgroup, which was authorized by the Comprehensive Addiction and Recovery Act of 2016, to update best practices for prescribing pain medication and for managing chronic and acute pain.
- In September, NIH, DOD, and VA announced a pain management research collaborative. Collectively, the agencies announced a joint research partnership of $81 million over six years to support research related to pain management in the military and veteran community.
- In June, an AHRQ-funded study found that mandatory-access provisions for prescription drug monitoring programs—i.e., requiring clinicians to query the program prior to prescribing a controlled drug—are significantly associated with a reduction in prescription drug abuse, specifically reduction in opioid abuse among young adults 18-24 years of age.
- OIG collaborated with the Department of Justice regarding the establishment of a new Opioid Fraud and Abuse Detection Unit and is preparing to provide critical, continuing support to the unit's ongoing work. The unit will focus specifically on opioid-related healthcare fraud using data to identify and prosecute individuals who are contributing to the opioid epidemic. Already, the collaborative effort resulted in the selection of 12 judicial districts around the country where OIG has assigned Special Agents to support 12 prosecutors identified by the Department of Justice.

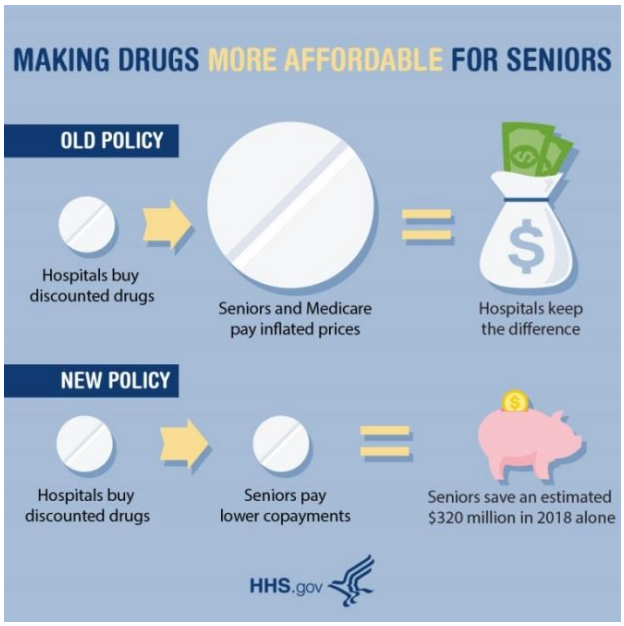
Addressing Serious Mental Illness and Suicide

- HHS established the Interdepartmental Serious Mental Illness Coordinating Committee (ISMICC) to report on advances in research on and access to services for individuals with serious mental illness and serious emotional disturbance, as well as evaluate the effect federal programs to address serious mental illness have on public health.
- At the end of August, SAMHSA convened the inaugural meeting of the ISMICC. In December, at the second ISMICC meeting, the committee's non-federal members released their comprehensive report and recommendations.
- The "Empowered Communities for a Healthier Nation" Initiative at OASH's Office of Minority Health awarded $5.2 million to projects across 15 states aimed to provide support for minority and/or disadvantaged communities disproportionately impacted by the opioid epidemic, childhood obesity, or serious mental illness.
- IHS announced a new funding opportunity, the Zero Suicide Initiative, to assist awardees in improving the care of those at risk of suicide within the Indian health systems by building comprehensive culturally informed systems of care.
- HRSA awarded over $200 million to more than 1,100 community health centers across the country to increase access to mental health and substance abuse services.

- Community health center behavioral health specialists, funded by HRSA, provided services to nearly 2 million behavioral health patients, an increase of about 20 percent from last year.

Taking On the High Cost of Drugs

- FDA approved 1,027 generics in FY17, a record for the number of FDA generic approvals in a given year.
- FDA approved a record share of first-cycle generic drug approvals, 26 approvals out of 87 approvals issued in October—an all-time record high of 29.9 percent first cycle approvals. (The previous record was 14.3 percent first-cycle approvals.)
- In May, FDA announced a Drug Competition Action Plan to tackle the problem of high drug costs through increased approval of generic drugs and stronger, healthier competition. In June, Commissioner Gottlieb announced the plan's first two major actions:
  - Publishing a list of drugs with expired patents but no approved generics
  - Expediting the review of generic drugs for which there are fewer than three existing generic competitors
- CMS announced that the average premium for a Part D prescription drug plan would decrease for the first time in five years.
- HHS finalized a proposal to change reimbursement for Medicare Part B drugs purchased through the 340B program that could save seniors on Medicare up to $3.2 billion in co-pays over ten years.
- CMS's 2018 Physician Fee Schedule updated payment policies for biosimilars, which will promote innovation in the biosimilars market to ensure millions of patients will have access to new lower-cost therapies.
- In June, FDA announced an Orphan Drug Modernization Plan, a major effort to address orphan drug issues.
- As part of the Orphan Drug Modernization Plan, in August, a month ahead of its self-imposed deadline, FDA successfully eliminated the backlog of over 200 requests for orphan drug designation.



- In December, FDA issued a draft guidance that would close an important loophole in the orphan drug program that allows sponsors to avoid conducting additional research into pediatric diseases.

Protecting Life and Religious Liberty

- In October, HHS announced two companion interim final rules that provide conscience protections to Americans who have a religious or moral objection to paying for health insurance that covers contraceptive/abortifacient services.
- HHS actively participated in a comprehensive interagency initiative to rapidly implement the January 23 Presidential Memorandum reinstating and expanding the Mexico City Policy to ensure U.S.-funded global health activities protect human life at all stages.
- OCR dramatically increased its enforcement of conscience protection statutes in 2017, including the Weldon, Coats-Snowe, and Church Amendments and Section 1553 of the Affordable Care Act. As of the end of 2017, the office was currently conducting eight investigations under its authorities, in contrast to the office conducting less than ten investigations from all of 2009 to 2016 combined.
- In October, the Center for Faith-Based and Neighborhood Partnerships issued a Request for Information seeking input in identifying barriers that religious and faith-based organizations face as they seek to participate in HHS programs and support the HHS mission.

Stopping Waste, Fraud, and Abuse

- To protect the fiscal integrity of the Medicaid program, CMS announced that it will no longer accept state proposals for demonstrations that rely on Designated State Health Programs (DSHP) funds. DSHP is a financing mechanism that has raised oversight concerns, because it is inconsistent with the federal-state financial partnership established under the Medicaid statute by allowing states to effectively bypass contributing their full state share toward Medicaid expenses.
- OIG participated in the largest national Healthcare Fraud Takedown Day in history: More than 400 defendants in 41 federal districts were charged with participating in fraud schemes—predominantly involving organized criminals, not licensed physicians—that involved about $1.3 billion in false billings to Medicare and Medicaid. As part of the takedown, OIG served 295 individuals with exclusion notices for conduct related to opioid diversion and abuse.

- OIG protected the integrity of HHS programs and the people they serve by barring bad actors from programs and recovering stolen taxpayer dollars. Between January 20 and October 31, together with law enforcement partners, OIG brought 1,106 criminal and civil actions and recovered close to $3.1 billion for HHS programs and victims.
- The pharmaceutical company Mylan entered into a corporate integrity agreement with OIG and agreed to pay $465 million to resolve allegations it violated the False Claims Act by knowingly misclassifying EpiPen to avoid paying rebates owed to Medicaid.
- As part of OIG's commitment to helping support efforts to reduce opioid addiction and abuse, a physician was charged in a 16-count indictment for his alleged participation in a multi-faceted $20 million healthcare fraud scheme involving the submission of false and fraudulent claims to Medicare and Medicaid and the illegal distribution of oxycodone and other controlled substances.
- eClinicalWorks, one of the nation's largest electronic health records (EHR) vendors, entered into a $155 million settlement to resolve allegations of False Claims Act and anti-kickback statute violations. As part of the settlement, eClinicalWorks agreed to an innovative five-year corporate integrity agreement with OIG covering the company's EHR software.
- OIG launched a campaign to combat medical identity theft committed against Medicare beneficiaries, which aims to educate beneficiaries and other stakeholders and encourage reporting through the OIG Hotline and ACL's Senior Medicare Patrol.

- The Senior Medicare Patrol program provided 1,203,986 individuals with information and assistance related to preventing, detecting and reporting Medicare fraud.
- In September, FDA participated in Operation Pangea X, a major global operation to crack down on the online marketing of illegal prescription drugs, including opioids. As part of this effort, FDA sent 13 warning letters to the operators of 401 websites and seized 100 website domain names.

Streamlining and Modernizing Government

- HHS launched and began to implement elements of its agency reorganization plan, *ReImagine HHS*. Following the submission of thousands of ideas and a two-week workgroup session with more than 150 career employees, the department coalesced around six strategic shifts, with ten initiatives falling within them. Full-time leaders from within the career staff were selected for each initiative and begun researching and constructing a business case for the initiatives. The shifts are:
    - *Leveraging the Power of Data*
    - *Restoring Market Forces*
    - *Putting People at the Center of HHS Programs*
    - *Making HHS More Innovative and Responsive*
    - *Generating Efficiencies*
    - *Moving to a 21st Century Workforce*

- An Office of Personnel Management ranking based on the 2017 Federal Employee Viewpoint Survey placed HHS No. 1 in the category of large federal agencies for employee engagement.
- HHS also moved up to No. 2 in the large agency category of the Partnership for Public Service Best Places to Work rankings—the highest ranking the department has ever received.
- Over 3,000 HHS managers completed optional updated performance management refresher training from the Office of Human Resources, focused on improving the supervisory knowledge of the performance process, as well available options for addressing poor performance.
- The Program Support Center (PSC) began reducing the number of configurations within the department's travel system from 14 to 3, with full completion of the process expected in the third quarter of 2018.

- The PSC simplified and modernized the department's onboarding process for certain employees, reducing the standard interval for clearing new employees from 74 days to 29 days.
- The Assistant Secretary for Preparedness and Response (ASPR) reduced its procurement lead timelines from 315 to 105 days.
- The Office of the CTO announced its 2017 Ventures Fund Projects to provide funding and support for innovative ideas to dramatically improve efficiency within the department. The five projects are 1) Optimizing Cyber-Molecular Surveillance of Viral Hepatitis; 2) Leveraging Health Information Technology to the Fight Against Zika; 3) Internet Devices to Improve Animal Care; 4) Electronic Signature Capture and Data Transfer for IHS; and 5) Streamlining Acquisitions of Lab Supplies.

- The CTO Ignite Accelerator program streamlined the grant review process at NIH's National Institute of Allergy and Infectious Diseases (NIAID) by creating an electronic tool that eliminated manual grant processes and reduced the amount of time needed to score and review applications.
- The CTO provided design sprints and lean assessments to IHS as it evaluates its electronic health records system and provided the Office of Medicare Hearing and Appeals with new lean and agile assessments and recommendations for improving its appeals process.
- ACF's Office of Child Care increased state capacity for required comprehensive background checks within the Child Care and Development Block Grant Program while setting a realistic deadline for states to meet the new challenge. States continue to comply with state background check requirements.
- Since January 20, OCR reduced the time to process the more than 33,000 HIPAA privacy and security and civil rights complaints it receives annually from 6 months to 15 days.
- OCR released a number of resources throughout the fiscal year to help the healthcare industry respond effectively to cybersecurity threats, including issuing a checklist that clearly and concisely set forth the steps for a HIPAA covered entity or its business associate to take in response to a cyber-related security incident.

Promoting U.S. Public Health Interests Internationally

- On the global stage, HHS, through the Office of Global Affairs (OGA), CDC, NIH, and other divisions:
  - Headed a U.S. delegation at the WHO Executive Board meeting, and voted on the finalists for the election of WHO Director General;
  - Led the U.S. delegation at the World Health Assembly in Geneva, the governing body of the World Health Organization (WHO), and cast the vote on behalf of the U.S. for the new WHO Director-General;

  - Forged a relationship with the newly elected WHO Director-General in order to press for needed WHO reforms and to advance U.S. interests by making WHO more effective, responsive to U.S. concerns, and a better value for U.S. taxpayers' money;
  - Announced, on behalf of President Trump, the continued U.S. support for global health security in general and the Global Health Security Agenda in particular, commitments that will serve to keep Americans safe from the threat of infectious diseases arising abroad;
  - Participated in the 4th Global Health Security Agenda (GHSA) High Level Ministerial Meeting in Kampala, Uganda, attended by CDC Director Brenda Fitzgerald;
  - Signed on to the Kampala Declaration, declaring support for extending the Global Health Security Agenda until 2024 to accelerate the implementation of the International Health Regulations;
  - Attended the first-ever G20 Health Ministerial meeting in Berlin to work on an international strategy to combat pandemics and the challenges of antimicrobial resistance;
  - Signed a Memorandum of Understanding with Vietnam to establish a National Public Health Reference Laboratory while carrying out collaborative projects in laboratory investigation, including the use of new technologies, research, surveillance, and evaluation;
  - Met with Chinese officials to emphasize the administration's priority of preventing drug trafficking and drug abuse, including of opioids;
  - Led the U.S. delegation to the 29th Pan American Sanitary Conference in Washington, D.C.;

  - Continued to engage on outbreak response globally, e.g., by working with partners to help contain Zika across the Americas region;
  - Conducted numerous bilateral meetings with members of foreign ministries of health to further U.S. global health policy interests;
  - Collaborated with India on a U.S.-Indian Health Dialogue in New Delhi, India;
  - Led the U.S. delegation to the WHO Global Conference on Noncommunicable Diseases in Montevideo, Uruguay, and worked to ensure WHO allowed private sector involvement and input at that conference; and
  - Supported the expansion of the interagency U.S. President's Malaria Initiative (PMI) to five more African countries (now a total of 24), benefiting almost 90 million additional people at risk of malaria, and led rigorous impact evaluations highlighting the success of malaria control efforts in reducing child mortality across sub-Saharan Africa.
- As part of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), HHS worked in more than 50 countries and supported 35 percent of all people on life-saving antiretroviral HIV/AIDS treatment worldwide, including 7.3 million of the 13.3 million total individuals supported by PEPFAR as of September 30, 2017.
- Through PEPFAR, HHS supported five African countries to approach control of their HIV epidemics in 2017, an achievement unthinkable when PEPFAR began in 2003.
- As part of the Global Polio Eradication Initiative, CDC helped vaccinate children in the three most hard-to-reach areas of Pakistan, Afghanistan, and Nigeria.
- CDC assisted multiple countries in responding to many international infectious disease outbreaks, including Ebola in the Democratic Republic of Congo, monkeypox in the Republic of Congo and Nigeria, cerebrospinal meningitis in Nigeria, typhoid fever in Zimbabwe, and anthrax in Namibia.

Modernizing Food and Pharmaceutical Regulation

- In May, FDA delayed implementation of its menu-labeling rule for restaurants and retail establishments in order to solicit additional input about how best to implement the rule.
- In November, FDA published draft guidance on the menu labeling requirements. The proposals in this guidance provided much needed regulatory clarity to stakeholders and flexibility in complying with the

regulation, while ensuring that consumers are provided with valuable calorie information.

- FDA took a critical step to modernize and gain efficiencies by adopting a new framework for pharmaceutical inspections with European Union regulators, which will lower inspection costs and enable FDA to better target inspection resources to other parts of the world where there may be greater risks.
- FDA signed an arrangement with the Australian Department of Agriculture and Water Resources to recognize Australia for having a comparable food safety system to the United States, which gives the two governments a framework for partnering in a variety of areas that range from scientific collaboration to outbreak response.
- FDA announced FY17 awards for State Produce Implementation Cooperative Agreement Plans under the Food Safety Modernization Act, including $9.1 million in increased investment.
- In September, FDA launched a search tool to make the FDA Adverse Event Reporting System (FAERS) more user-friendly. FAERS allows consumers, providers, and researchers to access data on adverse events associated with FDA-approved drugs and biologics.

Improving Public Health

- FDA released a new comprehensive plan for tobacco and nicotine regulation, with the goal of cutting nicotine content of combustible cigarettes to levels that are minimally addictive or non-addictive. The initiative was called "one of the most important public health initiatives of this century" by the *Washington Post* editorial board.

- In November, FDA announced the formation of an internal Nicotine Steering Committee to critically examine the agency's regulatory approach to therapeutic nicotine products to assist with smoking cessation. The committee will also work to develop and implement nicotine policy and regulation to address the public health problems related to tobacco use in the U.S.
- In September, FDA permitted the marketing of a mobile app to help treat substance use disorders related to alcohol, cocaine, marijuana, and stimulants. The app, meant to be used in conjunction with outpatient therapy, is a new tool patients with these substance-use disorders can use to improve their health outcomes.
- In June, HRSA announced approximately $15 million in funding for the Genesee County Healthy Start Program to provide health and social services for women, infants, and

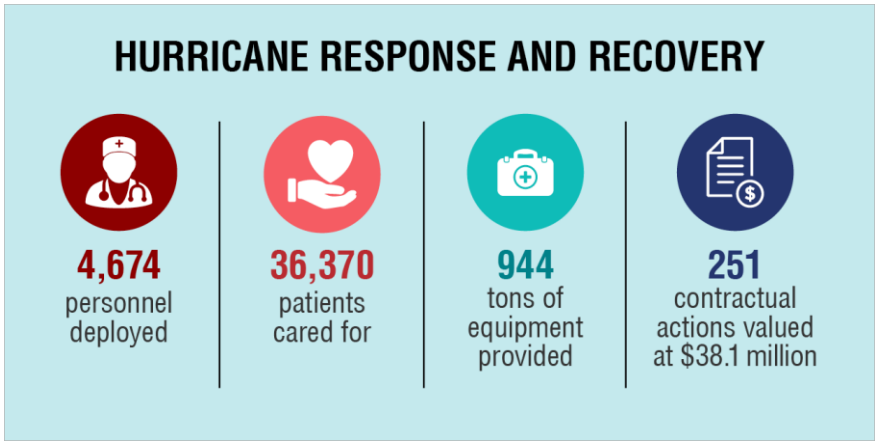
their families who have had, or are at risk for, lead exposure in Flint, Michigan, and the surrounding community.

- CDC aided local governments in responding to Hepatitis A outbreaks in several states, using state-of-the-art genetic tests to confirm cases and trace chains of person-to-person transmission.
- CDC updated the Vaccine Adverse Event Reporting System, to "VAERS 2.0," bringing the system fully online and updating it for the first time since it was created in 1990.
- CDC expanded support for Perinatal Quality Collaboratives to 13 states. These networks of perinatal care providers and public health professionals aim to improve health outcomes for mothers and babies on issues including maternal opioid use and neonatal abstinence syndrome.
- OASH and ACF's Office of Planning, Research, and Evaluation and Family and Youth Services Bureau announced a new research and evaluation collaboration to support and improve teen pregnancy prevention and sexual risk avoidance programs.
- OASH completed its report to congress on "Young Adults and Transitioning Youth with Autism Spectrum Disorder," on the federal government's activities to support youth with Autism Spectrum Disorder as they mature to adulthood.
- ASPE hosted the first National Research Summit on Care, Services and Supports for Persons with Dementia and Their Caregivers, which brought together the top researchers on care and services to discuss best practices and recommendations for improving care and services for people living with dementia and their families. The Summit produced numerous recommendations for federal agencies, states, and private industry groups.
- In October, SAMHSA awarded $166 million over five years to 79 community organizations for the prevention of HIV among high-risk populations and the treatment of co-occurring behavioral health disorders and HIV.

Responding to Hurricanes Harvey, Irma, and Maria

- ASPR led and managed around-the-clock response operations for weeks in support of public health and medical needs for communities impacted by disasters, in particular Hurricanes Harvey, Irma, and Maria. Specific to these three response operations:
  - ASPR deployed 4,674 personnel, both federal employees and trained volunteers;
  - ASPR treated 36,370 patients in partnership with other federal agencies;
  - ASPR provided 944 tons of equipment, including 796 caches of supplies totaling $65.5 million; and
  - ASPR awarded 251 contractual actions valued at $38.1 million.

- As part of HHS's response, U.S. Public Health Service Commissioned Corps officers deployed in support of public health emergencies and crises, including deploying over 1,200 officers in response to Hurricanes Harvey, Irma, and Maria.
- Surgeon General Adams and Assistant Secretary for Preparedness and Response Robert Kadlec traveled to Puerto Rico and the U.S. Virgin Islands to assess the situation and witness the strength of communities working to rebuild.



- CDC activated its Emergency Operations Center on August 31, 2017, with over 611 CDC staff members supporting the response to the three hurricanes, providing scientific and technical assistance in areas such as environmental health, laboratory testing, immunization, epidemiology, and surveillance, as well as logistics, staffing, communications, analytics, management, and other support functions. Among other actions:
  - CDC provided guidance and technical assistance for re-occupation of homes, including building & home assessments; safe drinking water and wastewater use; mold; chemical and other hazardous substance exposure; shelter sanitation and safety; food safety; generator safety and carbon monoxide (CO) poisoning.
  - CDC implemented an unprecedented partnership with the Department of Veterans Affairs medical clinics in Puerto Rico to conduct active public health surveillance, assessing nearly 14,000 charts to identify infectious diseases, mental health disorders, CO monoxide poisonings, injuries and other hurricane-related illnesses.
- CMS rapidly issued waivers within the Medicare, Medicaid, and CHIP programs to ensure continuity of care for beneficiaries of these programs.
- The cross-HHS emPOWER Initiative supported numerous emergencies and provided geographic data on Medicare beneficiaries who are electricity- and-healthcare-service dependent and were potentially at risk due to severe flooding and prolonged power outages. The system informs local authorities, so they can reach out and respond if necessary, and was updated in 2017 to version 2.0.
- ASPR created and filled a new Director of Disaster Science position to reflect the growing importance of improving the science behind preparedness and response. During the hurricane response, the Director utilized satellite remote sensing to accurately determine flooding locations, guided decisions in protecting healthcare

critical infrastructure, and conducted research to map sewage contamination in floodwaters to protect worker and volunteer health.

- After Hurricane Maria, FDA started monitoring approximately 90 medical products manufactured in Puerto Rico to mitigate potential shortage situations, including approximately 50 medical devices, approximately 30 drug products, and about 10 biological devices/biologics.
- FDA helped address a shortage of IV fluids manufactured in Puerto Rico, in conjunction with manufacturers of these products, by temporarily allowing the importation of IV saline products from facilities outside of the U.S., encouraging the expansion of production at existing facilities to meet shortfalls and expediting review of new product applications to help address this shortage.
- FDA worked with government partners to prioritize a small number of critical facilities based on public health needs, including those plants that manufacture IV saline bags, to gain earlier access to the electrical grid. By the end of 2017, most companies making critical products in Puerto Rico had returned to commercial power.
- Two ACL subject matter experts on aging and disability provided ongoing support to the HHS Secretary's Operations Center (SOC) for the Elderly and Disability Taskforce. The Taskforce coordinated with ASPR to ensure that ACL programs and stakeholders are represented in immediate and long-term recovery missions for areas affected by the 2017 hurricanes.
- ACF's Office of Refugee Resettlement (ORR) led the coordination and provision of temporary assistance to individuals evacuated by the Department of State from the Caribbean as a result of Hurricane Maria. This emergency repatriation effort resulted in the successful evacuation of approximately 2,776 individuals repatriated from Saint Martin, Anguilla, and British Virgin Islands.
- ACF collaborated with federal and nongovernmental partners to restore human services programs affected by disasters. This supported the recovery of disaster survivors, especially at-risk populations, through key human services programs such as TANF, Head Start, and ACF-supported child care providers.
- As part of the Hurricane Maria relief efforts in Puerto Rico, OIG participated with other state and federal agencies in conducting site visits at nursing homes throughout the island, investigating potential quality of care issues, and providing assistance/resources such as food, water, and hygiene products to nursing home residents.

- OIG, along with other federal, state, and local agencies, actively engaged in Hurricane Irma relief and recovery efforts in Florida, reviewing nursing home safety matters and continuing to monitor other areas affected by the recent hurricanes.

Maintaining and Enhancing Disaster Preparedness

- The HHS Secretary's Operations Center monitored and tracked approximately 65 events throughout 2017.
- ASPR provided public health and medical support at multiple events and incidents, including the Presidential Inauguration, the Presidential Joint Address to Congress, Hurricanes Harvey, Irma, Maria, and Nate, the California wildfires, the Peace Officers Memorial Event on the Mall, the July 4th Celebration on the Mall, and the United National General Assembly meetings in New York.
- ASPR coordinated the department's pro-active response to the Wannacry and Petya cybersecurity events.
- ASPR's Office of Emergency Management conducted exercises with U.S. and international partners including: continuity of operations for HHS; with the Federal Emergency Management Agency on the Golden Shield exercise in New York, NY (mass fatality/mass injury); with Department of State on the Tranquil Shift exercise (transporting Ebola patients); with the Department of Defense (DOD) on the Integrated Advance exercise (mass migration across the southern border); with DOD on Hidden Peril exercise (influenza pandemic); with DOD and Israel on Dark Wave 5 (weapons of mass destruction attack on U.S. and Israel); as well as principal and senior official exercises with the White House.
- In accordance with determinations made by the Secretary and based on ASPR recommendation, FDA issued an Emergency Use Authorization to enable the use of a product to treat nerve agent exposures.
- ASPR's Office of Emergency Management awarded $228.5M to strengthen healthcare system preparedness and response through Hospital Preparedness Program cooperative agreements to 62 health departments in all 50 states, U.S. territories, D.C., Chicago, Los Angeles County, New York City, and all freely associated states.
- The Biomedical Advanced Research and Development Authority (BARDA) continued to advance preparedness for radiation threats by providing pre-emergency-use authorization for a radiation exposure test

and replacing half of a stockpile of a radiation drug that must be dispensed daily (Neupogen) with a drug that can be administered weekly (Neulasta), saving space and money and improving response abilities.

- In July, BARDA signed a Memorandum of Understanding with NASA to work together on researching radiation and infectious threats, leveraging the experiences and resources of both organizations.
- BARDA, with governmental and non-governmental partners, held Operation Downpour, a full-scale chemical decontamination exercise to evaluate and refine PRISM, BARDA's recently published guidance for mass patient decontamination. 94 volunteers were decontaminated in 28 minutes using optimized procedures.
- BARDA continued work through Project Bioshield and other avenues to advance study and production of burn treatments, including the completion of several clinical trials and the development of international partnerships.
- In November, ASPR held its largest-ever annual BARDA Industry Day, fostering information sharing and partnership with over 1,000 external stakeholders.

Fighting Infectious Disease

Zika

- ASPR continued to lead policy coordination around the nation's response to the Zika virus, including at the 17th Ministerial Meeting of the Global Health Security Initiative, a multilateral partnership with the G7 plus Mexico, which focused on strengthening the links between the law enforcement sector and the public health and medical sector.
- CDC released a Zika Interim Response Plan, a Zika public awareness campaign, and a "Roadmap for Parents of Babies Infected with Zika Before Birth."
- CDC laboratories processed nearly 150,000 Zika testing specimens, in addition to developing and distributing laboratory test kits and reagents across the United States and internationally.
- CDC developed and updated clinical guidance for healthcare providers caring for pregnant women, babies, and children with possible Zika infection.
- CDC funded 44 states, 2 territories, 3 freely associated states, and 5 cities to increase follow up and surveillance capacity of Zika infection in mothers and babies.
- CDC worked with FDA to obtain an Emergency Use Authorization for the first automated Zika test, as well as making new specimens available for test development and finalizing the trial protocol for a multi-candidate Zika vaccine trial.
- BARDA and FDA advanced the development and availability of multiple vaccines and diagnostics for Zika. One vaccine supported by BARDA is continuing to move forward in clinical trials, and FDA authorized the use of six additional diagnostic tests for Zika, including one diagnostic authority test that was supported by BARDA (DiaSorin).

- HHS announced an $8.9 million agreement to further develop a Zika virus test that could expand the nation's testing capacity for the virus, help those who are affected by Zika access the treatment they need, and potentially lead to lower costs for patients. If the test proves successful, it could become available at nearly 2,000 testing sites nationwide.

Influenza

- Building upon years of collaboration between CDC and China CDC's influenza experts, CDC and other HHS agencies worked with China to respond to an unprecedented number of human infections with a new strain of avian influenza H7N9 virus during the fifth wave of H7N9 activity in that country.
- HHS authorized funding and brought together private-sector partners to continue the development and production of a new H7N9 vaccine for the National Pre-pandemic Influenza Vaccine Stockpile. Specifically, ASPR:
    - Awarded multiple contracts to initiate manufacturing of 20 million doses of pandemic vaccine for H7N9 to address the increasing threat of H7N9 circulating in Asia;
    - Oversaw the financing of over $70 million to procure a pre-pandemic stockpile in response to the emergence of the H7N9 influenza virus in Asia; and
    - Awarded task orders for H7N9 83 percent ahead of allotted timeframes, ensuring procurement could occur rapidly.
- BARDA continued to advance clinical studies for influenza vaccines from Vaxart, Sanofi Pasteur, and Protein Sciences Corporation.

Healthcare Associated Infections and Antibiotic Resistance

- OASH's Office of Disease Prevention and Health Promotion (ODPHP) announced the new 2020 hospital targets and measures for the National Action Plan to Prevent Health Care-Associated Infections (HAI).
- ODPHP convened the Federal Steering Committee for HAI Prevention to plan Phase IV of the National Action Plan, which will focus on the relationship between antibiotic stewardship and HAIs.
- CDC took steps forward in 2017 through its Antibiotic Resistance (AR) Solutions Initiative. For instance:
    - In 2017, CDC scaled up its containment strategy that detects and aggressively responds to emerging resistant threats, nationwide. For example, successful implementation of CDC's containment strategy by local response teams limited the multi-drug resistance fungus, *C. auris*, to only one case in both Connecticut and Oklahoma. No additional cases were detected in 2017.

  - With ongoing technical support from CDC, in 2017, public health labs tested more than 12,000 clinical or colonization isolates through the AR Lab Network, accelerating response times and increasing the nationwide capacity to identify and stop the spread of new resistance.
- CDC expanded the use of the AR Isolate Bank, which enables a growing number of microbiologists, drug and diagnostic manufacturers, and researchers to access CDC's collections of resistant organisms—called isolates—to validate diagnostics in their labs.
- CDC launched a national public education effort focusing on improving how Americans use antibiotics, called "Be Antibiotics Aware: Smart Use, Best Care."

Other Infectious Threats

- On December 1, FDA announced the approval of the 200th antiretroviral drug application under PEPFAR, which was launched in 2003.
- In November, NIH's NIAID and two private sector partners began a Phase 2b clinical trial to test the safety and efficacy of an experimental vaccine regimen for HIV.
- In 2017, 4 products funded by BARDA research received FDA approval, bringing the agency's total to 34 since its establishment.
- BARDA continued work with its private sector partners to prepare for and address Ebola, including analysis of a completed study on an Ebola vaccine in Sierra Leone, an RFP to fund final development and procurement of Ebola vaccines for national preparedness, the completion of a Phase 1 study by the pharmaceutical company Regeneron for an Ebola treatment cocktail, and the initiation of access to the treatment ZMapp at several clinical sites.
- BARDA also worked to maintain and advance preparedness through new agreements and completed clinical trials with private sector partners to address botulism, smallpox, and anthrax.
- CDC disease detectives supported state and local health departments in effectively responding to numerous infectious disease outbreaks, including outbreaks of Seoul virus infections linked to pet rats, Lyme disease in Arkansas, *Brucella* RB51 in New Jersey and Texas, and many foodborne disease outbreaks (e.g., *E. coli* in soy nut butter, *Salmonella* in papayas).
- In May 2017, CDC published a "Vital Signs" report on healthcare-associated Legionnaires' disease and worked with CMS to implement their new measure requiring

that Medicare-certified healthcare facilities develop and adhere to policies and procedures to reduce the risk of Legionella and other waterborne pathogens.

- A new CDC study found that the tetanus, diphtheria, and pertussis vaccination during the third trimester of pregnancy prevented more than three out of four (78 percent) cases of pertussis in babies younger than two months.
- OASH's National Vaccine Prevention Office announced the first UpShot Awards, to recognize and celebrate exceptional individuals and organizations advancing the National Vaccine Plan.
- The Tick-Borne Disease Working Group was officially established in August, as part of implementing the 21st Century Cures Act, to provide expertise and review efforts within HHS related to all tick-borne diseases to help ensure interagency coordination, minimize overlap, and examine research priorities. Members of the Working Group were named and the first public meeting was held in December.

Coordinating with Government Partners in Addressing Refugee Issues

- ACF's ORR heightened screening of unaccompanied alien children and their sponsors before release to help ensure the safety and well-being of the UACs and the communities into which UACs would be released. ORR consulted with federal partners, including the Departments of Justice and Homeland Security, to enhance consultations on release procedures and determinations.
- In 2017, ORR placed a new emphasis on its commitment to community safety, especially in the light of MS-13 gang activity. ORR has been in contact with local law enforcement to partner with them on gang prevention and community safety activities, and will be releasing more information about its Gang Prevention and Community Safety Initiative.

Supporting the Health of Tribes and Tribal Communities

- IHS opened two new healthcare facilities in February: the Desert Sage Youth Wellness Center in Hemet, California, and the Choctaw Nation Regional Medical Center in Durant, Oklahoma.
- IHS began piloting a standardized patient experience of care survey for use by all IHS direct service outpatient primary care facilities, designed to provide locally actionable feedback to staff based on patients' experiences of care.
- The IHS Quality Framework Steering Committee formed a Performance Accountability Metrics workgroup to develop a dashboard focused on accountability for quality assurance and improvement activities in IHS facilities, addressing recommendations in a Government Accountability Office report.
- Secretary Price helped build a trusting relationship with Indian Tribal Nations and Alaskan Natives through the Secretary's Tribal Advisory Committee, holding the first-

ever meeting of the body in Indian Country in September and appearing via video conference to address the annual Direct Service Tribes Meeting in July.

- At the Secretary's Tribal Advisory Council meeting in September, HHS announced plans to raise the thresholds required for approval of tribal capital projects, and eliminate the need for approval entirely for congressionally authorized or tribally funded projects.
- IHS awarded FY 2017 Planning and Negotiation Cooperative Agreement awards to three Tribes and Tribal organizations to support their planning and preparation necessary to assume responsibility for providing healthcare to their Tribal members as authorized by Title V of the Indian Self-Determination and Education Assistance Act.

- The Rosebud IHS Hospital was surveyed in August by the Centers for Medicare & Medicaid Services (CMS) to determine implementation of the plan of correction approved by CMS following a previous survey in June 2017, and was found to have completed its Systems Improvement Agreement, restoring it to normal status within the Medicare and Medicaid programs.
- IHS published new ambulatory care patient wait time standards for primary care and urgent care, setting a mean of 28 days or less for primary care and a mean of 48 hours or less for urgent care.
- IHS developed a standardized patient experience of care survey for uniform use and administration across all IHS ambulatory primary care sites, including hospital outpatient departments.
- IHS, in conjunction with the Pediatric Integrated Care Collaborative (PICC), part of the Johns Hopkins Center for Mental Health Services in Pediatric Primary Care, announced ten locations that will participate in a new year-long pilot project to integrate trauma-informed care at IHS and tribal facilities.
- In October, ACF's Administration for Native Americans partnered with the Department of Interior's Bureau of Indian Education and Department of Education to host the annual Native Languages Summit in Albuquerque, New Mexico. The summit supported Native American communities seeking to retain and revitalize indigenous languages. This year the summit also celebrated 10 years of implementing the Esther Martinez Native American Languages Preservation Act.

Promoting Personal Independence, Work, and Efficiency in Human Services

- In August, ACF's Office of Family Assistance rescinded guidance from the previous administration that encouraged states to apply for a waiver of some TANF work requirements.
- ACF launched the "Promoting and Supporting Innovation in TANF Data Project," which will support innovation and efficiency of state-level TANF programs by enhancing the use of data from TANF and related human services programs.
- ACF proposed for comment new ways to make Head Start's quality assessment and grant renewal system more effective at determining quality while lowering the administrative burdens on grantees.

- In September, ACF's Office of Regional Operations launched a two-year regional public-private partnership with the National Conference of State Legislatures, "A Whole Family Approach to Jobs: Helping Parents Work and Children Thrive."
- In September, ACF awarded a contract for a new TANF Data Innovations project to support innovation and efficiency in state-level TANF programs by enhancing the use of data from TANF and related human services programs.
- ASPE launched the EMPOWERED project to document the array of work requirements, performance measures, and child support cooperation requirements across human services programs to help facilitate improved coordination.
- ACL published frequently asked questions to help centers for independent living implement new requirements for independent living programs established in the Workforce Innovation and Opportunity Act of 2014, which expanded their purview to include the transition of young adults with disabilities from secondary school to adult life.
- The ACL Administrator announced disability employment as a fifth pillar of emphasis for the division's work, and developed a task force to address the ongoing issue of helping people with disabilities find meaningful employment.
- In September, six Partnerships in Employment grants were awarded by ACL to work on transforming state systems to increase competitive integrated employment for youth and young adults with intellectual and developmental disabilities.

Maximizing the Promise of Health IT and Data

- HHS announced two departmental priorities for health IT: improving the usability of health IT while reducing its burden on providers and making sure that health information is interoperable.
- The Office of the National Coordinator for Health IT (ONC) began work implementing congressional mandates on interoperability, developing a comprehensive stakeholder engagement plan and beginning to assess current structures and seek public comment on a potential framework.
- On July 24, ONC hosted over 500 diverse health IT stakeholders (in-person and virtually) to discuss existing national trust infrastructures used to exchange health information electronically and to share their views on electronic data sharing best practices. This and upcoming activities by ONC are focused on implementation of key provisions in the 21st Century Cures Act.
- ONC successfully closed out the previous Health IT Policy and Health IT Standards committees established under the Health Information Technology for Economic and Clinical Health (HITECH) Act—and established a new charter in support of the new Health IT Advisory Committee (HITAC).
- ONC initiated a rulemaking process to include provisions to address information blocking and identify key characteristics of open APIs without specific effort, which will ease payers' ability to analyze health data and find savings and efficiencies.
- ONC began implementing the Trusted Exchange Framework and Common Agreement provision of the 21st Century Cures Act by convening two large-scale stakeholder meetings attended by more than 1,200 stakeholders and completing a public comment process to receive feedback on considerations, concerns, and success stories related to the exchange of health data across networks.

- ONC worked in close coordination with OIG to advance policies to address information blocking, meeting with stakeholders as a part of preliminary fact-finding on issues relevant to the implementation of Section 4004 of the Cures Act.
- In September, AHRQ released the "Compendium of U.S. Health Systems, 2016," the nation's first publicly available database that gives researchers, policymakers and healthcare administrators a snapshot of the nation's health systems. Hospitals in these health systems account for roughly 88 percent of U.S. hospital beds and 92 percent of

U.S. hospital discharges. The online resource was developed by the agency's Comparative Health System Performance Initiative, a collaborative to examine health systems' use of evidence-based medicine and explore factors that contribute to high performance.

Protecting Patient Privacy

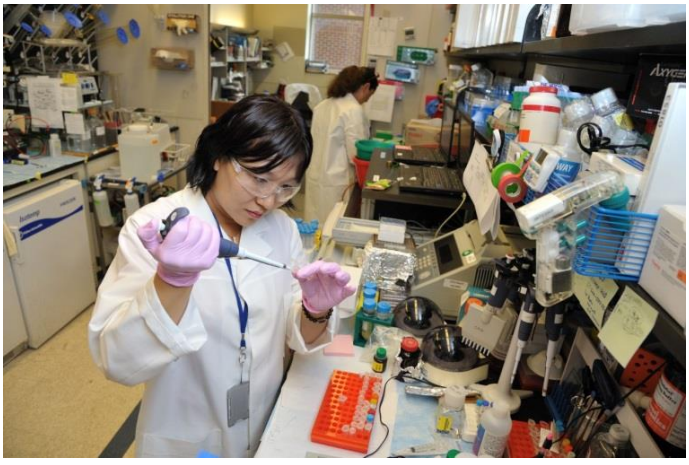
- In 2017, OCR reduced processing time and greater customer service for investigations of HIPAA violations. Over 30,000 complaints were resolved, including 8,000 complex matters, and over 22,000 telephone inquiries were answered and processed. OCR collected $19.8 million in settlement funds under HIPAA, and held 280 outreach events, a new record.
- In July, OCR launched a revised web tool for reporting HIPAA breaches that features improved navigation for both those looking for information on breaches and ease-of-use for organizations reporting incidents, and highlights the most recent incidents and what measures have been taken to address them.

Advancing Life-Saving Research

- In August, FDA approved the first gene therapy in the U.S., a cell-based gene therapy for certain children and young adults with a type of leukemia.
- In October, FDA approved a cell-based gene therapy for certain types of non-Hodgkin lymphoma, which came out of research conducted at the National Cancer Institute, and is the second ever gene therapy approved by FDA.
- In December, FDA approved the third gene therapy in the U.S., a treatment for children and adults with an inherited eye defect that can result in blindness.
- NIH supported research to advance the science of gene editing through CRISPR technology, including work that developed the first technique to edit RNA and a new technique to correct, rather than remove, specific gene mutations.
- NIH grantee Joachim Frank and two other scientists were awarded the Nobel Prize in Chemistry for their work in developing Cryo-EM, a method for freezing biological material to enable easier examination.
- NIH-funded researchers also made advances in Cryo-EM that allow researchers to capture the physical structures of proteins previously thought to be too small to image,

allowing researchers to detail tau filaments and amyloid fibrils seen in excess in the brains of people with Alzheimer's disease, opening the door for potential new Alzheimer's treatments.

- NIH-funded researchers identified a particular subset of cancer patients likely to benefit from immunotherapy based on a particular genetic defect within a tumor.
- Based on these findings, the FDA approved expanded use of an immunotherapy drug for people with any solid tumor with that feature, marking the first cancer treatment ever approved to treat tumors based on a specific genetic feature.
- Researchers within NIH or supported by NIH released studies with the following scientific advances:
    - A dissolving microneedle patch for vaccines that has the potential to be self-administered;
    - An experimental HIV vaccine regimen that elicited immune response in an early-stage clinical trial called APPROACH; and
    - An experimental Ebola vaccine that elicited a year-long immune response in a large randomized clinical trial.
- Researchers within NIH or supported by NIH released studies finding the following:
    - A robotic exoskeleton may help alleviate crouch gait in children with cerebral palsy;
    - Higher brain glucose levels may mean more severe Alzheimer's;
    - Separating analysis of side effects could hold the key for safer opioids;
    - A particular medication can improve efficacy of oral immunotherapy for multiple food allergies; and
    - A gene-based Zika vaccine is safe and immunogenic in healthy adults.
- In October, NIH officially launched the Partnership for Advancing Cancer Therapies (PACT), a public-private partnership between NIH and 11 biopharmaceutical companies. PACT partners will invest a total of $215 million over five years in immunotherapy research.



- At the beginning of March, NIH began accepting applications for proposed supplemental projects to currently funded research into deadly childhood cancers. Later that month, NIH began accepting applications for supplemental proposals to two grant programs meant to spur the development of cutting-edge cancer technologies. These supplemental grants were made possible by the 21st Century Cures Act and are an example of the

Administration's support for innovative cancer research, including through the Cancer Moonshot.

- In June, NIH began beta testing for the "All of Us" Research Program, a component of the Precision Medicine Initiative. All of Us is a nationwide, longitudinal research program that seeks to study the health, environment, and lifestyles of 1 million Americans in order to further the development of individually tailored medical care.
- In August, NIH publically released the All of Us initial protocol, an important first step in outlining the processes that the program will follow when collecting information from participants and safeguards that will be put in place to protect the privacy of program participants.
- Throughout the fall, NIH announced grants and partnerships with a variety of organizations to prepare for large-scale enrollment of participants in All of Us.
- NIH intramural researchers identified a number of tumor genes that make the tumors susceptible to immunotherapy treatments, which are one of the most promising areas of cancer research and a focal point of the Cancer Moonshot and PACT.
- NIH awarded $18.9 million to promote the effective use of genome sequencing in clinical care, with a special focus on diverse and underserved populations. These awards are an important step toward making this resource, an important tool in the diagnosis of certain diseases and conditions, more widely available.
- NIH launched the Next Generation Researchers Initiative, a plan to bolster support to early- and mid-career investigators and increase evaluation capacity for NIH's research portfolio.
- In May, NIH altered a longtime policy to allow researchers to share "preprints," or draft research that has not undergone peer review, in order to speed up the process of scientific dialogue and discovery.
- In October, NIH announced nearly $170 million in awards for the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative. Total 2017 funding for the BRAIN initiative was over $260 million.
- In November, NIH announced $9 million in awards for the NIH Data Commons Pilot Phase to seek best practices for developing and managing a data commons, a crucial step in implementing new authorities under the Cures Act to allow NIH to require its extramural researchers to share data.