U.S. Department of Health and Human Services

Open Government Plan

Version 4.0

September 2016

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EXECUTIVE SUMMARY

Among the first actions undertaken by President Obama upon entering the Office was the President's Memorandum on Transparency and Open Government issued on January 21, 2009. HHS has prepared its fourth edition of the Open Government Plan in compliance with the elements required by the Office of Management and Budget. This plan addresses aspects of government transparency, collaboration, and participation across all agencies.

The new features of this plan address advances in financial reporting in response to new legislative requirements, advances in digital strategies, and open source code aimed at accelerating modern digital technology adoption. Past efforts in promoting open innovation, and open data have continued to accelerate by their application in priority areas across HHS agencies.

This plan incorporates seven new "flagship" initiatives that address transparency, collaboration, and participation. These select activities represent cross-agency collaborations that bring new technologies, processes and policies to address high priority initiatives.

Consistent with the efforts advanced in the last three Open Government Plans, this effort for 2016-2018 are aligned with the Department's Strategic Plan, in particular, *Strategic Goal 4: Ensure Efficiency, Transparency, Accountability, and Effectiveness of HHS Programs.* HHS will engage our employees and stakeholders to emphasize the principles of open government throughout their service of our mission.

1 OVERVIEW OF PROGESS FROM VERSION 3.0 OF THE HHS OPEN GOVERNMENT PLAN

In July 2014, the U.S. Department of Health and Human Services (HHS/Department) released its second version of the Open Government Plan, which incorporated nearly 50 projects and activities focused on transparency, collaboration, and participation. In that plan, we also incorporated a new effort in whistleblower protections, digital services strategies, and proactive disclosure mechanism. Since then, we continue to follow the course of these initiatives and have made important contributions and progress toward the goals set forth in the plan.

For our Version 3.0 plan, we also implemented seven cross-cutting flagship initiatives. Major expansion of the data transparency effort has taken place throughout almost all of the HHS agencies. Technology enhancements to enable better use of the data, promotion of machine-to-machine interactions that provide better quality services to the public, and an underscoring of the roles of agencies in achieving modern information age services have taken hold throughout the HHS Operating and Staff divisions (OpDivs and StaffDivs, respectively). Over the last two years, there have been major investments of resources and talent from HHS programs in developing infrastructure, staff, and program management to address "big data" efforts. Further progress was achieved in understanding better uses of information, such as through behavioral insights and user design principles, to build better tools and services to serve the public. The efforts over the last two years have transitioned from the initial efforts of data liberation toward enhanced usability and improvements in health and health care.

HHS has established several administrative structures to focus on data quality and usability. These efforts have brought increased user input into the design of healthdata.gov and other information resources that support the broad communities of data users. Across HHS there has been an intense effort to use data within programs, promote innovations through challenge competitions, and place greater emphasis on project designs to use metrics and data reporting as a means to make more informed decisions along the project life cycle.

2 OVERVIEW OF HOW VERSION 4.0 OF THE OPEN GOVERNMENT PLAN WAS DEVELOPED

With each edition and update of our HHS Open Government Plan, we engage our teams, leaders, and stakeholders in a variety of processes aimed at gaining thorough, innovative, and diverse perspectives in the ways we engage in transparency, collaboration, and participation. The Secretary and Deputy Secretary are actively engaged in the process of communicating goals and principles across the organization's workforce, as well as meeting with senior executives to emphasize programmatic implementation of these strategies.

This year, our planning process has been anchored by its senior accountable officials, Ellen Murray, the Assistant Secretary for Financial Resources, and Susannah Fox, the Chief Technology Officer. We engaged a variety of committees including our Innovation Council, the New Media Council, the Freedom of Information Act (FOIA) Council, and others to take on specific aspects of the planning. Our base website at http://www.hhs.gov/open and other websites, such as http://www.hhs.gov/idealab and http://www.healthdata.gov, provide the public with interactive pathways to address our open government strategies. Additionally, our agency-wide communications Yammer network, and email announcements provide input for a number of new ideas used in the plan. A public solicitation of ideas was sought for three weeks beginning on July 11, 2016. The input from a draft version of the plan is then integrated into the final plan for Version 4.0.

3   TRANSPARENCY

3.1 ADMINISTRATIVE APPROACHES TO ENHANCE AVAILABILITY OF DATA

Open Health Data at HHS

Open data at HHS has become an integral piece of supporting the agency's mission. Sharing and disseminating our data resources internally and externally with innovators has reaped enormous benefits for all users and provides valuable insights back to HHS. Every OpDiv in the Department continues their work to improve their open data capacity and capabilities. Each effort is increasingly focused on supporting HHS' core mission categorized by four strategic goals: Strengthen Health Care; Advance Scientific Knowledge and Innovation; Advance the Health Safety and Well-Being of the American People; Ensure Efficiency, Transparency, Accountability, and Effectiveness of HHS Programs.

Strengthen Health Care

The Centers for Medicare & Medicaid Services (CMS) is one of several OpDivs contributing to strengthening health care by providing a growing array of data that are instrumental in improving health care quality, making coverage available to the uninsured, and improving population health through the meaningful use of health information technology (IT) among many others. Following the implementation of the Affordable Care Act (ACA) CMS makes Health Insurance Marketplace data available supporting transparency. Equality in health care delivery is also a focal point of the Department. The CMS Mapping Medicare Disparities tool is an interactive map using CMS claims data that will be used to identify areas of disparities between subgroups of Medicare beneficiaries. Data resources will continue to emerge from HHS that will help the health care ecosystem remove these inequalities. HHS supports a variety of initiatives to promote adoption of health IT and standards among health care providers. The programs and policies that scaffold national health IT improvements produce open data on the Health IT Dashboard run by the Office of the National Coordinator for Health IT. Here users will find datasets on ongoing program performance, surveys of health care providers and other data related to planning and policy making.

Advance Scientific Knowledge and Innovation

HHS leverages its research investments to guide the transformation of clinical and translational science programs to reduce the time needed for laboratory discoveries to become treatments for patients. Research supported by HHS is not only yielding many benefits right now, but it will also have a long-term impact on the future of our nation's health, economy, and communities. Following the tenets of the Public Access to Research Data Policy, six HHS OpDivs (NIH, CDC, FDA, AHRQ, ASPR, and ACL) are actively pursuing plans to make the results of federally funded research data openly available. A noteworthy advancement is being piloted by the National Institutes of Health as part of the Big Data to Knowledge (BD2K) initiative. DataMed is a prototype biomedical data search engine. Its goal is to discover data sets across data repositories or data aggregators. The number of datasets available via DataMed will increase massively as the agency moves this project from pilot to implementation in the future. Similarly the Centers for Disease Control and Prevention (CDC) make hundreds of datasets available for further insights into public health, surveillance and epidemiology. CDC is actively engaging the public to support advancements in these domains, applying past learnings from outbreaks like Ebola to current efforts to track and treat the Zika virus. During the Ebola outbreak the technology and development community sought sources of data to help combat the spread of the disease. CDC has since established a GitHub repository for public collaboration and knowledge sharing to control the spread of the Zika virus. These, and many others activities across the Department, are significant advancements in the availability of research data to advance scientific knowledge and innovation.

Advance the Health Safety and Well-Being of the American People

From the Food & Drug Administration, openFDA will continue to evolve as an exemplary platform for open safety data, allowing access to data about drug adverse event, drug recall enforcement reports, medical devices, and food recalls to name a few. The FDA is expanding its catalog of application programming interfaces (APIs) and the user community's ability and engages the innovator community on open platforms like GitHub and StackExchange.

Our efforts to ensure efficiency, transparency, accountability, and effectiveness of HHS programs will take several forms in the coming years, a few of which are highlighted here. The HHS Freedom of Information Act (FOIA) office is planning to update agency FOIA regulations with a new proposed rule at 45 C.F.R. Part 5, proactively embracing the FOIA Improvement Act

of 2016. The rulemaking will, among other goals, embrace the public's right to request information with updated procedures that coincide with modern technology. Additional transparency work has been done by the HHS Office of the Inspector General (OIG) which makes the results of evaluation and audit reports publicly available. The OIG has been instrumental in the investigations of the Medicare Fraud Strike Force's work to reduce fraudulent Medicare billing. OIG, CMS, and the U.S. Department of Justice (DOJ) collaborate on the use of interagency data resources that are not publicly available, but are made open to the OIG and DOJ for program integrity and law enforcement actions.

HealthData.gov serves as the discovery resource for publicly available data assets, as well as a platform for communications, commentary on, and feedback about the data to improve the public's understanding of each data set. The platform helps new data users discover resources they may not otherwise know exist. This site is a flexible platform that acts as a discovery resource for new and seasoned users across the health care ecosystem, from researchers to technology developers, and health care professionals to academia. Any organization or individual is free to employ the data to solve problems in the transformation of our nation's health care system through data driven innovations in areas such as: research; technology development; health care delivery; academia; policy making; and human services delivery.

Going forward HHS will continue to spur innovation by participating in hackathons, launching prize and challenge competitions, and leading informational in-person and online sessions to foster public engagement without open data assets. The annual Health Datapalooza convenes HHS data curators, technology developers, entrepreneurs, policy makers, researchers and more to explore the opportunities available through open data innovation and entrepreneurship. Each year HHS open data is on display as companies large and small demonstrate the alternative value they've derived from these data resources. HHS will continue to support the Datapalooza as it provides a strong signal for the trajectory of health care data analytics, how companies are using open data to fuel their innovations, and areas where the Department should focus its open data efforts in the future.

Public Provider Enrollment Files

CMS is committed to strengthening program integrity, as well as supporting the provider and supplier community through increased transparency. The continued growth of programs that require enrollment in Medicare fee-for-service as a prerequisite has steadily increased, as has the demand for information about Medicare enrollment from the healthcare industry. To meet

these needs CMS began publishing a list of all providers and suppliers enrolled in Medicare. This public provider data allows users, including other health plans, and researchers the ability to access Medicare data.

The Public Provider Enrollment file set consists of individual and organization enrollment information on all providers and suppliers nationwide who are approved to bill Medicare. This includes key unique identifiers, enrollment type and state, names, NPI, specialty, and limited address information (city, state, zipcode). This data also focuses on data relationships as it relates to Medicare Provider Enrollment and the reassignment of benefits. The information in the file is extracted directly from the Provider Enrollment Chain and Ownership System (PECOS), and will be updated quarterly. The information will only be updated through submission of updates to enrollment information via PECOS. Providers and suppliers would need to contact their respective Medicare Administrative Contractor (MAC) to make enrollment updates, or by going to https://pecos.cms.hhs.gov. Updates will be shown with the next release of the file.

The long-term goal of this initiative is to continue to expand data elements available in the files, and eventually consolidate other existing public lists of provider information, such as the Ordering and Referring File, Part D Prescribing File, and Revalidation Lists. Initial release of the data consisted of individual and organization provider and supplier enrollment information similar to what is on Physician Compare. Future releases will include data elements based on industry feedback and will align with other CMS projects.

CMS believes the release of the enrollment data provides a clear and transparent way for providers, suppliers, state Medicaid programs, private payers, researchers, and any other interested individual or organization to leverage Medicare provider enrollment information.

Improving Temporary Assistance for Needy Families (TANF) Financial Data Collection
The Administration for Children and Families' (ACF)-196 TANF Financial Data Collection Form was designed to monitor expenditures by grant year and ensure compliance with various statutory requirements governing the use of federal funds and state Maintenance-of-Effort (MOE) expenditures. The Department, Congress, research organizations, and other stakeholders use the data collected to gain an understanding of the types of activities on which states are spending their funds and analyze trends in how states choose to distribute their

program funds. Accurate and complete expenditure data is crucial as it provides the foundation for a well-informed policy analysis.

After consideration of comments received from interested parties and Office of Management and Budget (OMB) approval, the Office of Family Assistance (OFA) introduced a new quarterly TANF financial data form: the ACF-196R, which was effective starting in FY 2015. The ACF-196R implements two basic changes to TANF quarterly financial reports: modifying and expanding the list of expenditure categories, and changing the accounting method used to report expenditures and monitor grant awards.

In order to eliminate ambiguity in definitions, create categories and definitions that are mutually exclusive, and gain greater insight into how states spend TANF and MOE funds, without placing an undue reporting burden on states, OFA revised the expenditure categories and accompanying definitions used in TANF financial data collection. OFA also added the ACF-196R–Part 2, which requires narrative descriptions of expenditures reported as "Other," and assistance and non-assistance "Authorized Solely Under Prior Law," as well as an explanation of the methodology used to estimate expenditures, as appropriate.

The accounting methodology is also improved, as states are now required to report actual expenditures made in a fiscal year with each open grant year award. If a state needs to adjust an expenditure reported in a prior year, it will revise the report for the fiscal year in which that expenditure occurred, rather than account for that adjustment in the current year's report. OFA also worked with ACF's Office of Administration, which developed the capacity to generate real-time reports that sum expenditures made with each open grant year award during the fiscal year. The quarterly reporting methodology and new data collection system facilitate both the monitoring of grants, as well as the ability to obtain accurate fiscal year expenditures to inform TANF policy analyses.

The improvements to transparency are already evident: in FY 2015 only 4.1 percent of TANF and MOE funds were categorized as "other," compared to 14.7 percent in FY 2014. OFA plans to work with states and the Office of Grants Management to continue clarifying expenditures in the "other" category. OFA will also engage in ongoing dissemination activities to communicate the changes to TANF financial reporting and share the FY 2015 data.

Open Government – Head Start

Head Start is a federal program that promotes the school readiness of children ages birth to 5 from low-income families by enhancing their cognitive, social and emotional development. In addition to education services, programs provide children and their families with health, nutrition, social, and other services. Head Start services are responsive to each child and family's ethnic, cultural, and linguistic heritage.

Since its inception, Head Start has served more than 33 million children. In 2015, Head Start was funded to serve nearly one million children and pregnant women in centers, family homes, and in family child care homes in urban, suburban, and rural communities throughout the nation.

At the Office of Head Start (OHS), we are committed to making information available to the public in creative, innovative, and effective ways to ensure a transparent and open government that is truly accessible. In the past two years, we have reached milestones while also setting new goals. We developed and released a mobile app for Apple and Android devices which provides customized mobile-friendly access to resources and locator on the Early Childhood Learning and Knowledge Center (ECLKC) – the Head Start website. OHS released improvements to the Head Start locator on ECLKC so users could better navigate to a Head Start location and made enhancements to the Program Service Report web application to help users better understand the reports. In addition to these enhancements, we also released the Career Center, the Funding Opportunities Announcements Locator, and implemented increased security by adding the federally mandated Two-Factor Authentication. Finally, OHS migrated the ECLKC from the traditional and outdated co-located hardware and into a cloud-based hosting environment.

Currently, we are beginning the transition to a new open source content management platform (Drupal8 CMS) that will make information available to the public for programmable use. This will also allow for sharing content through syndication by RSS or embed codes. We will roll out the platform progressively during FY 2017. We are also working on the MyPeers pilot, an online platform that will connect Head Start staff across the nation to promote peer-to-peer learning.

Moratoria Provider Services and Utilization Data Tool

As part of its commitment to transparency, on June 22, 2016, the Centers for Medicare & Medicaid Services (CMS) made its first quarterly update to the Moratoria Provider Services and

Utilization Data Tool (Data Tool). CMS can utilize this tool to retrieve data to help assess geographic and health service areas that might be considered for a moratorium on a new provider or supplier type in a given geographic area. Users of the tool will find a set of interactive maps and a dataset showing national, state and county-level provider and utilization data of ambulance and home health services.

In addition to updating the data for these services, CMS is committed to adding data about other provider and supplier services, and this Data Tool now includes claims data for Independent Diagnostic Testing Facilities (IDTFs) and Skilled Nursing Facilities (SNFs) even though these provider services are not part of our current temporary moratoria efforts. The new data for all service categories covers the 2015 calendar year.

Medicare claims data were analyzed for a 12-month reference period and are scheduled for quarterly updates to reflect the most recent 12-month reference period. The most recent update not only covers the original 12-month reference period (covering October 1, 2014 through September 30, 2015), it now includes claims data from January 1, 2015, to December 31, 2015. To facilitate analysis of the data, CMS has included a (new Technical Appendix for user convenience).

The Data Tool is available through the CMS website at: **https://data.cms.gov/moratoria-data.**

Increasing Formulary Transparency for Essential Health Benefit Plans

Effective for plan years beginning in 2016, the Centers for Medicare & Medicaid Services (CMS) established formulary requirements for non-grandfathered individual and small group market plans, on and off of the Marketplaces. These requirements include publishing an up-to-date, accurate, and complete list of all covered drugs on the plan's formulary drug list, including any tiering structure that it has adopted and any restrictions on the manner in which a drug can be obtained. The list must be easily accessible to plan enrollees, prospective enrollees, the State, the Marketplace, HHS, the U.S. Office of Personnel Management, and the general public. A formulary drug list is easily accessible when: it can be viewed on the plan's public Web site through a clearly identifiable link or tab without requiring an individual to create or access an account or enter a policy number; and if an issuer offers more than one plan, when an individual can easily discern which formulary drug list applies to which plan. The purpose of these requirements is to improve the transparency of formulary drug lists for enrollees and our goal

with this provision is to ensure that the formulary drug lists are accurate, complete, and up-to-date.

Increasing Transparency of Qualified Health Plans' (QHPs) Provider Directories

Effective for plan years beginning in 2016, the Centers for Medicare &Medicaid Services (CMS) established provider directory requirements for qualified health plans (QHPs). These QHP issuer requirements already included making plan's provider directories available to the Marketplace for publication online in accordance with guidance from HHS and to potential enrollees in hard copy upon request. In the provider directory, the QHP issuer must identify providers that are not accepting new patients. Under the new requirements, the QHP issuer must publish an up-to-date, accurate, and complete provider directory, including information on which providers are accepting new patients, the provider's location, contact information, specialty, medical group, and any institutional affiliations, in a manner that is easily accessible to plan enrollees, prospective enrollees, the State, the Marketplace, HHS, and the Office of Personnel Management (OPM). A provider directory is easily accessible when: the general public is able to view all of the current providers for a plan in the provider directory on the issuer's public Web site through a clearly identifiable link or tab and without creating or accessing an account or entering a policy number; and if the QHP issuer maintains multiple provider networks, the general public is able to easily discern which providers participate in which plans and which provider networks. The purpose of these requirements is to improve the transparency of provider networks for QHP enrollees and our goal with this provision is to ensure that provider directories are accurate, complete, and up-to-date.

State-based Marketplace Public Use Files

The State-based Marketplace Public Use Files (SBM PUFs) are an initiative to provide more information to the public and affected stakeholders (e.g. consumer groups, web-brokers) about a standard set of State-based Marketplace data. These metrics are shared with HHS by SBMs and the National Association of Insurance Commissioners (NAIC). In conjunction with the Federally-facilitated Marketplace Public Use Files (FFM PUFs), the SBM PUFs can be used by researchers and other stakeholders to gain unprecedented insight into the functioning of health insurance markets throughout the United States.

The SBM PUFs provide information to stakeholders on benefits and cost-sharing, rates, plan attributes, business rules, service area, and networks. This large dataset brings together

information about the SBMs and the Affordable Care Act (ACA), at a more granular level than survey data, on the state of health insurance coverage in states that have implemented their own Marketplaces. At present, many SBMs provide information to the public through regular releases but this information is not widely publicized and does not adhere to a standard set of reported metrics. The SBM PUFs fill this gap and create a single, internally consistent set of data that allows analysis and comparison of information between the SBM states. Additionally, HHS welcomes efforts by stakeholders to evaluate the differences between SBM markets and FFM markets using this dataset. While fragmentation has characterized the market for commercial health insurance prior to the ACA, HHS believes that the combination of commercial health insurance data can help to reduce this fragmentation.

Health Insurance Marketplace Public Use Files

The Health Insurance Marketplace Public Use File (PUF) contains comprehensive data on Qualified Health Plans (QHPs) and Stand-alone Dental Plans (SADPs) whose primary audience is intended for researchers and others interested parties. The files provide detailed information about QHPs and SADPs offered on HealthCare.gov, including information about essential health benefits, plan design, cost-sharing structure, premium rates, rate application rules, and service area. Eight files make up the Marketplace PUF: (1) Benefits and Cost Sharing PUF, (2) Plan Attributes PUF, (3) Rate PUF, (4) Business Rules PUF, (5) Service Area PUF, (6) Network PUF, (7) Plan ID Crosswalk PUF, and (8) Machine Readable PUF. This year, CMS will release a transparency in coverage PUF that will provide information on claims payment policies and procedures and claims denial information, among other things. The Marketplace PUF shows plan data in States with Federally-facilitated Marketplaces (FFMs) and States that operate State-based Marketplace using the Federal Platform (SBM-FPs), including data on Multi-State Plans (MSPs).

HRSA Health Center Program Data and Health Center Profile

HRSA's Bureau of Primary Health Care (BPHC) hosts webpages that display data reported by all health centers receiving primary care grants authorized under Section 330 of the Public Health Service Act, namely the Uniform Data System (UDS). These health centers include grantees of the Community Health Center, Migrant Health Center, Health Care for the Homeless, and Public Housing Primary Care Programs. Additionally, a modified version of the UDS is submitted by health centers designated as "look-alike" entities (that meet all requirements applicable to federally funded health centers but do not receive federal operating

grants). The UDS captures aggregate information at the health center level on the number and types of patients served, services delivered, staffing profiles, and financial information on health measures and health outcomes that align with national quality efforts. Health center data are available on the UDS webpages at the national, state, and health center levels. Complementing UDS data, the webpages display a series of acknowledgement badges that recognize health centers that: leverage patient electronic health records at all delivery sites and used by all providers; earned patient-centered medical home recognition; exceeded clinical performance targets for the CDC's Million Hearts initiative; and received quality improvement usability by depicting multiple complex data points with a badge. For instance, the Million Hearts badge represents performance data cross multiple clinical measures: aspirin use, blood pressure control, cholesterol control, and smoking cessation. Prominently placed on each health center's profile webpage, badges foster friendly competition among health centers to improve quality improvement systems, promote patient-center care practice, and leverage data for public health initiative. Finally, the health center level webpages provide access to service area maps that summarize the location of health center delivery sites and zipcode origins of patients being served.

Indian Health Service – Improving Patient Care

The Improving Patient Care program is establishing the Patient Centered Medical Home model of care throughout hospitals and clinics within the 12 Indian Health Service Areas. Since 2008, this patient-care model has improved the quality of health care, provided greater access to care, and strengthened the positive relationships between the care team, patients, their families, the community, and the Tribe. The purpose of the Improving Patient Care program is to assist outpatient primary care teams in their efforts to achieve a Patient Centered Medical Home standard of care and to support the pursuit of formal Patient Centered Medical Home recognition.

Data management and analysis will drive improvements and success will be measured by achievement of clinical and process industry-benchmarks, as well as ultimate recognition or certification of participating sites as Patient Centered Medical Homes. Currently, the Indian Health Service is developing a standardized set of measures that will align with the Centers for Medicare & Medicaid Services. The measures will include process and outcome measures. The goal measures set will be to evaluate clinical outcomes, the performance of the health facility, and the health system.

HRSA National Center for Health Workforce Analysis

The National Center for Health Workforce Analysis (the National Center) informs public and private sector decision-making related to the health workforce by expanding and improving health workforce data, disseminating workforce data to the public, improving and updating projections of the supply and demand for health workers, and conducting analyses of issues important to the health workforce.

In 2014, the National Center released a report on "The Future of the Nursing Workforce: National- and State-Level Projections 2012-2025" and a report on the "Distribution of U.S. Health Care Providers Residing in Urban and Rural Areas" which presents supply and distribution data of practitioners in 32 health occupations across urban and rural areas. In 2015, the National Center released reports on "National and State-Level Projections of Dentists and Dental Hygienists in the U.S., 2012-2025" and Sex, Race, and Ethnic Diversity of U.S. Health Occupations (201-2012)." In addition to these reports, the National Center also released factsheets on the supply and demand for a number of health occupations and factsheets summarizing the accomplishments for over 40 programs funded by Bureau of Health Workforce. The National Center has also funded several Health Workforce Research Centers that support high quality, impartial, policy relevant research on the health workforce to assist decision makers at the federal, state, and local levels to better understand health workforce needs. The most recent center is focused on Behavioral Health and was funded in collaboration with SAMHSA.

For more information and to access the reports of the National Center at
http://bhwr.hrsa.gov/healthworkforce/

HRSA Ryan White HIV/AIDS Program Annual Client Level Data Report

The inaugural Ryan White HIV/AIDS Program Annual Client Level Data Report (RWHAP CLD) was published in December 2015 and features Ryan White HIV/AIDS Program Services Report (RSR) data on all clients served by the RWHAP during calendar years 2010 through 2014. The publication provides an in-depth look at demographic and socioeconomic factors among clients served as well as selected analyses to measure RWHAP's progress toward achieving key objectives of the National HIV/AIDS Strategy: Updated to 2020. The RSR is the annual reporting instrument that agencies and organizations use to report data related to

organizational characteristics, provider/site characteristics, and client characteristics. In 2016, the Ryan White HIV/AIDS Program Supplemental Client-Level Data Report, Eligible Metropolitan Areas (EMA) and Transitional Grant Areas (TGA) reports were published as an addendum to the RWHAP CLD Report. This addendum features client-level data for all clients served by RWHAP providers within EMAs/TGAs during calendar years 2010 through 2014.

Health Resources Services Administration (HRSA) HIV State Profiles
The State Profiles provide detailed state-level information on the Ryan White HIV/AIDS Program and the HIV/AIDS epidemic in the U.S. The Ryan White HIV/AIDS Program funds primary care and support services for people living with and affected by HIV disease that lack health insurance and financial resources for their care. The program also funds training, technical assistance, and demonstration projects to advance the work of funded agencies. Every year, recipients of Ryan White HIV/AIDS Program funds are required to report to the Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau how those funds have been used to provide services to low-income and underserved individuals and families living with HIV/AIDS.

Myhealthfinder
The implementation of the ACA has been a marque example of open government. Building upon improving the transparency about costs and options for health insurance and tools and resources to acquire it, HHS has also developed and is syndicating personalized guidance for ACA-covered clinical preventive services. Myhealthfinder (healthfinder.gov/myhealthfinder) is a user-centered resource for consumers to get personalized recommendations for clinical preventive services. When users enter their age, sex, and pregnancy status (if applicable), they receive tailored results that include links to related health topics where they can learn about health conditions they could be preventing through these services.

New results are added to myhealthfinder when a clinical recommendation is released or updated. All myhealthfinder content is written in plain language for consumers of all literacy levels, including people with low literacy or low health literacy. Myhealthfinder contributes to open government by bringing to light for all Americans the medical science conducted behind the scenes of the ACA-covered recommended preventive services. The tool personalizes these recommendations by mirroring the outcomes research on clinical preventive services conducted according to sex, age and pregnancy status. It is prominently displayed on healthfinder.gov, an

award winning HHS trusted resource known for its user-friendly content and design. Major HHS public facing websites use myhealthfinder as their original source for ACA-covered preventive service content including HealthCare.gov, HHS.gov and CDC.gov/prevention.

Myhealthfinder is available in three forms: an API, a full feature code which is easier to incorporate, and a widget which is the simplest option of all. The syndicated content is customizable based on queries and available in either XML and JSON formats. Myhealthfinder is now the authoritative, go-to resource for consumers to understand the who, what, why, and how of the clinical preventive services that HHS recommends. Myhealthfinder is an ongoing initiative and expected to expand its personalization and syndication.

3.2 TRANSPARENCY INITIATIVES

Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) Initiatives – Public Notification of Emerging Signals for Medical Devices

CDRH is responsible for the regulation of products that meet the statutory definition of a medical device. At the time a medical device reaches the market, it has a benefit-risk profile that health care providers, patients, and consumers use to make treatment decisions. However, not all information regarding benefits and risks for a given device may be known before it reaches the market. New information about a device's safety and/or effectiveness, including unanticipated adverse events, may become available once the device is more widely distributed and used under real-world conditions and in broader patient populations. Also, subsequent changes made to the device, its manufacturing process, or its supply chain might lead to new safety problems. CDRH considers new information suggesting a new potentially causal association or a new aspect of a known association between a medical device and an adverse event to represent a "signal." An "emerging signal" is a signal for which the Agency has conducted an initial evaluation and determined that the information has the potential to impact patient management decisions and/or the known benefit-risk profile of a device.

CDRH is currently putting in place a process by which each emerging post-market safety signal under evaluation by a cross-Center team will be assessed for potential early public notification (e.g., before all relevant information has been gathered and analyzed). This includes an established set of factors to be used in making the decision, the timelines for making re-

assessing the decision, and the processes and timing for updating such notifications. The Center plans to finalize a guidance document that speaks to this effort, which it will begin instituting in the coming months.

Through this activity, CDRH is attempting to increase its public transparency by adopting a more consistent approach to sharing new device performance-related information that comes to light in the postmarked period while it is still under evaluation. Timely notification about those emerging signals is intended to provide health care providers, patients, and consumers with access to the most current information concerning the performance and potential benefits and risks of marketed medical devices to enable them to make informed decisions about their treatment options. It may also produce more enhanced vigilance on the part of clinicians, risk managers, patients and consumers and reduce or limit the number exposed to potential risk while the issue is being further evaluated. The awareness raised by a notification may also promote voluntary reporting of events to FDA. This, in turn, may provide the Agency with additional insight into the issue and assist in the formulation of potential risk mitigation strategies or recommendations.

FDA Medical Device Regulatory Guidance Webinars

CDRH issues approximately 40 draft/final guidances each year. These guidances are developed, in part, to help the medical device industry understand what to include in its medical device marketing applications. In 2014 FDA/CDRH began to offer public webinars for industry to discuss the contents of guidances and answer any of industry's questions about them. A webinar includes the Subject Matter Expert discussing the purpose, content, changes and clarification of the guidance. A significant 2-way dialogue/question and answer session follows this presentation in which the participants can ask specific clarifying questions. These webinars are held two weeks after the issuance of guidance to allow stakeholders time to read the guidance and schedule time to participate. On average 1,000 sites participate in these webinars; some webinars include as many as 2,000 participants. Following webinar presentations, slides, and transcripts are posted to CDRH's webinar website for future viewing. Since 2014 CDRH has held 41 webinars, reaching at least 41,000 sites... Informing and educating the medical device industry ensures better quality submissions, and CDRH's 2-way dialogue with its stakeholders helps it to produce better guidance in the future.

National Institutes of Health (NIH) Plans for Increasing Access to Digital Scientific Data

The NIH has a long history and continued commitment to ensure that, to the fullest extent possible, the results of federally-funded scientific research are made available to and are useful for the general public, industry, and the scientific community. The NIH has maintained the principle that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health. Validation and progress in science are predicated on access to research results. The NIH has developed a number of policies to support this effort and has many activities underway to further promote sharing of data, such as the 2003 *NIH Data Sharing Policy* (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html), the 2014 *NIH Genomic Data Sharing Policy* (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html), and the 2015 *NIH Intramural Human Data Sharing Policy* (https://oma1.od.nih.gov/manualchapters/intramural/3016/).

On February 22, 2013, the White House Office of Science and Technology Policy (OSTP) released its memorandum entitled *Increasing Access to the Results of Federally Funded Scientific Research* http://www.whitehouse.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf). In February 2015, in response to this memorandum, the NIH issued the *NIH Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research* (http://grants.nih.gov/grants/NIH-Public-Access-Plan.pdf). The goals of this directive are in keeping with the NIH's ongoing and future commitments to facilitate data sharing, and the NIH Plan outlines mechanisms for expanding and strengthening access to data and publications from NIH-funded research. In the near future, and after public engagement, the NIH is planning to expand upon its 2003 *Data Sharing Policy* and develop a data management and sharing policy that will apply to all NIH-funded research, regardless of funding level.

Many of the NIH activities related to public access to digital scientific data are overseen by the NIH Scientific Data Council (SDC), an internal NIH committee comprised of senior NIH leaders and staff. The SDC was originally created in 2013 and constituted as part of a multifaceted expansion of NIH programs and governance related to data science. The SDC, in a trans-NIH manner, addresses the growing challenges and opportunities associated with 'big data' and data science in biomedical research, thereby improving data utilization by the research community in order to transform the impact of biomedical, clinical, and public health research.

Key major milestones and anticipated completion dates:

- January 2015: The *NIH Genomic Data Sharing Policy* became effective and is now being implemented across all NIH Institutes and Centers. This policy applies to all NIH-funded research that generates large-scale human or non-human genomic data, regardless of the funding level, and use of these data for subsequent research.

- October 2015: The *NIH Intramural Human Data Sharing Policy* became effective and is now being implemented across NIH Institutes and Centers with the purpose of responsible sharing of all human data and secondary research with human data generated in the NIH Intramural Research Program (IRP).

- 2014 – Present: Many other NIH programmatic initiatives are also advancing implementation elements discussed in the *NIH Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research* (Public Access Plan). In particular, through the NIH Big Data to Knowledge Initiative (BD2K), awards have been made for the development of:
    - A Commons as a shared virtual space in which data and associated analytics can be utilized.
    - A data catalog in the form of a data discovery index, called bioCADDIE (biomedical and health care data discovery index ecosystem) to facilitate the FAIR principles of **F**inding, **A**ccessing, **I**nteroperating, and **R**eusing data.

- 2016 - 2017: The Scientific Data Council's Sustainability Working Group will develop and implement economic, technical, and administrative approaches to enhance long-term support of biomedical data resources.

- Fall 2016: In order to inform the development of a future NIH data management and sharing policy that would encompass the different types of data generated by the vast amount of research supported by the NIH, the NIH will first establish priorities for data sharing. The priority setting process will involve obtaining stakeholder input on a number of topics, such as data sharing strategy (e.g., what data should be shared; which data types have the greatest value for secondary analysis; costs and value of sharing different types of data; long-term preservation and sustainability of sharing data; metric for assessing biomedical repositories; and standards for citation of data.

- Fall 2016: The Final Rule on Clinical Trials Registration and Results Information Submission (https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission) and the final NIH Policy on Dissemination of

NIH-Funded Clinical Trial information
(https://www.federalregister.gov/documents/2016/09/21/2016-22379/nih-policy-on-the-dissemination-of-nih-funded-clinical-trial-information) were released. The rule furthers the implementation of a statutory mandate for registering and submitting results information to ClinicalTrials.gov for certain clinical trials of FDA-regulated products. The NIH Policy establishes the expectation that all investigators conducting clinical trials funded in whole or in part by NIH will ensure that these trials are registered at ClinicalTrials.gov. The new regulation and complementary policy promote broad and responsible dissemination of information on clinical trials.

- 2016-2019: The NIH plans to develop, to seek stakeholder input on, and to release and implement a new data management and sharing policy that will apply to all NIH-funded research, regardless of funding level.

NIH Accelerating Medicines Partnership (AMP) Type 2 Diabetes Knowledge Portal

The AMP Type 2 Diabetes (T2D) Knowledge Portal is aimed at advancing type 2 diabetes research and treatment, and includes data from over 100,000 genetic samples obtained from clinical consortia supported by the NIH and the Foundation for the NIH. Encouraging greater collaboration between and participation of the scientific community and all interested in diabetes and genetic research, this online library allows open-access searching of human genetic and clinical information on type 2 diabetes. Individual data remains confidential. Truly a source for big data, the portal includes information from a growing list of major international networks, collected from decades of research.

By using human genetic samples, the portal provides a way to identify the most promising therapeutic targets for diabetes from troves of potentially relevant human data. The innovative curation and the scale of data enable researchers to translate differences in an individual's genome into an understanding of how those differences affect a person's risk of developing type 2 diabetes. The portal also enables advances in Precision Medicine, where investigators can examine genetics and disease in relation to differences in race, ethnicity, and locality.
The knowledge portal makes genetic and clinical information searchable in myriad ways to help researchers identify and describe the effects of genes on disease, test biological hypotheses, and conduct many other analyses. The portal is publicly searchable and can be used as a tool

to learn about genetics and health. In 2016, the portal enhanced its accessibility to the public, allowing anyone to query detailed data from the portal. The portal is also available in Spanish. By making available the fruits of government-funded research, the portal increases transparency of how those research dollars have been spent and encourages users to amplify the government's investment by finding new uses for that data in scientific inquiry.

Office of Medicare Hearings and Appeals

The Office of Medicare Hearings and Appeals (OMHA) has undertaken a number of activities focused on increasing transparency into the Administrative Law Judges (ALJ) hearing process administered by the agency. These initiatives include:

ALJ Appeal Status Information System (AASIS)

Individuals appealing unfavorable decisions regarding the coverage or payment of Medicare claims and other related matters need timely acknowledgement of the receipt of their appeals and definitive contact information should they need to make an inquiry regarding the status of their appeals. To meet this need, OMHA implemented AASIS, a web-hosted solution that allows individuals to verify receipt of their appeals, view updates to the status of appeals, and find contact information for ALJ staff assigned to adjudicate the appeal.

Electronic Case Adjudication and Processing Environment (ECAPE), Appellant Public Portal

ECAPE is a public facing portal that will serve as a full two-way communication tool and will allow authorized parities to file requests for hearing, submit additional evidence, check appeal status, and view the appeal case file contents online once implemented.

Adjudication manual

This provides agency staff with a single resource for policy and procedural guidance that can be updated on a rolling basis. The manual sets forth a standardized business process aimed at increasing consistency for appellants and provides a framework to move from a paper-based to a fully electronic adjudication process which will further increase access and transparency to the administrative appeals process through features such as online access to real-time case status information and the administrative record.

Data Transparency Initiative

The agency is developing reports, to share additional workload and appeal disposition information with the public and appellant community on its website and will update this information on a regular basis in future years.

3.3 PROACTIVE DISCLOSURES

Centers for Disease Control and Prevention (CDC) Public Access Platform
In order to keep pace with emerging public health challenges and the need to share research and information the CDC has developed CDC Stacks. CDC Stacks is a free, digital repository of scientific research and literature produced by CDC. This online archive is composed of curated collections tailored for public health research needs, is retained indefinitely, and made available for public health professionals, researchers, and the general public to promote public health literacy.

Public health and scientific advancement are best served when scientific information is openly shared and used by the public, public health professionals, health care providers, educators, policy makers and private sector organizations. With greater public access, CDC can maximize the effect and impact of public health science and improve the health of the nation. Through its public access policy CDC has provided access to over 7,700 peer reviewed publications. This has resulted in over 1.2 million article accessed that would have otherwise required payment.

CDC Stacks brings together documents spanning public health topics as well as the history of CDC. Collections include the first 30 years of Morbidity and Mortality Weekly Report (MMWR), CDC Open Access, and Influenza Surveillance Reports. CDC Stacks also contains a collection of both current as well as archival CDC guidelines and recommendations. CDC Stacks is a fully featured archive allowing users to search the full text of all documents as well as browse journal articles by public health subjects. Public health is a broad topic and so are the types of documents found in the repository with new documents added every week.

By leveraging an open source software model CDC has not only been able to develop new code rapidly but has been able to share that code with the public as well as other federal agencies. In the spirit of shared services the CDC is currently supporting the National Oceanic and Atmospheric Administration document repository system and is in the process of launching the Department of Transportation document repository system. This inter-agency collaboration not

only provides new ideas and strength in numbers it also comes at a considerable cost savings to the government.

FDA Center for Veterinary Medicine Initiative – NARMS Now: Integrated Data

The National Antimicrobial Resistance Monitoring System (NARMS) is a collaborative project of state and local public health departments, FDA's Center for Veterinary Medicine, CDC, and the U.S. Department of Agriculture (USDA). This national public health surveillance system tracks changes in the antimicrobial susceptibility of intestinal bacteria found in ill people (CDC), retail meats (FDA), and food animals (USDA). The NARMS program helps promote and protect public health by providing information about emerging bacterial resistance, the differences between resistant infections and susceptible infections, and the impact of interventions designed to limit the spread of resistance.

Consistent with the National Strategy for Combating Antibiotic-Resistant Bacteria (CARB) goals and HHS' and USDA's Open Government policies, in 2015 NARMS published online a new format called NARMS Now: Integrated Data. This format contains the entire collection of NARMS enteric bacterial isolates collected over 18 years (1996-2013) from all three agencies for *Salmonella, Campylobacter, E. coli* and *Enterococcus.*

The NARMS data are available in a spreadsheet format that can be downloaded and analyzed by commonly used software applications. Data fields include sample identifiers, sample source, dates of collection, and antimicrobial susceptibility testing results. In 2016, NARMS began to include resistance determinants and accession numbers that can be used to access whole genome sequences housed in the NARMS GenBank bioproject on the National Center for Biotechnology Information (NCBI) website. NARMSNow: Integrated Data is updated on a regular basis as new information is generated.

In the near future, NARMS Now: Integrated Data will be incorporated into the integrative displays associated with the NARMS integrated Reports to allow readers to visualize the findings across the various sample sources in NARMS.

FDA Proactive Posting of Medical Device Premarket Notification Submissions

CDRH receives approximately 2,000 FOIA requests each year, 90 percent of which are for FDA-cleared medical device premarket notification submissions. In 2015 CDRH began to

proactively post redacted FDA-cleared market notifications. For a device to receive FDA clearance via the Medical Device Premarket Notification process, manufacturers must demonstrate substantial equivalence to another FDA cleared device that is not subject to premarket approval. Access to FDA-cleared marketing applications is an integral part of the submission process for the medical device industry. As of July 2016, 553 redacted premarket notifications have been posted, with the plan to post more each month. In fiscal year 2016 CDRH has noticed a 19 percent decline in its incoming requests, which both reflects more timeliness in the public access of information and reduced cost to the FOIA program.

FDA Public Posting of Food, Cosmetic, and Dietary Supplement Adverse Event Data

Center for Food Safety and Applied Nutrition (CFSAN) Adverse Event Reporting System (CAERS) collects reports about adverse health events and product complaints related to CFSAN-regulated products, namely conventional foods, dietary supplements, and cosmetics. For the first time, FDA is planning to post CAERS data on FDA.gov. The same information will be made available through OpenFDA but in a downloadable format. This first posting of CFSAN's CAERS contains adverse event reports submitted since 2004. FDA will update the information quarterly to ensure that the public has the most current information available about adverse events reported in relation to these commodities.

This new initiative provides an opportunity to provide researchers, consumers and health professionals easy access to information that was once only available under FOIA. The purposes underlying posting of the data are to: 1) to achieve greater transparency and 2) to make it easier for those in the scientific community and other requestors to access and examine the data in their work to advance and promote public health.

FDA uses such adverse event reports as part of its overall strategy to monitor the safety of foods, cosmetics, and dietary supplements. FDA hopes that the increased transparency this initiative will afford will help to spur the submission of more detailed and complete reports from consumers, health care providers and other members of the public. Complete and detailed reports are immensely helpful to the agency when identifying safety signals and targeting particular products for further scrutiny.

The information to be posted summarizes what was reported to the agency and does not represent any FDA conclusions about whether a product actually caused a reported adverse

event. The data to be posted include the product name, industry code, symptom(s), outcome, reporter's sex and age, date the consumer first experienced the adverse event, date the report was entered into the system, and CAERS ID number. All reports are voluntarily submitted to FDA from consumers, health professionals, and industry, with the exception of mandatory reports dietary supplement manufacturers receive.

Users of the database can download data from the fda.gov website as a .csv file or can access the data through OpenFDA. Academics and other statisticians are likely to use these OpenFDA data, which are in an API format.

The Certified Health Information Technology Product List (CHPL)

The Office of the National Coordinator for Health Information Technology (ONC) administers the Certified Health Products List (CHPL); the comprehensive database of all health IT products certified by the ONC Health IT Certification Program. In 2016, ONC launched a new, more open, and transparent version of the CHPL that makes more of the certification data accessible in open data formats to the public and provides access to the data through application programming interfaces (APIs). The CHPL now provides open data formats for corrective actions for certified health IT, mandatory disclosures of the types of costs and limitations related to a certified health IT, and, for health IT certified to the 2015 Edition Health IT Certification Criteria (2015 Edition), testing and usability results. These data are now available through open APIs, a downloadable dataset, and through use of the CHPL website. The open CHPL is a resource for app and web developers, health care and health IT researchers, health care providers, and health care consumers to access data and information about the health IT products certified by ONC to improve the quality, cost, and efficiency of care delivery.

3.4 PRIVACY

In compliance with OMB guidance and other requirements, HHS routinely provides privacy compliance reports that define the framework for how the agencies meet requirements of the Privacy Act of 1974 and other policies.

These include the following public resources and reports to OMB and Congress:

Privacy Impact Assessments as required by Section 208 of the E-Government Act (http://www.hhs.gov/pia)

New or Altered Privacy Act System of Records Reports (http://hhs.gov/foia/privacy/sorns.html)

New, Altered, or Renewed Matching Program Reports (available through the Federal Register)

Executive Order 13636 Privacy and Civil Liberties Assessments (https://www.dhs.gov/publication/executive-order-13636-privacy-civil-liberties-assessment-report-2016)

Health Insurance Portability and Accountability Act Compliance Reports to Congress:

- Report to Congress on Privacy Rule and Security Rule Compliance (http://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/reports-congress/index.html)
- Reports to Congress on Breach Notification Program (http://www.hhs.gov/hipaa/for-professionals/breach-notification/reports-congress/index.html)

3.5 WHISTLEBLOWER PROTECTION

HHS, Assistant Secretary for Administration, Office of Human Resources (OHR), Strategic Programs Division (SPD) oversees the coordination and implementation of the 2302(c) Certification Program for the Department. The Department has over 70,000 employees located throughout the United States and in at least 12 international locations.

The Department's Office of Inspector General (OIG) established the Whistleblower Protection Ombudsman (WPO) as required by the Whistleblower Protection Enhancement Act of 2012. WPO's comprehensive webpage includes rights and remedies of potential whistleblowers and the responsibilities of HHS supervisors; other frequently asked questions; and links to the OIG Hotline, the Merit Systems Protection Board, and the Office of Special Counsel (OSC).http://oig.hhs.gov/fraud/whistleblower/

The Department obtained 2302(c) certification from OSC in 2015 and expects to continue to satisfy all certification requirements (recertification is due in 2018). The overall plan for obtaining maintaining certification standards for the Department includes coordination with seven servicing human resources offices. This team approach is required considering the number and locations of HHS employees throughout the world.

The points of contact from each operating/staff division gather information on their current procedures, and they are trained on the 2302(c) certification program and their role, and coordinate requirements for local 2302(c) compliance. The designated contact is responsible for ensuring compliance for the areas and locations served and reporting to SPD annually.

Information is maintained OHR's under the "Whistleblower Protection" section and includes educational resources, contact information, and links to the OSC and other relevant websites.

An email blast is sent periodically from the Secretary to all employees informing them of their rights and remedies. The email includes links to information required (https://osc.gov/Pages/Outreach-2302Cert.aspx) for distribution under the 2302(c) certification program (e.g., Your Rights as a Federal Employee, Know Your Rights When Reporting Wrong, etc.) This email blast will be issued annually.

An email blast from the Secretary to all managers and supervisors informing them of the prohibited personnel practices (PPP) and the Whistleblower Protection Act (WPA), training requirements, and a link to the required training.

A notification system has been set up through the HHS Learning Portal ensuring that training is provided to and completed by supervisors and managers every three years.
In addition to HHS plans, OIG has obtained its own certification from OSC. The OIG has demonstrated its commitment to protecting whistleblowers within the Department by establishing a WPO as required by the Whistleblower Protection Enhancement Act of 2012. The WPO has established a webpage with contact information at http://oig.hhs.gov/fraud/whistleblower/ and frequently asked questions (FAQs) at http://oig.hhs.gov/faqs/whistleblower-faq.asp. The FAQs include information about the rights of potential whistleblowers and the remedies available to them if they experience retaliation, and the responsibilities of HHS supervisors. They also include direct links to the OIG Hotline, the

Merit Systems Protection Board, http://www.mspb.gov/appeals/whistleblower.htm, and OSC (http://www.osc.gov/), which has primary jurisdiction over complaints alleging whistleblower reprisal. In June 2013, the OIG notified HHS employees about the WPO via email using the Department's blast email system. That email included a link to the WPO webpage and the email address at which the WPO can be contacted. The OIG also requested that the Department's ethics counselors forward this email to all Special Government Employees for which they are responsible.

3.6 RECORDS MANAGEMENT

HHS Records Management Program

The top priority for the HHS Records Management Program still remains the acquisition of a uniform Electronic Records Management System in accordance with goals identified in OMB Memorandum M-12-18, *Managing Government Records Directive,* August 2012. The decision to pursue such a system was a significant part of the Records Management Transition Plan draft which was updated in 2013. In preparation for acquiring that system, the HHS Records Management personnel conducted an inventory of the Department's records schedules, updated file plans and created records schedules for the agency's automated information systems according to OMB Memorandum M-12-18 section 2.2. An Executive Committee, consisting of representatives from the Department and all of its Operating Divisions, was established to justify the need for an Electronic Records Management System, and to define its required functionality and oversee its analysis and implementation.

HHS personnel analyzed the records management capabilities in both manual processes and the multiple automated information systems employed throughout HHS and concluded a uniform solution for electronic records management was needed for several reasons. Some of the electronic records management solutions in use throughout HHS were not satisfying the minimum requirements for such systems. Since the number of records managed by those automated information systems was growing exponentially, the HHS personnel determined better solutions for electronic records management, verified as meeting National Archives and Records Administration expectations, were needed and a uniform solution would be more cost-effective than evaluating each independent automated information system in use and correcting them all separately. Additionally, the volume of records not yet managed electronically was also

growing exponentially and the cost and logistics of managing the records was becoming unmanageable.

The HHS personnel that developed the Records Management Transition Plan realized compiling an inventory of the Department's records schedule and file plans was prerequisite to acquiring an automated information system that could manage all records for the Department. The Department has met the prerequisite.

The Department is actively attending conferences and hosting Records Management vendors for solutions that will address the M-12-18 Managing Government Records Directive to manage all permanent electronic records electronically to the fullest extent possible by December 2019. In addition to attending conferences and hosting vendors, the Department is also communicating with its Information Technology Infrastructure and Operations (ITIO) team to leverage the current SharePoint software as a possible solution.

The Department will meet the two short-term priorities that are due by the end of 2016:

a.) Department's Records Management Program is the acquisition of an enterprise Email Record Keeping System. The Department began a phased rollout of its Email as a Service initiative, which has since been renamed "My Work Place" to most of its OpDivs and StaffDivs. The inclusion of Microsoft 360 Email as a part of "My Work Place" allows the department to meet the M-12-18 mandate which states by December 31, 2016 all Federal agencies must manage all email records in an electronic format and that Email records must be retained in an appropriate electronic system that supports records management and litigation requirements including capability to identify, retrieve and retain records for as long as needed. Those HHS OpDivs not implementing "My Work Place" are required to ensure their platforms meet the minimum requirements outlined for "My Work Place." To further enhance management of emails, the Department Record Officer is working with the Department's Information Technology office to explore/create additional RM automation tools and functionality to assist users with management of Email.

b.) The Department will meet the directive for all paper and non-electronic records to be identified, and to create and submit record schedules to the National Archives by

December 31, 2016. The Department's OpDivs began inventory of records in 2013 and all have either submitted schedules for records they identified or they are in the process of submitting the remaining schedules to the National Archives.

Data Standardization

At OMB's request, HHS is leading a research project on the standardization of data elements and data element definitions for the Federal grants lifecycle. HHS initiated the project by examining over 1,100 individual data elements and their associated definitions using a set of 17 individual data sources. Key leaders in the grants community who worked on the development of information collections through the framework of the Grants Policy Council (GPC) and Grants Executive Board (GEB) were interviewed, and GPC documentation reviewed and analyzed line-by-line.

Though data standards exist throughout the financial assistance community, they are not always consistently defined or used across Federal agencies. This lack of consistent implementation of standards results in duplicative infrastructure within and among both Federal agencies and recipients, and creates challenges to the assurance of high quality publicly shared financial data. The goal of the financial assistance administrative data standardization initiative is that every set of approved data elements will have the same meaning across the grants administration lifecycle – from pre-award activities through to post award reporting, for the whole Federal government. As grants data standards are developed, data quality gaps may be identified in systems like the CFDA and USAspending.gov. Establishment of these standards and ultimately remediation of gaps in systems will foster improved data quality for all federal financial data associated with financial assistance awards. Implementation of these standards will also result in reduced administrative burden on recipients, who will be able to collect, store, and report consistently defined data more efficiently throughout the lifecycle of an award. The intended result of this effort is a set of approved data elements that will have the same meaning across the grants administration lifecycle – from pre-award activities through to post award reporting, for use by all federal grant making agencies. The goal of this initiative is that every set of approved data elements will have the same meaning across the grants administration lifecycle – from pre-award activities through to post award reporting, for the whole Federal government.

On May 9, 2014, President Obama signed the Digital Accountability and Transparency Act of 2014 (DATA Act) into law. The purpose of the DATA Act is to expand the current reporting requirements of the Federal Funding Accountability and Transparency Act (FFATA) by establishing government-wide financial data standards and increasing the availability, accuracy, and usefulness of federal spending information. In order to meet this goal, the DATA Act requires agencies to report additional information on federal spending. Once available, this detailed data could serve as a tool for better oversight, management decision-making, and innovation inside and outside of the federal government. When implemented, the DATA Act will provide the opportunity to better understand how federal programs and investments can improve the lives of the American public and make program delivery more effective.

Subsequent to the passing of the DATA Act, HHS was designated by the Office of Management and Budget (OMB) as the executing agent of the Grants portion of the pilot required under Section 5 of the DATA Act. In this role, HHS is tasked with establishing and reporting the results of a pilot program that targets the reduction of burden in federal grant recipient reporting.

While HHS demonstrated its commitment to reporting transparency since the inception of FFATA, we recognize the significance and complexity of implementing the DATA Act requirements and our role serving as OMB's executing agent for the grants Section 5 Pilot. In October 2014, HHS established a DATA Act Program Management Office (DAP) to ensure successful implementation of the requirements contained within the statute and to lead all efforts in the execution of the grants Section 5 Pilot.

For the purposes of HHS implementation, DAP serves to provide as a cohesive agent between the four business communities within HHS that are critical to implementation, those being; budget, finance, financial assistance, and procurement. In accordance with OMB/Treasury guidance and to better enable the efforts of the DAP, HHS designated a Senior Accountable Official (SAO) with the ability to coordinate activities across these communities. The actions taken provide the organizational groundwork necessary to fully engage HHS stakeholders through regular working group sessions and strategy meetings. To date this approach has performed Department-wide inventories of cross-community systems, facilitated a common understanding of the data standards, and communicated reporting requirements germane to the DATA Act.

With transparency in mind, DAP shares government–wide standards and their perceived impacts on HHS during weekly meetings with critical stakeholders that have institutional knowledge and influence across the four business lines. These meetings provide a forum to discuss an implementation strategy and allow stakeholders to provide input into the ongoing data standardization process. In turn, these critical leads have mobilized stakeholders within their communities to establish working groups to analyze specific impacts and issues that affect their functional areas. HHS also collaborated extensively as an active member of the Interagency Advisory Committee (IAC) to provide substantive community-specific and cross-cutting feedback to OMB and Treasury in support of government-wide standardization and related policy considerations. Examples of HHS's existing IAC leadership roles include the Council on Financial Assistance Reform (COFAR), Budget Officers Advisory Council (BOAC), and Award Committee on eGov (ACE) / Financial Assistance Committee on e-Gov (FACE). HHS will maintain its commitment to data transparency within the Department, and share knowledge to ensure effective implementation goals as well as actively promoting the Grants Section 5 Pilot.

HHS designed six testing models for the Grants Section 5 Pilot that was approved by OMB. Under this partnership HHS is developing a technical proof of concept to build a data standards repository. The Common Data Elements Repository (CDER) Library provides direct benefit to the federal community and the public to facilitate the implementation of the DATA Act. The CDER Library is designed to house standard data elements and associated data element definitions, and makes the common standards available for government-wide use in information collection activities, and visually accessible to the public to increase their own understanding of the information being displayed and collected in support of federal programs.

Additional information on HHS's DATA Act implementation and Section 5 Grants Pilot activities can be found here: http://www.hhs.gov/about/agencies/asfr/data-act-program-management-office/

Data standardization is also being explored within ACF through adoption of the National Information Exchange Model (NIEM), a cross-governmental data exchange tool. NIEM provides a common data model and data exchange methodology that enables consistent understanding of terms and definitions, as well as implementation of standardized cross-disciplinary data sharing projects. ACF manages a Human Services Domain with NIEM, which is currently

supporting child welfare, child support, human trafficking, and other programs. Use of NIEM allows these efforts to share data within the human services community, as well as more easily share with external stakeholders such as juvenile justice and the courts. NIEM also enables enhanced support for privacy and security requirements by focusing on data specific controls rather than system level as is standard practice today.

This effort is being led by ACF with participation from the Office of Child Support Enforcement, the Children's Bureau, and the Office of Planning, Research, and Evaluation. More information on these and related activities can be found at ACF's interoperability website: http://www.acf.hhs.gov/about/interoperability.

3.7   FREEDOM OF INFORMATION ACT (FOIA) REQUESTS

HHS Age of Open/Pending Initial FOIA Requests
The HHS Office of the Secretary (OS) supports the department-wide implementation of the "intelligent case management" concept. The OS FOIA Office developed a quarterly report, produced with data submitted by HHS OpDivs that provides a point in time forecast of future production performance by the HHS FOIA offices.

Although the HHS average response times were below the government-wide averages for "simple," "complex," and "expedited" requests, in FY 2015, it is a Department-wide goal to significantly improve response times for all FOIA requests. Therefore, beginning with the data reported as of the end of January 2017, the OS FOIA Office will publish to the HHS FOIA website, the open/pending request data submitted by the HHS OpDiv FOIA offices. This additional transparency will demonstrate the commitment by the HHS OpDivs to implement the tenets of active and "intelligent case management" to identify and accurately assess the classification and age of all open, pending requests and focus Department-wide processing efforts to significantly improve future response times.

3.8 WEBSITES (DIGITAL SERVICES STRATEGY)

The Department's signature website is www.hhs.gov. In addition, each OpDiv and StaffDiv maintains its own website, and the Department manages a number of topical dot-gov websites including eight priority websites, three of which are cross-federal agency sites. HHS Digital

Strategy webpage is at http://www.hhs.gov/digitalstrategy. The Department is currently engaged in a long-term project to reimagine HHS.gov. Called Project-H, this multi-disciplinary effort is based on the following precepts, many of which follow the Federal Digital Strategy:

- • Research-based redesign
- • Customer-focused plain-language content
- • Mobile-first design; any platform, any time
- • Topically organized (replacing office/program-based organization)
- • Institute Lifecycle Content Management
- • Focus on HHS/Office of the Secretary information and services; leverage

OpDiv's information focus on their unique missions

- • Search-based navigation, augmented by organic browse
- • Institute consistent site and social branding
- • Balance push and pull
- • Increase customer engagement (expand from passive to proactive)
- • Embrace WCAG 2.0 and insure accessibility for all

We have made significant progress on several foundational aspects of Project-H.   HHS is identifying and engaging with key data customer groups like these to help expand the value of our health data assets and prioritize the release of new data. To assist that prioritization, HHS intends to capitalize on the quantity and quality of user demand it receives through various feedback channels, as well as focusing on the identification of strategically relevant data assets tied directly to HHS's articulated strategic goals. To ensure the customer feedback loops are meaningful and robust HHS will regularly review feedback processes and refine them as opportunities and challenges present themselves.

3.9 PUBLIC NOTICE

FDA Public Posting and Availability of Comments Submitted to FDA Dockets

In the past, FDA generally did not publicly post on the www.regulations.gov docket comments individuals submitted in their individual capacities, which was a policy developed largely out of concern that individuals, when submitting their comments, may not have realized that their names, addresses, and identifying information would be publicly viewable. In 2010, as part of its Transparency Initiative, FDA proposed changing this practice "so that comments submitted at http://*www.regulations.gov* from people self-identified as individual consumers are posted on

that website in the same manner as other comments." On September 18, 2015, FDA implemented this proposal by announcing that it will generally post comments from people self-identified as individual consumers as it posts other comments on that website.

This practice will increase the transparency and public utility of FDA's public dockets, thereby better enabling its public dockets to meet their intended functions of sharing information and encouraging an open exchange of ideas. FDA has included new information and standard instructions for submitting comments in all *Federal Register* documents requesting or providing for the submission of comments. The instructions explain how to submit comments to the docket on that particular document via electronic means and also explain the process for submission of comments, in written/paper format, that the commenter wishes to mark as confidential.

FDA Office of Regulatory Affairs (ORA) Enforcement Report using Internet RES (iRES)

The internal Recall Enterprise System (iRES) system was launched in March 2016 and fully automates the posting of recall data to the Enforcement Report (Title 21 CFR Part 7.50) by eliminating many of the manual aspects of previous methods and allowing records to be available to the public sooner. In mid-2012, FDA began using iRES, which utilizes a database that is populated directly from FDA's internal Recall Enterprise System (RES), to make available to the public weekly reports of recalls once they have been classified (i.e., Class I, II or III) and to allow for searching and displaying of all recall records in the database. Recall data are propagated to this database when Centers identify that a recall is ready to be posted to the Internet. iRES allows for newly classified recalls and for updates or corrections to recalls already published in the Enforcement Report to be made more readily available to the public. Future enhancements to iRES (which are slated for October 2016) improve searching ability in the weekly Enforcement Report and allow manipulation of the dataset returned in a query, as well as improve support for using the Enforcement Report on mobile devices. Enforcement Report recall data can also be queried using the iRES application programming interface (API) which allows IT systems to query recall data, minimizing the need for the manual review, download, and data entry steps needed to enter recall data into other systems. Printable views of the weekly Enforcement Report and exporting to .csv format are also available in order to provide as many options as possible for the public to view recall records.

FDA Inspections Database

The Inspections Database, first published in mid-2011, is an online database providing the public with access to a central repository of FDA-conducted inspections. The database displays

inspection information such as firm name and location, Inspection End Date, Program Area, and final inspection classification (i.e., NAI, VAI, and OAI) and is updated twice a year. Posting the final inspection classification provides the public with a basis and rationale for FDA's enforcement actions FDA pursues against an establishment, seeks to promote informed marketplace choices made by the public and industry, helps to encourage compliance, and improves the public's understanding of how FDA works to protect the nation's health. Future enhancements include streamlining publishing updates to the Web and increasing the frequency of the updates.

FDA Data Dashboard

The FDA Data Dashboard, launched September 2014, provides the public a cloud-based, dynamic tool to access FDA transparency data using data visualizations and an enhanced user experience. The Data Dashboard presents FDA data pertaining to inspections, compliance and recalls in easily understood graphical formats, confers drill-down capability from graphs to view the underlying data, enables filtering of underlying data to limit results, and allows export of both graphs and underlying data. In addition, the Data Dashboard builds relationships between the various datasets that are utilized and displays all compiled information in one location. Future enhancements to the Dashboard, scheduled for 2017, consist of increasing the amount and diversity of the data it makes available to include imports (i.e., refusals, import lines, etc.) and developing dashboards related to programs implementing the Food Safety and Modernization Act (FSMA).

FDA Filer Evaluations Outcome Report

Commonly known as the filer report on FDA's external website, the FDA Filer Evaluations Outcome Report was established several years ago to provide trade statuses of Filers that import regulated products into the United States. The report provides what is known as the status to the public on a dedicated webpage along with any explanations and displays information demonstrating whether a Filer has had any issues. With this report, the public can see whether the Filer is new to importing FDA-regulated products or obtain the history of the latest evaluation conducted on the Filer. The report is updated on a monthly basis to help provide the most current information available.

FDA Import Web Project

This project is designed to update FDA's web presence to provide clear and understandable information to the public about FDA's import coverage and operations. Over the past two years, the Division of Import Operations and Office of Communications have developed content and posted more than 40 webpages covering all aspects of FDA's import operations, describing the entry process and FDA field operations, enforcement actions taken by FDA, import data systems, points of contact throughout the Agency, and resource links for the importing community. The final pages were posted in July 2016 and are currently available on FDA.gov. FDA will formally announce this new web presence via internal and external communications in September 2016. The new webpages provide transparency into FDA's import program and will provide better understanding of FDA's import operations to the regulated import community and the public.

FDA Food Safety Modernization Act – High Risk and Non-Risk Inspections

The FDA Food Safety Modernization Act (FSMA) established a mandated inspection frequency for food facilities that must register under the Bioterrorism Act. All "high-risk" domestic facilities must be inspected within five years of FSMA enactment and no less than every three years thereafter. All non high-risk domestic facilities must be inspected within seven years of enactment and no less than every five years thereafter. FDA makes publicly available the criteria used in defining high risk and non high-risk domestic food facilities. In addition, at the end of each fiscal year, the agency will make available the number of high risk and non-high risk inspections for each state.

3.10   CONGRESSIONAL REQUESTS

The legislative branch of our Federal government has intense interest in the work conducted by HHS. Like the public, Members of Congress and their staff frequently direct letters, emails, and phone calls to the Department that require timely and responsive reply.

Responding to Congressional Inquiries: Workflow Practices

The topic areas of interest to Members of Congress are very broad in scope as is the nature of the requested actions. For example, some requests may be on behalf of a Member's constituent who is looking for certain types of information or assistance with an issue. In other cases,

Members request formal reports, technical documents, budget information, and answers to key questions regarding a particular issue.

The Office of the Assistant Secretary for Legislation (ASL) coordinates congressional requests across the Department. Congressional requests may come directly to ASL or to agency legislative affairs offices. ASL performs many additional functions, including developing responses to requests on behalf of the Secretary and staff offices within the Office of the Secretary. ASL also coordinates testimony, clearance of proposed legislation and responses to congressional inquiries.

With regard to formal incoming requests ASL assigns a lead OpDiv or Staff Div and an ASL staff member to coordinate development of the response and clearance of the transmittal to the Member's office. For these situations, the assignment often requires a "delivery date" for formulating the draft response. In other cases, Members or their staff may make informal inquiries to ASL that may be handled less formally through phone conversations or email.

Proactively, ASL may also contact congressional offices for those who are very interested in particular topics to inform them of upcoming events, reports, or activities that may be of interest. Throughout the process, ASL and the OpDiv legislative offices maintain working knowledge of legislative activities of relevance to health and human service activities. ASL and HHS OpDiv legislative offices track pending legislation closely, arrange for responses to requests, and manage hearing preparation across the Department.

ASL Divisions
The office consists of six divisions:

Immediate Office of the Assistant Secretary for Legislation: Serves as principal advisor to the Secretary with respect to all aspects of the Department's legislative agenda and Congressional liaison activities.

Office of the Deputy Assistant Secretary for Discretionary Health Programs: Works on the legislative agenda and serves as the lead liaison for discretionary health programs. This portfolio includes health-science-oriented OpDivs of the HHS including the National Institutes of Health, the Food and Drug Administration, the Centers for Disease Control and Prevention, the

Health Resources and Services Administration, the Office of the Assistant Secretary for Preparedness and Response, and the Office of the Surgeon General, among others.

Office of the Deputy Assistant Secretary for Mandatory Health Programs: Works on the legislative agenda and serves as the lead liaison for the Centers for Medicare and Medicaid Services as well as the Indian Health Service.

Office of the Deputy Assistant Secretary for Human Services: Works on the legislative agenda and serves as the lead liaison for the Departments' human services and aging program divisions, including the Administration for Children and Families, and Administration for Community Living

Congressional Liaison Office: Serves as the lead liaison to Members of Congress by notifying them of HHS activities and initiatives, maintaining the Department's grant notification system and coordinating agency response to congressional inquiries.

Office of Oversight and Investigations: Responsible for all matters related to congressional oversight and investigations, including those performed by the Government Accountability Office.

The organizational structure chart and staff list for the Office of the Assistant Secretary for Legislation can be found at: http://www.hhs.gov/asl/divisions/divisions.html#clo

Grants

The ASL Congressional Liaison Office (CLO) responds to congressional inquiries about grant awards; notifies congressional offices of grant awards made by the Department; and facilitates technical assistance regarding grants to Members of Congress and their staff.

ASL grant information can be found at: http://www.hhs.gov/asl/Grants/grants.html

Testimony

A complete listing of testimony by the Secretary and other Department officials before the United States Congress can be found at: http://www.hhs.gov/asl/testify/2016/testimony.html

3.11   DECLASSIFICATION

In general, most documents held at HHS that have a national security classification were originally classified by another department or agency. Decisions and the process for the declassification of this material rest with their originators.

HHS does have original classification authority and has classified a small number of documents. Declassification of documents, due to time or lack of continuing need for protection, is executed via specific and routine review.

Declassification Authority

The authority to declassify information rests in the following officials:

- The Secretary with respect to all information over which HHS exercises final classification authority;
- The original classification authority, as designated by the Secretary, a successor of the original classification authority, or a supervisor of either;
- The official of the originating agency who authorized the original classification;
- The Director, Office of Security and Strategic Information (OSSI), with respect to all classified documents originated by a HHS-predecessor agency and being retained for some official reason, following the coordination with the HHS operating division or staff division that has subject matter interest in the documents.

When there is some doubt concerning the classification of a document, the information must be transmitted for review to the Director, OSSI, for review and to an agency with proper subject matter interest and original classification authority -- at which point that the agency will decide to declassify, or extend the initial classification level.

Annual Review

All classified documents in the possession or control of an organization are subject to an annual review conducted by the Classification Security Officer of the organization. This review is conducted to identify documents that require declassification or destruction and must be

accomplished prior to the HHS Annual Status Report on Classified National Security Information.

Automatic Declassification

All classified documents will have a maximum classification life of 25 years from the date of its original classification, unless the Director of the Information Security Oversight Office within the NARA has determined that the document may be exempt from automatic declassification.

Mandatory Review Requests for Declassification

Anyone may request a review for declassification of information. These requests are submitted to the Director, OSSI, as either a mandatory review request or under the FOIA review process.

If the request is approved, the Director, OSSI, must then declassify all HHS-originating information by marking it to reflect the change, authority for and date of declassification. If the requested information cannot be declassified in its entirety, declassified portions that constitute a coherent segment are released, and if the information cannot be released in whole or in part, the action office must provide the reasons for denial. In cases where declassification is denied, in whole or in part, the Director, OSSI, in coordination with the HHS FOIA office, must notify the requestor of the final determination and reasons for denial, as well as the right to appeal within 60 working days of the receipt of the denial.

HHS may also require a fee for declassification review requests, which may be appealed if the requested information is not declassified and released in whole.

Information regarding declassification can be found at
http://www.hhs.gov/open/plan/opengovernmentplan/transparency/requestsforinfo.html.

3.12   OPEN INNOVATION METHODS

Among the HHS efforts to further engage our audiences in transparent ways, we have promoted a variety of crowdsourcing and open innovation methods. HHS recently completed its annual report on competitions and open innovation activities. Now in the fifth year since the

COMPETES Reauthorization Act of 2010 ("COMPETES Act"), HHS has continued its prolific use of the authority to stimulate, solicit, and implement effective solutions to problems large and small. In FY2015 HHS continued to design and administer more complex prizes and challenges, using on average bigger cash incentives, establishing partnerships within and outside the Federal government, and tackling more ambitious and critical problems. The following highlight some of our major findings and observed trends.

HHS completed a total of 18 competitions and launched 7 more during FY2015, totaling $2.1m in cash incentives, more than doubling the total from FY2014. Competitions at HHS have continued to evolve, with increasing complexity of design and problem statements better aligned with programmatic goals.

Serial Challenges are Gaining Prestige and Demonstrating Impact

The NIH DEBUT Challenge and the NCI-supported Neuro Startup Challenge are instances of a series of challenges that have gained notoriety and prestige. A third series, the Climate and Health Innovation Challenge Series, was launched this year. All three of these challenge series are public-private partnerships. The DEBUT Challenge, now having completed its fourth iteration, seeks to challenge biomedical engineering undergraduate students to solve tough engineering problems, has become prestigious competition among biomedical engineering faculty across the country. In fact, many senior design courses now require developing entries for DEBUT. The National Institute of Biomedical Imaging and Bioengineering, DEBUT's sponsors, have now created a partnership with VentureWell that will add additional prize money next year focused on the development of business plans and place enable greater emphasis on entrepreneurship.

The Neuro Startup Challenge built on the foundations of the Breast Cancer Startup Challenge, has built a robust community of students, investors, mentors, and inventors. These challenges have led to the creation of 27 new startups, trained over 1000 students in entrepreneurial skills, and increased the likelihood of taking NIH inventions to market. All the individual challenges have been run in collaboration with the nonprofit Center for Advancing Innovation, which has helped raise prize money from the Avon Foundation (Breast Cancer) and the Heritage Provider Network (Neuro).

The NIEHS Climate Change and Environmental Exposures Challenge, Esri's Human Health and Climate Change App Challenge, and the CDC Dengue Fever Project are part of a partnership between NIH, HHS, and Esri that launched the Climate and Health Innovation Challenge Series, aimed at stimulating innovation in understanding and addressing the impact of climate change on human health. The Dengue Fever Project was a product of an interagency effort that included CDC, DOD, NOAA, and others.

Piloting is an Increasingly Common Prize Design Element

As the ambition and scale of problems addressed through prizes and challenges has increased, so too has the need to equip participants with the momentum to continue work beyond the competition. In response, several challenges are include pilot phases, providing an opportunity for prototypes to be tested and therefore supported after the competition. ONC's Market R&D Pilot Challenge was specifically designed for this purpose, asking health IT companies to partner with clinics to perform small-scale testing and validation of products in real patient environments. HRSA's Bridging the Word Gap Challenge, launched in late FY15, also builds in a third pilot phase to test technological interventions solicited in the first two phases.

Additionally, several prizes and challenges currently in development are including a pilot phase. Both inter-agency and public-private partnerships are now more commonly used by HHS its prize competitions. Partnerships, formal and informal, are more commonly utilized by HHS in the planning, execution, and follow-up strategy. In some cases, such as the HHS RWJF Provider Network Challenge, the partnership was primary used for promotional purposes. In other cases, the partnerships were more complex and comprehensive. Over half the competitions completed in FY15 and three more set to conclude in FY16 used either an interagency or a public-private partnership model. Although partnership mechanisms varied considerably, they all enabled agencies to pool resources and increase visibility and overall impact.

As part of a Memorandum of Understanding with the United Kingdom National Health Service (NHS) HHS and NHS each ran concurrent, near-identical yet distinct challenges to create tools that leverage data to address the obesity epidemics. The U.S. version, the U.S. Obesity Data Challenge, was itself a collaboration among HHS, the de Beaumont Foundation (which provided the prize purse), and the Health Data Consortium. The parallel challenge model allowed

collaboration with the UK government to amplify the message in both nations yet conform to requirements of the COMPETES Act.

Competitions are Seeking Impactful Solutions to Areas of High Departmental Priority

The FDA Food Safety Challenge sought solutions that will directly affect how FDA performs its regulatory duties. Both NIH (Harnessing Insights from Other Disciplines to Advance Drug Abuse, Innovations in Measuring and Managing Addiction Treatment Quality) and SAMHSA Opioid Overdose Prevention Challenge are seeking better ways to address the nation's opioid epidemic. The U.S. Obesity Data Challenge, Aetna Foundation, HHS, and NHIT Collaborative Innovating for the Underserved Business Plan Challenge, and Bridging the Word Gap Challenge seek to address health disparities and stimulate health innovation directed and underserved communities.

Institutionalization of Prize Activity at HHS

HHS has always taken a customer-centric approach to the institutionalization of prize activity. Support for prize activity is therefore ultimately driven by the demand of those HHS offices which recognize value in the tool. The HHS IDEA Lab and the Assistant Secretary for Administration have collaborated on listening and responding to this demand from within the Department. Both aim to create safe spaces for innovation and prizes are one of the best tools available, an umbrella under which federal agencies and solvers can meet each other. In fact, 67% of competitions reported "engage with new people and communities" as a primary goal.

In part as a result of our broad outreach efforts within HHS, we have seen great diversity of usage among the 11 HHS OpDivs. Additionally, exactly 50% of the completed competitions in FY2015 were affiliated with HHS offices with prior experience in running challenges. That suggests that those offices do not view prizes and challenges as a one-off novelty but rather as a tool worth of the time investment. Simultaneously, it shows that new offices are continuing to take a chance on this relatively new tool. As in the past, we are using customer-centric approaches to identify remaining barriers to the use of this mechanism and crafting approaches that will directly respond to those barriers.

More Contract Vehicle Options

In 2013, we experienced a gap in challenge platform services due to the disruption of challenge.gov. We filled part of this gap by creating a common contract vehicle for prize management support and platform use. In the first phase, we made blanket purchase agreement (BPA) awards to three vendors, Luminary Labs, Sensis and its platform partner Skild, and Capital Consulting Corporation on the GSA 541-4G Schedule. The vehicle has been used by HHS OpDivs to create five individual contracts with vendors for challenge management services. One weakness in the original vehicle that customers identified was a lack of simplified access to cost-effective platforms without also having to buy expensive management services. To that end, we recently expanded the contract vehicle to include direct access to five challenge platforms, HeroX, Tongal, Health 2.0, Patexia, and Department of Better Technology. Additionally, we are exploring interagency agreements with other Departments to leverage other existing contracts with management service and platform providers.

HHS Competes Bootcamp Pilot

The novelty of the challenge mechanism still presents a steep learning curve for offices who wish to use it. In particular, the majority of likely sponsors have little interest in gaining expertise in its nuances; rather, similar to establishing contracts and grants, they seek to rely on the expertise of others to guide them. As a direct response to this observation, we piloted a two-week virtual bootcamp in July 2015 that provided HHS teams an opportunity to develop a prize idea in an accelerated, peer environment with access to mentors and experts within and outside HHS. We enrolled 11 teams initially, two dropped out, another two merged into one, and another decided to collaborate with one of the mentors. Two challenges have already launched. We received overwhelmingly positive feedback from the participating teams, in particular regarding the access to both prize/challenge mentors and legal, policy, procurement, 508 compliance, and Paperwork Reduction Act compliance mentors. A full, expanded version is currently being planned in 2016.

Community Engagement

In FY2015, HHS continued to increase the awareness of prizes among its OpDivs by engaging in variety of site visits and presentations. HHS staff presented at several strategy meetings

within HHS OpDivs, continue to play a heavy consultative role to program offices, and have cultivated an active network of mentors and experts.

Overall, we continue to experience growth and evolution in our use of the COMPETES prize competition authority. In 2016, we expect a significant increase in the total cash incentives offered, as several multi-million dollar prizes are expected to launch. FY2016 is also the last full fiscal year of the current Administration, and we are working to develop strategies to ensure that these tools continue to be readily accessible into the next Administration. As we move forward into FY2016 and beyond, we will build on the progress we made in FY2015 by continuing to expand the awareness of the tool within HHS and simplifying the process for sponsors to run a prize or challenge. In particular, we will focus on the following:

- Simplifying the prize and challenge execution process
- Creating a recurring bootcamp, based on the pilot run in 2015, that provides HHS offices with more focused mentorship and an accelerated peer learning environment
- Continuing to increase participation among HHS OpDivs in the use of the prize competition authority
- Placing greater emphasis on the use of prizes and challenges to stimulate innovation in human services
- Complementing the upcoming launch of a Federal-wide prizes and challenge toolkit (expected launch in 2016) by redesigning the content for HHS
- Continuing to improve communication among program, acquisition, budget, legal, and leadership offices

3.13 ACCESS TO SCIENTIFIC DATA AND PUBLICATIONS

On February 22, 2013, the Director of the White House Office of Science and Technology Policy (OSTP), Dr. John Holdren, issued a memorandum to all agency and department heads entitled, "Increasing Access to the Results of Federally Funded Scientific Research." The memo directed federal agencies with more than $100 million in annual conduct of research and development to develop plans for increasing public access to peer-reviewed scientific publications and digital data resulting from federally funded research investments.

Agency Implementation Plans

Within HHS, five operating divisions meet this threshold: the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Agency for Healthcare Quality and Research (AHRQ), and the Administration for Community Living (ACL). Additionally, the Assistant Secretary for Preparedness and Response (ASPR) is voluntarily developing a public access plan for their portfolio of funded projects. Each of the operating divisions has developed its own public access implementation plan, in accordance with the Department's common approach.

Progress Report

Following the Office of Science and Technology Policy's introduction of a mandate to federal agencies to increase their access to the results of federally-funded research, many agencies sought out PMC to manage their requirements under the directive. The NLM has signed agreements with five HHS agencies: the CDC, the FDA, the Agency for Health Research Quality, the Administration for Community Living and the Assistant Secretary for Preparedness and Response. Additionally four other federal agencies have entered into similar agreements: the Department of Veteran Affairs (VA), the National Institutes of Standards and Technology (NIST), the National Aeronautics and Space Administration (NASA), and the Environmental Protection Agency. The NLM has already received submissions from investigators employed or supported by CDC, FDA, VA, and NIST.

To date, scientists funded by NIH and other agencies have made more than 420,000 author manuscripts available in PMC. As of FY2016, the NIH is also making these papers available for download in a format that will allow robust text analysis and data mining.

NIH STAR METRICS/Federal RePORTER
The NIH has taken the lead role in developing STAR METRICS (Science and Technology for America's Reinvestment: Measuring the Effect of Research on Innovation, Competitiveness and Science), a partnership between science agencies and research institutions to explore new ways to document science investments and communicate results to the public. The long-term goal of STAR METRICS is to develop a common empirical infrastructure that will be available to all recipients of federal funding and science agencies.

STAR METRICS has had two levels of activity. The Level I goal was to describe the scientific workforce supported by federal funding through collaboration with grantee institutions. The STARMETRICS public private partnership on Level I successfully spurred the development of the academic consortium project UMetrics https://www.btaa.org/projects/umetrics, a common, large-scale, automated data platform on the research enterprise. As demonstrated in a recent publication in *Science,* the Umetrics consortium is focused on gathering and analyzing big data to understand the structure of the research workforce, the nature and evolution of collaborations, and the results of research.

Going forward from 2016, STAR METRICS is focused on developing an open data infrastructure and tools to enable the documentation and analysis of the inputs, outputs, and outcomes of federal investments in science, made available through Federal RePORTER (http://federalreporter.nih.gov/), which allows agencies government-wide to document their research investments in a standard format that allows for text searching of abstracts across agencies. The STAR METRICS initiative increases government transparency by allowing members of the public to view and search the scientific investments made by federal government agencies. This program allows for scientific investments to be linked to outputs and outcomes at a trans-agency level that allows for an empirical basis for science policy.

3.14   OPEN SOURCE SOFTWARE

Overview and Approach

HHS is actively using and repurposing free open source software and collaborating with interagency and intra-agency partners given the numerous benefits associated with the shared approach. Consistent with the Federal Source Code Policy, usage of open source software can fuel innovation, lower costs, and benefit the public. The federal Policy is designed to support improved access to custom software code developed for the Federal government. Furthermore, open source software can support the Digital Government Strategy's "Shared Platform" approach, which enables Federal employees to work together-both within and across agencies to reduce costs, streamline development, apply uniform standards, and ensure consistency in creating and delivering information.

Using FOSS allows for product customization, advances interoperability between tools, and improves the overall quality of the final product. This creates real economic value by lowering the burden of replicating similar work or by allowing the private sector to build off of and create new businesses around previously-developed code. The 2014 passage of the Federal Information Technology Acquisition Reform Act (FITARA) created an opportunity to significant policy and administrative reform, including the requirement that each agency have a software asset and management plan. While much of the software asset and management plan focuses on category management and acquisition of software licenses, the implementation of FITARA also provides agencies with an opportunity to bolster their use of free open source software, include it within the software asset and management plan for greater transparency, and share it throughout the agency to illustrate the value of free open source software when compared with expensive software licensing and potential vendor "lock-in".

The HHS CIO's office, as well as other agency divisions, has been conducting asset analysis and is creating and planning to share a listing of available contracts with agency leaders. To the extent practicable, this creates yet another opportunity to break down the silos by centralizing active, upcoming, or discarded open source software projects and coding in order for HHS and other agencies to identify, collaborate, or piggyback off of existing projects to lower costs and maximize savings to taxpayers.

There is currently no mechanism in place for broadly sharing code among Federal Agencies exclusively, though some of the source code repositories shared publicly are meant to be more beneficial to other Federal Agencies than to the public at large. For example, the source code repository named "ckanext-datajson" in the HHS collection is meant to help other Federal Agencies meet expectations of the Open Data Initiative by providing an extension to the open source CKAN application that many Federal Agencies use to catalog the datasets they make publicly-accessible.

Location and Examples of Publicly-accessible Code

Various organizations within HHS have openly shared code on the GitHub website, popular among open source projects. The repositories of source code made available to the public can be easily viewed by visiting the website locations anonymously, (i.e. without logging in to a GitHub account).

The two most popular locations where HHS publishes source code on GitHub are https://github.com/HHS and https://github.com/HHSIDEALab. A smaller number of source code repositories shared publicly by HHS can be found at https://github.com/FDA and https://github.com/AHRQ. Open FDA is another popular resource for developers and researchers, who will have easy access to high-value FDA public data through RESTful APIs and structured file downloads. In short, our goal is to make it simple for an application, mobile, or web developer, or all stripes of researchers, to use data from FDA in their work.

We've done an extensive amount of research both internally and with potential external developers to identify which datasets are both in demand and have a high barrier of entry. As a result, our initial pilot project will cover a number of datasets from various areas within FDA, defined into three broad focus areas: Adverse Events, Product Recalls, and Product Labeling. These API's won't have one-on-one matching to FDA's internal data organizational structure; rather, we intend to abstract on top of a myriad of datasets and provide appropriate metadata and identifiers when possible. Of course, we'll always make the raw source data available for people who prefer to work that way (and it's good to mention that we also will not be releasing any data that could potentially be used to identify individuals or other private information).

Pillbox is one of the largest free databases of prescription and over-the-counter drug information and images, combining data from pharmaceutical companies, Food and Drug Administration, National Institutes of Health, and Department of Veterans Affairs. Pillbox for Developers is a resource for getting open access to the data processing code, understanding the methodology, and contributing to the project.

TurboTax, in conjunction with HHS, has released Benefit Assist, a new open source software tool to help feed more Americans. Americans who don't have enough money for food, approximately one in six Americans, will have an easier time finding out if they are eligible and applying for Supplemental Nutrition Assistance Program (SNAP)/Food Stamps with the release of Intuit TurboTax Benefits Assist as free and open source software and with the software code freely available as hosted by CMS following collaboration with New York City Council Member Ben Kallos. States that currently must administer SNAP will be able to save money by using Benefits Assist and can collectively build upon it to reduce overhead and save our nation billions.

Intuit's TurboTax launched Benefit Assist in 2015, offering to screen 30.7 million Americans who file taxes with TurboTax an opportunity to learn if they are eligible for SNAP and even submit an application using tax information they had already entered. In 2016, Benefit Assist was expanded to include Federal Communications Commissions' Lifeline free mobile phone service. Now in an effort to see even more Americans served Intuit is releasing the source code for its Benefit Assist search, rules engine, as well as benefit rules and definitions using the free and open source GNU Affero General Public License so that anyone whether state government, non-profit or a developer can freely use, share and improve upon Benefit Assist to fight hunger.

President Barack Obama has laid the groundwork to streamline access to nutrition, home energy, cash assistance, and other human services necessary to stay healthy facilitated by integrating eligibility and enrollment with Medicaid and CHIP at the state-level through the Affordable Care Act, Executive Order 13563, Executive Memorandum, waivers, and guidance. Enhanced federal funding is available through 2018 for each state to integrate, interoperate, and improve the delivery of federally assisted benefits to their residents by leveraging information sharing across health and human service agencies to automatically recertify or provide benefits.

In order to expand access to government human service benefits and in partnership with the Robert Wood Johnson Foundation's State Health Reform Assistance Network the Centers for Medicare & Medicaid Services at HHS Idea Lab, have developed a free and open source tool that States can use to facilitate Modified Adjusted Gross Income (MAGI) eligibility determination for Medicaid and CHIP called "MAGI in the Cloud," freely available on GitHub. The free and open source software is now operated and maintained by the New England State Consortium Systems Organization and in use by the District of Columbia, New Jersey, North Dakota and Tennessee. The Benefit Assist tool's source code will be freely available alongside "MAGI in the Cloud" available at https://github.com/HHSIDEAlab. The HHS Assistant Secretary for Planning and Evaluation (ASPE) has been working on a comprehensive project to modernize their systems, switching from the use of legacy systems to open source software. This multi-year project involves a complete analysis, redesign, migration, implementation, and maintenance of a new web content management system (WCMS) as well as a public-facing website, intranet, and two legacy databases as well as hosting and marketing. The HHS Office on Women's Health recently awarded a new contract to modernize an aging online data query system, which will only use free open source software, including robust mapping tools that take advantage of

modern web geographic information system (GIS) technology and Open Geospatial Consortium standards. The new, interactive online data query system will feature a user-friendly computer interface for queries that actively accesses and ingests data from a variety of sources using machine readable outputs, such as APIs.

Approach to Collaboration, More Broad Usage, Centralization of, and Publicly-available Free Open Source Software Code

HHS, like many other agencies, continues to make better use of open source software in developing or redeveloping aging legacy systems while finding collaborative, innovative ways to share these efforts and successful outcomes throughout the federal government as well as the public at-large.

HHS actively collaborates on various projects with digital and open source software leaders, including the U.S. Digital Service and GSA's 18F. 18F has recently rolled out Cloud.gov, an open source Platform-as-a-Service (PaaS) solution, which will further enhance HHS' ability to embrace and share more open source software tools.

4 PARTICIPATION AND COLLABORATION

FDA's Center for Drug Evaluation and Research Initiatives – Clinical Outcome Assessment Compendium (Pilot version)

Capturing outcomes that are important to patients in clinical trials is a high priority for FDA. The pilot COA Compendium is part of FDA's efforts to foster patient-focused drug development. The COA Compendium is intended to facilitate communication and to improve clarity and transparency to drug developers and the research community by collating and summarizing clinical outcome assessment information for many different diseases and conditions into a single resource. It can be used as a starting point when considering how certain clinical outcome assessments might be utilized in clinical trials and will likely be most informative in early drug development. The public is referred to the following FDA Web sites for additional background information:

http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/UCM459231.htm and
http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/UCM481225.pdf

The COA Compendium has been under development since 2013. Its pilot version was released for public comments on January 14, 2016, and we anticipate continued development work in the next few years. The Compendium is intended to be a living document on the FDA website.

FDA Center for Drug Evaluation and Research (CDER) Small Business and Industry Assistance (SBIA) Program

CDER SBIA's mission is to engage with small pharmaceutical business and industry by providing timely and accurate information on human drug development and regulation. CDER's vision is to ensure that every industry representative can always find the resources they need, allowing for a clear and efficient development process.

CDER SBIA employs several ongoing avenues through which it accomplishes its goals:

Direct Communication Services:
- Dedicated telephone numbers and an email address available for industry, and responds to thousands of emails and phone calls every year.

- [CDER SBIA Chronicles](#), an electronic newsletter, which highlights a specific regulatory issue every other month.
- [CDER Small Business and Industry Education Series](#), web-based learning tutorials as part of a larger platform, CDERLearn, which contains educational tutorials offered by all of CDER.
- [CDER Small Business and Industry Assistance LinkedIn Showcase Page](#), a niche, dedicated page that allows the Agency to provide specific audiences/stakeholders with targeted information.
- [Conferences](#): CDER SBIA hosts several conferences each year, including spring and fall Regulatory Education for Industry (REdI)) conferences (in collaboration with the Center for Devices and Radiological Health), and topic-specific REdI Conferences. Many of these conferences are available for attendance in-person or virtually. Conference presentations are publically available online post event. These events provide open Q&A sessions.
- Exhibits and Presentations: SBIA staff exhibit and speak at several conferences throughout the year.
- [Small Biz Buzz](#), regular email updates to educate industry on new regulations, guidances, and meetings.
- [Webinars](#) including frequent and timely webinars on various topics of interest to industry; highlights on recent regulation, initiatives and guidances. These events provide open Q&A sessions.
- [Webpage](#): Web entry platform customized to the needs of small pharmaceutical entities. The website [*www.fda.gov/cdersbia*] contains a wealth of information regarding development and other considerations for marketing drug products.

FDA Modernizing Pharmaceutical Manufacturing to Ensure a Safe and Reliable Drug Supply Chain

This initiative facilitates the incorporation of new and emerging manufacturing technology into the pharmaceutical industry to increase the reliability and quality of medications available in the U.S.

Shortages of medications and drug recalls pose a risk to public health by reducing access to critical treatments, and FDA determined that an unacceptably large number of shortages are due to flaws in the manufacturing process, leading to poor quality medications. Unfortunately,

current production methods often have been in place, largely unchanged, for many decades. Thus, achieving a safe and reliable drug supply chain will demand technical advances in pharmaceutical manufacturing.

In 2014, the Agency created the Emerging Technology Team (ETT) to engage with the pharmaceutical industry and to support the adoption and use of novel and emerging technologies in pharmaceutical development and manufacturing. It is clear that innovative manufacturing technologies (e.g., new dosage forms, new manufacturing processes, or new testing methods) have great potential to increase efficiency, agility and reliability in the pharmaceutical manufacturing sector. ETT makes every effort to ensure that many companies have the opportunity to participate and that a wide variety of novel manufacturing technologies are considered.

The Emerging Technology Program takes an innovative, collaborative approach to engagement on the topic, both internally and externally. ETT members are drawn from across FDA and bring a wealth of technical expertise, regulatory insight, and institutional knowledge and experience to the group. Industry participants in the program work with ETT early in the technology development process, discussing progress and challenges and addressing technical and regulatory concerns in advance of submitting drug applications for FDA's evaluation. Industry partners benefit from the program by drawing upon FDA expertise and by resolving many questions before an application is submitted, FDA benefits by learning about new technologies before they first appear in applications for review and inspection, and the public benefits from greater access to high-quality medications.

Recently, ETT issued a formal Draft Guidance for Industry to increase awareness of the project. This augments information about the group in press accounts, in proceedings from technical workshops, in the peer-reviewed literature, and in the *[Report to the President Accelerating U.S. Advanced Manufacturing](#)* from the President's Council of Advisors on Science and Technology.

Finally, recognizing that pharmaceutical production and sales occur around the globe, ETT will be sharing the lessons learned at FDA with its sister regulatory agencies in other countries. Collaborations and conversations with European and Asian regulators "spread the word" about the activity and its benefits to industry, regulators, and the public. FDA Emerging Technology

Program will be both a catalyst for advancement in production methods and a stabilizing force for the pharmaceutical market in the future.

FDA Center for Food Safety and Applied Nutrition – Genome Trakr Network

One of the most significant challenges associated with foodborne disease outbreak investigation has been a lack of ability to rapidly identify the source of a contamination event and rapidly eliminate it from the food supply. Despite the best efforts of food safety experts, tools available for tracking and tracing foodborne outbreaks were simply too slow and insufficiently resolved to effectively pinpoint the source of an outbreak, resulting in weeks of effort, and in many cases, preventing identification of its cause. Now, whole genome sequencing (WGS) is being used to distinguish relationships among bacterial pathogens with sufficient certainty to potentially identify sources of bacterial contamination of the food supply down to the farm level. FDA spearheaded the development of the GenomeTrakr, a sustainable network of public health laboratories using WGS to investigate foodborne illness outbreaks and attribute illnesses to specific food products, processing or farming practices, or geographic regions.

The program is changing the way that foodborne illnesses are investigated, allowing authorities to investigate small illness clusters before there is a chance to sicken large numbers of people. The network is linked by a common, publicly accessible database that uses a common sequencing platform, with common laboratory and quality control procedures, common on-board training, and a common metadata (sample information) standard. Since its inception in 2012, the network now includes 12 federal, 16 state and 9 international laboratories. Federal partners collaborating with FDA on Genome Trakr include CDC, USDA, and NIH. Leveraging NIH\NCBI's IT and bioinformatic resources for analysis and data storage allows FDA to focus its efforts on a rapid expansion of WGS capacity to collaborating state laboratories. The network has built a database of over 47,000 and 10,000 *Salmonella* and *Listeria monocytogenes* genomes, respectively, from real time surveillance and historical collections. This database has supported multiple foodborne illness outbreak investigations and is fundamentally changing the way that outbreak investigations are conducted and will be performed in 21 – 24 state laboratories in fiscal year 2019.

FDA-iRISK® – Increasing Capacity and Collaborations

FDA-iRISK® is a web-based system for modeling food-safety risks and solutions. It is freely available to anyone in the world and currently has more than 2,800 registered users from 141

countries/regions and is used in every continent. The system has been developed to encourage collaboration and sharing, with built-in abilities to share developed modules or entire models with the whole community or with selected partners. FDA has developed and continues to develop a rich repository of food safety models and modules for everyone to use or adapt. The food safety risk assessment modeling system, its features, and its extensive documentation were designed to allow for complete transparency with regard to data, methods, and results generated from any model developed. FDA-iRISK was a finalist in round 6 of the HHSinnovates program and has been granted a registered trademark.

FDA-iRISK mathematically simulates risk scenarios and interventions, using many automated features that reduce the time and labor-intensive process needed for food-safety risk assessment. Government, industry, and others can use the resulting predictions to inform decisions about food-safety priorities and policies. FDA-iRISK also provides a much-needed international, Web-based platform for sharing and collecting information about risks and interventions in the global food supply. This easily accessed tool is available to anyone for free, including entities in countries that export food to the United States.

A peer-reviewed tool with many built-in features and mathematical equations, FDA-iRISK enables users to enter data that represent their respective food-safety issues and to modify those scenarios, to predict the impact that changes to various points in the production chain for a given food will have on foodborne illness. It enables users to predict and compare, not only the number, but also the severity (measured in disability-adjusted life years – "DALYs") of cases of illness associated with various food-and-contaminant combinations and scenarios.

Since the initial launch of FDA-iRISK in 2012, FDA has continued to expand the tools capacity. FDA-iRISK 2.0 was made public on FoodRisk.org in March 2015 (http://foodrisk.org/exclusives/fda-irisk-a-comparative-risk-assessment-tool/). FDA is developing new scenarios to examine a variety of food safety questions and to estimate total dietary risk burden of contaminants. FDA is also collaboratively working with industry, the private sector, other U. S. government agencies, and international regulatory bodies to advance these and other kinds of predictive capabilities in FDA-iRISK.

Over the next two years, FDA will make available additional features that increase the capacity and collaboration abilities of the risk assessment modeling system, including expanded sharing

capacity and features to model cross-contamination, accommodate microbial toxins, and quantitatively evaluate uncertainty. FDA will reach out to industry, academic, government, and international partners to adapt the model interface to better link to relevant existing software tools to simultaneously expand the capacity of the risk assessment modeling system as well as the system's accessibility to food safety scientists. Also during this period, FDA, working with partners in industry, academia, and government agencies around the world, will develop a framework for sustaining and expanding FDA-iRISK in the future, ensuring it continues to reflect state-of-the-art methods and approaches used in food safety quantitative risk assessment.

FDA Center for Tobacco Products Exchange Lab

The Exchange Lab offers free, open and easy access to FDA-created science-based tobacco education content that any organization can place on its website or social media channel to amplify prevention messaging and expand reach to important audiences. The Exchange Lab includes more than 100 content items focused on public health education, tobacco research, retailer information, and tobacco regulations and compliance, with more content added regularly. This information is available in a variety of media formats—including interactive widgets, text with related images, infographics, videos and tweets—all of which can be added to new or existing websites in three quick and easy steps. Material used from the Exchange Lab is automatically updated to ensure that websites always display the most current tobacco regulatory and scientific information.

Office of Partnerships Contracts and Grants File Retrieval and Evaluation Database (F.R.E.D.)

Launched in 2015, F.R.E.D. is a custom-built software application, utilizing Microsoft Access, to create a unified platform capable of tracking in great detail the various aspects of the Office of Partnerships multi-million dollar contracts, grants, and cooperative agreements. This resource will provide a one-stop shop for data storage, standardization, and aggregation regarding a funding vehicle's specifications, invoices, reports, reporting due dates, and contact information. The F.R.E.D. has also been designed to be scalable. It is capable of adding future programs and reports when needed for particular datasets. This initiative will increase the efficiency in answering data calls and inquiries, as well as provide for improved accuracy in financial analytics.

FDA Scientific Research Impact Initiative

The Scientific Research Impact initiative opens broad new vistas of transparency, participation, and collaboration to the public. The initiative, aligned with HHS public access policy to publications developed from federally-sponsored research programs, establishes for the first time, central management of the Office of Regulatory Affairs (ORA) lab efforts to: (1) conduct mission-supportive research; (2) publish/showcase scientific work through professional channels (including peer-reviewed journals and abstracts/posters presented at scientific conferences/meetings); and (3) form public private partnerships (PPP) as well as establish collaborative training programs designed to educate other regulators on ORA's regulatory standards. This initiative demonstrates both transparency and participation/collaboration while 1) advancing regulatory science, 2) broadening dissemination of scientific knowledge, 3) informing regulatory decision-making, 4) catalyzing action, and 5) advancing public health. One specific goal of the overarching initiative is to publish ORA scientific/regulatory method papers on FDA's website to facilitate public access to them. Creation of website links to scientific papers will start in FY2016 and is targeted for completion by the end of FY2018 (Q4). Other key major milestones and anticipated completion dates include FY2017 Q2 posting on FDA's public-facing web-site followed by quarterly updates thru FY2018.

FDA Office of Regulatory Affairs Ombudsman

The position of ORA Ombudsman was created in October 2015. The primary purposes of the position are to: (1) informally and in an unbiased manner, find solutions, when possible, to problems that arise with external partners, including industry, other government agencies, and consumers; and (2) improve communication between ORA employees and stakeholders through outreach and education, helping both sides become more aware of the other's needs.

FDA Egg Safety Regulatory Program Standards Development

This three-year cooperative agreement is intended to fund the self-assessment of state egg regulatory programs, provide recommendations for national egg regulatory program standards for state programs to adopt, and share egg inspection data and program information between FDA and grantees. The goal of this cooperative agreement program is to facilitate long-term improvements in the national food safety system by strengthening interagency collaboration, improving states' regulatory and surveillance protection programs for eggs, and developing national egg regulatory program standards for states. Under this cooperative agreement, state agencies will make recommendations to establish national egg regulatory program standards for

States to adopt. In addition, effective strategies for FDA and the states to share egg inspection data will be identified. Funds will be used to conduct egg program self-assessment, review state/federal laws and regulations pertaining to eggs, and identify or create an electronic system to facilitate sharing of egg inspection information. An ultimate objective of this initiative is to enhance the capacity of egg safety regulatory entities to take appropriate action to protect the public health.

FDA Office of Regulatory Affairs (ORA) Partnership Agreement Initiative

FDA's ORA has used partnerships as a means of strengthening existing relationships with state agencies. A Partnership Agreement is a formal written document between FDA and the partner organization, which clearly defines each partner's activities and responsibilities for accomplishing a specific program objective. Partnership Agreements also produce measurable outcomes related to programmatic objectives and/or operational needs. Over the past two years, ORA's Office of Partnerships (OP) has revamped the partnership agreement process to ensure involved partners are meeting the goal of maximizing the available resources in the most efficient and effective manner consistent with achieving a high level of consumer protection. Following the development of a Partnership Agreement SOP in February 2015, OP has reviewed, edited and counseled many offices that have drawn up their own valid partnership agreements. For example, in response to the Fukushima emergency, a Partnership Agreement was established between FDA and the Alaska Department of Environmental Conservation (ADEC) in May 2016 enabling ADEC to borrow a portable Gamma-ray analysis system affording the State radio-analytical capacity and expertise and emergency response capability for continued monitoring of Alaskan Coastal water finfish for radionuclides. FDA also has some partnership agreements under development. Partnership Agreements enable FDA and the partner agencies to demonstrate a mutual commitment to shared goals and objectives without obligating fiscal resources.

FDA and State of California Department of Public Health (CDPH) Human Food Mutual Reliance Pilot (MRP)

This new initiative between the California Department of Public Health (CDPH) and FDA's Office of Regulatory Affairs (ORA) constitutes a further commitment to build the infrastructure and capacity of State, local, territorial, and tribal regulatory agencies to promote a national Integrated Food Safety System (IFSS). The purpose of this pilot between FDA's Los Angeles and San Francisco Districts and CDPH is to better align our food safety regulatory systems,

reduce unnecessary duplication, enhance information sharing and, to the extent possible, leverage resources so that the agencies can better meet their public health objectives.

The pilot focuses on the interdependence of FDA and CDPH food safety programs. It seeks to achieve comparability in each program's food safety inspections, complaint investigations, sample analysis, compliance activities, response activities, and recall-related work to enable each program to rely on inspections conducted by the other in meeting its inspectional obligations. Both the FDA participants and CDPH will focus on cooperative completion of the combined inspection workloads for regulated facilities. The pilot is also intended to identify effective methods for utilizing partner agency's work products to support public health advisories, warning letters, or judicial actions based in whole or in part on the partner agency's work products.

This initiative spans from April 2015 to September 2016. An evaluation to determine next steps will ensue. During Phase 1 of the pilot (April 2015 – September 2015), each agency provided 100 food inspections that its partner agency was able to count towards completing its inspectional workload. During Phases 2 and 3 of the pilot (October 2015 – present), each agency shared established food inventories and selected firms to inspect with a commitment to share the results with its agency partner. By relying on inspectional data from its agency partner, neither agency had to inspect over 250 firms during its inspectional cycle. This has reduced duplication of effort while enhancing the effectiveness of food safety oversight.

FDA and California Food Emergency Response Team (CalFERT) Collaborates with California Leafy Greens Marketing Association (CA LGMA)

California continues to be the country's largest agricultural producer, producing over 52% of the nation's fresh market vegetables and leafy greens. With an increased number of foodborne-outbreaks over the years associated with fresh produce, particularly leafy greens, FDA and the State of California have devoted significant resources to reducing the incidence of illness associated with contaminated leafy greens. The CalFERT was first adopted in 1999 as a joint Rapid Response Team (RRT) to respond to investigations of outbreaks associated with leafy greens, with a focus on regulatory actions and intervention strategies designed to prevent them and their contamination sources. CalFERT wanted to expand and share the lessons learned from each outbreak response incident with external produce industry organizations. This grass roots-driven initiative began in 2011, which has had several iterations, and is ongoing. This has

resulted in CalFERT members' working with the California Leafy Greens industry to respond more swiftly and collaboratively to remove products contaminated with microorganisms of public health significance from the market.

FDA Rare Disease Annual Training

As part of FDA's Prescription Drug User Fee Act (PDUFA) V commitments, the Rare Disease Program in the Office of New Drugs provides annual training on rare disease drug development. This training is conducted for review staff and includes extensive participation by other HHS agencies such as NIH and CMS, as well as representatives from patient stakeholder groups, families who are caregivers of patients suffering from rare diseases, and the regulated industry. Most recently, this training was attended by over 175 people. This training began in March 2011 and has been held every year since. It is expected to continue at least through 2022 since it is an ongoing commitment under PDUFA VI.

HRSA Addressing HIV Care and Housing Coordination through Data Integration to Improve Health Outcomes along the HIV Care Continuum

The Health Resources and Services Administration (HRSA) and the U.S. Department of Housing and Urban Development (HUD) have partnered on this initiative that seeks to identify models for the electronic integration of housing and HIV care data systems to better coordinate service delivery and enhance patient navigation to improve health outcomes along the HIV Care Continuum. The funded recipients worked to increase the interoperability of HIV data systems, such as the Homeless Management Information System and RWHAP's CAREWare, to measure housing's impact on the health outcomes of Housing Opportunities for Persons with AIDS program clients.

NIH NCI Cancer Research Ideas: Engaging the Cancer Community in the Cancer Moonshot

In April 2016, the National Cancer Institute, in consultation with NIH leadership and the White House, created a Blue Ribbon Panel (BRP) as a working group of the National Cancer Advisory Board. The panel, comprised almost entirely of non-Federal experts, was given the charge to lay out the scientific vision for the Cancer Moonshot. They were also given a firm and aggressive deadline of end of summer 2016 to deliver a report of key recommendations, requiring all 28 members and over 130 members of seven working groups, to dedicate countless personal and professional hours to accomplish what was needed.

To further support the Blue Ribbon Panel, NCI launched Cancer Research Ideas, an on-line ideation tool through which individuals submitted their recommendations for accomplishing the goals of the Cancer Moonshot, on topics ranging from cancer prevention to advancing the understanding of the origins of cancer to reducing cancer health disparities. The community could also submit ideas via email and by calling NCI's Cancer Information Service. Additionally, the Blue Ribbon Panel conducted listening sessions with two professional organizations. The Cancer Research Ideas website was open for 10 weeks and was promoted through social media (Twitter, Google Hangouts), blog post, and exhibit space at major professional meetings.

When the site closed on July 1, the panel received more than 1,600 ideas and comments. Specifically, 848 ideas and 515 comments were submitted from 1,300 registrants. The ideas ranged from new areas of scientific research to proposed changes in how participants find out about and join clinical trials. This level of engagement, enabled by technology, is unusual in the cancer research community. Members of the BRP working groups reviewed and considered the submitted ideas as they deliberated on the cancer research priorities for the Cancer Moonshot. A final report from the BRP was presented to the National Cancer Advisory Board on September 7, 2016.

NIH World RePORT

Over the past decade, global concern about the disproportionate burden of disease and mortality in low-income countries, especially in sub-Saharan Africa, has led to a substantial influx of funding for research by many donor and research agencies. Questions have been raised about whether these international efforts could be better coordinated.

As a first step, the NIH Office of Extramural Research and the Fogarty International Center created World RePORT (the World Research Portfolio Online Reporting Tool), a freely available online resource at http://WorldRePORT.nih.gov that provides access to nine major research funding organizations' portfolio of research activities in sub-Saharan Africa and Southeast Asia. In addition to NIH-funded research, the site includes research funded by a wide array of public and private entities. Each funding organization's projects are plotted geographically and can be searched with keywords in project titles and abstracts, and filtered by year, country, and funding organization. A data-export feature allows the user to build individual datasets for further analyses and customized reporting.

In 2016-2018, World RePORT is being expanded worldwide, to include projects directly or indirectly by the supporting agencies. A goal of World RePORT was to increase the visibility of the *indirect* research activity -- the foreign component of domestic grants that are undertaken in locations other than where a research grant is funded – as well as *direct* activity. In fall 2016, a redesigned World RePORT site will be made available that includes worldwide directly-supported projects, and enhanced tools for searching, mapping, and exporting data. By the end of 2017, the funders will be providing enhanced data on worldwide, indirectly-supported projects through the redesigned site.

NIH Open Science Prize

The Open Science Prize is a unique collaborative effort between the National Institutes of Health, UK-based Wellcome Trust, and the Howard Hughes Medical Institute designed to encourage and recognize the development of new tools, products, and services that use open digital content to help solve pressing public health and biomedical research challenges. As a first of its kind international challenge competition between these organizations, it is an example of an innovative funding method that is successfully stimulating international collaborations around open data.

The Open Science Prize was announced in October 2015. Contestants worldwide were invited to submit ideas that could be developed into prototypes of services, tools, or platforms that could enable open content to be discovered, accessed and re-used in ways that will advance research and public health. In order to qualify, each finalist team was required to be an international partnership, composed of at least two or more individuals or entities of which at least one is based in the United States and another is based in another country.

In the first phase of the competition, contestants were invited to submit their ideas. Finalists are being given $80,000 for development of a prototype by December 1, 2016. A grand prize winner, to be selected from among the six finalists, will be announced in early 2017. The grand prize winner will receive $230,000 to advance their winning project.

In total, 96 submissions were received representing 450 innovators from 45 countries across 5 continents. Each proposal selected as a finalist represents an original approach to either synthesizing available data to create new knowledge or creating platforms that allow for the

integration of such knowledge.

The goal of the Open Science Prize is to support the development and prototyping of services, tools, and platforms to overcome these hurdles to ensure data can be used to advance discovery and spur innovation. The Open Science Prize is enabling new types of research, new types of knowledge, new types of collaboration, and new ways of thinking. The tools developed by the finalist teams represent the tip of the iceberg in terms of what is, and what could be created, using open digital content.

Innovation Lab and QuBBD Program

The NIH and the National Science Foundation (NSF) are collaborating to encourage collaborations between biomedical scientists and quantitative scientists. Using both extramural grants and Innovation Labs, teams are being developed and supported.

Quantitative Biomedical Big Data (QuBBD) is a competitive extramural grant program that is designed to support research at the intersection of the biomedical and data sciences by encouraging new inter-disciplinary and multi-disciplinary collaborations that focus on innovative and transformative quantitative approaches to address biomedical challenges. .

The NIH and the NSF have been jointly sponsoring a series of Innovation Labs. These are intensive, facilitated workshops where new teams of early-career biomedical and quantitative investigators are mentored through the process of building multidisciplinary research programs. The Innovation Lab focused on precision medicine in 2015 and mHealth in 2016.

Breaking Barriers to Give Adults with Hearing Loss Better Access to Affordable Hearing Health Care

Several HHS divisions are joining with other Federal agencies, public advocacy groups, private industry, and the National Academies of Sciences, Engineering, and Medicine (National Academies) to transform hearing health care in the United States. The NIH estimates that 28.8 million adults in the United States have hearing loss significant enough that a hearing aid would help them, yet only one in four has ever used one.

In June 2016, the National Academies released the consensus study report, which includes 12 key recommendations to dramatically enhance consumers' ability to find and fully use the

appropriate, affordable, and high-quality services, technologies, and support they need to manage hearing loss. The recommendations include key institutional, technological, and regulatory changes that would improve access and affordability, expand the range of hearing devices and technologies available to consumers, and increase education and awareness of hearing loss. In addition, the report calls for more evidence-based information for the public and increased transparency of fee structures for devices and services, compatible technologies, and patients' rights to their hearing health care records so they can make more informed decisions.

The President's Council of Advisors on Science and Technology (PCAST) also recently called for major changes to America's hearing health system. In October 2015, PCAST's letter report to the president, *Aging America & Hearing Loss: Imperative of Improved Hearing Technologies*, recommended sweeping changes that the federal government can make to simultaneously decrease the cost of hearing aids, spur technology innovation, and increase consumer choice options.

In August 2016, the NIH and other federal agencies will begin prioritizing and implementing key recommendations in partnership with the National Academies and private organizations. Innovative approaches to change the current hearing health system and engage health consumers, professionals, and other stakeholders will remain the focus of our efforts over the coming years.

An Innovative Public Comment Database Provided Public Input for Use in Developing U.S. Dietary Guidelines Policy

HHS and USDA jointly release the Dietary Guidelines for Americans (Dietary Guidelines) every 5 years. As part of the process for developing the 2015–2020 Dietary Guidelines, HHS and USDA convened an independent 2015 Dietary Guidelines Advisory Committee (Advisory Committee) that was charged with submitting its findings and recommendations to the Secretaries of HHS and USDA in the Scientific Report of the 2015 Dietary Guidelines Advisory Committee (Advisory Report).

A transparent public comment database was created by ODPHP for the public to have a role in the advisory committee's process and to comment on its final report. The public was able to submit and read comments online. Categories and topic areas were identified for easy access to upload comments and attachments, including research articles and data reports, petitions

and letters, etc., to support public entries. HHS and USDA accepted written public comments for the Advisory Committee throughout the Advisory Committee's deliberations over 18 months and on its Advisory Report. Over 29,000 public comments were received and these along with federal agency comments informed revisions to the Dietary Guidelines.

The public comment database was uniquely developed in collaboration and participation with cross-agency USDA staff, meeting Federal Advisory Committee Act requirements for transparency, and reaching target audiences in a highly innovative manner, with a product that can be modeled for future advisory committees.

Mid-Course Review of the National Vaccine Plan
The HHS National Vaccine Program Office (NVPO) updated the National Vaccine Plan (NVP) in 2010 with broad input from federal and non-federal partners and guidance from the National Vaccine Advisory Committee (NVAC). The NVP is the nation's blueprint for our vaccine and immunization enterprise and provides a strategic approach for preventing infectious diseases and improving the public's health through the optimal use of vaccines. The 2010 NVP provided a comprehensive strategy to enhance all aspects of the vaccine ecosystem, including research and development, supply, financing, distribution, safety, informed decision-making by consumers and health care providers, vaccine-preventable disease surveillance, vaccine effectiveness and coverage monitoring, and global coordination. Anticipating that there were likely to be both scientific and policy changes within the ten-year scope of the 2010 NVP, a mid-course review was built into the 2010 NVP. Since the release of the NVP in 2010, the landscape has changed including the passage of the ACA.

NVPO led the development of a mid-course review of the NVP with the goal of assessing whether the priorities set in 2010 should be adjusted to ensure that the plan continued to be responsive to current environmental realities. This review is intended to reflect on the priorities and progress toward goals laid out in the NVP.

Stakeholders were engaged including academia, industry, pharmacies and pharmacists, health care providers, philanthropic organizations and consumer groups to provide an independent and balanced vision for moving forward with the NVP. The National Vaccine Advisory Committee, a federal advisory committee made up of non-federal voting members, were also asked to independently evaluate NVPO's findings and conclusions. The NVAC discussions occur during

public meetings held approximately every three months. At the next public meeting in September, NVAC will discuss and vote on its final recommendations.

Administrative Law Judges

The Appellant Climate Survey is used to measure appellant satisfaction with the appeals experience, controlling for appeal outcome. The survey is conducted annually by a third-party vendor using recognized statistical sampling methodologies to ensure a random selection of hearing participants. The contractor conducts the survey and compiles and analyzes the resulting data. Results are used to make program improvements for case processing and identify training needs for staff as well as generally gauge progress made in increasing satisfaction among appellants.

The appellant forum is an open meeting where staff provide updates to appellants on the status of operations; relays information on a number of initiatives designed to mitigate the backlog of claims appeals awaiting adjudication; and provides information on measures that appellants could take to make the administrative appeals process work more efficiently.

Office of the National Coordinator for Health Information Technology (ONC) Tech Lab

The health IT landscape has changed considerably since the Health Information Technology for Economic and Clinical Health (HITECH) Act. The ONC Tech Lab will guide ONC's work to adapt and evolve ONC's standards and technology work processes to align and connect to changes in policy and in the industry. In concert with the ONC Health IT Certification Program, this principled approach will provide internal and external stakeholders with common connection points to ONC's standards and technology efforts. ONC will use the Tech Lab's organizing structure to help it focus on what ONC can uniquely contribute to improve existing standards and build consensus around those that best serve specific interoperability needs. The Tech Lab will ensure through engagement and testing that standards have been rigorously tested and are consistently implemented. The four focus areas of the Tech Lab are:

(1) Standards Coordination – Working with standards development organizations (SDOs) and industry stakeholders; (2) Testing and Utilities – Testing tools for developers and providers to test their health IT functionality in the field; (3) Pilots – Supporting implementation pilots for standards, including the Interoperability Standards Advisory (ISA); and (4) Innovation – Working

with start-up communities, administering challenges, and forward looking standard and technology activities.

FDA Transitions to the Automated Commercial Environment/International Trade Data System (ACE/ITDS)

In February 2014, President Obama signed an executive order calling all government agencies involved in international trade to work together to streamline import and export processes for America's businesses. The executive order also established the Border Interagency Executive Council (BIEC), an interagency body that provides strategic leadership and policy guidance to improve coordination among agencies with border responsibilities and between the U.S. Government and the trade community. The BIEC includes executives from the Departments of Agriculture, Commerce, Defense, Health and Human Services, Interior, Justice, State, Transportation, and Treasury. National Security Council (NSC) Staff, National Economic Council (NEC) Staff, and representatives from the Office of Management and Budget (OMB) and the United States Trade Representative (USTR) also attend. In response to the Presidential mandate, the Food and Drug Administration (FDA), which chairs the BIEC Risk Management Committee, Customs and Border Protection (CBP), and 46 partner agencies, began collaborating to improve technologies and policies that would, in turn, facilitate trade.

Together, the Government developed a fully-electronic processing infrastructure, the Automated Commercial Environment/International Trade Data System (ACE/ITDS). This technology transformed the nation's import process and allows industry to provide a standardized set of import information to the Government in one "single window" and to receive coordinated Government responses in the same manner. This represents improved processes, as past information was submitted, often redundantly, to multiple Government agencies rather than as one set of harmonized information to one Government agency. A fully-electronic, coordinated system allows the Government to receive information more quickly and process cargo more expeditiously.

With more than 35 million lines of FDA-declared shipments in 2015 representing approximately 20% of the nation's total imports, FDA played a key role in this streamlining initiative and demonstrated ongoing transparency, participation, and collaboration to accomplish this task. FDA worked closely with CBP to develop requirements and build a new interface in which FDA would receive entry-related data and send responses. FDA also modernized its systems to be

able to receive and process new information. In addition to working with Government partners, FDA worked closely and consistently with the Trade Support Network and brokers, importers, and software developers nationwide to collaboratively construct a standardized set of requirements. FDA has issued a Federal Register Notice regarding a proposed rule related to the submission of FDA import data in ACE. FDA made information more accessible by creating a DUNS portal and making updates to public websites. FDA hosted more than 700 outreach events and technical assistance sessions to engage and educate trade partners on changes to the import process. FDA also implemented a 24/7 help desk in order to provide around-the-clock support and assistance to industry during this transition.

After a successful pilot, ACE became the official system of record for all imports in July 2016. FDA completed its milestones on time and within budget. As of July 2016, FDA successfully processed approximately 9 million import transactions. Industry participation is currently at 99%. Throughout the next few years, FDA will continue to partner with industry and other agencies to improve processes and implement additional functionality, updates, and capabilities that further streamline the process.

FDA Office of Partnerships Grant Funding Objective Review Board Panel Member Recruitment Initiative

When making grant funding awards, the Objective Review Board (ORB) process is required to have unbiased and qualified objective reviewers undertake a comprehensive review of all grant applications. In the past individual grant program managers identified qualified individuals. ORA's Office of Partnerships, Contracts and Grants Staff has developed an ORB panel member recruitment strategy that broadened the target reviewer pool beyond individuals within ORA or another FDA Center to include reviewers from CDC, USDA, HHS, as well as association and industry leaders. This recruitment process also streamlined the ORB reviewer assignment process by centralizing it and directly providing grant program managers directly with names of qualified individuals to choose from, creating a more efficient process. This process further benefited FDA by providing over 40 qualified objective reviewers over 21 million dollars.

FDA Improving Enforcement Efficacy by Leveraging Advanced Technology and Expertise

A sophisticated but easy-to-use device developed in FDA labs has revolutionized the detection of counterfeit products, making the process much quicker and cheaper. The handheld, battery-operated and Counterfeit Detector is already being used at U.S. border crossings, international

mail facilities, and in remote areas overseas. Now, bids will be solicited from industries that can mass produce the device for expanded use around the world.

The first version, Counterfeit Detector 1, or CD1, was developed at FDA's Forensic Chemistry Center (FCC) in Cincinnati. The device uses ultraviolet light sources, including those employed in crime scene investigations, and infrared light to examine packaging and products as varied as drugs, cosmetics, food, medical devices, and cigarettes. Since 2005, FDA scientists have been working on enhancing the technology – the result is CD5.

Governments, nonprofit organizations, and businesses have greeted the device with enthusiasm and, in some cases, have worked together to use CD5 to address serious health threats. For example, FDA partnered with the U.S. Agency for International Development, the Presidential malaria Initiative, and U.S. Pharmacopeia to deploy the device in an African country plagued by counterfeit malaria drugs. The deployment was funded by the Skoll Global Threats Fund.

Demonstration at conventions, such as the American Association of Pharmaceutical Scientists, generated interest in wider distribution to public, private, and nonprofit groups. The FDA lab is now developing an acquisition plan to solicit bids from companies capable of manufacturing the CD5.

FDA Office of Regulatory Science (ORS) Public Private Partnerships (PPPs) Initiative

Office of Regulatory Science initially developed PPPs with industry and academia in response to the FSMA mandate to "identify new and rapid analytical techniques, including commercially-available techniques that can be employed at ports of entry." This initiative has been central to FDA's efforts to broaden participation and collaboration with academia and industry and aligns well with the HHS' public access policy regarding publications developed from federally-sponsored research programs. These PPPs have yielded innovative rapid detection systems that can be used to probe various FDA regulated products for contamination and/or adulteration. In FY2012, ORS began a four-year partnership with the Oak Ridge Institute for Science and Education (ORISE), and seven ORISE Fellows are currently working on seven scientific projects with ORS principal investigators (PIs), serving as linkages to academic or industry partner Co-principal investigators. These PPPs have heavily relied on and benefited tremendously from utilization of fellowship programs as a cornerstone in ORA's formation of PPPs. ORS has

received a number of testimonials from its partners extolling the virtues of the ORISE program. ORS believes, with sustainable funding either through grants, Broad Agency Announcements (BAAs), or other mechanisms, it will be successful in leveraging PPPs now and into the future.

5   FLAGSHIP INITIATIVES

NIH Precision Medicine Initiative® (PMI) Cohort Program

The PMI Cohort Program, part of President Obama's larger Precision Medicine Initiative, is a landmark longitudinal research effort that aims to engage 1 million or more U.S. participants to improve our ability to prevent and treat disease based on individual differences in lifestyle, environment, and genetics. PMI Cohort Program participants, reflecting the rich diversity of the U.S., will contribute a wide range of health, environment, and lifestyle information. If they so choose, they will answer questions about their health history and status, share their genomic and other biological information through simple blood and urine tests, and grant access to their clinical data from electronic health records. In addition, mobile health devices and apps will provide lifestyle data and environmental exposures in real time. This will be accomplished with essential privacy and security safeguards. As partners in the research, participants will have ongoing input into study design and implementation. Importantly, participants will have access to a wide range of their individual data and aggregate study results.

In addition to strong participant engagement, the program will benefit from collaborations across the country with leading academic institutions, medical centers, and industry partners. The PMI Cohort Program will empower participants, health care professionals, and researchers to work together, creating a new model of research in which people become true partners in the process, not research subjects. Through this collaboration, the program aims to accelerate the biomedical advances that will improve the health of future generations.

Open Payments Program

CMS is dedicated to providing greater transparency through education, outreach, partnership, strategic communications and data releases. Open Payments is a national program that promotes this objective by publishing data on the financial relationships between the health care industry and health care providers.

As required by the Affordable Care Act, whenever drug or medical device companies make payments to covered physicians or teaching hospitals, or when physicians or teaching hospitals have invested in these companies, this information must be reported to CMS. Reported payments include such things as consulting fees, research grants, travel reimbursements, and other gifts that drug or device companies provide to physicians and teaching hospitals. This data is then made available to the public, including patients, each year at CMS.gov/OpenPayments.

The purpose of Open Payments is to provide greater transparency to the public about the financial relationships between physicians and the health care industry. The Open Payments program does not identify financial relationships that are beneficial or those that may indicate conflicts of interest. Rather, this transparency program was intended to shed light on the nature and extent of these relationships.

CMS publishes a full calendar year (known as a "program year") of payment data on June 30th of the following year, as well as updates from previous program periods. In addition, CMS updates or "refreshes" the Open Payments data approximately six months after its initial publication in order to reflect any data corrections made since the initial data publication.

In program year 2015, health care industry manufacturers reported $7.52 billion in payments and ownership and investment interests to physicians and teaching hospitals. This amount is comprised of 11.90 million in total records, attributable to 618,931 physicians and 1,116 teaching hospitals. Over the course of the Open Payments, program since 2014, CMS has published 28.22 million records, accounting for $16.77 billion in payments and ownership and investment interests.

CMS Blue Button

CMS established Blue Button in 2010 to allow Medicare beneficiaries to download their CMS claims history via the MyMedicare.gov portal in text or PDF formats. While these data formats are relatively easy for beneficiaries to read, they may not be sufficient to meet growing beneficiary needs around analyzing and/or sharing their health data.

As a result, CMS is working to enhance the current Blue Button service to provide a developer-friendly, standards-based data Application Programming Interface (API) that enables

beneficiaries to connect their Medicare claims data to the applications, services, and research programs they trust. CMS is utilizing the HL7 Fast Health Interoperability Resource (FHIR) framework to ensure data is in a structured format that can be accepted by a wide range of applications. The agency is also putting the beneficiary in control of their own health data by designing an interface on top of the FHIR API that will enable beneficiaries to choose when to connect their data to third-party applications. The agency anticipates piloting new Blue Button functionality in the Summer/Fall of 2017.

HRSA Title V Maternal and Child Health (MCH) Block Grant Program Transformation
The Title V MCH Block Grant Program is the nation's oldest federal-state partnership that seeks to improve the health and well-being of women (particularly mothers) and children. Title V funds are distributed to grantees from 59 states and jurisdictions. Scientific advances in developmental origins of health and disease, life-course health development, clinical care and public health, coupled with recent changes in the health care and funding environments, created a need to reexamine the structure of the Title V MCH Block Grant to States program.
HRSA undertook an effort to transform the Title V MCH Block Grant Program to reduce burden, maintain flexibility, and increase accountability. To develop a common vision for improving, innovating, and transforming the Title V MCH Block Grant, HRSA engaged stakeholders and other national, state, and local leaders; families; and other partners. Ultimately, the transformation aims to improve accountability by better measuring performance and impact, and better demonstrate the returns on investment for Title V in bettering the health and well-being of mothers, children, and families in the U.S.

One area of focus in revising the program's National Performance Measures (NPMs) is for the Federal MCH program to assume lead responsibility in ensuring that each measure has a national data source, which will allow for timely, reliable and valid data reporting. In addition to being actionable and allowing for greater accountability, the new performance measure framework is intended to track areas where the State MCH programs can best demonstrate the impact of their Title V investments.

These transformational changes to the Title V MCH Block Grant Program mandated the development and deployment of a new Title V Information System (TVIS). TVIS is a web-based system that operationalizes the three aims of the transformation: reducing burden to states, maintaining state flexibility, and improving accountability. The TVIS is comprised of two parts.

The first part is the Title V MCH Block Grant Data Entry System, which is used by state/jurisdictional Title V Block grantees to submit their annual financial, program and performance data. The TVIS Data Entry includes streamlined data entry (rich text editor fields), built-in checks and validations to ensure data quality, fewer data reporting forms, pre-populated national outcome and performance measure data (as available from national data sources) and to be more intuitive to navigate. A five-year State Action Plan Table is available for entering SMART objectives and evidence-based or –informed strategies/measures for each National Performance Measure. The second part is the TVIS Web Reports System, which is a web-based interface that allows public users to generate reports from the Title V data. Users are able to search national and state level data on key measures and indicators of maternal and child health in the US, view national and state Title V MCH Block Grant financial and program data, and acquire information on an individual state Title V MCH Health Block Grant Program.

Patient-Focused Drug Development

As part of FDA's PDUFA V commitments, the Office of Strategic Programs and the Office of New Drugs have partnered on the Patient-Focused Drug Development program. Two critical considerations in FDA's regulatory decisions are FDA's assessment of the disease and its severity and how well current treatment options meet the needs of patients. FDA developed a structured approach to obtain the patient perspective on these important considerations in facilitated public settings for specific diseases. With public input, FDA identified 24 disease areas to be the subject of individual meetings attended by patients and patient representatives, FDA review staff from the relevant therapeutic review divisions, regulated industry, Congressional staff, and others. The information conveyed in each meeting and in a public docket is summarized in "Voice of the Patient" reports that are made available to review staff for consideration when reviewing new proposed therapies in these disease areas. The reports are also published on FDA's website:

http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm368342.htm

Quality Rating System (QRS)

Based on Section 1311(c)(3) of the Affordable Care Act, CMS developed the Quality Rating System (QRS) to: provide useful information to consumers of Qualified Health Plans (QHPs) offered through a Health Insurance Marketplace (Marketplace), provide actionable information that QHP issuers can use for performance improvement, and facilitate oversight of QHPs. Based on Section 1311(c)(4), CMS also developed the Qualified Health Plan Enrollee

Experience Survey (QHP Enrollee Survey) to yield consumer experience data that will be used in the QRS. As a condition of certification and participation in the Marketplaces, QHP issuers are required to collect and submit third-party validated QRS clinical measure data and QHP Enrollee Survey response data that will be used by CMS to calculate QRS scores and ratings. The QRS measure set includes 43 measures that address areas of clinical quality management; enrollee experience; and plan efficiency, affordability, and management. QHP issuers are required to collect and submit data for 43 measures. QHP issuers should refer to each measure's technical specifications, which specify criteria for determining the eligible population and ability to submit data for the measure.

CMS uses a standardized methodology to calculate QRS scores and ratings based on the measure data that the QHP issuers submit for their Marketplace products by state. The methodology uses a hierarchical structure to group measures into components (composites, domains, summary indicators), which are then used to form a single global rating (using a 5-star scale) for each QHP. Throughout the development of the QRS, CMS has obtained stakeholder comment to inform every part of the program, including establishing requirements, selecting measures, developing the rating methodology and refining operations and processes for data collection, submission and validation.

CMS will pilot the display of QRS star ratings in six states whose consumers use HealthCare.gov during the 2017 open enrollment period (November 2016). The pilot will include consumer testing of the display of QRS star ratings to maximize the clarity and consistency of the information provided to consumers and to assess how to display the QHP quality rating information on HealthCare.gov.

Innovative and Active - A Public Comment Database Plays Role in the Physical Activity Guidelines Development Process
A unique public comment database was recently created for the Physical Activity Guidelines update process. The database, open for comment for the next two years throughout the Physical Activity Advisory Committee process, will play a role in the development of the Physical Activity Guidelines for Americans.

Office of the Assistant Secretary for Health, in collaboration with the Centers for Disease Control and Prevention, the National Institutes of Health, and the President's Council on Fitness, Sports

& Nutrition, is leading the development of the second edition of the Physical Activity Guidelines for Americans (Physical Activity Guidelines or the Guidelines). All collaborative agencies encourage and promote the use of the public comment database as an important way to provide input to the Advisory Committee members and to the Federal government.

The Physical Activity Guidelines is an essential resource for health professionals and policymakers. The current edition includes recommendations for Americans ages 6 years and over and provides science-based advice on how physical activity can help promote health and reduce the risk of chronic disease. The Guidelines serves as the primary, authoritative voice of the federal government for evidence-based guidance on physical activity, fitness, and health for Americans.

Members of the public are welcome to submit comments to the Advisory Committee for consideration as they deliberate and develop their future Scientific Advisory Report. An additional comment period will be open to submit comments to the Federal government, based on the final Physical Activity Guidelines Advisory Committee's Scientific Advisory Report. All comments will be reviewed and used in developing the second edition of the Physical Activity Guidelines, slated for publication in 2018.

6   SUMMARY

Substantial progress has been achieved on the cross cutting initiatives established in the first three versions of the HHS Open Government Plan. HHS Operating and Staff Divisions have continued to emphasize the principles of transparency, collaboration and participation in addressing our mission.

The Version 4.0 plan continues to draw from strategic principles outlined in our operating plans and is tied programmatically to deliverables for them. Emphasis is made throughout this plan on the application of innovative processes and applications of technology to improve on each programs' ability to achieve its goals.

HHS reaches out to its stakeholders and many partners to continue to bring their best ideas forward. Our message is that the effort to make government processes more open at HHS is

dependent on the public to succeed. We invite you to make your voice heard and engage us at http://www.hhs.gov/open.

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