

## **U.S.** Department of Health and Human Services

## **Open Government Plan**

Version 3.0

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#### **EXECUTIVE SUMMARY**

The third installment of our open government plan outlines several forward-looking goals and highlights the work that all of our Operating and Staff Divisions anticipate conducting to build on past successes. It also includes all of the elements required by the Office of Management and Budget Open Government Directive issued after the President's Memorandum on Transparency and Open Government on January 21, 2009. The aspects of government transparency, collaboration, and participation have many meanings and applications in our large organization, with a very broadly and diversely defined mission of serving the public. Our planning approach embraces diversity of opinion, promotes dialogue across the organization, and seeks solutions through open innovation practices across our OPDIVs and STAFFDIVs. To accomplish this we use a variety of ways to seek input from within the organization and leverage that to engage the public. In an organization of this size, it is impossible to capture every program and activity that embraces open government practices. Instead, in this plan, we draw upon best practices, key examples of new concepts, and multiple networking and committee structures embedded in the HHS organizational framework.

New features addressed in this plan include our work to promote proactive disclosures of information, our reporting mechanisms for privacy compliance, our efforts to enhance workforce knowledge of whistleblower protections, and how we are advancing our digital services strategy that uses public feedback to enhance our virtual connections with Americans.

This year, seven new "flagship" initiatives open broad new vistas of transparency, participation, and collaboration to the public. Common among them is the embrace of new technology platforms, high level of consumer engagement in the processes, and the high impact that these efforts are deemed to provide in improving health, health care, and services to the public. In addition, the plan highlights connections to new administrative guidance on open data, the expanded HHS public access policy to publications developed from federally-sponsored research programs, and other mandated activities across HHS that relate to open government practices.

We also issued a new strategic plan<sup>2</sup> this year, which outlines our general, strategic vision for HHS. In this plan, we integrated open government principles to provide new opportunities for applying focus and accountability. This plan includes new elements of engaging the workforce to reinforce the elements of the plan and to empower employees to bring innovative solutions into the discussion and action. While aspects of open government principles permeate throughout the entire plan, *Strategic Goal 4: Ensure Efficiency, Transparency, Accountability, and Effectiveness of HHS Programs* focuses

<sup>&</sup>lt;sup>1</sup> http://www.whitehouse.gov/open/documents/open-government-directive

<sup>&</sup>lt;sup>2</sup> Department of Health and Human Services Strategic Plan for 2014-2018. http://www.hhs.gov/strategic-plan/priorities.html

specifically on our open government activities and demonstrates the commitment to them for the foreseeable future.

Since the publication of our second open government plan in 2012, we advanced many important programmatic areas that underscore our commitment to the spirit of open government. While the landmark work involved in implementing the Affordable Care Act may be the most recognizable example of open government in the past two years, with improved transparency about the costs and options for health insurance and the tools and resources to acquire it, and millions of more citizens now participating in our health care system, HHS has many other initiatives that have met the marks established in our last plan. For example, within the Office of the Secretary, the IDEA Lab was developed to establish new pathways and programs that equip the workforce with new workflow processes, new methods, and communication and analytic tools that will help accelerate the adoption of open government principles. Through specific projects and activities, we plan to test alternative approaches to improve communications, fiscal reporting, oversight, and other management activities. While some of these methods may not succeed with the first attempt, this work better equips us with information about our organization to make a more informed effort at finding solutions in the future. We will also be sharing with our employees and stakeholders the results of open government projects at the department, so that others can learn the work and apply them to their own situations and challenges. In addition, we'll be emphasizing the use of goals and metrics in projects that will allow us to know where we are making progress and learn where new approaches and greater effort is needed.

#### 1 OVERVIEW OF PROGRESS FROM VERSION 2.0 OF THE HHS OPEN GOVERNMENT PLAN

In 2012, the U.S. Department of Health and Human Services (HHS/Department) released its second version of the Open Government Plan, which incorporated nearly 70 projects and activities focused on transparency, collaboration, and participation. In that plan, we also incorporated a new effort in "smart disclosure" and new initiatives were presented as opportunities to participate in open government programs. 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 that plan, we also implemented several cross-cutting flagship initiatives. Through the HHS Innovation Fellows Program, which is now identified as the HHS Entrepreneurs Program, HHS is able to address difficult and complex projects that require highly specialized expertise from non-governmental talent pools. A national talent search is conducted to identify the best talent to come on board the government and join a team. Each year, we identify five to seven projects, and from the search, we choose up to 10 "external" entrepreneurs to join the federal workspace. Now in its third year, the program has been very successful in recruiting highly qualified talent, shaping project design, and bringing in innovative project management methods, such as lean and agile development methods into government. More can be learned about this entrepreneurs program at <a href="http://www.hhs.gov/idealab/pathways/hhs-entrepreneurs/">http://www.hhs.gov/idealab/pathways/hhs-entrepreneurs/</a>. In addition, HHS has now fostered similar principles in recruiting new talent to critical problems but does so in partnership with non-governmental organizations in the HHS Innovator-in-residence program. More information about this can be found at <a href="http://www.hhs.gov/idealab/pathways/innovator-in-residence/">http://www.hhs.gov/idealab/pathways/innovator-in-residence/</a>.

Over the last two years, massive expansion of the data transparency effort has taken place throughout most 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.

Another flagship initiative was focused on new collaboration to promote medical products innovation. There have been many advances in the research areas that are rapidly accelerating the transfer of scientific knowledge into medical practice. The engagement of patients and consumers has been a strong point across the continuum of product development. The Patient-Centered Outcomes Research Institute (PCORI, http://www.pcori.org) provides innovative programs for patient engagement in research, new models for data sharing, and advances in the use of information and communication technologies to facilitate new product development. The National Center for Advancing Translational Sciences has launched a wide array of programs and initiatives to facilitate new product development and establish new diagnostic and therapeutic approaches to rare diseases. New regulatory systems, advisory methods, and strategies have been put in place to enhance the benefits and safety of health information products. The Food and Drug Administration Safety and Innovation Act was also recently enacted. A wide spectrum of efforts are underway to engage experts from many sectors and the public to address administrative health IT functions, health management health IT functions, and medical device health IT functions. The work is ongoing but has had a wide array of input using innovative strategies for public comment and stakeholder engagement. These are a few of the wide ranging and innovative activities that were conducted over the last two years to accelerate improvements in health and the engagement of the public in their development.

#### 2 OVERVIEW OF HOW VERSION 3.0 OF THE OPEN GOVERNMENT PLAN WAS DEVELOPED

Our Open Government Plan is embraced eagerly by the HHS leadership. The Secretary and Deputy Secretary are actively engaged in the process in communicating goals and principles across the organization's workforce, as well as meeting with senior executives to emphasize programmatic implementation of these strategies. Our leadership has spoken publicly across the country in many capacities to highlight the attributes of our open government principles.

This year, our planning process has been anchored by its senior accountable officials, Ellen Murray the Assistant Secretary for Financial Resources, and Bryan Sivak, 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. We also met with civil society groups and advocacy community members that represent stakeholders across our organization. We developed the plan collaboratively, and encouraged participation across the organization and included multiple opportunities for public comment on the hhs.gov/open website to ensure this plan aligned with open government principles and addressed a variety of insights and viewpoints.

#### 3 TRANSPARENCY

## 3.1 ADMINISTRATIVE APPROACHES TO ENHANCE AVAILABILITY OF DATA

The Department of Health and Human Service is committed to making health and human service data open and easily accessible as defined in OMB Memorandum M-13-13, *Open Data Policy-Managing Information as an Asset (Open Data Policy)*. The Department has made progress to institute the Enterprise Data Inventory (EDI) framework as outlined in the Project Open Data implementation guide.

One of the main tenets of the Open Data Policy is to strengthen data management and release practices. This means all Department data should be available in an open and machine readable format. In November, 2013, the Department created and released its first Public Data Listing, which cataloged all public Department data sets in the JSON file format. This JSON file is posted on the Healthdata.gov website and is available to the general public. These publically released data sets make up the core of the EDI. In the future, after a robust workflow process is developed and implemented for the Department by the Health Data Leads, current non-public data sets may be identified for release to the public.

The Department, after conducting a review and analysis of various candidates, has identified an information management system to function as the repository for the Department EDI. The HHS Enterprise Architecture Repository (HEAR) will serve as the enterprise data repository. Extending the repository metamodel will support the expansion and enrichment of all data assets created or collected by HHS. In addition, the repository serves as the authoritative source for HHS IT Systems and related data. The OPDIVs will have the ability to record dataset entries related to their major IT investments in the repository. HEAR is scalable and will be modified to support the capability to generate the EDI report in the required JSON file format. By the 3<sup>rd</sup> Quarter FY14, the repository is scheduled to be operational to capture the metadata attributes for public, non-public, and restricted data sets in the HHS inventory.

In the future, the Department will institutionalize procedures to continue to promote interoperability and openness of structured information by modifying the existing Enterprise Performance Life Cycle for HHS IT system acquisitions in order to document the data sets for new or modified information systems as a part of the Department's system development process.

HHS takes multiple approaches when identifying data assets that are not yet publicly available. The HHS Health Data Leads represent institutional knowledge about the department's data assets and conduct regular outreach to their colleagues in their divisions as part of an active process of traversing the department in search of new data liberation opportunities. The department also welcomes input from the public about data assets that they're interested in utilizing in new and novel ways that are not publicly available. HealthData.gov offers feedback loops for public comments and suggestions about

opportunities to make new data sets publicly available. The timeframes for online publication can vary depending on a number of factors including the current state of the data (whether it exists in an easily manipulated format), presence of Personally Identifiable Information (PII), or the level of data quality that exists in the dataset. The goal is to make data available in a timely fashion while ensuring privacy is protected and quality is maintained.

As noted above, HHS will require all Information System acquisition and enhancement projects to document the associated data assets in the EDI. Those data assets will be reviewed for security and privacy impacts, such as whether the data is subject to the mosaic effect, contains PII, or is subject to the Health Insurance Portability and Accountability Act (HIPAA) protections. Additionally, language in contracts and grants will require updating the EDI as needed for any data assets produced. Some of the data assets added to the EDI through these processes and the appropriations of the availability of these data sets to the public will be evaluated over time.

The expanded EDI will be periodically reviewed by the Health Data Leads to assess whether additional data assets can be publicly released.

#### 3.2 TRANSPARENCY INITIATIVES

## Public Involvement in Evidence-based Research (AHRQ)

Over the past few years, the Agency for Healthcare Research and Quality (AHRQ) has opened up the process of suggesting, developing, and reviewing the systematic reviews conducted under several of its Evidence-based Research Center (EPC) programs, including reports developed for the United States Preventive Services Task Force (USPSTF). The Web sites for the USPSTF and other AHRQ programs that systematically review or conduct meta-analyses of existing research studies on a topic now have opportunities for public suggestion of new topics, public input into a topic's research plan, and public comment on the resulting draft report. Anyone—including individuals and organizations—can nominate a topic for the USPSTF to consider for evaluation for a future recommendation.

Once a topic is selected for systematic analysis, a small group of USPSTF members, called topic leads, works with researchers from an AHRQ EPC to create a draft Research Plan to guide the systematic review of the evidence. The Research Plan consists of an analytic framework, key questions, and a literature search strategy or research approach. Each draft Research Plan is posted for public comment for 4 weeks. The USPSTF topic leads, with the assistance of the EPC researchers, review all of the comments received, revise the draft plan, and develop a final Research Plan. The final Research Plan is then posted on the USPSTF Web site.

After the systematic review is conducted in line with the final Research Plan, a Draft Report is posted to the Web site for 4 weeks to permit public comment. At the end of that time, the Draft Report is taken down to allow the USPSTF and EPC staff to consider the comments and finalize the report. Since

December 2011, the AHRQ-supported USPSTF posted for comment 26 Draft Research Plans; beginning in March 2013, comments were sought on 9 Draft Evidence Reports, while comments on finished Reports began in July 2010.

## S3: Science, Safety, and Security Program

The S3: Science, Safety, and Security Program allows the U.S. Government to share policies and best practices relating to biological risk management in an effort to develop collaborative relationships with the life science community and other stakeholders to raise awareness about efforts to promote progress in the life sciences while preventing and deterring its misuse. The S3 Program website (http://www.phe.gov/s3) had been established to provide a single, coordinated portal for scientists, laboratory staff, policy makers, and the public to locate and link to existing Federal and Non-Federal resources on biorisk management. The website was launched in May of 2010 through interagency collaboration and the support of the White House Office of Science and Technology Policy (OSTP). The S3 website is hosted by HHS/Office of the Assistant Secretary for Preparedness and Response (ASPR). Since 2010, the website has been continuously updated with new materials that agencies and departments across the US Government contributed to. The S3 program also includes the S3 newsletter (an online publication which discusses meetings, government policies and publications, as well as international events relevant to biological research and biorisk management) and the S3 outreach booth (which is used at scientific meetings).

The S3 program is working to create a redesigned website to improve usability, appearance, and the ability to rapidly update materials as needed. A significantly larger set of materials has been prepared for the website and is currently undergoing interagency review. The new materials will include a searchable listing of regulatory and safety information on biological agents, launching initially with the Tier 1 Select Agents and Toxins, and eventually expanding to include the full Select Agent list. In response to stakeholders, the new website will eventually include expanded materials on import and export controls, transportation security, biorisk management, and agricultural biosafety and biosecurity.

In addition to the expanded explanatory content, the new S3 website will also include the Interactive Learning Center (ILC) as a resource for educators and students in the life sciences. This section will include interactive learning tools such as trivia challenges and a set of quizzes. The interactive tools set may also expand in the future to include case studies, slide decks, teaching materials, and in-class resources for professors and biosafety officers. The ILC is a direct response to frequent stakeholder requests for materials to assist in teaching biorisk management and in helping to engage students in independent learning.

The S3 website allows the interagency to work cooperatively in communicating with the public on biosafety and biosecurity efforts across the U.S. Government. Interagency collaboration and the support received from OSTP had been crucial to the success of the S3 program and will continue to be key aspects of the expansion of S3 efforts. In the future, the S3 website will evolve in response to stakeholder requests for materials or expanded information and establish itself as a central resource for government policy and general information on biosafety, biosecurity, and handling of biological agents.

#### Administrative Law Judge (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 regarding 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, the Office of Medicare Hearings and Appeals (OMHA) is developing the Administrative Law Judge (ALJ) Appeal Status Information System.

This web hosted solution will meet the following needs of the Appellants by:

- Verifying that OMHA has received their appeals
- Facilitating inquiries, including status of in-process appeals
- Providing contact information for the OMHA hearing office and the ALJ to whom the appeals have been assigned.

#### Electronic Case Adjudication and Processing Environment, Appellant Public Portal

OMHA needs to move from paper-based case processing to an electronic processing environment because of the exponentially growing workload. To accomplish this, OMHA has initiated the Electronic Case Adjudication and Processing Environment (ECAPE) project. ECAPE will allow OMHA to work appeals electronically. The Appellant Public Portal (APP) is one component of ECAPE.

The APP will be a public facing internet portal, integrated with ECAPE. The portal will serve as a full two-way communication tool between OMHA and the appellant throughout the adjudication process, and will allow authorized parties to file requests for hearings, submit additional evidence, check appeal status, and view the appeal case file online. The APP will be implemented in two phases:

- Phase I will allow a guest user (without registration) to file a request for hearing online, check status of an appeal, and upload additional evidence.
- Phase II targets organizations that frequently file appeals and will allow a registered user to file a
  request for hearing online, upload additional evidence, check status of appeal, view the case file,
  access electronic correspondence, and establish and maintain an appellant profile.

## **Energizing Data to Better Tell Their Story: data.CDC.gov**

The Centers for Disease Control and Prevention (CDC) has a long track record of regular data releases like those from the surveillance of foodborne and infectious diseases, morbidity and mortality, behavioral risk factors for youth and adults, and more. Each program at CDC has its own procedures and preferred formats for releasing data, from ASCII and SAS-Xport files, to Crystal Reports, Excel files, PDFs, and other formats. Users must know where and how to find each database, and even then, export options may be limited or not available.

Data can tell the story about what is going on in our communities and around the world, but to be truly useful, it must convey specific actionable messages. It must also be delivered to audiences that need it most, in formats they can understand and easily use.

CDC has launched an open platform that gives data stewards the ability to publish selected data in readily usable, portable, and "energized" formats. End users are able to filter and create visualizations in bar charts, trend lines, and maps and can then embed those visualizations in their own websites and apps. Hosted on a Socrata platform and powered by an application-programming interface (API), data.CDC.gov helps turn data into a powerful communication tool. The API also frees data to be innovatively visualized in other ways, through powerful tools such as ChartJS and D3, while allowing data stewards to maintain control of the numbers and update them automatically. We are putting data into action and taking it to the public in ways that are easily consumed.

The site was launched in August 2013 and as of the end of April 2014, data.CDC.gov now hosts over 200 live data sets, and counting. CDC's Morbidity and Mortality Weekly Report (MMWR) is publishing data regularly to the site; the Behavioral Risk Factors Surveillance System has published prevalence and trends data on tobacco use and healthcare access; and other programs are publishing data on flu vaccination coverage, leading causes of death, and even CDC.gov web and syndication metrics.

Enabling the effective visualization of data and the localization of data helps tell the story in ways that resonate for specific audiences. With data.CDC.gov, CDC can build data widgets that can toggle between national aggregate estimates and state-level estimates. This gives state and local health departments the ability to take federally-produced data and visualizations and customize the views, on-the-fly, for their local area.

CDC is building capacity in state and local health departments by providing free, evidence-based health content for reuse and allowing the federal government to do the maintenance. We will soon give these partners the capacity to localize materials for their audiences, either by combining with additional local messaging or controlled adaptation based on CDC data. Open government and open data also allows our commercial health care stakeholders to take this to the next level by sending our science based health messages and content directly to patients and consumers through electronic health records and personal health records systems, or through health monitoring applications and devices.

Although CDC has been releasing data to the public and sharing syndicated content for years, data.CDC.gov is our first step in the arena on a consolidated, agency-wide level, in a way that enables us to energize data and put it into action not only for ourselves but for our partners and the public. While data.CDC.gov helps us meet the directives of U.S. Government's Open Data and Open Government Initiatives, the value that data.CDC.gov brings to the public health system is the efficient reuse of quality, evidence-based health messaging, tailored by data, and delivered to the public in easily consumable form.

## **Improving Public Access to Scientific Manuscripts through CDC Stacks**

CDC Stacks is a free, digital archive of scientific research and literature produced by the CDC. This online archive is composed of curated collections tailored for public health research needs. This repository is retained indefinitely and is available for public health professionals, researchers, as well as the general public, and is accessible at: <a href="http://stacks.cdc.gov">http://stacks.cdc.gov</a>.

CDC Stacks provides access to current CDC research and literature such as the Open Access Collection. In addition, CDC Stacks offers a historical perspective that was previously not available, such as the first 30 volumes of the MMWR.

As a fully-featured repository, CDC Stacks provides the ability to search the full text of all documents, browse journal articles by public health subjects, and explore the curated collections of documents on relevant topics. Additional collections and ongoing additions to existing collections are planned for the future.

In an effort to further improve the public's access to CDC generated scientific information, CDC plans to begin posting intramural peer-reviewed manuscripts to the CDC Stacks website within 12 months of publication, at no cost to the public. The goal will be start-up of the system in late summer 2014 with the posting of the approximately 500 documents currently in-queue, and then weekly additions moving forward.

# <u>Centers for Disease Control & Prevention (CDC) Office of Public Health Scientific Services (OPHSS)</u> <u>Informatics Innovation Unit (IIU)</u>

CDC's Informatics Innovation Unit (IIU) is a resource for the CDC and the public health community that studies, prototypes, and tests new and innovative technology-based tools and resources to maximize programmatic public health impact.

IIU engages in applied new research and development projects that support innovative public health uses of IT. To do so, IIU provides information, consultation, and support for new informatics solutions for public health practice; rapidly creates prototype tools and solutions to facilitate the testing of hypotheses; and provides an optimal, flexible, and scalable environment for rapidly developing prototype public health informatics solutions for testing and evaluation.

IIU supports both transparency and collaboration initiatives through many of the services it provides. IIU follows an open-source philosophy, and uses tools consistent with this. All of IIUs projects are open and reusable. CDC makes the programming code and its documentation public available to enable others to modify, repurpose, or improve the tools. IIU provides a flexible physical collaboration for CDC staff, usable for demonstrations, training and software development.

IIU provides a wide variety of services to overcome barriers which may be present at any of the stages of the "Innovation Lifecycle" – idea, design, prototype, pilot, production, evaluation. Specifically, it has been involved in developing guidelines, evaluations, and recommendations to CDC & public health

community. IIU has also provided expertise in Human Computer Interaction, visualization, and software design and development

Recently IIU has been focusing on "thorny" innovation challenges, including novel data visualization, big data, mHealth and cloud computing.

More information on the IIU can be found at: http://www.phiresearchlab.org

## **Health Indicators Warehouse**

The Health Indicators Warehouse (HIW) (http://www.healthindicators.gov) provides web services access to a large curated database to foster innovative uses of high value federal data assets. Public use files are available from across the Department, however often these files are in a format that makes the data inaccessible to most users, the data lacks the necessary metadata to inform potential users, and the data assets are not available from a single source. The HIW addresses these challenges of current and potential users of federal data assets.

The demand for high quality pre-tabulated data on health and its determinants has been increasing in recent years. These data are used to assess community health, target populations health issues, evaluate the efficacy of interventions, track changes in health outcomes, and for many other purposes. There are hundreds of datasets collected by the Department and other organizations. Analysts often have to navigate a myriad of websites or contact multiple organizations to obtain needed data. There is a need to streamline processes of accessing these data.

Launched in February of 2011, HIW provides the public health community, IT developers, and others with an accessible web-based application offering high quality population health data and descriptive metadata from over 1,100 indicators amounting to more than 150 GB of content. Each indicator's metadata describes the methodology and data source. Users do not have to navigate across numerous venues to download these data. The HIW also has an API, which is a source code-based specification for computer-to-computer communication. The API allows application developers to easily download data directly from HIW and create innovative third party applications.

#### **Network of Patient Safety Databases**

The coming availability of non-identifiable information on patient safety events from the Congressionally mandated<sup>3</sup> Network of Patient Safety Databases (NPSD; funded by AHRQ) of patient safety event data submitted by provider institutions through the AHRQ-managed Patient Safety Organizations, or directly to the NPSD by health care providers, will facilitate the aggregation of sufficient volumes of patient safety event data to identify more rapidly the underlying patterns and causes of risks and hazards associated with the delivery of health care services. The Patient Safety Act directs AHRQ to incorporate the non-identifiable trend data from NPSD in its annual *National Healthcare Quality Report*. This trend data, as with other quality and disparities data, should be included in the HIW.

In the Patient Safety and Quality Improvement Act of 2005, also known as The Patient Safety Act.

#### **Downloadable Provider of Services file**

The Centers for Medicare & Medicaid Services (CMS) recently posted the Provider of Services file (POS file; <a href="http://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Provider-of-Services/index.html">http://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Provider-of-Services/index.html</a>) on the CMS website. The POS file contains data on characteristics of hospitals and other types of healthcare facilities, including the name and address of the facility and the type of Medicare services the facility provides, among other information. The POS file does not contain any individually identifiable information about beneficiaries. This file is one of the best sources for information on Medicare-enrolled institutional providers. The data is a valuable resource to a variety of stakeholders including researchers and application developers.

This file has previously only been available to the public for a fee. Now, the POS files are being made available as free downloads. The most current four quarters as well as the annual files for each previous year are available on the CMS website for download.

## **Chronic Condition PUFs and Dashboards**

CMS Chronic Conditions Public Use Files and Dashboards (<a href="http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/index.html">http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/index.html</a>) provide information on prevalence, utilization, and Medicare spending for specific chronic conditions and multiple chronic conditions. These data can be used to inform policymakers, local health leaders, and health systems about resource utilization of patients with chronic diseases. The Chronic Condition data are available as tabular geographic data reports, maps, chart books, and interactive dashboards covering 2008 to 2012. CMS updates these products annually with an additional year of data.

## **Geographic Variation PUFs and Dashboards**

The Medicare Geographic Variation PUF (<a href="http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Geographic-Variation/index.html">http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Geographic-Variation/index.html</a>) is a series of downloadable tables and reports that contain demographics, spending, utilization, and quality indicators at the state, HRR, and county-level. These PUFs enable researchers and policymakers to evaluate geographic variation in the utilization and quality of health care services for the Medicare fee-for-service population. The GV PUF also contains standardized spending figures, which remove the effects of the geographic adjustments that Medicare makes for its payment rates, allowing comparisons of per capita spending across regions. CMS has also released GV Dashboards that present per-capita spending using standardized dollars at the state and county level in an interactive format. CMS updates the PUFs and dashboards annually to include an additional year of data.

#### **Qualified Health Plan Benefit and Pricing Data**

CMS provides data on certified medical and dental plans in the Federally-facilitated Marketplace that allows for transparency on premiums, service areas, levels of coverage, benefits, cost-sharing, and links to more plan information. The data allows researchers and consumers insight into the benefit structures

of qualified health plans that are offered in the Marketplace. Updated data is posted to HealthCare.gov after the annual Qualified Health Plan certification process.

## **Marketplace Enrollment Data**

HHS releases regular reports on the number of consumers enrolling in qualified health plans through the Health Insurance Marketplaces, including data related to enrollment by age, gender, type of plan, level of coverage, financial assistance, and race/ethnicity. The data is provided for all Marketplaces run or supported by the Federal or State governments. The report is intended to provide information describing any increases in coverage to be used by states, issuers, and consumer advocates. Reports are published throughout annual open enrollment periods.

## **Medicare Shared Savings Program (Shared Savings Program)**

The Shared Savings Program, established by section 1899 of the Social Security Act, P. L. 74–271, promotes population based care by recognizing and rewarding Accountable Care Organizations (ACOs) that lower growth in health care costs while meeting performance standards on quality of care. Under this new payment and service delivery program, ACOs bring health care providers together in new ways to coordinate and improve the quality of care for patients across settings—including doctor's offices, hospitals, and post-acute settings.

CMS has announced interim results for ACOs starting in 2012 and ACOs have completed two quality reporting cycles that includes performance measurement on patient experience of care and other outcome based measures. Since April 2012, ACOs have been able to request monthly Medicare Part A, B, and D Medicare claims-line feeds that include beneficiary-level claims data, including encounters by service type, procedures, and supplies for beneficiaries seen by their providers. Currently, CMS is sharing beneficiary-level claims data, where appropriate under applicable law, with over 250 ACOs on over 4 million Medicare fee-for-service beneficiaries. CMS also provides quarterly and annual aggregate utilization and expenditure data feedback reports, including quality performance data directly to ACOs and their participating providers to support their care coordination and quality improvement efforts.

## Open Payments (Sunshine Act) National Transparency Program

Also known as the Physician Payment Sunshine Act of 2009 (Sunshine Act), the Open Payments Act is a national transparency initiative intended to provide unprecedented public disclosure of the financial relationships that exist between industry and physicians. Industry and physician collaboration can be beneficial, promoting the discovery and development of new technologies that improve individual and public health. However, financial ties between medicine and industry may also lead to unintended adverse consequences in other aspects of medicine, such as: clinical practice, clinical and basic research, medical education, standards setting, and medical publications.

While financial ties alone do not signify an inappropriate relationship, Open Payments is necessary to:

- ensure transparency of reporting financial ties;
- reveal the nature and extent of relationships;

- prevent inappropriate influence on research, education, and clinical decision-making;
- avoid conflicts of interest that can compromise clinical integrity and patient care; and
- minimize risk of increased health care costs.

CMS will collect from the industry the payments and other transfers of value the industry makes to physicians and teaching hospitals and post it on a public website. This will be a national resource for beneficiaries, consumers, and providers to better understand relationships between physicians, teaching hospitals, and industry. No such national public database has existed to date.

The public websites which includes CMS, Healthdata.gov and other locations (available on September 30, 2014) will be designed to increase access to and knowledge about these relationships for consumers to make informed decisions.

This program involves an extensive amount of external engagement and collaboration with the program stakeholders. These stakeholders include physicians, teaching hospitals, industry companies such as drug manufacturers, representative organizations, federal and state agencies, congress, researchers, and of course, the public-at-large. CMS has developed a wide array of outreach tools to ensure that all of the program stakeholders are aware of this new program and safeguard program compliance including the first CMS mobile applications. These mobile apps are designed to help facilitate the tracking of the various payments or other transfers of value as they occur throughout the year. Learn more at: <a href="https://www.go.cms.gov/openpayments">www.go.cms.gov/openpayments</a>.

## Improving Temporary Assistance for Needy Families (TANF) Financial Data Collection

The Administration for Children and Families' (ACF)-196 Temporary Assistance for Needy Families (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. HHS, 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 pending Office of Management and Budget (OMB) approval, effective FY 2015, the TANF financial data collection will involve two forms: the ACF-196R, which states will submit on a quarterly basis, and the ACF-196, which states will use to adjust expenditures submitted during fiscal years (FY) prior to FY 2015. (Note, after a state expends all funds for grant years prior to FY 2015, it will no longer need to use the ACF-196). Approval of the ACF-196R would result in 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 – the Office of Family Assistance (OFA) is proposing to revise the expenditure categories and accompanying definitions used in TANF financial data collection. We are also adding ACF-196R–Part 2, which will require 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 will also be improved, as states will be 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. Specifically, if a state needs to adjust an expenditure reported in a prior year after FY 2014, it will revise the ACF-196R pertaining to the fiscal year in which that expenditure occurred. If the adjustment is for an expenditure submitted in a fiscal year prior to FY 2015, the respondent will revise the ACF-196 pertaining to the relevant grant year for expenditures cumulative through FY 2014. (Because a state will only use the ACF-196 for this purpose, the reporting burden associated with this form will be significantly reduced.) This methodology facilitates both the monitoring of grants, as well as the ability to obtain accurate fiscal year expenditures to inform TANF policy analyses.

## **HHS Grants Forecast)**

HHS's Grants Forecast website provides information about planned and potential funding opportunities across HHS OPDIVs discretionary grant programs. Grant opportunity "forecasts" are prospective in nature, and subject to availability of funds, once those funds are made available to the OPDIVs. The website facilitates access for persons interested in applying for HHS grants and is a part of strategic planning in grants administration. The Forecast is structured to mirror the content within Grants.gov and serves as a precursor to it for potential HHS grants applicants, and also contains cardinal elements of the Catalog of Federal Domestic Assistance (CFDA). The system has quick search and advanced search options, in addition to the integration of social networks for the promotion of funding opportunities. In FY2013, 714 potential grant opportunities were posted on HHS Grants Forecast, 505 of those records migrated eventually to Grants.gov as full blown competitive funding opportunities announcement. 85,309 people visited the website in 2013, and there was an unprecedented surge in October 2013 during the government shutdown. HHS's Grants Forecast Team continues to focus on ensuring that the full complement of HHS's planned grant activity data is posted by its OPDIVs to the Grants Forecast; and is teaming with other Department groups to facilitate greater access to Tribes and traditionally underrepresented communities. The Forecast is a successful grants planning tool that has benefitted from constant dynamic development, frequent adjustments to customers' needs and feedback, and constant updating of features and website functionality. The main drivers of the Forecast include Office of Grants Policy Oversight and Evaluation (OGPOE) strategic direction, OPDIV participation and collaboration, IT support from the ACF, and increased public demand for greater transparency of HHS funding opportunities and planned spending.

## **Grants.gov**

The Grants.gov (<a href="http://www.grants.gov/">http://www.grants.gov/</a>) program management office is managed by HHS. Grants.gov is an E-Government initiative operating under the governance of OMB. Under the President's Management Agenda, the office was chartered to deliver a system that provides a centralized location for grant seekers to find and apply for federal funding opportunities. Today, the Grants.gov system houses information on over 1,000 grant programs and vets grant applications for 26 federal grant-making agencies, which can be found at <a href="http://www.grants.gov/web/grants/applicants/applicants/applicants-resources/agencies-providing-grants.html">http://www.grants.gov/web/grants/applicants/applicants-resources/agencies-providing-grants.html</a>.

Grants.gov provides a centralized "FIND and "APPLY" portal for federal agencies to post discretionary grant opportunity information and for individuals and organizations to apply for these opportunities. Grants.gov is supported by 26 federal agencies, with HHS as the Managing Partner. In FY2013, on behalf of the Federal grant-making community, the Grants.gov system posted nearly 4,000 funding opportunities, and processed over 257,000 applications. There were, also, 46,398 new Authorized Organization Representative registrations – an increase of 17.88% over FY2012. Additionally, the system's "FIND" capability was improved through several releases designed to improve security; search performance; applicant notifications, grantor web services, and updates to technical products such as Oracle, Symantec, and Java.

Grants.gov has implemented changes such as easier navigation, faceted search, and new downloadable form features in response to user requests and internal assessments. The results of our efforts have been met with overwhelming acceptance by users who now enjoy easier access to features and information they need to increase their productivity. The new features have resulted in fewer calls to the Grants.gov call center. The now intuitive site allows users to spend more of their time on the site searching for grants and submitting applications versus reading help content. Now when users conduct a search, more applicable results are returned, ordered by relevance. The website was also given a much needed facelift that was well-received by the Grants community. Grants.gov is much easier to navigate and provides fast and easy access to frequently used functionality and information. Users can now search for grants and website content directly from the home page or conduct a more advanced search on an enhanced and intuitive dedicated search page (http://www.grants.gov/web/grants/searchgrants.html). When Applicants download applications or instructions, the file is automatically downloaded to the user's machine. This seemingly small change improves the usability for inexperienced users as it is now easier for them to save their completed applications while working on it and not risk losing their work. The forms repository page was updated to provide Applicants and Grantors more visibility into upcoming OMB form expiration dates. Users now have more up-to-date information on active and retired forms available to them.

Going forward, Grants.gov enhancements will improve the ability of potential grantees to find opportunities by saving their searches and simplifying the user interface. Grants.gov will also be adding an easy to use and flexible capability to send and manage Grant opportunity notifications, allowing users to quickly see when new opportunities are available that match their needs. In the near future, applicants will have the ability to download PDF renderings of their submitted applications. Applicants

will then see their applications in the same way as the evaluator if the evaluator also uses the PDF generated by Grants.gov. There will be added functionality to help applicants fill out their forms. In addition, applicants will have the ability to export data from a form on one submission to a same form in another submission. Applicants will also be able to pre-populate a new budget year with the budget year-1 data in R&R Budget forms. The template management Web pages will be updated to allow Grantors to view the forms before publishing. The system's availability and reliability will be improved thru modernization of the system architecture and refresh hardware. By building redundancy in the system, system downtime will be minimized. Grants.gov Program Management Office is partnering with the OMB on the possibility of expanding Grants.gov system and web portal so that the website can be utilized as a single gateway to a wide array of grants-related information.

## **Tracking Accountability in Government Grants System**

The Tracking Accountability in Government Grants System (TAGGS; <a href="http://taggs.hhs.gov/">http://taggs.hhs.gov/</a>) is a robust reporting tool developed by HHS's Office of Grants and Acquisition Policy and Accountability (OGAPA). The TAGGS database is a central repository for grants awarded by the eleven HHS OPDIVs. TAGGS tracks obligated grant funds at the transaction level – which means that every time an award is made or modified OPDIVs provide TAGGS with updated financial information related to the total grant award amount. HHS is actively engaged internally and with external stakeholders as part of the government's collaborative efforts to increase transparency and improve the quality of data posted on the Web while adhering to new Federal requirements.

HHS is working diligently to improve the public accessibility to meaningful data as exemplified by HHS's revised TAGGS Annual Report. HHS recently unveiled the department's new 2012 TAGGS Interactive Annual Report that provides users with multiple views of HHS data through rich visuals, graphics and charts. In previous years the Annual Report was paper based, and the report, even when published on the TAGGS website reflected a paper-based format. The Annual Report now tracks and accounts for HHS spending and provides high quality data to the public and external stakeholders via an interactive display Based on the success of the interactive annual report, HHS will begin updating TAGGS in 2014. The system was last overhauled in April 2011 to improve navigation, search processing, access to standardized spending reports, accessibility, data accuracy through the implementation of additional data validation checks for internal controls, functionality through the use of analytic tools and usability by providing short videos with How-to tips, and to accommodate legislative requirements associated with the Recovery Act and the Affordable Care Act (ACA). The TAGGS Update Project seeks to enhance the user experience through the development of an intuitive, simple, yet innovative design that is easily adaptable to new and existing users. Key enhancements will include: improved search capabilities, shorter path to information, database structural improvements, new style layout, greater use of graphics and explanatory text to facilitate improved public understanding. The goal is to provide a better serviceable tool to the public and internal HHS by enabling greater access to high-quality digital government information. Modifications are focused on improving the user experience, improving accessibility to the information, and the continuous effort to improve the underlying data. The TAGGS Team has also directed the creation of the internal Data Quality Database Application (DQDA), also known as the "TAGGS Heat Map." The DQDA tool uses a color coded system to formally capture,

monitor, and report on the timeliness, completeness, and accuracy of HHS grant award information. The business intelligence gained through the full implementation of the new website and the DQDA will result in actionable tasks to improve data quality and to further goals and objectives of the broader Open Government Initiative.

## **USAspending**

USASpending.gov (<a href="http://usaspending.gov/">http://usaspending.gov/</a>) is an online database launched in December 2007 to provide the public with free centralized access to Federal spending information, uphold accountability, and provide transparency of Federal funds. Federal awards reported through USASpending.gov include grants, sub-grants, loans, cooperative agreements, contracts, subcontracts, purchase orders, task orders, and delivery orders as well as other forms of financial assistance.

To further meet the requirements of the Federal Funding Transparency Act (FFATA), HHS has increased efforts to strengthen data quality and reporting to USAspending.gov starting with CMS unreported aggregated direct payments and non-FAR contracts for the CFDA programs totaling over \$500 billion dollars. In February 2014, HHS posted previously unreported FY 2012 Medicare data at the aggregate-level to USASpending.gov and in its ongoing efforts to close data gaps is working closely with CMS to report FY 2013 and FY 2014 data to USAspenind.gov. HHS is also working collaboratively with CMS to automate the data submission process and determine whether the data reported at a highly aggregated level could be reported at a lower level in the future.

On June 12, 2013, OMB issued a memorandum entitled "Improving Data Quality for <u>USASpending.gov</u>". The memorandum provides additional guidance and requirements to Federal agencies for ensuring the accuracy and completeness of <u>USAspending.gov</u> prime Federal award financial data, comparing and validating <u>USAspending.gov</u> funding information with data in the agency's financial system and reporting accuracy rates to OMB. HHS grants, acquisition and financial communities are collaborating to provide reasonable assurance that <u>USASpending.gov</u> is reporting accurate and reliable information via quarterly reconciliation of data provided to <u>USASpending.gov</u> and audited financial data captured in HHS Global Unified Financial Management System.

## **System Award Management System**

The System for Award Management (SAM; <a href="https://www.sam.gov/">https://www.sam.gov/</a>) is the Official U.S. Government system that consolidated the capabilities of Central Contractor Registration (CCR)/ Federal Agency Registration (FedReg), Online Representations and Certifications Application (ORCA), and the Excluded Parties List System (EPLS). SAM and the Integrated Award Environment are governed by the Award Committee for E-Government; and HHS is one of the seven voting members. The governance structure also includes a grants/financial assistance committee, which HHS co-chairs, and an Acquisition committee that includes HHS as a voting member.

Additionally, HHS is a member of the SAM Change Control Board (CCB) and participates fully in its initiatives and new releases, including the plan to fully integrate all nine systems previously managed by GSA into the SAM system. These systems are used at various phases of the life cycle of Grants and

Contracts. Business needs of these various user communities dictate how they interact with the systems and whether they are a provider or a consumer of the information. The six remaining systems that will be integrated over the next five years are the Electronic Subcontracting Reporting System (eSRS)/FFATA Subaward Reporting System (FSRS), Federal Business Opportunities (FedBizOps), Wage Determinations Online (WDOL), Catalog of Federal Domestic Assistance (CFDA), Federal Procurement Data System – Next Generation (FPDS-NG), Past Performance Information Retrieval system (PPIRS)/Contractor Performance Assessment Reporting System (CPARS) /Federal Awardee Performance and Integrity Information System (FAPIIS).

As active members of the CCB, HHS has provided feedback and input on the General Services Administration's (GSA) plan of action for the next five years. In addition, HHS has established an internal Change Review Board (CRB) Support Team consisting of those in the grants and acquisition community closest to the requirements. The internal CRB Support Team participates and facilitates the review of all change requests to the CCB by articulating the needs of the Department for incorporation in the overall plan. HHS' Change Review Board (CRB) and CCB are extremely active with the various GSA-SAM Focus Groups for the rebuild/redesign of the 9 disparate systems within the System for Award Management. The HHS CRB and its agency points of contact actively participate in the user acceptance testing for all change requests prior to implementation into SAM.

## **Catalog of Federal Domestic Assistance**

The Catalog of Federal Domestic Assistance (<a href="https://www.cfda.gov/">https://www.cfda.gov/</a>) is a tool that provides a full listing of all Federal programs available to State and local governments (including the District of Columbia); federally-recognized Indian tribal governments; Territories (and possessions) of the United States; domestic public, quasi- public, and private profit and nonprofit organizations and institutions; specialized groups; and individuals. HHS uses this tool as a mechanism to check the accuracy and completeness of its reporting. HHS has CFDA coordinators across the Department who participate in maintenance of data in CFDA.gov.

HHS's Office of Grants Systems Modernization (OGSM) has partnered with OGPOE to assemble a team to track, review, analyze, and recommend policy changes to improve the accuracy and timeliness of data in CFDA.gov. The team examined policy, process and technology to determine how to improve the utilization of the tool. Over the course of four months the team was able to reconcile approximately 850 billion dollars for fiscal year 2012. HHS also maintains involvement with CFDA.gov initiatives through the establishment of a Change Review Board (CRB) tasked with providing input and feedback with the intent of contributing to CFDA.gov's improved functionality and capability. The HHS Change Review Board consists of the CFDA Coordinators who are representatives of each OPDIV/STAFFDIV. HHS has incorporated "lessons learned" from this analysis into the government-wide technical strategies supporting SAM and USASpending.gov.

## <u>Public Access to Neuroactive & Anticonvulsant Chemical Evaluations (PANACHE)</u>

The National Institutes of Health (NIH) is presenting a new online database that contains public and non-confidential chemical structures and biological data for compounds which have been screened for

efficacy and toxicity in animal models of epilepsy and related seizure disorders as part of the Anticonvulsant Screening Program (ASP; <a href="http://www.ninds.nih.gov/research/asp/index.htm">http://www.ninds.nih.gov/research/asp/index.htm</a>) at the National Institute of Neurological Disorders and Stroke (<a href="http://www.ninds.nih.gov/">http://www.ninds.nih.gov/</a>). In addition to structural information, visitors to the site will find biological data, with permission from the supplier, for each compound submitted to the ASP for testing. The availability of this information in a public access database introduces a new phase of a government-sponsored project that began in 1974 in an effort to establish worldwide collaborative relationships among government, academia, and industry focused on the search for therapeutic interventions and cures for the epilepsies and other related disorders. This international network includes over 460 different suppliers from 30 countries and four continents. The database currently includes 150 structures.

## **STAR METRICS/Federal RePORTER**

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 is led by the NIH, the National Science Foundation (NSF), and OSTP. The NIH is the host institution for the STAR METRICS consortium which presently consists of the NIH, NSF, US Environmental Protection Agency (EPA), US Department of Agriculture, and OSTP.

STAR METRICS has two levels of activity. The Level I goal is to describe the scientific workforce supported by federal funding through collaboration with grantee institutions. Level II is aimed at developing an open data infrastructure and tools to enable the documentation and analysis of the inputs, outputs, and outcomes of federal investments in science. Level II has begun creating this infrastructure through use of a new tool, Federal RePORTER (<a href="http://federalreporter.nih.gov/">http://federalreporter.nih.gov/</a>), which allows agencies government-wide to document their research investments in a standard format that allows for text searching of abstracts across agencies.

More information about the STAR METRICS initiative can be found at: <a href="https://www.starmetrics.nih.gov">https://www.starmetrics.nih.gov</a>.

## **Open Access to Biomedical Research Information**

The National Library of Medicine (NLM) continues to maintain and expand PubMed Central® (PMC), a free digital archive of biomedical and life sciences journal literature that provides public access to the full-text versions of more than 3 million research articles, including those produced by NIH-funded researchers. Plans are underway to extend the use of PMC to serve as the repository for publications resulting from research supported by other HHS agencies. Expansion of ClinicalTrials.gov, which provides open access to clinical trial information, will continue. ClinicalTrials.gov currently includes some 170,000 registered studies and summary results for more than 13,000 trials.

## **APIs Encourage Innovation by Information Resource Developers**

NLM is a major provider of biomedical research and health information, supporting access to more than 30 terabytes of data by more than 3 million users each day. To extend access to these resources even more broadly and to support further innovation by developers, NLM provides an API to many of their information services. An API is a set of routines that an application uses to request and carry out lower-level services performed by a computer's operating system. The API provides the means by which external developers can develop novel computer and mobile applications using NLM resources. Supported NLM APIs are listed on an API website (<a href="http://www.nlm.nih.gov/api/">http://www.nlm.nih.gov/api/</a>), along with information about any additional terms and conditions of use.

## Pillbox: A Pharmaceutical Identification and Reference System

NLM'S PillBox (pillbox.nlm.nih.gov) service makes available more than 5,000 high quality images of solid oral dosage medications, or pills, drawn from multiple NLM and Department of Veterans Affairs (VA) programs. Designed to make government drug labeling data accessible and usable for health IT developers, clinicians, and the public, Pillbox provides information about a pill's appearance, including: color, size, shape, imprint, and score, as well as its brand/generic name, ingredients, and the National Drug File identification number. Researchers and product developers may obtain the images and accompanying metadata via an applications programming interface (API) at <a href="http://Rxlmage.nlm.nih.gov">http://Rxlmage.nlm.nih.gov</a>. Pillbox's API, data, and images are powerful tools for drug identification and reference, offering exciting opportunities to build medication-related applications and services. This project is the result of collaboration with the Food and Drug Administration's Center for Drug Evaluation and Research (CDER), the VA Medication Image Library (MIL) program, and pharmaceutical manufacturers.

## Clinical Vocabulary Standards for Electronic Health Records

In close collaboration with the Office of the National Coordinator for Health Information Technology (ONC), NLM provides ongoing funding for the clinical terminologies designated as U.S. standards for meaningful use of electronic health records (EHRs) and health information exchange. NLM's support allows these standards to be updated regularly to reflect new drugs, tests, and changes in biomedical knowledge and health practice — and also allows them to be used free-of-charge in U.S. systems that support health care, public health, and biomedical research. NLM produces and maintains a growing number of convenient vocabulary subsets to help EHR developers and users transition to use vocabulary standards, including subsets of frequently encountered patient problems, frequently ordered tests, and medications currently available in the U.S. market. The Value Set Authority Center, released in collaboration with ONC, CMS, the HHS Office of the Secretary, and others, provides authoritative access to the standard vocabulary components of clinical quality measures. The inclusion of standard terminology in EHRs enables more effective clinical decision support by making it easier to link information in a patient's record to the knowledge relevant to that record.

## Toxicology in the 21st Century (Tox21) Program

The Toxicology in the 21st Century (Tox21) program is aimed at developing better toxicity assessment methods. The goal is to quickly and efficiently test whether certain chemical compounds have the potential to disrupt processes in the human body that may lead to adverse health effects. The quantitative high-throughput screening (qHTS) robotic system, developed at the National Center for Advancing Translational Sciences (NCATS), increases the rate at which chemicals are tested, and profiles compounds over a wide range of concentrations. These qualities make qHTS technology ideal for toxicology testing, with the potential for advancing the goal of more accurate and timely public health decisions.

Toxicological evaluation of chemicals is poised to take advantage of the on-going revolution in biology and biotechnology. This revolution is making it increasingly possible to study the effects of chemicals using cells, cellular components, and tissues — preferably of human origin — rather than whole animals.

The completed first phase of Tox21 used NCATS' qHTS robotic system to test 2800 compounds in more than 50 assays. The resulting data are published in public databases, such as the National Library of Medicine's PubChem, the US Environmental Protection Agency's ToxCast and Aggregated Computation Toxicology Resource, or National Institute of Environmental Health Sciences' Chemical Effects in Biological Systems. All screening data also have been made available by NCATS on the freely-accessible PubChem database: to date, more than 50 million data points have been uploaded to public databases.

The second phase of this project will test a collection of 10,000 compounds at NCATS. Consortium partners have and will continue to develop a range of secondary and tertiary follow-up assays to further define and characterize activities identified in initial high-throughput screens. All testing results are made public through the NIH and the US Environmental Protection Agency (EPA) chemical toxicity databases and as new data sets arise, the NIH will continue to make them available to the research community.

In addition, NCATS has created a Tox21 chemical inventory browser, which is freely available and provides researchers with additional information about the chemicals.

#### BioAssay Research Database (BARD)

BARD is a chemical biology database that provides well-organized and fully annotated bioassay data generated by the NIH Molecular Libraries Program (MLP). The data has been generated by hundreds of biologists, chemists, informaticians, and engineers that run high throughput screens against a common chemical library of over 350,000 compounds across several hundred biological targets and pathways. The focus on the biological systems has been on unprecedented targets that have been neglected by the pharmaceutical industry.

Drug discovery scientists working on rare or neglected diseases can search for potential therapeutic leads for further pre-clinical development. The scientists can query specific biological targets and find

compounds with desirable properties that modulate the target. These compounds can be further optimized into drug leads through medicinal chemistry optimization.

BARD currently hosts data for more than 350,000 compounds, 4,000 bioassays and over 300 chemical biology or early stage therapeutic development projects. It has been in beta status and will be going into live production status in mid-2014. The data are accompanied by a user-friendly Web-based interface that enables simple searching abilities across diverse chemical biology data.

## <u>Publicly Available Databases for Aging-Related Secondary Analyses in the Behavioral and Social Sciences</u>

The Division of Behavioral and Social Research, Publicly Available Databases for Aging-Related Secondary Analyses in the Behavioral and Social Sciences website (http://www.nia.nih.gov/research/dbsr/publicly-available-databases-aging-related-secondary-analyses-behavioral-and-social) snapshots of selected publicly available data collections supported in whole or in part by the National Institute on Aging (NIA) Division of Behavioral and Social Research to promote understanding of aging populations both domestically and throughout the world. NIA encourages its researchers to develop efficient and feasible data sharing plans, to reinforce open scientific inquiry, and to promote the testing of new or alternative hypotheses and methods of analysis. This compendium is intended to serve as a useful first step in a researcher's search for a potentially suitable dataset to address a particular question or questions of interest. Links to relevant study websites are included for those seeking additional information.

## Assistant Secretary for Planning and Evaluation US Social & Behavioral Insights Team (ISBT)

The Assistant Secretary for Planning and Evaluation is pleased to announce that the US Social & Behavioral Insights Team (SBST), who presented at that meeting, is soliciting proposals for collaboration for the 2014-2015 year.

The SBST works with agencies to embed behavioral insights into the design and delivery of federal programs and to rigorously evaluate their effectiveness. Such interventions can often be implemented quickly and at low cost, yet still have meaningful effects. For example, merely adding a blank space to a flu vaccine mailer where recipients can write down when and where they plan to get vaccinated has been shown to significantly increase uptake.

# <u>Health Resources and Services Administration (HRSA) houses the National Center for Health Workforce Analysis in the Bureau of Health Workforce (BHW)</u>

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.

This spring, the National Center released the findings of the 2012 National Sample Survey of Nurse Practitioners which provides accurate national estimates of the Nurse Practitioner (NP) workforce along

a number of dimensions including aspects of education, certification, and practice of NPs. In the fall of 2013, the following two reports were released; "Projecting the Supply and Demand for Primary Care Practitioners Through 2020," and "The U.S. Health Workforce Chartbook." To access the National Center reports visit the website at <a href="http://bhpr.hrsa.gov/healthworkforce/">http://bhpr.hrsa.gov/healthworkforce/</a>.

## **Flu Mapping Tool**

The National Vaccine Program Office (NVPO), in partnership with CMS, created this mapping tool as a resource for researchers, providers, and health care workers to track influenza (flu) vaccination claims rates of Medicare beneficiaries in real-time.<sup>4</sup> The new tool includes information for every community in the United States.

By clicking on any state or searching for a specific location, the tool generates the number of Medicare beneficiaries living in a specific area and indicates the flu vaccination claims rates. The tool also retrieves flu vaccination claims data for specific racial or ethnic populations within a state or community and shows if there are differences by race in the flu vaccination claims rate. Finally, data for disabled Americans under age 65 and covered by Medicare Fee-for-Service can also be seen.

The mapping tool shows claims data only for those covered by Medicare Fee-for-Service. This includes more than two-thirds of Americans aged 65 and over, as well as disabled Americans under age 65, but this information may not be representative of other groups. This tool should be used to compare relative vaccination rates between different locations, populations and different weeks, months and years. Some flu vaccines given may not be recorded in the claims database due to administration at alternative sites or lags in claims submission and, as a result, the vaccination rates shown here may be an underrepresentation of actual coverage rates.

By tracking Medicare Fee-for-Service claims, updated every week, the tool provides up-to-date flu vaccination claims information for Medicare beneficiaries in every community in the United States. While these data don't convey data for all populations in a given locality, it does provide an excellent snapshot of vaccination coverage for the group at greatest risk for complications - those over the age of 65. The map also displays flu vaccination claims data for specific racial or ethnic populations within a state or community, thereby demonstrating if there are disparities in the flu vaccination claims rate.

## **HealthMap Vaccine Finder**

The HealthMap Vaccine Finder is a free online service that helps consumers locate vaccine providers (e.g., pharmacies and health clinics). By entering an address or zip code, an individual can easily find nearby providers of recommended adult vaccinations. This tool previously only included flu vaccine providers (and was called the Flu Vaccine Finder) and has now expanded to include all vaccines that doctors routinely recommend for adults. The HealthMap Vaccine Finder is an expansion of the Flu Vaccine Finder, and lists more than 50,000 providers across the country that offer flu vaccinations,

<sup>&</sup>lt;sup>4</sup> Claims are defined as requests for reimbursement submitted to CMS by health care providers.

<sup>&</sup>lt;sup>5</sup> The claims rate is the number of flu vaccine claims relative to the number of beneficiaries.

searchable by vaccine delivery type (nasal spray, shot, etc.) and location. The use of the website is free to consumers as well as to providers of adult immunization services. Adult providers who want to increase information to the public about vaccine services available in their practice can upload their information about which vaccines they offer at their location.

#### **Adjudication Manual**

OMHA will issue a manual for OMHA staff containing the day-to-day operating procedures for processing cases, which will also be placed on the OMHA website so the public has access to the manual. The adjudication manual will adopt the most effective and efficient case processing practices, while ensuring a high quality product and adherence with all legal requirements.

It is anticipated that the manual will increase consistency across adjudicators while preserving adjudicator discretion to address the unique circumstances of a case. The manual will also provide 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.

## Medicaid & CHIP Monthly Applications, Eligibility Determinations, and Enrollment Report

Beginning in November 2013, CMS began issuing a series of monthly reports on state Medicaid and Children's Health Insurance Program (CHIP) data, which represents state Medicaid and CHIP agencies' eligibility activity for the calendar month. These reports include state data and analysis regarding applications to Medicaid and CHIP agencies and the State Based Marketplaces (SBMs), eligibility determinations made by the Medicaid and CHIP agencies, and state data on total enrollment in the Medicaid and CHIP programs.

The Affordable Care Act, P.L. 111-148, created a "no wrong door" approach, which means that individuals can apply for health coverage through the Marketplace or the Medicaid or CHIP agency (if it is a separate agency) in their state. Regardless of which "door" they choose, individuals can get eligibility determinations for all types of health coverage, including financial assistance to help pay for coverage, and have their accounts routed to the program for which they are eligible. This means that for a full picture of Medicaid and CHIP activity, the numbers in these reports—which come from the state level—need to be understood in concert with the numbers reported on Health Insurance Marketplace enrollment.

The data included in these reports are submitted to CMS from state Medicaid and CHIP agencies as part of the Medicaid and CHIP Performance Indicator process and supplement data on Marketplace activity released by the HHS. Through the Medicaid and CHIP Performance Indicator process, states report on a common set of indicators designed to provide information to support program management and policymaking. State Medicaid and CHIP programs submit data to CMS on a range of indicators related to application, eligibility and enrollment processes.

All 50 states and the District of Columbia ("states" hereafter) are in the process of implementing the ACA simplifications to the Medicaid and CHIP application and eligibility determination processes and

making technology upgrades to transition to streamlined, data-driven eligibility determination systems. As states shift to these new eligibility and enrollment systems, we will continue to see improvements in reporting capacity.

## Centers for Medicare & Medicaid Services (CMS) Virtual Research Data Center (VRDC)

In November 2013, CMS launched the Virtual Research Data Center (VRDC), a new mechanism for researchers to access CMS data. CMS VRDC (<a href="http://www.resdac.org/cms-data/request/cms-virtual-research-data-center">http://www.resdac.org/cms-data/request/cms-virtual-research-data-center</a>) is a virtual research environment that provides timelier access to Medicare and Medicaid program data in a more efficient and cost effective manner. Researchers working in CMS VRDC will have direct access to approved data files from their own workstations and be able to conduct their analysis within CMS secure environment. They will also have the ability to download aggregated reports and results to their own personal workstation.

Historically, CMS has fulfilled researchers' data requests by preparing and shipping encrypted data files. However, given the rapidly growing demand for Medicare and Medicaid data, the agency wanted to build a less resource-intensive means of responding to data requests from researchers. The VRDC will help CMS meet these demands while also ensuring data privacy and security and reducing the cost of data access for most users.

## <u>Centers for Disease Control and Prevention (CDC) Wide-ranging Online Data for Epidemiologic</u> <u>Research (CDC WONDER) Informatics Program</u>

CDC's Wide-ranging Online Data for Epidemiologic Research (CDC WONDER) Informatics Program supports public access to online databases, reports, references, and links to external data systems containing a wide range of highly valuable public health information. The core of CDC WONDER is a query engine that allows ad hoc queries to over 350GB of online databases. Custom queries can more specifically support a user's needs as opposed to static published reports. More information on the CDC WONDER can be found at: http://wonder.cdc.gov/.

CDC WONDER supports collaboration initiative through engaging in activities across government agencies and with nonprofit organizations. For example, CDC WONDER collaborates on providing statistical analysis and public access to data from data stewards in organizations across the CDC and external partners which include: state health departments, local cancer registries, the National Cancer Institute (NCI), Food and Drug Administration (FDA), the National Aeronautics and Space Administration, the National Oceanic and Atmospheric Administration, and the University of Alabama at Birmingham School of Public Health. CDC WONDER also collaborates with external partners by sharing source code so partners can build and host their own online databases.

CDC WONDER supports transparency initiatives by providing powerful access to public health data which can be used by the public for purposes such as data based policy decision making processes, media or agency reporting, academic research, general curiosity, etc. Public users successfully query a diverse collection of datasets, from a range of sources, which can all be found in one location, and are all accessed through a standard, simple, yet powerful interface, which is configurable to the needs of each

dataset. One of the most important features of CDC WONDER is that it can make more granular level data available to the public that can be made available through other means, such as file downloads, which are restricted to more summarized levels of data due to privacy safeguards. CDC WONDER can provide privacy safeguards by applying, to the results of a user's ad hoc queries, real time suppressions which conform to the data provider's confidentiality agreements and restrictions.

CDC WONDER supports smart disclosure initiative by providing data to consumers via a standard interface to multiple and varying datasets and its capability to make data available to consumers in real time. The public health data available through CDC WONDER allows the consumers to make better informed personal or public policy decisions.

CDC WONDER continues to add new types of public health data as well as recent years of data to existing datasets.

#### 3.3 PROACTIVE DISCLOSURE

## **Proactive Disclosure of Information of Significant Interest**

In an effort to meet the public's need for information and avert the need to submit FOIA requests, CMS proactively makes appropriate information available on CMS website. CMS identifies and posts frequently requested information on the website in accordance with applicable laws. On a semi-annual basis, the Office of Strategic Operations and Regulatory Affairs also sends a data call to all CMS components requesting that they identify information of significant public interest. The information identified is then posted to CMS website, including our FOIA page (<a href="http://www.cms.gov/center/freedom-of-information-act/index.html">http://www.cms.gov/center/freedom-of-information-act/index.html</a>). For example, to increase the ability of the public to access, download, and use data sets that are generated by CMS, we were able to integrate the FOIA web and link to the CMS Data Navigator (<a href="http://dnav.cms.gov/">http://dnav.cms.gov/</a>) which includes 350 data sources.

The CMS Administrator is committed to this initiative and strongly encourages active CMS component participation.

## **Proactive Pre-Disclosure Notification for Contracts**

CMS has incorporated into its contracts a pre-disclosure notification provision to alert contractors that awarded contracts may be released to the public, and to require the contractor to submit to CMS any proposed redactions (under FOIA disclosure exemptions) within thirty (30) calendar days of the contract award. This proactive pre-disclosure notification significantly reduces FOIA processing time and allows contracts that are the subject of high public interest or visibility to be released shortly after being awarded. CMS plans to proactively post awarded contracts at: <a href="http://www.cms.gov/About-CMS/Contracting-With-CMS/ContractingGeneralInformation/">http://www.cms.gov/About-CMS/ContractingGeneralInformation/</a>.

## 3.4 PRIVACY

Per OMB guidance and other requirements, HHS has prepared several privacy compliance reports, which explain how the Department meets privacy requirements. Table 1 provides the name of the report, with the recipient(s) of the report and applicable URLs of websites where the reports can be accessed.

**Table 1. HHS Privacy Compliance Reports** 

Name of Report Submitted by HHS	Recipient	URL of Website where it can be viewed by the public
Senior Agency Official for Privacy Section of the Annual Federal Information Security Management Act Report	Office of Management and Budget, Congress	n/a
Privacy Impact Assessments as Required by Section 208 of the E- Government Act	Public	http://www.hhs.gov/pia/
New or Altered Privacy Act System of Records Reports	Office of Management and Budget, Congress	http://hhs.gov/foia/privacy/sorns.html
New, Altered, or Renewed Matching Program Reports	Office of Management and Budget, Congress	These reports are published on an individual basis in the Federal Register
Biennial Computer Matching Activity Report	Office of Management and Budget	n/a
EO 13636 Privacy and Civil Liberties Assessments	Department of Homeland Security	http://www.dhs.gov/publication/executive- order-13636-privacy-and-civil-liberties- assessment-report-2014
Section 803 report on Privacy and Civil Liberties Activities	Congress, Privacy and Civil Liberties Oversight Board	Posting is pending completion of the report.
Health Insurance Portability and Accountability Act Compliance Report	Congress	http://www.hhs.gov/ocr/privacy/hipaa/enforcement/compliancereptmain.html

#### 3.5 WHISTLEBLOWER PROTECTION

HHS, Assistant Secretary for Administration, Office of Human Resources (OHR), Strategic Programs Division (SPD) will oversee 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.

To date, 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 plans to register to obtain 2302(c) certification from OSC by August 31, 2014, and expects to satisfy all certification requirements by December 31, 2015.

The overall plan for obtaining certification 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.

- Identify points of contact from each operating/staff division to gather information on their
  current procedures, educate them on the 2302(c) certification program and their role, and
  coordinate requirements for local 2302(c) compliance (July 31, 2014). The designated
  contact will be responsible for ensuring compliance for the areas and locations served and
  reporting to SPD annually.
- Add information to OHR's webpage to include educational resources, contact information, and links to the OSC and other relevant websites. (January 2015)
- Issue an email blast from the Secretary to all employees informing them of their rights and remedies. The email will include links to information required
   (<a href="http://www.osc.gov/outreachRequirementsCertification.htm">http://www.osc.gov/outreachRequirementsCertification.htm</a>) for distribution under the 2302(c) certification program (e.g., Your Rights as a Federal Employee, Know Your Rights When Reporting Wrong, etc.) (March 2015) This email blast will be issued annually.
- Issue 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. (October 2015)
- Set-up automatic notification through the HHS Learning Portal to ensure training is provided to and completed by supervisors and managers every three years. (October 2015)

In addition to HHS plans, OIG is pursuing its own certification. OIG plans to register to obtain 2302(c) certification from OSC by June 30, 2014 and expects to satisfy all certification requirements by December 31, 2014. The OIG already meets two of the five requirements for obtaining certification. It provides information about PPPs, the WPA, and OSC as part of its new employee orientation process and its website has a link to the OSC website. The OIG plans to meet two additional requirements -- placing informational posters at all HHS OIG facilities and providing information to all OIG employees about PPPs and the WPA -- by August 31, 2014 (and annually thereafter). It plans to meet the final requirement, which involves training supervisors on PPPs and the WPA, by December 31, 2014. The OIG will also provide training on PPPs and the WPA to all supervisors on a three year cycle.

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 <a href="http://oig.hhs.gov/faqs/whistleblower-faq.asp">http://oig.hhs.gov/faqs/whistleblower-faq.asp</a>. 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, <a href="http://www.mspb.gov/appeals/whistleblower.htm">http://www.mspb.gov/appeals/whistleblower.htm</a>, and OSC (<a href="http://www.osc.gov/">http://www.osc.gov/</a>), 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

The top priority for the Department's Records Management Program is the acquisition of a uniform Electronic Records Management System, which correlates to priority 3(a) (6) in the Presidential Memorandum, *Managing Government Records*, dated November 28, 2011. The decision to pursue such a system was a significant part of the Records Management Transition Plan draft which was updated in 2013 and currently being coordinated throughout HHS. 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 the Office of Management and Budget Memorandum M-12-18 section 2.2 dated August 24, 2012. An Executive Committee, consisting of representatives from the Department and all of its OPDIVs, was established to justify the Electronic Records Management System acquisition, 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 the National Archives and Records Administration (NARA) 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 a prerequisite to acquiring an automated information system that could manage all records for the Department. That prerequisite is met so the Department's highest priority in the Records Management Program is now the acquisition of the Electronic Records Management System.

The system will be deployed to all OPDIVs and STAFFDIVs of the Department of Health and Human Service. The implementation will be a phased rollout to all OPDIVs and STAFFDIVs and is tentatively scheduled to begin the fall of 2014.

By December 31, 2016, the Senior Agency Official shall work with the Agency Records Officer to ensure records schedules have been submitted to NARA for all existing paper and other non-electronic records.

By December 31, 2016, Federal agencies must manage all email records in an electronic format. 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.

## 3.7 FREEDOM OF INFORMATION ACT (FOIA) REQUESTS

## CDC and the Agency for Toxic Substances and Disease Registry (ATSDR) transparency initiatives

CDC and the Agency for Toxic Substances and Disease Registry (ATSDR) takes its transparency responsibility to the public seriously and is committed to providing as much information as possible as quickly as possible. Specifically, the CDC Freedom of Information Act (FOIA) Office has recently improved the FOIA public website to encourage interested parties to search CDC's website containing vast amounts of information and data resources. In conjunction, CDC programs are being actively encouraged to increase their posting of content earlier and more comprehensively. The CDC FOIA Office is also more actively posting information, links to hot topics, and frequently requested information on the FOIA website.

The CDC (including ATSDR) FOIA Office is centralized with a staffing full-time equivalent ceiling of 15 and is currently staffed at 12 which includes two recently hired new employees with FOIA experience. CDC as an agency also has 41 FOIA Coordinators in the program offices that facilitate FOIA routing requests

to responsible program staff that may have records, tracking responses, and providing responsive materials to the central FOIA Office.

The CDC/ATSDR FOIA Office is operating under a significant backlog consisting of approximately 580 cases involving approximately one million pages. CDC has established goals to reduce the backlog and median response time by 10% per year, and increase the proportion of responses completed within 20 days through the following initiatives:

- A review of the FOIA process was conducted resulting in several improvement action items which are underway.
- CDC is upgrading its systems supporting FOIA processing including:
- Transition to the latest version of the FOIA system (FOIAXpress version 9) which includes some key new features and functions to improve FOIA handling efficiency.
- Investments in new hardware (servers, scanner) to provide better document handling performance.
- Development of a SharePoint solution to automate the handling of e-document submissions from program offices to the FOIA Office
- The FOIA Office has just completed an extensive FOIA Standard Operating Procedure (SOP) manual to guide FOIA staff in efficient and consistent handling of the process.
- A request for proposal for FOIA contractual support services has been released to initially acquire three FOIA analysts and the resulting contract will be extensible to increase the number of contract staff as may be needed. The contract is anticipated to be awarded by June/July 2014. This will increase the overall FOIA staffing by 25%.
- The FOIA Office has also recruited an attorney to join the FOIA Office on detail to assist with reducing the backlog of appeals.

The CDC FOIA Office utilizes a multi-track system for processing requests and strives to strike a balance when processing simple and complex requests. FOIA staff communicates regularly with requesters. FOIA staff consults with program staff to determine the types of records in our files, and then works with requesters to ascertain the types of documents in agency files which are most beneficial to the requester.

Subject Matter Experts are engaged at the program level to review predecisional portions of documents and are encouraged to release as much information as possible. Absent a strong foreseeable harm justification, documents, or portions thereof, will be released without redactions.

CDC's headquarters and FOIA Office are in Atlanta, GA. CDC's FOIA Office holds internal training sessions with FOIA staff as well as with program officials and program staff throughout the year. CDC's FOIA Office arranged to have Food and Drug Administration (FDA)'s long-standing FOIA Officer to conduct a training session for CDC FOIA staff in February of 2014 for two days. CDC supports the Department of Justice and Office of the Assistant Secretary for Public Affairs (ASPA) webinars.

The CDC website is being updated regularly and links are provided to program websites to allow the public to get up-to-date information, thereby possibly eliminating the need for some FOIA requests. CDC's public FOIA website is at: <a href="http://www.cdc.gov/od/foia/">http://www.cdc.gov/od/foia/</a>.

## CMS FOIA Web Page Redesign

CMS is continuously reviewing and updating its website to facilitate the FOIA process and promote existing online resources. The Office of Strategic Operations and Regulatory Affairs launched a redesign of the FOIA pages on CMS.gov (http://www.cms.gov/center/freedom-of-information-act-center.html), creating a feature that allows a requestor to check the status of their FOIA request by entering the control number and personal identification number (PIN) provided in the FOIA acknowledgement letter. CMS also established a "Look What's New" section to direct the public to newly posted datasets, which in the spirit of openness and transparency includes records identified as of sufficient public interest to warrant automatic disclosure on the agency's website. This section contains the link to large structured datasets including the highly sought after CMS physician referral pattern data and the Medicare provider utilization and payment data. From the FOIA webpage, the public can also access the data.medicare.gov (https://data.medicare.gov/) and data.cms.gov (https://data.cms.gov/) websites to access other CMS datasets on hospitals, nursing homes, health plans and many other health care settings and subjects.

CMS is working collaboratively across CMS to continue to improve the timeliness and visibility of datasets and other information posted to the website.

## **CMS FOIA Staffing and Organizational Structure**

In order to respond to the large volume of FOIA requests, CMS operate its FOIA program through both a centralized and decentralized FOIA network. The Office of Strategic Operations and Regulatory Affairs, Openness, Transparency and Accountability Group (OTAG), Division of Freedom of Information (DFOI) is the organization that oversees and manages the FOIA program for the agency and is the focal point for implementing the provisions of the Act. The Regional Offices and corresponding Medicare Administrative Contractors provide coordination and responses to the majority of simple, direct reply requests that do not involve disclosure analysis or redaction of records.

DFOI is tasked with addressing the most complex requests received by CMS and its contractors. The responsive records involve detailed disclosure analysis to determine whether it is necessary to apply statutory exemptions to protect personal privacy, confidential business, pre-decisional and deliberative information from disclosure. In general, CMS follows a government-wide practice of first-in, first-out request processing as a result of case law determinations in the Federal Courts.

CMS is pleased to report a FOIA backlog reduction that exceeded the 10% Presidential mandated goal in our FY 2013 Freedom of Information Act (FOIA) Annual Report to the Department. In keeping with the Department's open government and transparency initiatives, we made substantial improvements in our FOIA activities including:

Reducing our backlog – initial requests that have not been processed within 20 working days
 to 1,426 at the end of FY 2013, a 16.4 percent reduction from FY 2012.

- Reducing our total pending initial FOIA requests (open plus backlog) to 3,383 at the end of FY 2013, an 8.6 percent reduction from FY 2012.
- Processing 99.8 percent of our remaining initial FOIA requests from FY 2011.
- Processing 99.4 percent of our remaining FY 2012 open FOIA requests.
- Processing 94.8 percent of the 51,364 FOIA requests received in FY 2013.
- Closing the 10 Oldest Initial Requests and 10 Oldest Appeals that were reported in the FY 2012 CMS Annual FOIA Report.
- Implementing the FOIA Contractor Portal within the Strategic Work Information Folder Transfer (SWIFT) system to provide a global tracking and reporting system for all FOIA requests administered by CMS and the Medicare Administrative Contractors, Fiscal Intermediaries and Carriers.
- Working within CMS and with other HHS components to put more useful CMS materials on the Web and to liberalize our disclosure policies.
- Maintaining the resources we committed to FOIA, while meeting our commitments under the Affordable Care Act and ongoing programmatic responsibilities.
- The updated SWIFT FOIA system supports all aspects of the FOIA program, including: redaction, exemption tracking, letter generation, fee tracking, invoice generation, and appeals tracking. As a result, CMS has improved FOIA processing times and reduced the backlog of open requests from 10,312 in FY 2009 to 1,426 in FY 2013. The SWIFT FOIA technology facilitates an electronic workflow process that is less prone to human error, reportable, and visible, for CMS, which administers approximately 80% of the FOIA requests received by the U.S. Department of Health and Human Services.

#### **FDA FOIA Backlog Reduction**

- FDA will continue to focus on reduction of its FOIA backlog. Since 2007, FDA has reduced its
  backlog by approximately 70 percent. The OPDIV will focus on training of existing FOIA staff
  and hiring additional full-time equivalent in certain OPDIV components. In addition,
  components will review their operating procedures to determine where efficiencies can be
  improved.
- FDA will utilize technology and transparency initiatives to reduce the number of incoming FOIA requests by making records available proactively.
- FDA will work proactively with requesters to assess their needs, negotiate document production, and reduce FOIA processing time.
- FDA will refresh its FOIA tracking and document storage system

#### **Indian Health Service (IHS) FOIA Backlog Reduction**

The Indian Health Service (IHS) FOIA backlog is reduced due largely to Transparency, Participation and Collaboration. We have only three FOIA cases in backlog for the first time in many years.

There are several factors that led to this achievement. Most importantly, it is all facets of providing excellent customer service by establishing and maintaining working relationships with IHS employees. This was done with the help of training, consultations, and the guidance being provided to requesters and IHS staff so that they can ensure that the FOIA responsibilities are successfully carried out. We anticipate that by the end of the year, for the first time, IHS will have a FOIA policy.

In the spirit of transparency, the IHS has released more information relating to contracts that it had previously withheld and put under the "umbrella" of the protection of information for business entities. The discretionary releases dealt more with information related to solicitations or contracts; or information about the awards of grants, rather than detailed commercial information. Specifically, this would be any information such as Data Universal Numbering System Number, Insurance Information, and some budget/financial breakdowns as they relate to IHS funds and/or American Recovery and Reinvestment Act funds.

We continue to post widely-requested information on the IHS FOIA website and provide the most up-to-date information to the public, by maintaining a strong relationship with those program offices that we have worked with, in order to be provided the responsive information being requested. For instance, we have consulted with several program offices at the Headquarters level to add their program sites on the FOIA website; and have discussed with those program offices about what information they may have to contribute to the Frequently Requested Records portion of the FOIA staff site and also what links (to other sites or program pages) that they believe would be helpful to the public.

We continue to ensure that the FOIA program's website is easily read and accessible under Section 508 of the American Disability Act. This year, the IHS website has undergone many improvements and kept in line with those changes (not specific to Section 508 accessibility only). In line with those changes, the FOIA website was continuously tested to be sure that it was still accessible and that documents were complete and easily accessed under the format that they were posted. We continue to "test" the links each quarter and respond quickly to feedback from others about the ease of our site. If problems arise, FOIA staff work with IT staff to have them corrected as soon as possible.

Another factor that we feel led to the reduction in the backlog was also the expertise of the FOIA Coordinators at the Area level. Because those coordinators have extensive background in health records, knowledge of the FOIA, HIPAA, records management, and vast knowledge of their area programs; we were better able to receive complete records in response to a request for materials.

We posted several PowerPoint presentations on FOIA and Privacy Act to explain the difference between the two to the public.

http://www.ihs.gov/FOIA/index.cfm?module=dsp foia elec read room

#### National Institutes of Health (NIH) FOIA Process

NIH has a very effective system for responding to requests. FOIA processing at NIH is decentralized; in addition to the central NIH FOIA Office, each NIH Institute & Center (IC) and several NIH Office of the Director (OD) components has its own FOIA Requester Service Center staffed by a FOIA Coordinator with release authority. By having processing located directly in the IC, the FOIA Coordinators have greater knowledge of the location of requested files, which decreases search time. Because the FOIA Coordinators and the Program Staff are colleagues within the same organization, there is greater cooperation regarding reviewing proposed redactions which decreases review time.

Requests may be sent to either the NIH FOIA Office or directly to the IC/OD component FOIA Requester Service Center. Contact information is located on the NIH FOIA website. The FOIA Coordinator identifies all offices within the component reasonably likely to have responsive records and initiates a search. All responsive records are reviewed and if nothing is to be denied, the FOIA Coordinator will process the records and respond directly to the requester.

Any records requiring a denial are forwarded to the NIH FOIA Office for review, along with copies of all relevant correspondence, the records for denial, and a detailed program statement explaining the reason for the denial. The program statement must describe the harm that would be caused by release of the material.

#### **Steps Taken to Reduce Backlog:**

Since the issuance of the Open Government Directive, NIH has reduced its backlog of FOIA requests from 70 requests at the end of FY 2009 to 26 requests at the end of FY 2013. The most effective and simplest step continues to be regular monitoring of the list of pending requests, identifying those that have been pending the longest and meeting with the responsible FOIA Coordinator and FOIA Public Liaison. Enhancements made to the NIH FOIA Tracking System enable the FOIA Officer to monitor all agency activity as a whole as well as monitor the activity of individual FOIA Requester Service Centers. In addition, FOIA Coordinators can monitor their own request load with ease. Increasing backlogs can be spotted and addressed before they become problems. Finally, prompt triage of incoming requests to identify those where negotiation may be appropriate and effective also has helped to reduce processing times and increase requester satisfaction.

Each NIH FOIA Requester Service Center has a FOIA Public Liaison. A complete list is located on the NIH FOIA website: http://www.nih.gov/icd/od/foia/servicecenter.htm.

#### **Program Support Center (PSC) Backlog Reduction**

As part of our efforts to reduce our number of pending requests (as well as the pending requests of the PHS OPDIVS whom we service on appeal), we offer various training programs upon request that are tailored to the audience.

For example, we are planning to present a "cross-training" to one of our program offices which is meant to educate both program personnel and FOIA personnel. This program office, the Office of Research Integrity (ORI), accounts for the majority of PSC FOIA's pending requests. The goal of this presentation

is to inform the program personnel of their requirements under the FOIA as well as PSC FOIA's expectations of them. It will also inform the FOIA staff of the special concerns faced by ORI and other issues specific to that program. This sort of training will foster a trust between the office staff and further PSC FOIA's understanding of the records which will, in turn, result in processing requests more quickly.

PSC FOIA has also hired additional staff to work on pending requests and appeals, including a temporary contract worker. This additional workforce has already begun to see significant success. As stated above, in the past two months alone, PSC FOIA closed more requests and appeals than it had previously this fiscal year.

#### **HHS QUARTERLY FOIA DATA**

Quarterly FOIA data reported to the Department of Justice and posted on <a href="www.FOIA.gov">www.FOIA.gov</a> is publicly available at: <a href="http://www.hhs.gov/foia/quarterly/index.html">http://www.hhs.gov/foia/quarterly/index.html</a>

#### **Links to Agency Annual FOIA Reports**

http://www.hhs.gov/foia/reports/index.html

http://www.hhs.gov/foia/reference/2014 intro.html

#### 3.8 WEBSITES (Digital Services Strategy)

The Department's signature website is <a href="www.hhs.gov">www.hhs.gov</a>. In addition, each OPDIV 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 <a href="http://www.hhs.gov/digitalstrategy">http://www.hhs.gov/digitalstrategy</a>.

The Department is currently engaged in a year-long 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 foundation aspects of Project-H. For example, we have reduced the number of files on the site by 79% (from 215,000 to 45,000). We have designed and are implementing a vastly improved search program. Our Voice of Consumer application now appears on every page and provides critical customer input into both our redesign and how/what we communicate. We have developed and deployed a new API-based content syndication system and storefront that allows the average web manager to embed HHS content on their site. We are integrating social media, expanding beyond Facebook and Twitter to incorporate emerging third-party platforms to engage diverse audiences that may never visit a government website.

HealthData.gov (<a href="http://www.healthdata.gov">http://www.healthdata.gov</a>) 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 healthcare ecosystem, from researchers to technology developers, and healthcare professionals to academia. Any organization or individual is free to employ the data to solve problems in the transformation of our nation's healthcare system through data driven innovations in areas such as: research; technology development; healthcare delivery; academia; policy making; and human services delivery.

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.

Here are some of the ways HHS seeks opportunities for public engagement:

- HealthData.gov (http://www.healthdata.gov)
  - Through this catalog data is available in multiple formats for maximum utilization by health care ecosystem participants. Human readable data and machine readable data formats are accessible which are spawning and feeding key transformations across health care and the delivery of human services. HHS is working to make broader volumes of machine readable data available.
  - The "Ideas" tab (<a href="http://www.healthdata.gov/ideas">http://www.healthdata.gov/ideas</a>) on the site is designed to invite the public to provide feedback to HHS. An idea could be anything from the submissions of data that you'd like to see cataloged on the platform, to ways you would like to see the site improved, or suggestions for communications about data assets and their uses. These submissions are very informative for our data liberation strategy so send in your great ideas! The section is divided into "Most

Recent" submission which is ordered by the date the idea was posted, and "Most Popular" which are ranked by the number of public votes that idea has received. Each idea can be voted on by the public using a five (5) star rating system (one (1) is the lowest rating, five (5) is the highest).

- The "Q & A" tab (<a href="http://www.healthdata.gov/questions-answers">http://www.healthdata.gov/questions-answers</a>) offers users an opportunity to ask questions and receive answers from Health Data Initiative (HDI) staff about the data. HHS is working to associate a direct point of contact individual, by name and email address, with each data set listing in the catalog. This will allow direct interactions about the data with the experts who have cataloged it. The tab is broken down by "Most recent" and "Most popular".
- Our Blog (<a href="http://www.healthdata.gov/blog">http://www.healthdata.gov/blog</a>) offers a robust source of information about the HDI's activities including the availability of new data, some of the creative and innovative uses of health data, and the technological advancement of healthcare and human services delivery supported by data's broadening availability.
- The HDI staff makes every attempt to address ideas, questions and answers, and blog responses in a timely fashion.
- Health Datapalooza! (<a href="http://www.healthdatapalooza.org">http://www.healthdatapalooza.org</a>) This perennial health data event is a favorite among entrepreneurs, innovators, policy makers, data geeks, researchers and more. The HDI is widely represented during this event put on by the Health Data Consortium (<a href="www.healthdataconsortium.org">www.healthdataconsortium.org</a>), a public private partnership between government, non-profit, and private sector organizations working to foster the availability and innovative use of data to improve health and health care. HHS welcomes this opportunity to engage face-to-face with the many innovators that are using, or seeking to use, publicly available sources to support their work and initiatives.
- Social Media More than ever before topical conversations are occurring through social media and the open health data movement is no exception.
  - You can follow the HDI on Twitter @HealthDataGov. From this account you will see announcements about new opportunities, new blog posts, and information from others on Twitter that we think is important (which could also be something you post).
  - Join the health data community online using the Facebook page U.S. Department of Health and Human Services Innovations! <a href="https://www.facebook.com/pages/US-Department-of-Health-and-Human-Services-Innovations/443533355685557?">https://www.facebook.com/pages/US-Department-of-Health-and-Human-Services-Innovations/443533355685557?</a> <a href="https://www.facebook.com/pages/US-Department-of-Health-and-Human-Services-Innovations/443533355685557?">https://www.facebook.com/pages/US-Department-of-Health-and-Human-Services-Innovations/443533355685557?</a> <a href="https://www.facebook.com/pages/US-Department-of-Health-and-Human-Services-Innovations/443533355685557">https://www.facebook.com/pages/US-Department-of-Health-and-Human-Services-Innovations/443533355685557?</a> <a href="https://www.facebook.com/pages/US-Department-of-Health-and-Human-Services-Innovations/443533355685557">https://www.facebook.com/pages/US-Department-of-Health-and-Human-Services-Innovations/443533355685557</a>? <a href="https://www.facebook.com/pages/US-Department-of-Health-and-Human-Services-Innovations/443533355685557">https://www.facebook.com/pages/US-Department-of-Health-and-Human-Services-Innovations/443533355685557</a>? <a href="https://www.facebook.com/pages/US-Department-of-Health-and-Human-Services-Innovations/443533355685557">https://www.facebook.com/pages/US-Department-of-Health-and-Human-Services-Innovations/443533355685557</a>? <a href="https://www.facebook.com/pages/US-Department-of-Health-and-Human-Services-Innovations/US-Department-of-Health-and-Human-Services-Innovations/US-Department-of-Health-and-Human-Services-Innovations/US-Department-of-Health-and-Human-Services-Innovations/US-Department-of-Health-and-Human-Services-Innovations/US-Department-of-Health-and-Human-Services-Innovations/US-Department-of-Health-and-Human-Services-Innovations/US-Department-of-Health-and-Human-Services-Innovations/US-Department-of-Health-and-Human-Services-Innovations/US-Department-of-Health-and-Human-Services-Innovations/US-Depa

 The HDI is also participating in communities on LinkedIn, bringing the information directly to you in established LinkedIn Groups that have been working in the areas we care about the most. Look for us in various communities on LinkedIn.

#### 3.9 PUBLIC NOTICE

There are many avenues through which HHS informs the public about significant agency activities and business. ASPA serves as the Department's principal public affairs office, leading efforts across HHS to promote transparency, accountability, and access to critical public health and human services information through multi-channels to the American people.

Collectively, ASPA-managed websites (including HHS.gov and other sites) received 41.5 million visits in FY 2013 by over 32 million unique visitors. These visitors benefitted from substantive improvements to HHS.gov including a significant refresh of the HHS.gov home page and the Secretary's site. For example, in June 2013, ASPA launched HHS.gov/HealthCare, a website for consumers who are interested in learning about ACA benefits and provisions. The site averages more than 66,000 visitors each week. The site has more than 30 blogs featuring announcements and information on ACA benefits and the Marketplace. ASPA has written the majority of the blogs.

ASPA strategically uses social media and digital services to support the larger communications goals of HHS and share news and vital health information. HHS.gov launched an official HHS Facebook page in June 2013, which reached nearly 70,000 likes by the end of September 2013. The HHS.gov Twitter account (@HHSgov) went from 205,000 followers in October 2012, to 307,000 followers by the end of September 2013.

ASPA has worked diligently to improve the infrastructure required to maintain a robust digital program. In FY 2013, ASPA completed the transition of all Internet websites and web applications hosting from dedicated physical servers in a government datacenter to a cloud infrastructure. ASPA also successfully completed a multi-year project to raise the standard of 508 compliance for all HHS-managed websites. Over 95 percent compliance was achieved across Department websites.

Additionally, the HHS Entrepreneur program is supporting ASPA's multi-year Strategic Communications Planning Project. This project is modernizing how departmental publications and on-line content is developed and reviewed. The result will help ensure that content is audience driven (consistent with the Digital Government Strategy) and outcomes that demonstrate increased impact are common practice.

To make sure that the public gets accurate health care, public health, and human service information in a timely and transparent manner, ASPA plays a key role in Department-wide coordination of daily news announcements ASPA processed 7,696 interview requests, issued 181 news releases and 82 media advisories, and reviewed 921 OPDIV news releases, advisories, and other press materials on topics

including HIV/AIDS, food safety, disease outbreaks, mental health, and suicide prevention. One important way in which the public is made aware of upcoming Federal Advisory Committee Act (FACA) meetings is through the Federal Register. Notices of upcoming FACA meetings must be published at least 15 days in advance in the Federal Register. Committees will also put dates of their meetings on their website. The FACA Database (<a href="http://www.facadatabase.gov/">http://www.facadatabase.gov/</a>) contains a public listing of all the HHS Committees (<a href="http://facadatabase.gov/committee/committees.aspx?aid=76">http://facadatabase.gov/committee/committees.aspx?aid=76</a>) and the committee websites. A second source of information about agency activities and business can be obtained through the main HHS website. The HHS Assistant Secretary for Public Affairs provides media advisories for important HHS events and also offers email updates and RSS Feeds on important HHS activities via the news page (<a href="http://www.hhs.gov/news/email/index.html">http://www.hhs.gov/news/email/index.html</a>). In addition, the HHS operating and staff divisions maintain their own calendars of events, subscription services, public bulletins, and social media sites.

In addition to ASPA, the Federal Register also provides an important source for public information about upcoming Federal Advisory Committee meetings. The FACA Database (<a href="http://www.facadatabase.gov/">http://www.facadatabase.gov/</a>) contains a public listing of all the HHS Committees and their websites.

#### 3.10 CONGRESSIONAL REQUESTS

HHS follows a workflow process when responding to Congressional requests. The administrative process, along with the agency's staffing and organizational structure may be found on our Open Government website at:

http://www.hhs.gov/open/plan/opengovernmentplan/transparency/requestsforinfo.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 <a href="http://www.hhs.gov/open/plan/opengovernmentplan/transparency/requestsforinfo.html">http://www.hhs.gov/open/plan/opengovernmentplan/transparency/requestsforinfo.html</a>.

#### 4 PARTICIPATION AND COLLABORATION

#### **IDEA Lab**

The IDEA Lab has several initiatives focusing on participation and collaboration among HHS agencies: HHS Innovates; HHS Entrepreneurs; HHS Ignite; HHS Ventures; HHS Competes; and HHS Buyers Club. HHS Innovates is a mechanism through which HHS recognizes, rewards, and inspires innovation. Launched in 2010, this contest has undergone six rounds of competition to date. HHS employees have submitted nominations of innovations for nearly 500 exciting new staff-driven innovations, and over 60,000 votes have been cast by our employees during the community voting phase. Over the last two rounds of the contest, we have opened up the voting to include input from the public. During this time, over 55,000 page hits were recorded, with our analytics demonstrating viewings from all 50 states and the territories. The opportunity for open voting on the selection of winners by the public brings opportunities for the Department to engage with the public to learn about innovation activities at HHS. As a result of the public engagement, a number of HHS-led innovations have scaled and been further adopted outside of the confines of HHS. Over the coming years, we plan to make continual enhancement to the program as we experiment with new ways of recognizing employee-led innovation.

The <u>HHS Entrepreneurs Program</u> is a cross-cutting opportunity focused on leveraging the expertise, knowledge, and skills of experts from outside the federal government in partnership with internal teams to address major mission-related challenges. This program was launched in early 2012 and is now in its third cohort. Additionally this program has served as the model for the Presidential Innovation Fellows Program. The HHS Entrepreneurs Program aims to bring external ideas and expertise into HHS's own innovation process and rapidly create, develop, engage, and accelerate innovation. Startup organizations have demonstrated that rapid iteration between various versions or features of a product can yield success. Rapid iteration techniques create valuable products and/or solutions quickly while minimizing waste (time, effort, money) in the development cycle. HHS would like to boost innovation by working with external expertise to create a risk-taking culture that encourages dynamic new models of business. More information about the fellows program can be found at:

http://www.hhs.gov/idealab/pathways/hhs-entrepreneurs/.

#### **HHS Buyers Club**

The HHS Buyers Club, launched in April 2014, is a project primarily focused on addressing a critical problem in Government, effective and efficient procurement of information technology. Given the expansion and impactful role of digital services throughout government, there are many opportunities to improve existing procurement methods used to support government services, directly benefitting the public. Government access to and use of technologies that support data and information management are lagging behind the private sector. According to the 2013 Chaos Manifesto (http://www.versionone.com/assets/img/files/CHAOSManifesto2013.pdf) from the Standish Group

(<a href="http://www.standishgroup.com/">http://www.standishgroup.com/</a>), all IT projects in excess of \$10 million were found to be challenged or failed, 52% and 48%, respectively. Of course, this only leaves a 10% success rate. Innovative strategies to leverage federal acquisitions processes are needed to seek both better value and outcomes for the services we provide the public. Increasing the success rate requires participation and collaboration by key stakeholders throughout each acquisition, from identifying the problem/need to ensuring deliverables are met. The following three elements are essential for the aforementioned:

- 1. Testing innovative procurement methodologies for IT service acquisition (and sharing the results in Use Cases for everyone to benefit),
- 2. Developing newer, easier, and effective procurement models and processes, and
- 3. Engaging all key stakeholders with effective Education/Outreach

Collaboration and participation by OPDIVs and STAFFDIVs is encouraged as it will exponentially improve outcomes, eliminate barriers, and lead to concentrated strategic sourcing across the agency.

#### **HHS Ignite & Ventures**

HHS Ignite and HHS Ventures support projects at different stages of maturity: Ignite is for the testing of new ideas; Ventures is for the scaling of proven ideas. Both efforts catalyze internal project ideas that can be completed within very compressed time frames. Teams selected into HHS Ignite are provided support over a 3 month period; Ventures teams are given 9. These projects are exploratory in nature. Selected teams are introduced to lean startup as a methodology for problem solving and project implementation. In the entrepreneurial spirit, Ignite and Ventures projects are iterative, their impacts measurable, and their solutions scalable.

By exposing teams to a network of innovators and equipping them with the methodologies and tools used by successful startup companies, HHS Ignite and HHS Ventures provide a space in which small HHS-led teams can try new ways of carrying out the HHS mission.

As these efforts are cyclical, the milestones are as well. Milestones include: solicitation of proposals; reviewing and selecting proposals; a 'Boot Camp' to kick-start the projects; a 'shark tank' at the end of the projects where results are presented; evaluation of the projects' impacts.

Ignite supports small teams with ideas that come from all across HHS. While operating within Ignite, project teams are exposed to modern ways of operating which include those upheld by the President's Open Government Directive. Teams are asked to report on a regular basis the progress of their efforts. Teams are encouraged to "get out of the building" and interact directly with potential end-users within Industry and the populace. Ignite and Ventures also employ "mentors" from the private sector to provide feedback and methodological coaching to the HHS-led teams.

Further, while these teams must be led by HHS-staff person, many teams include individuals from outside of government.

#### **HHS Competes**

In the last 2 years, HHS, through its HHS Competes program, has seen a tremendous growth in the use of crowdsourcing tools to openly engage and partner with the public to identify and solve solutions to tough problems. Over 100 crowdsourcing prize competitions have now been run by or in partnership with HHS since 2011 under the America COMPETES Reauthorization Act, P.L. 110-69. Many of these competitions were designed to solicit direct input from the public on important issues such as smoking, maternal health, cancer survival, accessibility of health information, suicide prevention, high-risk drinking, patient empowerment, ulcer prevention, and heart disease. Some notable highlights on past and current/future are below:

Office of the National Coordinator for Health IT – i2 (Investing in Innovation)

ONC concluded its trailblazing i2 challenge contract, through which it ran 27 individual competitions were administered, many of which were done in collaboration with other HHS agencies and even other federal agencies outside HHS. The initiative resulted in a number of advances in creating, through crowdsourcing with the public, a suite of software and mobile applications that impacted healthcare across many domains. ONC is currently following this up with another initiative to pilot health IT products in hospitals, communities, and direct to consumer settings.

FDA launching Food Safety Challenge

The FDA will soon announce a prize competition that will challenge the public to identify and demonstrate the feasibility of next generation technologies for food-borne pathogen detection. This is a direct effort by FDA to employ collaborative and participatory tools to truly identify the most promising solutions from across the United States.

• My Air My Health Challenge

HHS's collaborative effort with EPA led to a successful prize competition called My Air My Health to challenge the public to propose technologies to better collect personal health data linked with air quality data in an effort to better understand their relationship.

Additionally, HHS is currently expanding its offering of resources to agencies interested in participating in crowdsourcing activities. HHS is in the process of awarding a series of contracts, each in a specific category of prize competition (ideation, communications, scientific, hardware, and one for a simple DIY web platform) to crowdsourcing management and platform vendors. HHS has also begun creating a crowdsourcing learning series that will be publically available and offer lessons drawn from past experiences and current expertise. In the spirit of open government, HHS is also making data on its past crowdsourcing activities, including success metrics, open and publically available on its IDEA Lab website.

### The Office of Family Assistance (OFA) HHS Entrepreneurs Project

The Office of Family Assistance (OFA) was one of six programs approved by former Secretary Sebelius to participate in the HHS Entrepreneurs Program. The HHS Entrepreneurs Program is a Departmental initiative established to create a culture that supports risk-taking and accelerates innovation. By

participating in the HHS Entrepreneurs Program, OFA seeks to improve grantee program implementation to better meet the needs of the low-income populations it serves through the adoption of a low cost, replicable methodology to better assess grantee client problems and identify solutions. OFA provides \$235 million in discretionary grants annually to improve the lives of low-income families by promoting economic self-sufficiency, responsible fatherhood, healthy marriages, and family strengthening. Two issues arise with monitoring awarded grants:

- a. service delivery does not always align with the day-to-day realities and challenges faced by low-income individuals and families, interfering with their ability to access and benefit from the programs that grantees provide; and,
- b. grantees may not have the staff, time, or expertise to conduct analyses and/or develop solutions to address these barriers.

To address these issues, OFA seeks to learn the design-thinking discipline to equip its grantees and staff with replicable approaches, to assess, create, identify, and implement innovative solutions, to common challenges related to service delivery and program implementation. OFA's interest in learning design thinking is not only to provide technical assistance to its grantees and to build capacity of its grantee organizations, but it also seeks to integrate the discipline of design thinking internally, so as to become a more design-minded organization. A simplified acquisition solicitation was posted in March 2014. For more information on the content of the contract related to this initiative, please view the solicitation in FedBizOpps

(https://www.fbo.gov/index?s=opportunity&mode=form&id=607315225e4bd1b3c745de8db2fd0010&tab=core&cview=1).

OFA is in the process of transforming its internal culture to one that is more design-centered and providing formal training in design thinking for both grantees and OFA staff.

#### Pill Image Identification Challenge

The 3D Informatics Program at NLM has created an open source database of over 5,000 pill images, complete with their associated identification metadata. As the only open source resource for prescription solid form pharmaceuticals, it offers an important research opportunity in automated pattern recognition. To speed the development of algorithms to dynamically recognize and identify unknown pills, NLM is planning a public challenge initiative for FY2015. The pattern recognition community will be invited to develop pill recognition algorithms that will be tested against a series of pill pictures taken on mobile phones. The submission that accurately identifies the most pictures will be the winner.

#### **NIAAA's New Twitter Program**

Addressing the need for transparency, participation, and collaboration, NIH, National Institute on Alcohol Abuse and Alcoholism's (NIAAA's) Twitter account (@NIAAAnews) provides timely updates on alcohol-related news to thousands of individuals and organizations. In its first year, the NIAAA's Twitter

feed attracted more than 8,000 followers, a level of popularity that illustrates the NIAAA's success in providing needed information in a "form that the public can readily find and use." The NIAAA's Twitter followers receive messages highlighting scientific advances, free publications, public exhibits, and other current events related to alcohol use disorders. Through Twitter, the NIAAA is able to engage the public and "tap into the expertise of individuals and organizations across the country" -- private stakeholders, nonprofit groups, academic research centers, health professionals, treatment providers, and government agencies. It is a transparent platform that gives the public the opportunity to learn and ask questions about publicly funded alcohol research. To date, the NIAAA has hosted two Twitter chats (one on holiday drinking and another on treatment options) that allowed a public conversation with NIAAA experts. Additional chats are planned.

#### **PRISM Online Training**

PRISM Online Training is an hour-long Web-based workshop that helps researchers and other health care professionals use clear, audience-centered language in consent forms and other print materials for patients and study subjects. The training is based on well-documented health literacy principles and includes: background information on health literacy and readability, a detailed overview of plain language writing and editing strategies, before-and-after examples, editing exercises, and links to other helpful resources. The training is in the public domain and has reached more than 1000 users to date, with more than one-third completing a course evaluation and providing consistently high ratings. NIH, CDC, and Health Literacy Missouri are among dozens of organizations nationwide that drive traffic to PRISM through links on popular resource pages.

# National Institute on Alcohol Abuse and Alcoholism's (NIAAA) College Presidents Working Group and Interventions Matrix project:

Each year, almost 2,000 college students die from alcohol-related unintentional injuries, nearly 100,000 are victims of alcohol-related sexual assault or date rape, and approximately 700,000 are assaulted by another student who has been drinking. To help prevent these and other harmful outcomes, the NIAAA has sponsored a longstanding initiative to bring research to the forefront of the national discussion about college drinking. Currently, the NIAAA is spearheading a collaborative process known as the College Presidents Working Group. The purpose of this working group is to engage university presidents in an ongoing dialogue about the problem and to create a tool that will help administrators evaluate what they are currently using and choose wisely from among dozens of possible college drinking interventions going forward. This initiative embodies the open government call for participation and collaboration. Two development teams, each comprised of three highly respected college drinking researchers, created a comprehensive data base that characterized available interventions, according to a long list of attributes including the quality of the research supporting them. The data was then reviewed by 10 top researchers in the field, as well as, student life staff from the participating schools in the working group. The NIAAA is receiving additional input from 30 schools participating in Dartmouth College's National College Health Improvement Plan, a multi-year learning collaborative to address the problem of excessive alcohol use and related harms on campuses across the nation. Collectively, these

ongoing activities are informing the work of the NIAAA, as well as being disseminated throughout HHS, through the NIAAA's participation in the Behavioral Health Coordinating Council.

### An AHRQ Research Grant Program on Patient and Consumer Input for Implementing Evidence-Based Health Care

The purpose of this research grant program is to develop and demonstrate the use of deliberative methods in convening patients or the public to address complex issues related to the implementation of evidence into health care policies, programs, or other decisions that are designed to improve care, health outcomes, and research on improvements in a specific setting.

In an ideal clinical decision-making context, the patient plays an active role in deciding the best course of care based on his or her own values and preferences in relation to the available evidence. Equally important, patients and the public have a role beyond the immediate clinical decision-making context, providing important insights at all levels of the health care system to assist clinicians, researchers, administrators, and policymakers in developing, designing, and managing health system policies, health care delivery, and research programs to best meet public needs.

Increasingly, our society is gaining an appreciation of the differences in viewpoints and priorities that can occur among patients, clinicians, researchers, and policymakers around an objective but often incomplete body of evidence. As such, there is an expanding need to learn how best to bring the patient's and public's perspectives into research and policy decisions that affect health care. AHRQ completed a Deliberative Methods Demonstration project in 2013, with results identifying promising attributes of these methods for gaining insight into public views. This newly initiated AHRQ research grant program will fund innovative projects that promote the active contribution of patients and the public in learning how best to implement and integrate evidence-based health care information in specific, community-based decisions affecting the quality of care.

Research projects funded under this new grant initiative will:

- demonstrate the use of deliberative methods for obtaining information from patients, consumers, or the public that is directly relevant to health care or health care research decision-makers;
- feature a partnership with an organization that is committed to patient or public input and the use of that information to inform specific decisions to improve health care or research; and
- evaluate the effectiveness of the particular deliberative approach used.

#### The National Vaccine Program Office Annual Report: The State of the National Vaccine Plan

The NVPO released an inaugural annual report: *The State of the National Vaccine Plan* in early 2014. This comprehensive progress report details the individual and collective efforts of HHS offices and agencies, along with many other federal and non-federal partners, to achieve the vision of the 2010 National Vaccine Plan.

The report highlights the advances and accomplishments made by HHS and its agencies in collaboration with its partners, including the U.S. Agency for International Development, the VA, and the Department of Defense (DoD). Accomplishments in the report reflect the ongoing coordination efforts undertaken by NVPO in fulfillment of its mission, and detail the breadth and scope of the vaccine-related activities of HHS agencies.

Initially created in 1994 and updated in 2010, the National Vaccine Plan provides a roadmap for maximizing the impact that vaccines can have on the health of individuals and communities, and provides a guiding vision for vaccines and immunization in the United States. It includes strategies and objectives for advancing vaccine research and development, financing, supply, distribution, safety, global cooperation, and informed vaccine decision-making among consumers and health care providers. The Annual Report details the many accomplishments in service to the vision of the National Vaccine Plan, and discusses the impact that these activities and goals achieved throughout the year.

The report highlights the advances and accomplishments made by the HHS and its agencies, in collaboration with its partners, including the U.S. Agency for International Development, the VA, and the DoD. Accomplishments in the report reflect the ongoing coordination efforts undertaken by NVPO in fulfillment of its mission, and detail the breadth and scope of the vaccine-related activities of HHS agencies.

Some the highlights in the report include:

- Vaccine research and development: Development of new influenza vaccines through collaboration between vaccine manufacturers, NIH, FDA, and the Biomedical Advanced Research and Development Authority.
- Vaccine safety: CDC and the FDA made important contributions to the monitoring of rotavirus vaccine safety.
- Vaccine communications: Several HHS agencies came together, under the leadership of the National Vaccine Program Office, to develop Vaccines.gov, a one-stop federal resource on vaccines and immunization.
- Vaccine supply, delivery, access, and use: Many HHS agencies have contributed to advances in the use of electronic health data to improve the vaccine tracking, coverage, and monitoring.
- Global immunization: FDA, NIH, and CDC worked with other federal and non-federal partners to support the creation of MenAfriVac®, which over 100 million people in Africa have received.

#### **Appellant Climate Survey**

OMHA Appellant Climate Survey is a survey of Medicare beneficiaries, providers, and suppliers who had a hearing before an ALJ at OMHA. The Appellant Climate Survey will be used to measure appellant satisfaction with their OMHA appeals experience, as opposed to their satisfaction with a specific ruling.

The survey is conducted annually by a third-party vendor using sampling methodologies to ensure a random selection of hearing participants. The contractor also conducts the survey and compiles and

analyzes that data for OMHA. Results from the survey are used to make program improvements for case processing and identify training needs for OMHA staff, as well as generally gauge progress made in increasing satisfaction among appellants.

#### **Request for Information for Workload Mitigation**

OMHA will release a request for information in the Federal Register for the Medicare claims appellant community. The request will solicit ideas and suggestions related to mitigating the backlog in the processing of Medicare appeals at the OMHA-level of the administrative appeals process. It is expected the request for information will be published in the Federal Register in summer 2014.

#### **Appellant Forum**

The appellant forum operates to provide updates to OMHA appellants on the status of OMHA operations; relay information on a number of OMHA initiatives designed to mitigate a growing backlog in the processing of Medicare appeals at the OMHA-level of the administrative appeals process; and provide information on measures that appellants could take to make the administrative appeals process work more efficiently at the OMHA-level. To help achieve these goals, the Department of Health Human Services agencies that administer the Medicare claims administrative appeal process (i.e., OMHA, the Departmental Appeals Board, and CMS provide updates from their areas of responsibility. Moreover, members of OMHA headquarters staff and Administrative Law Judges present information on key areas related to the appeals process.

## <u>Modernizing National Vital Statistics System (NVSS) to Improve Timeliness of Mortality Data and Associated Analytic Tools for Surveillance</u>

CDC/Office of Public Health Scientific Services (OPHSS)/National Center for Health Statistics (NCHS) Division of Vital Statistics and OPHSS/Public Health Informatics.

Public health surveillance guides efforts to detect and monitor diseases and conditions, assess the impact of interventions and assist in the management of and recovery from large-scale public health incidents. Today's ever-present, media-hungry environment pressures public health scientists, researchers and frontline practitioners to provide health information, on an almost instantaneous basis, responsive to public and policy maker concerns about specific geographies and specific populations. Actions informed by surveillance take many forms, such as policy changes, new program interventions, public communications and investments in research. Local, state and federal public health professionals, government leaders, public health partners and the public are dependent on high quality, timely and actionable public health surveillance data.

CDC recently developed the *Surveillance Strategy* to improve overall surveillance capabilities, and by extension, the public health system at large. This Strategy proposes to make essential surveillance systems more adaptable to the rapidly changing technology, more versatile in meeting demands for expanding knowledge about evolving threats to health, more adept at accessing and leveraging

healthcare data, and more able to meet the demands for timely and population-specific and geographically-specific surveillance data. It also seeks to consolidate systems, eliminating unnecessary reporting redundancies and burdens.

One of the systems targeted for improvement in the CDC Surveillance Strategy is the mortality component of the National Vital Statistics System. The ultimately goal is for the states and territories to be able to collect and transmit information on at least 80% of their deaths to National Center for Health Statistics within 10 days of the date of the event. This level of timeliness is critical for near real-time surveillance in detecting and defining pandemic and other calamitous events, for statistical analyses in showing shifts in causes of death by age, race/ethnicity and sex, and for more making policy and programmatic decisions at the state and federal levels. Achieving a next-generation electronic data collection tool for deaths will require an evolution in business and systems thinking about electronic reporting, one that minimizes the continuing cycle of expensive and inefficient systems with short "shelf lives".

This project entails securing the services of a private-sector technology entrepreneur to help guide the conceptualization and development of an innovative plan for the cost-efficient collection of death information that leverages new and/or emerging technologies, and then, through federal/state partnerships or through federal/state/private sector partnerships, assist in the building of this tool that will facilitate the efficient capture of death information at the state and local levels and the intergovernmental transfer of that information between the states and the federal government within the desired timely standards. It also entails conceptualizing, developing, creating, and/or testing informatics tools for enhancing and analyzing mortality surveillance data that can be generalized to other surveillance systems or activities; and identifying pilots and projects that may help turn these tools into practice. Both set of activities will require the active involvement of federal, state and private sector partners in conceptualization, design, building and implementing of these tools.

#### Administration for Children and Families (ACF) Tribal Advisory Council (TAC)

The ACF Tribal Advisory Council (ACF-TAC) was established at the request of tribal leaders. The purpose of the ACF-TAC is to assist and provide advice to ACF offices in carrying out their missions in tribal communities. Specifically, the ACF-TAC will inform ACF leadership on tribal priorities relating to social service programs and provide an avenue for ongoing dialogue on substantive issues impacting children and families in tribal communities. The ACF-TAC is an enhancement to the tribal consultation process and does not take the place of consultation.

## <u>Using Design Thinking to Reimagine Technical Assistance to Health Profession Opportunity Grants</u> (HPOG) Grantees

Authorized by the Affordable Care Act (ACA), P.L. 111-148, the Health Profession Opportunity Grants (HPOG) program prepares, trains, and supports TANF program recipients and other low-income individuals for stable, well-paying careers in health care. The demonstration projects are intended to address two pervasive problems: the increasing shortfall in the supply of qualified health care

professionals in the face of expanding demand, and the increasing requirement for a postsecondary education to secure a job with a living wage for families.

The Office of Family Assistance (OFA), within ACF, administers HPOG. In September 2010 and each year since, OFA awarded approximately \$67 million in grants to 32 postsecondary educational institutions, government agencies, Workforce Investment Boards (WIBs), community-based organizations, and tribal entities in 23 states. The 5-year grants may be used for training, education, and support services to prepare TANF recipients and other low-income individuals to enter and advance in the health care sector in occupations such as nursing, long-term care, allied health, health IT, and child care health advocate occupations.

The HPOG program is a demonstration project designed to build and share knowledge. An integral part of HPOG's success has been the program's technical assistance efforts with grantees. In the spring of 2013, OFA and JBS, the HPOG team's technical assistance contractor at the time, partnered with Peer Insight to go through a design thinking process with a primary objective to:

- better understand the needs of HPOG grantees, and
- reimagine Technical Assistance (TA) to HPOG grantees.

Design thinking is a deeply empathetic process used to understand the customer or end-user of a product or service. In order to really understand how an individual thinks and feels the discipline of design thinking borrows tools from anthropology, sociology, design, and engineering that help to uncover individuals' motivations, aspirations, and needs. Ultimately, it is a problem-solving technique that uses empathy to find the root cause of an issue, so that companies or organizations can create solutions that truly meet the needs of the people they are serving. One of the tools commonly used in design thinking is empathy interviewing. Empathy interviews are "an approach to finding out as much as possible about a person's experience as a 'user' of a space, a process, an objective or an environment" (http://dstudio.ubc.ca/toolkit/temporary-techniques/new-6-toolkit-techniques-3empathy-interview/). The HPOG Program Staff, together with members of our contracting teams, conducted a series of in-person empathy interviews with project directors, case managers, job developers, and instructors at a number of grantee locations over the course of a few months. Through the empathy interviews, we realized that we had neglected the instructors in the capacity building and knowledge sharing activities that we provided to grantees. With that realization, we continued to use the design thinking process to figure out what types of TA initiatives would be of value to instructors. We plan to continue working through the design methodology in order to deliver valuable TA interventions to our grantees and their partners.

We plan to continue to utilize Peer Insight's design thinking methodology (<a href="http://www.peerinsight.com/approach/">http://www.peerinsight.com/approach/</a>), which consists of the following steps:

- 1. Frame the Opportunity
- 2. Build Empathy
- 3. Visualize Concepts
- 4. Prototype

- 5. Co-create the Solution
- 6. Experiment in the Market to Validate

#### Interagency Career Pathways Workgroup/Request for Information

On April 23, 2014, the Departments of Education (ED), Labor (DOL), and HHS announced the release of a Request for Information (RFI) to support the development of high-quality career pathways systems. The RFI solicited information and recommendations from a broad array of stakeholders in the public and private sectors, as well as in state, regional, tribal, and local areas. This RFI marked the first time that the Departments were jointly collecting and analyzing information, a process that would yield important insights on: (1) benefits of and challenges to aligning diverse funding streams, programs, and stakeholders around career pathway systems; and (2) the current and potential future use of career pathways systems to help at-risk populations gain skills and access the middle class. At-risk populations include low-income youth and adults, low-skilled youth and adults, out-of-school youth, individuals with disabilities, TANF recipients, tribal communities, English learners, immigrants, rural populations, veterans, currently and formerly incarcerated individuals, dislocated workers, trade-affected workers, and many others.

The joint analysis will generate essential information that will inform policy development and the next generation of investments and technical assistance by providing greater clarity on the catalysts and obstacles to career pathways systems development.

#### **Enhancements to the Audit Resolution Tracking and Monitoring System (ARTMS)**

The Audit Resolution Tracking and Monitoring System (ARTMS) was built to respond to the Department's challenge to provide consistency and uniformity in audit resolution and debt management processes. ARTMS allows ACF to generate more reliable data of each fiscal year's financial activities in an effort to reconcile with OIG and the Program Support Center (PSC). ARTMS facilitates and simplifies the audit resolution process (OMB Circular A-133) that involves resolution and audit follow-up (OMB A-50) on audit findings. Automating this process has and continues to increase productivity, reduce costs, and improve customer service.

ARTMS was designed to limit the number of ACF's overdue audits by implementing responsibility and accountability for resolving each audit. The audit resolution process is 180 days before the audit becomes overdue by the OIG. Using ARTMS reduces the number of audits that shows up on ACF steward report for OIG.

#### **Single Audit Metrics Initiative**

The Single Audit Metrics Initiative focuses on the use of Single Audit metrics to reduce ACF program risk. In July 2011, HHS introduced the Single Audit Metrics Initiative to the Program Integrity Coordinating Council to use the results derived from Single Audit metrics to reduce HHS program risk. This initiative was prompted by the Executive Order 13520, Reducing Improper Payments and Eliminating Waste in Federal Programs, which required federal agencies to conduct analysis of their

programs, determine the extent of improper payments, and report on actions taken to reduce or identify and recover improper payments.

In November 2011, ACF volunteered to participate in the Single Audit Metrics Initiative. The TANF program was selected to pilot the Initiative, due to significant program dollars at risk and the high number of unclean audit opinions.

ACF identified TANF grantees that received an unclean audit opinion and reviewed these grantees' Single Audits to identify those findings that caused the unclean audit opinion. To address these audit findings, ACF incorporated cooperative audit resolution principles, like those contained in the Association of Government Accountants (AGA) Guide to Improving Program Performance through Cooperative Audit Resolution and Oversight Initiative (CAROI). Analysis of TANF's material non-compliant audit findings focused on the following:

- What is the issue that caused the finding (e.g., condition, criteria, cause, and impact)?
- Is the issue valid?
- Were other HHS programs or federal agencies affected by the audit finding?
  - o Are there impediments to correcting the issue?
  - O What actions are needed to successfully correct this issue?

Through implementing the Single Audit Metrics Initiative in the TANF program, the HHS/ACF Team identified the following best practices:

- Work collaboratively
  - The HHS/ACF Team consisted of HHS staff, ACF financial and program staff from the Central Office and Regions, OIG staff, and staff from other OPDIVs (when applicable).
  - The HHS/ACF Team built upon existing relationships with the grantee and auditor to discuss the audit findings and learn the issues from the grantee and auditor's perspectives.
- Conduct meetings with the states and auditors to learn the issues surrounding the audit findings, obtain updates on likelihood of repeat audit findings, and assess risks.
- Actively follow up with states on corrective actions taken, with the goal of obtaining a clean audit opinion.
- Assess changes needed to applicable Compliance Supplements.

The Initiative: (1) broadens the process from 'closing the audit finding' for audit resolution purposes to using cooperative audit resolution techniques to truly understand the underlying conditions and then working with the grantee to obtain corrective action and achieve a clean audit opinion; (2) strengthens the tone with grantees and their auditors on the agency's stance on conditions identified by audits that are likely to cause improper payments, fraud, waste, or abuse, and must be corrected; (3) promotes the proper implementation of the TANF program to ensure taxpayer dollars are used for their intended purpose.

As a result of this initiative, the following improvements were identified ACF-wide and Federal Government-wide:

- The interagency Council on Financial Assistance Reform Strong Program Oversight initiative includes Single Audit metrics modeled after the HHS approach.
- The American Institute for Certified Public Accountants (AICPA) modified standard report language to more clearly identify audit findings causing material non-compliance.
- ACF clarified compliance requirements to auditors and states during discussions held as part
  of gaining an understanding of the issue and the cooperative audit resolution process.
- ACF revised program compliance supplements for clarity (e.g., TANF and Foster Care).
- The 2013 update to the Federal Audit Clearinghouse Data Collection Form added collection
  of data in electronic format to allow the Single Audit metrics to be expanded to identify
  material weaknesses in internal control, significant deficiencies in internal control, and other
  risk indicators by audit finding and by federal program.

Through the Single Audit Metrics Initiative, ACF is encouraging grantees to implement necessary changes to achieve clean audit opinions.

#### **Child Support Intergovernmental Reference Guide**

The Intergovernmental Reference Guide (IRG) offers access to resource information for the child support community as well as the public. It provides child support agency contact information and child support policies and profiles. The IRG also contains Federal Information Processing codes for states, Bureau of Indian Affairs codes for tribes, and International Standards Organization codes for international countries used as identifiers in child support activities. The site provides policy profiles and contact information for state agencies and U.S. territories with federally funded child support programs: Guam, Puerto Rico, or the Virgin Islands. Within each state or territory, the user can drill down to the Profile tab, which contains the policy on topics such as age of majority, paternity, income withholding, and order establishment, enforcement, modification, and review; or the Contact tab, which contains phone numbers for the child support office and related programs. This same information is available for tribal agencies and countries that have agreements with the U.S. to exchange child support information.

#### **OCSE Families Web Page**

The federal Office of Child Support Enforcement (OCSE) communicates with parents through the Families page on the OCSE website. The Families page provides contact information, features timely government-wide initiatives and campaigns, and gives parents access to the Commissioner's Voice - a blog.

The state contact map provides accurate contact information (website, mailing address, and phone numbers) for all 50 child support state agencies and over 50 tribal child support programs. This allows parents direct access to their state and tribal child support program to discuss case-specific information or to facilitate access to child support services. The OCSE Families page also promotes government-wide initiatives that support families such as the Internal Revenue Service, Earned Income Tax Credit Campaign, and HHS' Insure Kids Now, Medicaid and CHIP enrollment efforts. Families are also able to provide feedback about our program and engage with the Child Support Commissioner through the Commissioner's Voice. A link to the blog is accessible on every page on our site.

The Families page also promotes plain language and features user-friendly manuals and instructions to help parents navigate the child support program. Some examples include:

- the infographic (<a href="http://www.acf.hhs.gov/programs/css/resource/how-do-i-apply-for-child-support-services">http://www.acf.hhs.gov/programs/css/resource/how-do-i-apply-for-child-support-services</a>) that outlines how to apply for child support services in three steps,
- the storybook illustration (<a href="http://www.acf.hhs.gov/programs/css/resource/lets-work-together">http://www.acf.hhs.gov/programs/css/resource/lets-work-together</a>) that explains how the child support program works with families to connect them to other services like health care and employment programs, and
- the child support handbook (<a href="http://www.acf.hhs.gov/programs/css/resource/handbook-on-child-support-enforcement">http://www.acf.hhs.gov/programs/css/resource/handbook-on-child-support-enforcement</a>) that provides detailed information about the program.

#### Food and Drug Administration (FDA) Transparency Dashboard

The objective of the FDA Transparency Dashboard initiative is to provide access to FDA data pertaining to inspections, compliance and recalls through data visualizations and an enhanced user experience. The Dashboard is supported by a commercially available dashboard tool, which allows for staging in a cloud environment and allows analysts with knowledge of FDA's business processes to combine and present data (internally and externally) without being fluent in programming languages. The use of the Dashboard allows diverse sets of business and program people to work in concert to design their own dashboards, analyze them, and explore the value of FDA's data for varied purposes and audiences. Such a tool helps leaders and managers make inroads to improve the Agency's data quality. Additionally, it improves the Agency's ability to easily access relational and comprehensive data on specific firms and products, as well as enhance the quality, efficiency and accuracy of data information being communicated to our external stakeholders including the public.

#### DS Connect™: The Down Syndrome Registry

It is estimated that there are about 250,000 people living with Down syndrome in the United States according to the Centers for Disease Control and Prevention. NIH has partnered with public and private organizations to create a centralized, secure national resource for storing and sharing health information about Down syndrome. The NIH-supported Down Syndrome Registry, DS Connect™ (https://dsconnect.nih.gov/), allows people with Down syndrome and their family members, researchers, and parent and support groups to share information and health history in a safe,

confidential, online database. Users can create and edit their customizable online profiles, share their profiles with Down syndrome investigators and biorepositories, and view information about medical research and Down syndrome-related events. DS Connect™ also provides access to general information about Down syndrome as well as aggregate de-identified data based on user responses to survey questions. Those with Down syndrome and their families create their password-protected profiles after providing online informed consent to participate in the registry. If registered users give permission to be contacted about a research study, then the registry coordinator may invite those users who are eligible to contact the clinician or researcher directly to sign up for the study or trial. The Registry complies with all regulations and laws governing privacy, personally identifiable information, and health data, and has been created on a Federal Information Security Management Act moderate platform to ensure that the health and demographic information is protected.

#### **Audacious Goals Initiative**

The National Eye (NEI) Institute launched its Audacious Goals Initiative (AGI; <a href="www.nei.nih.gov/Audacious">www.nei.nih.gov/Audacious</a>) in August 2012 with a prize competition that challenged members of the vision research community and general public to outline concepts for goals that would transform vision research or blindness rehabilitation yet would be achievable in a 10-15 year time frame. Ten winners presented their ideas in an open Audacious Goals meeting in February 2013, which brought together 200 scientific experts, clinicians, patients, and advocates for vision research to further develop the ideas. The ultimate selection to "Regenerate Neurons and Neural Connections in the Eye and Visual System" will focus on two target neurons, photoreceptors and retinal ganglion cells, which degenerate in major blinding diseases. AGI represents a bold departure from previous NEI planning efforts, and public participation and collaboration are not only consistent with the open government plan, but have pushed NEI to consider new perspectives while also energizing the research community.

#### **Big Data in Genomics**

NLM has been a focal point for "Big Data" in biomedicine for decades, a recognized leader in organizing and providing rapid access to massive amounts of genetic sequence data generated from evolving high-throughput sequencing technologies. NLM serves more than 30 terabytes of biomedical data to more than 3 million users every day, drawing on massive data archives. GenBank at the NLM's National Center for Biotechnology Information (NCBI), in collaboration with partners in the United Kingdom and Japan, is the world's largest annotated collection of publicly available DNA sequences, with 340 million sequences from 300,000 different species. Continuing development of large-scale data integration techniques with advanced information systems is key to expanding support for the accelerated pace of research made possible by new technologies such as next-generation DNA sequencing, microarrays, and small molecule screening. Some of the largest datasets, such as those from the NIH's 1000 Genomes Project, are also available in the cloud. This allows faster access and analysis by researchers who may be otherwise hampered by insufficient bandwidth or computing power.

#### **Health Information Exchange for Electronic Health Records**

NLM continues to make advances that will facilitate health information exchange and meaningful use of electronic health records. Researchers have developed advanced and heavily used APIs for medication data and nomenclature, produced novel algorithms for validating vocabulary components of electronic quality measure specifications and analyzed frequency data from multiple health care organizations to produce manageable subsets of large standard clinical vocabularies. They have also developed effective techniques for mapping clinical vocabularies to administrative code sets and have established partnerships to test the use and impact of personal health records.

#### National Institutes of Health (NIH) RNAi Screening Facility

NCATS oversees a state-of-the-art RNAi screening facility that accepts proposals from any NIH researcher. NCATS staff assists investigators with all stages of project planning and execution, beginning with assay development through genome-wide siRNA screens, informatics/pathway analysis and rigorous follow-up. Genome-wide siRNA screens for humans and mice are available.

Large-scale information on the biochemical makeup of small interfering RNA (siRNA) molecules is available publicly for the first time. These molecules are used in research to help scientists better understand how genes function in disease. Making these data accessible to researchers worldwide increases the potential of finding new treatments for patients.

As more gene-specific data arises through various approved and funded projects, more data will become available to the community. NCATS currently is working on a data release policy for RNAi data, once past a moratorium period, to be uploaded to a public database and made available to the scientific community.

### <u>Center for Scientific Review Contests to Gather Public Input on Ways to Maximize Fairness and</u> Impartiality in National Institutes of Health (NIH) NIH Grant Funding

To identify and implement new approaches for NIH to better understand and address racial disparities in NIH R01 grant funding, the NIH Center for Scientific Review (CSR) invited the scientific community and the public to enter two America COMPETES Act Challenges

(<a href="http://public.csr.nih.gov/Pages/Challenge.aspx">http://public.csr.nih.gov/Pages/Challenge.aspx</a>) that will award cash prizes for contestants who submit the best ideas for identifying (1) new Methods to Detect Bias in Peer Review (<a href="http://public.csr.nih.gov/Pages/Challenge1.aspx">http://public.csr.nih.gov/Pages/Challenge1.aspx</a>) and (2) Strategies to Strengthen Fairness and Impartiality in Peer Review (<a href="http://public.csr.nih.gov/Pages/Challenge2.aspx">http://public.csr.nih.gov/Pages/Challenge2.aspx</a>).

#### International Alzheimer's Disease Research Portfolio

A new database created to capture the full spectrum of current Alzheimer's disease research investments and resources—both in the U.S. and internationally—is now publicly available. The International Alzheimer's Disease Research Portfolio (IADRP), developed by NIA, in collaboration with the Alzheimer's Association, enables public and private funders of Alzheimer's research to coordinate research planning, to leverage resources, to avoid duplication of funding efforts, and to identify new opportunities in promising areas of growth. The newly developed resource, currently hosted and

maintained by NIA, helps to track and implement research goals of the National Plan to Address Alzheimer's Disease, announced by the U.S. Department of Health and Human Services Secretary Kathleen Sebelius in May 2012.

#### National Institutes of Health's National Institute of Nursing Research Innovative Question Initiative

In developing a research agenda for nursing science, NIH National Institute of Nursing Research (NINR) is guided by its Strategic Plan, *Bringing Science to Life*.

Under this Plan, NINR continues to support science to promote and improve the health of individuals, families, and communities. Over its nearly 30 year history, NINR has supported critical advances in nursing science in areas such as symptom science, wellness, self-management, and palliative and end-of-life research, broadening the understanding of health and illness across the lifespan.

In FY 2014, NINR launched the Innovative Questions (IQ) Initiative, to implement its Strategic Plan. Inspired by similar, successful efforts at the NIH and other grant-making organizations; the IQ Initiative is intended to engage the scientific community and the public in shaping the future of nursing science. Through the IQ Initiative, NINR is engaging in a dialogue with its stakeholders to encourage creative thinking, identify novel and unanswered scientific questions, promote results-oriented innovative research, and guide NINR-supported science over the next five to ten years.

The IQ Initiative consists of two components: a series of scientific workshops and a public website. The workshops, each one hosted by NINR and focused on a particular science area, bring together leading scientists to identify, to discuss, and to debate research questions that will point the way forward for nursing science over the next 5-10 years. The public website solicits innovative research questions directly from the scientific community, professional organizations, and members of the general public. Visitors to the website have an opportunity to review and comment on questions submitted by others, and to submit questions of their own. The feedback and questions generated from the workshops and the website will be reviewed by NINR and potentially developed into new research opportunities. The research generated through the IQ Initiative offers the promise of advancing the health of the nation through nursing science. For more information, visit <a href="https://www.ninr.nih.gov/IQ">www.ninr.nih.gov/IQ</a>.

#### **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 to increase efficiency and improve outcomes while ensuring that research institutions and universities are supported with these funds. The heads of the major research-funding and research organizations recognized the need to develop a public means to track these international research activities and partnered investments and to share their results with the broader research and funding community.

As a first step, the NIH Office of Extramural Research and Fogarty International Center created World RePORT (the World Research Portfolio Online Reporting Tool), a freely available online resource at <a href="http://worldRePORT.NIH.gov">http://worldRePORT.NIH.gov</a> that provides access to nine major research funding organizations' portfolio of research activities in sub-Saharan Africa. In addition to NIH-funded research, the site includes research funded by the Canadian Institutes of Health Research, European Commission Directorate General for Research, European and Developing Countries Clinical Trials Partnership, INSERM, Max Planck Society, UK Medical Research Council, Pasteur Institute, Swedish International Development Cooperation Agency, and Wellcome Trust. 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. Project details include project title, abstract, principal investigators and their organization, city and country, and hyperlinks that lead to related websites for more information. A data-export feature allows the user to build individual datasets for further analyses and customized reporting.

In 2014, World RePORT is being expanded beyond sub-Saharan Africa to include research in the South Asia and East Asia/Pacific regions. The number of research funding organizations participating in World RePORT is also expected to increase.

#### **5 FLAGSHIP INITIATIVES**

To highlight cross cutting areas across that demonstrate the commitment of HHS toward a more transparent, participatory, and collaborative government, this version of our plan features seven areas of work over the next two years as "flagship" initiatives. Opportunities that qualify for this designation must address all three dimensions of open government and demonstrate innovative approaches to the domain, or represent collaboration across two or more HHS agencies.

#### 5.1 HHS PUBLIC ACCESS POLICY FOR RESEARCH DATA

HHS is in the process of developing a coordinated public access policy approach to enhance the use of federally-funded research publications. The impetus for this endeavor stems from two main sources: 1) the February 22, 2013 Office of Science and Technology Policy Memorandum issued to the heads of federal agencies on "Increasing the Access to the Results of Federally Funded Scientific Research", and 2) Division H, Section 527 of the Consolidated Appropriations Act of 2014. The OSTP memo directs federal agencies with greater than \$100 million in annual research and development expenditures to prepare plans to ensure that peer-reviewed publications and digital scientific data are accessible to the public, the scientific community, and industry. The Appropriations language for FY2014 largely mirrors the language of the Appropriations Act, but is focused in its entirety on developing a public access policy that would allow the public to have access to research publications.

Four of our OPDIVs are participating in the response. These are: the National Institutes of Health (NIH); the CDC; AHRQ, and the FDA. Given that these OPDIVs have unique missions, oversee vastly different types of research portfolios, operate under separate legal authorities, and typically receive independent funding streams for their infrastructure, we determined it was most practical for each of these four agencies to draft their own implementation plans tailored to their particular research portfolios and stakeholder needs. Recognizing that many other HHS OPDIVs with smaller research portfolios conduct important research, all HHS agencies were invited to participate in the response. ASPR is also developing a public access plan for their portfolio of funded projects.

In developing our departmental research, our approach is to set forth guiding principles and a common framework around which our agencies can develop implementation plans tailored to the needs of their research communities and stakeholders. Our aim is to provide continuity in our policies across HHS where feasible; keeping in mind the particular needs of our research communities and data users. An important aspect of our planning effort takes into account the integration of the Public Access Memo with the requirements of the "Open Data Policy – Managing Information as an Asset" (<a href="http://www.whitehouse.gov/sites/default/files/omb/memoranda/2013/m-13-13.pdf">http://www.whitehouse.gov/sites/default/files/omb/memoranda/2013/m-13-13.pdf</a>). At an inflection point in history, we are well poised to strengthen our public access practices through

modifying existing policies or creating new ones, and through leveraging existing platforms and tools in order to make sharing of federally-funded research results a widespread practice for HHS-funded researchers.

The draft final plans are will provided to OSTP by June 2014. Pending OSTP review, we will issue final plans. It is expected that we will implement our public access policies in the spring of 2015 and they will become effective at the beginning of FY 2016 (October 1, 2015).

#### 5.2 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 of17 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 USA Spending.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.

The DATA Act requires the full disclosure of federal funds and the use of common terms, formats and definitions for key financial data elements. To meet this requirement the grants, finance, and acquisitions communities will need to use a common taxonomy and provide unambiguous definitions of

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<sup>&</sup>lt;sup>6</sup> The terms "financial assistance" and "grants" are used interchangeable in this section.

terms used in reports so that they are understandable to a non-federal audience. This effort will require cross OPDIV collaboration as well as collaboration with other agencies. As part of HHS's ongoing data standardization efforts, HHS is working with DoD on the development of common definitions for FFATA elements that can be used for Grants and Contracts. OPDIVs and STAFFDIVs are participating in the collaborative effort and will be asked for feedback on proposed definitions. Additionally, as standard data elements and associated definitions are agreed upon either within the grants community or across the financial assistance portfolio, both federal agencies and the public will require the ability to access these standards to understand their meaning and incorporate them into appropriate business processes. HHS, in partnership with OMB is developing a technical proof of concept to build a [grants] data standards repository. The Proof of Concept Tool provides direct benefit to the federal community and the public will facilitate the implementation of the DATA Act. The Proof of Concept Tool is designed to house standard data elements and associated data element definitions, and make 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.

**Table 3. DATA Act Timeline** 

Activity	Responsible Party	Deadline
Sec 3 – Post on the web information about each appropriations accounts, program activities, etc.	Treasury, OMB, Agencies	3 years after enactment and monthly when practicable (not less than quarterly) thereafter May 2017
Sec 4 – Develop and issue guidance on data standards	Treasury and OMB	1 year after enactment
Sec 4 – Report financial and payment data in	Agencies	May 2015  2 years after guidance
accordance with the new standards		• May 2017
Sec 4 – Ensure the new data standards are applied	OMB and	2 years after guidance
to the data on USASpending.gov	Treasury	<ul> <li>May 2017</li> </ul>
Sec 5 – Establish Pilot program that will generate	ОМВ	1 year after enactment,
recommendations to standardize reporting,		completed within 2 year pilot
eliminate duplication and unnecessary reports, and		established
reduce compliance costs		Establish Pilot by: May
		2015
		Conduct Pilot: May
		2015 – May 2017
Sec 5 – Report on results of pilot	ОМВ	90 days after pilot completion
		<ul> <li>August 2017</li> </ul>
Sec 5 – Guidance to agencies on how data standards	ОМВ	1 year after Report
can reduce burden and simplify reporting		<ul> <li>August 2018</li> </ul>
requirements/eliminate duplication		

#### 5.3 BIG DATA TO KNOWLEDGE

The mission of the NIH Big Data to Knowledge (BD2K) initiative is to enable biomedical scientists to capitalize more fully on the Big Data being generated by those research communities. With advances in technologies, these investigators are increasingly generating and using large, complex, and diverse datasets. Consequently, the biomedical research enterprise is increasingly becoming data-intensive and data-driven. However, the ability of researchers to locate, analyze, and use Big Data (and more generally all biomedical and behavioral data) is often limited for reasons related to access to relevant software and tools, expertise, and other factors. BD2K aims to develop the new approaches, standards, methods, tools, software, and competencies that will enhance the use of biomedical Big Data by supporting research, implementation, and training in data science and other relevant fields. This will lead to:

- Development of and access to appropriate algorithms, methods, software, and tools for all aspects of the use of Big Data, including data processing, storage, analysis, integration, and visualization;
- Appropriate protections for privacy and intellectual property;
- Development of a sufficient cadre of researchers skilled in the science of Big Data, in addition to elevating general competencies in data usage and analysis across the behavioral research workforce.

Overall, the focus of the BD2K initiative is the development of innovative and transforming approaches as well as tools for making Big Data and data science a more prominent component of biomedical research.

In the fall of 2013, the NIH committed \$27 million in FY14 to initiate a series of BD2K programs including Big Data Centers of Excellence, a Data Discovery Index Coordination Consortium, and Big Data Training programs. These and other newly developing Big Data programs will work together to strengthen the expertise and use of Big Data skills and approaches across biomedical research. These Big Data Centers of Excellence will support six to eight investigator-initiated centers that will improve the ability of the research community to use increasingly large and complex datasets through the development and distribution of innovative approaches, methods, and software, and tools for data sharing, integration, analysis and management. These centers will also provide training for students and researchers to use and develop data science methods. Ensuring that Big Data are discoverable and citable are essential to their usefulness, and the Data Discovery Index Coordination Consortium will help ensure that such data resources can be found and cited, both to enable their re-use but also to support attribution. Applications for the Centers were received in November 2013 and the announcement of the centers is expected by August 2014. Applications for the Data Discovery Index Coordination Consortium and Training Programs were received in the spring 2014 and announcement of awards are expected September 2014.

#### 5.4 OPENFDA

This new flagship initiative provides an exciting opportunity to spur innovation, advance regulatory science, and empower decision-making by providing software developers, researchers, consumers and health professionals, easy access to valuable FDA public data, making it simpler for them to use this data in their work to advance and promote the public health. The initiative leverages new technologies and methods such as cloud computing and open source software to unlock the tremendous public data and resources at FDA in a user-friendly way. OpenFDA will provide application developers (such as mobile app creators, web developers, and data visualization makers) the ability to quickly access datasets from FDA in structured, machine-readable formats so that they can be understood and parsed by a computer. By having the data available in this way, developers and innovators can create applications that quickly search, query or pull massive amounts of information instantaneously and directly from FDA on an "as needed basis", rather than having to download huge amounts of data and then reconstructing a usable database.

OpenFDA utilizes a search-based API to collect large amounts of existing public data such as Adverse Event Reports, Product Recalls, and Labeling that is of interest to consumers, the industry, and the public health community. This offers developers the ability to search through text within that data, ranking results much like a search using common web-based search engines would do. This method then allows them to build their own applications on top of OpenFDA, giving them a large amount of flexibility to determine what types of data they would like to search and how they would like to present that data to end-users. This enables a wide variety of applications to be built on one common platform, each with a specific purpose such as identifying critical safety signals, comparing related data, or informing trend analyses. This novel approach to data organization offers a scalable platform that can be easily searched and queried across many distinct datasets. It allows the locating of common identifiers when possible in a lightweight, reusable fashion that can be easily redeployed or altered to fit a variety of purposes, and provides an innovative "big data search and analytics solution". OpenFDA is launching a phased approach for this initiative so all datasets may not be available at the time of publication; however, the power of this new informatics tool will continue to offer tremendous benefits as additional phases are completed and new datasets are made available.

#### 5.5 MEDICARE PROGRAM PROVIDER DATA TRANSPARENCY

As part of the Obama administration's work to make our health care system more affordable and accountable, CMS has released data that summarize the utilization and payments for procedures and services provided to Medicare fee-for service beneficiaries by specific inpatient and outpatient hospitals, physicians, and other suppliers.

CMS has released hospital-specific payment and utilization data for FY 2011 and 2012 (http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-

Provider-Charge-Data/Inpatient.html) for the more than 3,000 U.S. hospitals that receive Medicare Inpatient Prospective Payment System (IPPS) payments. This data set includes for the top 100 most frequently billed discharges, paid under Medicare based on a rate per discharge using the Medicare Severity Diagnosis Related Groups (MS-DRGs). These MS-DRGs represent approximately 60 percent of total Medicare IPPS discharges from an acute care hospital that year. CMS has also released selected hospital outpatient payment and utilization data (<a href="http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Outpatient.html">http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Outpatient.html</a>) that includes estimated hospital-specific charges for 30 Ambulatory Payment Classification (APC) Groups paid under the Medicare Outpatient Prospective Payment System (OPPS) for Calendar Year (CY) 2011 and 2012. These data show significant variation in charges from hospital to hospital, including those within the same community, for services that may be provided in connection with a given inpatient stay or outpatient visit. Hospitals determine what they will charge for items and services provided to patients and these charges are the amount the hospital bills for an item or service. For both the inpatient and outpatient data sets, CMS is planning annual data releases.

In addition, CMS has released the Physician and Other Supplier PUF (<a href="http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Physician-and-Other-Supplier.html">https://data.cms.gov/use-and-Other-Supplier.html</a>) and the Physician and Other Supplier Look-up Tool (<a href="https://data.cms.gov/use-agreement/data-limitations/provider-explorer">https://data.cms.gov/use-agreement/data-limitations/provider-explorer</a>). The PUF contains information on utilization, payment (allowed amount and Medicare payment), and submitted charges organized by NPI, Healthcare Common Procedure Coding System (HCPCS) code, and place of service. It contains 100 percent final-action physician/supplier Part B non-institutional line items. CMS has also published this information in a look-up tool format on data.cms.gov. The look-up tool allow users to search for a provider by name, address, or NPI and returns information about the type and number of services provided, the number of beneficiaries treated, and the average payment and charges for such services. For each of these platforms, CMS is planning annual data releases.

Finally, CMS is planning to release a Medicare Part D Prescriber Utilization and Payment Data Public Use File (PUF) that contains information on utilization and costs (beneficiary out of pocket and total drug costs) of prescription drugs from the Medicare Prescription Drug Program. This data will be aggregated at the prescriber (using the National Provider Identifier (NPI)) and drug name (First Databank brand name variable). The data in the Part D Prescriber Utilization and Payment Data PUF will cover calendar year 2013 and contain 100% final-action Part D prescription drug events from all beneficiaries enrolled in the Medicare Part D program. This information has been of great interest to the public and has been the focus of several FOIA requests. Public release of this information creates greater transparency in the country's largest federal prescription drug program. CMS also plans to release a companion look-up tool to quickly find information on prescriptions prescribed by a provider by entering the provider name and/or location. An interactive dataset with filtering and sorting capabilities will also be available. CMS plans to release the PUF and look-up tool in late 2014.

#### 5.6 THE COMMUNITY GUIDE DECISION AND IMPLEMENTATION SUPPORT SYSTEM (DaISS)

The Guide to Community Preventive Services (The Community Guide) provides evidence-based recommendations about what works to improve public health and assists public health audiences with choosing programs and policies to improve health and prevent disease in their communities. Increasing pressures for public health decision makers to use evidence-based strategies underscore the need for The Community Guide team to find improved ways to disseminate recommendations of the Community Preventive Services Task Force (Task Force), to help decision makers implement strategies that best meet their individual needs and preferences, and to better understand how audiences use the recommendations. To address these needs, CDC's Community Guide Program is developing a decision and implementation support system ("DalSS"). The DalSS is being built to address the following goals and objectives:

- Enable timely identification of evidence-based strategies relevant to user needs
- Provide personalized evidence-based information based on user roles and interests
- Disseminate evidence-based strategies more widely to public health audiences
- Promote collaboration among decision makers in the application of evidence-based information
- Facilitate connections that lead to meaningful partnerships for public health practice
- Foster dialogue about how evidence-based strategies are implemented in 'real-world' settings
- Support open information exchange with various healthcare and public organizations

The DaISS does this through a simple but secure interface that will be accessible across various platforms, by providing smart search capabilities, and by offering personalized dynamic content and decision support to its users. The DaISS will also connect its users and allow them to collaborate with one another while respecting their privacy preferences. FY13 work included an extensive needs assessment, an environmental scan of available tools, and development and usability testing of a prototype. Build out of the first dimension of the DaISS is occurring in FY14.

The prototype provided proof of concept that the system will be able to utilize APIs to incorporate data from other public health-related sources to enhance the customizable experience, which is a key component of the system as meaningful use and open data become key players in the health space. For example, the DaISS can use geography-related health data to customize users' suggested content based on public health issues in that location. The DaISS will be interoperable with relevant HHS websites and initiatives including the Office of Disease Prevention and Health Promotion's Healthy People 2020, the National Institutes of Health (NIH)/NCI's Cancer Control P.L.A.N.E.T., etc.

The DalSS is being built using a combination of open source tools including Drupal and Apache Solr; Drupal is increasingly being used by government agencies for content management. Additionally, the DalSS is being architected in such a way that it can be transitioned to the Cloud at a future date.

The Community Guide is implementing the DaISS in a phased approach across three dimensions, which provides for incremental enhancements with each phase:

- Dimension I Represents the core functionality of the system (e.g. Dynamic and customized content)
- Dimension II Incorporates additional functionality to support user collaboration (e.g. User generated content)
- Dimension III Integrates sophisticated connectivity features (e.g. Integration with external systems)

#### 5.7 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. Head Start programs offer a variety of service models, depending on the needs of the local community. Programs may be based in: centers or schools that children attend for part-day or full-day services; family child care homes; or children's own homes, where a staff person visits once a week to provide services to the child and families. The Office of Head Start (OHS), within the ACF of HHS, awards grants to public and private agencies on a competitive basis to provide these comprehensive services to specific communities. In the interest of informing parents and policymakers about the location and quality of local Head Start grantees, OHS is committed to providing information on grantees to the public in ever increasing ways, including center locations, results of monitoring reviews, and Program Information Report (PIR) data.

The Open Government-Head Start Initiative provides information to parents and policy makers about the location and quality of local programs. We are sensitive to the broad audience and growing technologies in keeping this commitment. Our 2014 release of the Center Locations download page was targeted towards a developer or researcher, while our plan to add helpful program information to the Center Locator is targeted towards the family that wants to learn more about the Head Start program near their home. The source of data might be the same but the delivery of the information is thoughtfully different. This thoughtfulness in approach can be seen across our open data efforts, and results in a stronger and user-friendly open government. In our upcoming releases, we will continue to consider the audience and methods we can deploy to give the user the tools to explore our data.

Over the past two years, ACF has made substantial progress in making Head Start program information more transparent. In 2013, ACF implemented the Program Service Reports, which provide national and grantee-level information on PIR and federal monitoring of Head Start and Early Head Start programs. ACF also contributed to the HealthData.gov initiative by developing a Head Start location API. In the next iteration, ACF plans to continue this work towards transparency by enhancing the locator widget to include more program-level information, profile, options, annual reports, grantee-owned descriptions and improve user interface. ACF also plans to develop mobile apps on Apple and Android platforms to facilitate easier accessibility among users.

#### 6 SUMMARY

The HHS Operating and Staff Divisions have continued to make progress on key cross cutting activities outlined in the first two iterations of the HHS Open Government Plan. Throughout our internal and external governance approaches, the elements of transparency, collaboration, and participation are brought forward through new initiatives, application of new technologies, and new business processes.

In the new plan, we are integrating these principles with the execution of a new Departmental strategic plan that provides new opportunities for applying focus and accountability. This plan will include new elements of engaging the workforce to reinforce the elements of the plan and to empower employees to bring innovative solutions into the discussion and action. Within the Office of the Secretary, the IDEA Lab was developed to establish new pathways and programs that will equip the workforce with new workflow processes, new methods, and communication and analytic tools that will help accelerate the adoption of open government principles. Through specific projects and activities, we will be testing alternative approaches to improve communications, fiscal reporting, oversight, and other management activities. Some of these methods may not succeed with the first attempt, but we will be better equipped with information about our organization to make a more informed effort at finding solutions in the future. We will be sharing with our employees and stakeholders the results of these projects so that others can learn the work and apply them to their own situations and challenges. In addition, we will be emphasizing the use of goals and metrics in projects that will allow us to know where we are making progress and learn where new approaches and greater effort is needed.

As we begin to deploy this version of the HHS Open Government Plan, we call on stakeholders to share with us their ideas and experiences so we can learn more about how the specific activities described here can be best undertaken. We encourage everyone to review the plan, ask questions, and identify strengths and weaknesses that we can address along the way. The best approach is to share your comments with us at <a href="http://www.hhs.gov/open">http://www.hhs.gov/open</a>, where you can address general issues or comment on specific aspects of the plan.