Department of Health and Human Services

Open Government Plan

Version 2.0

April 9, 2012

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EXECUTIVE SUMMARY

As the lead federal agency charged with providing health and human services to all Americans, the challenges facing the U.S. Department of Health and Human Services are tremendous. Whether it is providing millions of children, families, and seniors with access to high-quality health care, keeping the food on Americans' shelves safe and infectious diseases at bay, or exploring new frontiers of biomedical research, we are working every day to give Americans the building blocks they need to live healthy and successful lives.

Transparency, collaboration, and participation are the key principles of Open Government. By sharing our data with the American people, we are creating new opportunities to develop products and services that can improve health and health care; by creating mechanisms for the public to contribute their ideas and share in the co-creation of solutions, we can harness the energy and expertise both inside and outside the government to achieve our goals.

Two years ago, we created our first Open Government plan. It featured five flagship initiatives and numerous actions to promote transparency, collaboration, and participation. HHS used this plan to make huge strides in publicly releasing strategic data assets. For example, we undertook important new initiatives such as the Health Data Initiative, which served as a key forum for our data liberation efforts. We also used new mechanisms, such as challenge competitions and broader engagement of social media, to let the public share fresh approaches with the Department. Our first Open Government plan was hailed as a model throughout government.

This plan is our second Open Government plan and is intended to build on our initial success. Our second plan provides key updates to previous initiatives as well as new approaches that we pledge to undertake in the next two years to further promote transparency, collaboration, and participation at HHS. This plan also incorporates new themes such as "smart disclosure," meaning that we will try to provide data to the public in ways to help Americans make more informed health and health care choices. In this new plan, we also identified three new flagship theme initiatives for HHS. These represent high-impact, cross-cutting and innovative approaches in areas such as advancing medical products, promoting culture change and innovation through an innovators program, and enhanced data quality and usability.

Achieving these goals will not be easy and we will need the help of our stakeholders, our employees, and the American people. Our Open Government team looks forward to providing periodic updates on our progress as we work together to carry out the vision set forth in this document.

PROGRESS REPORT ON OUR OPEN GOVERNMENT PLAN VERSION 1.0 IMPLEMENTATION

HHS published its final version of the initial Open Government plan in June 2010 and has published periodic implementation updates at hhs.gov/open. The plan had five flagship initiatives and more than 80 specific activities that have been tracked. HHS achieved nearly all of the initial plan's objectives and in many cases far exceeded the measures that were established. In the following sections, we briefly summarize highlights of the original plan.

1. LEADERSHIP, GOVERNANCE, AND CULTURE CHANGE

Since its creation in December 2009, the HHS Innovation Council has served as the main oversight and coordination body for the HHS Open Government plan, actively leading the way toward greater transparency, participation, and collaboration. The Council plays a pivotal role in facilitating communications and media outreach inside the organization, and to the public about the Plan. For example, through its subcommittees, the Council has advocated for and promoted the use of challenge competitions to acquire innovative solutions, social media in a wide-array of policy and program arenas, and ideation platforms and programs to promote good ideas. In addition, elements of HHS's Open Government activities were included in the HHS Strategic Plan for 2010-2015, a document that was published after the launch of the initial Open Government plan.

Several new offices and activities focusing on participation and collaboration have been developed since the plan's inception:

- The Office of the Secretary established a new position to coordinate HHS activities through the Executive Director for Innovation.
- The Center for Medicare & Medicaid Services Innovation, within the Centers for Medicare & Medicaid Services, created a variety of initiatives connecting collaborators to promote innovations in health care delivery.
- The Food and Drug Administration, through its new Center for Tobacco Products, has engaged in new technology platforms to communicate new regulations and policies for compliance on oversight of tobacco product sales.
- The Centers for Disease Control and Prevention established a new innovation fund to support early stage products offering new means for staff to collaborate with external organizations on new concepts for promoting better health.
- The Office of the Assistant Secretary for Health launched its Healthy People 2020 objectives and used a variety of community outreach activities to engage leaders in taking on new efforts to meet leading targeted indicators of health performance.
- A New Media committee of the HHS Innovation Council was formed to implement best practices and take on policy issues related to uses of new communication platforms to facilitate better information dissemination, outreach, and input from the public.

- The Secretary announced a task force in 2010 to address the dissemination of mobile health messaging technologies, such as text messaging. A prime example of this was the Text4Baby platform that enables new and expectant mothers to sign up for text messages about health and healthy behaviors for newborns. The task force also addressed broader uses of social media for enabling the dissemination of health information that are customized to meet specific audience needs.
- And, HHS recently addressed its ability to communicate with the public through a revision to its social networking policies thereby enabling HHS employees to use social networking platforms such as Twitter, Facebook, and YouTube for engaging with the public and providing new avenues for participation and collaboration on a wide array of matters.

In August 2011, Secretary Sebelius announced new plans for governance of data assets at HHS. Operating and Staff Divisions were given guidance on appointing representatives to the Health Data Leads community that meets semi-annually to report on transparency activities. Secondly, a new subcommittee of the National Committee on Vital and Health Statistics (NCVHS) was formed to address data access and use policies at HHS. The NCVHS featured a session at its March 2012 public meeting aimed at gaining input on new data services beginning in 2012 at the Centers for Medicare & Medicaid Services. The Health Data Leads serve important roles in working with stakeholder communities and are engaged with formal data presentations at many events featuring the Health Data Initiative.

2. TRANSPARENCY

HHS has posted more than 300 data sets and tools in data.gov since the plan started. In January 2011 HHS announced the launch of two key assets to give the public greater access and utility of data. The Health Indicators Warehouse is a new resource built through a multi-agency collaboration, and it houses more than 1,200 health indicators and highly-qualified data that are used to support research and applications. At the same time, HHS became the primary agency to build the new community in data.gov focused on health data, Healthdata.gov. These resources are now being widely promoted to create new uses in the form of information services and applications. More details are provided under the Health Data Initiative flagship activity. The data holdings in Healthdata.gov include every component described in the original plan including the publication of the Office of the National Coordinator for Health Information Technology Dashboard that was published in February 2012. Other key examples to demonstrate public value from HHS data include the HealthCare.gov website, originally launched in July 2010 to provide the public with new resources to find information resources on both public and private health insurance plan options that are suitable to the public.

Substantial progress has been made in many areas developed to support greater transparency and understanding about financial resource data. The HHS Open Government Financial Data Quality Plan was implemented and continues to meet projected timelines. Among the major successes of this plan was the completion of a new tool known as the Tracking Accountability in

Government Grants System (TAGGS) in 2011 which has received wide acclaim by members of the public interested in tracking federal expenditures in grant programs by region and program. The HHS Innovation Council works closely with the Office of the Chief Information Officer on close coordination of reporting on the Federal IT Dashboard. This effort provides public transparency toward best practices in expenditures and resource management of information technology across the federal government.

HHS has also established a working group, including Innovation Council members, to make the regulatory rulemaking and review process more accessible to the general public. The Department will provide updates through the HHS Open Government website. This website was also used to publish required notifications regarding the HHS prevention and public health fund associated with agencies appropriations for 2012. Agency plans for uses of the funds and details about how to track progress are provided through this site.

Transparency across the agencies has increased through the use of broadcast, web, and new media capabilities, including the launch of new media services in many Operating Divisions. The sharing of best practices and augmentation of skills and knowledge in information gathering, ideation platforms, and crowdsourcing techniques has been implemented and used extensively. The Innovation Council recently partnered with the HHS Federal Advisory Committee executive officers to conduct a survey demonstrating increasing trends of uses of these technologies to augment public participation and transparency of government action.

3. PARTICIPATION AND COLLABORATION

HHS has been working to increase public participation. For example, with the passage of the COMPETES Act of 2010, HHS has been implementing guidelines and procedures to promote the use of challenge competitions across HHS, including more than 50 challenge competitions conducted since the initial HHS Open Government plan. These serve as a highly effective way to receive new insights into HHS problems and attract new solutions providers to specific areas of high need for HHS agencies. The Office of the National Coordinator for Health IT initiated a challenge program that is helping other HHS agencies develop expertise in developing challenge competitions. These challenge competitions are being integrated into other programmatic areas to achieve continued development and implementation of prototype and early start up technologies. Program experts from across HHS have participated in communities of practice on activities aimed at engaging greater participation by the public. The Office of Technology Transfer (OTT) at the National Institutes of Health (NIH) is using web 2.0 tools to launch automated downloads of licensing and cooperative development activities for new medical products. Working with the Food and Drug Administration, OTT formed a regional private-public partnership in Maryland with BioHealth Innovation to bring entrepreneurs-in-residence on board to focus on commercializing market-relevant biohealth innovations and increasing access to early-stage funding.

To promote the uses of tools to enhance participation and collaboration, HHS established a toolkit for program managers to learn how to engage in innovation and collaboration activities, such as the use of challenge competitions. There are available a wide array of resources, galleries, and contacts for program managers to learn how their peers are using new tools to engage the public – available at the hhs.gov/open web site.

HHS's collaborative efforts in Open Government are engaging other federal agencies. A highly successful project conducted with the Veterans Health Administration and the Department of Defense is enabling large numbers of active duty military members, veterans, their beneficiaries, and recipients of Medicare services, to obtain health records. Known as "Blue Button," the project enables easy computer access to vital health information, making it available for customizable consumer use while maintaining privacy. More than 350,000 individuals have already accessed the Blue Button tools.

4. FLAGSHIP INITIATIVES

In 2010, HHS issued its Open Government plan with five flagship initiatives. All five initiatives achieved significant progress toward their milestones and continue to provide new capabilities to keep the public aware of and involved in government processes. Here is a brief summary of the progress made on each initiative.

The Centers for Medicare & Medicaid Dashboards, launched in 2011, simplify data while making them more accessible. These dashboards promote transparency and improve public understanding of the Medicare and Medicaid programs. By simplifying and making data more accessible through tools like dashboards, CMS hopes the questions asked and answered by researchers and policymakers will continue to accelerate efforts to improve the nation's health care delivery and payment systems.

The Food and Drug Administration was the primary agency on two flagship initiatives. The first, the FDA Transparency Initiative has had three phases and is proceeding according to its timeline. In 2010, FDA launched a web-based resource called FDA Basics that provides the public with information about FDA. In 2010, the FDA's Transparency task force addressed public disclosure processes about FDA regulated products and firms. In 2011, the task force addressed transparency issues related to FDA operations and decision making. In early 2012, FDA released a report identifying new initiatives to explore avenues to enhancing availability of FDA compliance and enforcement data. The second initiative, FDA-TRACK (Transparency-Results-Accountability-Credibility-Knowledge-sharing) is FDA's agency-wide program performance management system that monitors over 100 FDA program offices through key performance measures and projects. These measures and projects are developed by the program offices across the FDA and reported on a monthly basis. Each quarter, monthly performance data are analyzed, and senior managers present these data to FDA senior leadership. The project has met its timelines and is helping promote broader understanding of changes in performance across the agency.

A cross-agency initiative to improve the processing of Freedom of Information Act (FOIA) requests was also among the original five HHS flagship initiatives. At the time of the first plan there were significant backlogs among several HHS agencies. HHS FOIA offices engaged in an analytical approach to understand workflow and submission processes and identified opportunities for improvement. By targeting the agencies with extensive backloads and reassigning staffing to meet them, HHS was able to reduce the backlog of FOIA requests by more than 67%. HHS is also taking more proactive steps using technology and smart disclosure efforts to avoid the use of FOIA when information is more freely available. The "Blue Button" initiative enabling Medicare beneficiary access to their health information is an example. HHS FOIA leadership has been promoting meetings and detailed discussions about best practices in FOIA management.

The final flagship initiative, the Community Health Data Initiative (now renamed the Health Data Initiative), has been a major Open Government success. The core elements have been the development of a central data resource for new data users to identify data that can be used to create new applications and services. Annual meetings in partnership with the Institute of Medicine were held in 2010 and 2011. This past year, a public-private consortium, the Health Data Consortium, was formed with the Robert Wood Johnson Foundation to build stakeholder communities. More than 50 meet-ups, code-a-thons, and challenge competitions have been held to create new uses of data to improve health and health care. The efforts of the Health Data Initiative have now spread to many states and local communities who are creating their own open source data environments. HHS continues to play a key leadership role in advocating for an ecosystem of data users and data providers that create value for improved decision making by policy makers, the public, health care professionals, researchers, and many others. All of the milestones established in the original Open Government plan for this initiative were far exceeded and the momentum continues to grow, enabling data to benefit the public in new ways.

OVERVIEW OF THE DEVELOPMENT OF VERSION 2.0 OF THE OPEN GOVERNMENT PLAN

Building on the experiences and methods used in the original HHS Open Government plan in early 2010, this planning effort was strengthened by a number of new engagement activities including uses of technology, external input, surveys, and broader input opportunities. The planning process is coordinated by the HHS Innovation Council under the leadership of the Assistant Secretary for Administration and the HHS Chief Technology Officer. The Innovation Council is represented by senior leaders from all HHS Operating and Staff Divisions. In December 2011, a plan was developed by the Innovation Council and submitted to the HHS Deputy Secretary. In early January 2012, a request for input across HHS leadership was issued by Deputy Secretary Corr providing guidance on opportunities for input on the key elements of the plan, including transparency, participation, and collaboration.

Senior management and program officials across HHS agencies were provided a standard template to identify activities related to transparency, participation, and collaboration with the public. In addition, two specialized areas of activities were added to address "smart disclosure" practices and "big data" activities. Smart disclosure activities relate to how the government information is made available to help citizens use tools to make better informed decisions. "Big data" policies and programs refer to large collections of data and analytics used to interpret the meanings of data. The National Science Foundation and Office of Science and Technology Policy in the Executive Office of the President have led efforts to promote research and development, and policy considerations to address the opportunities and challenges of large datasets, including privacy and confidentiality. For the Version 2.0 Open Government plan, agencies were requested to submit planned activities for smart disclosure as well as big data. In addition, in early January 2012, HHS conducted a survey of program leaders, including each agency's chief information officer. This information will help determine ways in which large HHS data resources for public use applications are being viewed strategically to support Open Government principles.

HHS also engaged the public in seeking ideas and input into the plan. In late January 2012, a blog post on the planning process was posted and social networking platforms were activated seeking public input. A structured questionnaire directing citizens to more specific questions for comment on Open Government activities was also posted. These comments have been used to guide topic areas for inclusion in the planning process and shared with the Innovation Council. A detailed survey of the executive secretaries of HHS's more than 270 Federal Advisory Committees (FAC) was conducted, focusing on the FACs' use of technology and social networking to engage the public in more meaningful ways of participation in HHS policies and programs.

During the development of this plan, staff from the Innovation Council, with the aid of the Assistant Secretary for Administration, met with leadership from many of the Operating Divisions and Staff Divisions to inform them about Open Government planning processes. This led to more constructive discussions about what topic areas and planning processes were

underway to engage the public more effectively. These engagement efforts included more targeted outreach to stakeholder groups using webinars, blog posts, and other on-line outreach channels. Recent policy changes at HHS are helping to increase the use of social networking platforms for engaging the public more directly in seeking input on key issues and activities.

The planning process and input from the public will continue to be administered by the HHS Innovation Council including the review process and updates regarding implementation plans. The Innovation Council will also continue to coordinate with various committees focused on implementation of Open Government principles, including efforts to implement the HHS strategic plan for 2010-2015, the adoption of new media policies, and planning efforts to evaluate regulations in HHS that are redundant or no longer needed.

As the Open Government plan version 2.0 is put in place, continued outreach with the public is planned in settings and in situations where public input can be further integrated. New programs will bring new opportunities and capabilities for public input.

LEADERSHIP, GOVERNANCE, AND CULTURE CHANGE

The enactment of principles of Open Government across HHS has been guided by the HHS Innovation Council. The Council activities, as described earlier in this plan, continue to look deeply at more effective ways to use the talent and resources of HHS to engage the public, particularly on participation and collaboration capabilities. The Council has augmented its expertise with subcommittees and will continue to look for new opportunities to build on the successes of the past several years.

An example of the forward-looking view that the Innovation Council has on governance and leadership in our Open Government plan is the design of the new Innovation Fellows program described in detail under the Flagship Initiatives section of this plan. The projects supported by external fellows offer important ways for non-federal subject-matter experts to engage in meaningful projects across HHS.

The Innovation Council will also address activities identified by the public to improve communication and participation methods. Building on the survey information obtained from our Federal Advisory Committee executive secretaries, the Innovation Council may look at new ways to augment the uses of social media platforms to gain meaningful input on policies, regulations, and other key issues. New approaches to uses of crowdsourcing technologies, analytics from social networking data feeds, and other modern approaches to informing HHS programs will also be discussed.

The Innovation Council will also continue efforts to improve cross-agency collaboration using partnering opportunities on topic specific areas. Additional work will be done to increase the capabilities to partner with non-profit organizations and community-based groups to strengthen the capabilities for public engagement.

TRANSPARENCY

There are many elements of HHS business operations, programs, services, and policies that are critical to supporting the mission of each agency. In this section, we identify plans that are underway to support greater awareness about our operations through increased availability of data, enhanced tools and communications to disseminate our data, and to provide greater context and understanding about the meaning of our data.

While these efforts are organizationally associated with individual programmatic and agency specific functions, all of these activities relate to greater transparency and public understanding. Our efforts through this plan are to present a composite of these activities and draw general themes and directions that provide the public with an improved experience at using government data and information resources to benefit them.

The HHS Strategic Plan for 2010-2015 includes key aspects of organizational objectives to address transparency. Goal 4 of our Strategic Plan seeks to Increase Efficiency, Transparency and Accountability of HHS Programs and specifically includes objectives that emphasize the use HHS data to improve the health and well-being of the American people, and ensure program integrity and responsible stewardship of resources.

Specific Activities to Promote Transparency

HHS programs support and maintain vast databases of a wide array of activities from research, program management, health and human services delivery, training and education, and many more. Through the Health Data Initiative, substantial efforts have been made to provide greater ease of access to data resources, increase the amount of data that is being made available, and a wide array of activities to promote its use through innovative programs and projects. Provided here are narrative summaries of a few ways that data resources and tools will be enhanced to support transparency and understanding of HHS data resources.

1. IMPROVING CAPABILITIES TO UNDERSTAND DATA

The ability to use data from HHS sources is dependent on the resources and descriptors that are provided with it to provide specificity and context to its value. While HHS is at work making more data resources available through Healthdata.gov, increased efforts are underway to provide tools, and enhance the descriptive information about the data, i.e., metadata, in our data resources.

- ***Online Analytic System for National Health Interview Survey (NHIS) Analytic Tool***

  One way the National Center for Health Statistics/CDC is addressing the understanding of health survey data is through a new dual-component online, real-time analytic system for analysis of National Health Interview Survey (NHIS) data at the level of individual

respondents, or so-called microdata. One component will provide analyses of public-use NHIS microdata files and the second component will support analyses of public use NHIS microdata along with selected NHIS data that are restricted use files, with a focus on providing state-specific uses. The initial phase of the project—to ensure that new screening methods were developed that will meet the strict disclosure avoidance requirements of NCHS data systems while increasing accessibility and maintaining sufficient quality of the analyses—was recently completed. The developmental phase of the tool will be publicly available in early 2013.

- ***Closing Data Gaps in the Tracking Accountability in Government Grant Systems***

  The Tracking and Accountability in Government Grants system (TAGGS) is the single repository for HHS grant award data and is available to the public. TAGGS was established in 1995 and in large part addresses the HHS requirement associated with the Federal Financial Transparency and Accountability Act which requires federal agencies to publicly post all financial spending including grants, cooperative agreements, loans, and aggregated direct payment information. The 2012 initiative focuses on ensuring the full complement of Operating Division discretionary and non-discretionary data as posted to TAGGS with a special emphasis on development of a methodology used to aggregate and post "direct payment" information.

- ***CMS Enrollment Dashboard***

  For many years information on the numbers of beneficiaries enrolled in traditional fee-for-service, Medicare Advantage and Part D has been maintained and displayed on different parts of the CMS website. Therefore, in order to obtain a full view of Medicare enrollment internal and external users has to download multiple different files. The Medicare Enrollment Dashboard creates a user-friendly process whereby users can get a complete picture of Medicare enrollment across the multiple types of programs from 1966 to the present. The project will be initiated in early 2012 and will be maintained continuously.

- ***Guide to HRSA Health Center Networks***

  The Network Guide is a directory of Health Center Networks and offers helpful tips to engage directly with potential network partners. It is a user-friendly resource for grantees of the Health Resources and Services Administration (HRSA), safety net providers, and all health care organizations seeking information and technical assistance with their quality improvement and operational efforts. The Guide is a collaborative project between HRSA and the National Association of Community Health Centers and is due to be updated in March 2012.

- ***CMS Data Navigator***

  The CMS Data Navigator is a web-based search and retrieval tool that will reside on the CMS.gov website. The tool's purpose is to connect researchers, policy makers, fellow government employees, and the general public to various data resources that are available under an array of access policies. The Data Navigator tool will give users a simple point-and-click interface to conduct content searches based on a predefined catalog of keywords. Users will be able to use the tool to perform basic searches as well as very detailed advanced searches. Data Navigator results will include multiple types of CMS data and information, including:

  - publicly available data files
  - restricted-use data files
  - statistics
  - reports
  - fact sheets
  - interactive tools

  Navigator result sets will also include links to high profile CMS program data housed on external web sites (such as Kaiser and the Institute of Medicine).

  In addition to providing a robust search tool, the CMS Data Navigator will also provide user support with FAQ's, a keyword glossary, and an ability to ask data-related questions of subject matter experts. The Navigator will significantly improve transparency, allowing users to easily locate CMS data. Moreover, the Navigator is expected to reduce the number of Freedom of Information Act (FOIA) requests because CMS data users will find their data more easily. The Data Navigator tool will be available in June 2012.

- ***5 Star Quality Ratings for Medicare Performance Measurement***

  The Centers for Medicare & Medicaid Services (CMS) is committed to improving the Medicare Part C and Part D quality performance measurement system by focusing on improving beneficiary outcomes, beneficiary satisfaction, population health, and efficiency of health care delivery. As new measures are developed and adopted, they will be incorporated into the Plan Ratings published each year on the Medicare Plan Finder website and used to determine star ratings for quality bonus payments. The Medicare Advantage quality bonuses (also referred to as value-based payments) are an important step to revamping how care and services are paid for, moving increasingly toward rewarding better value, outcomes, and innovations.

  The current Plan Ratings-strategy is consistent with CMS's mission of better care, better health, and lower costs, with measures spanning the following five broad categories:

1. Outcome measures focus on improvements to a beneficiary's health as a result of the care that is provided.
2. Intermediate outcome measures help move closer to true outcome measures; controlling blood pressure is one example of an intermediate outcome measure where the related outcome of interest would be better health status for beneficiaries with hypertension.
3. Patient experience measures represent beneficiaries' perspectives about the care they have received.
4. Access measures reflect issues that may create barriers to receiving needed care; Plan Makes Timely Decisions about Appeals is an example of an access measure.
5. Process measures capture the method by which health care is provided.

In December 2011, CMS sent a Request for Comments to Part C and D sponsors, stakeholders, and advocates that described CMS's proposed methodology for the 2013 Plan Ratings for Medicare Advantage (MA) and Prescription Drug Plans. The purpose of this early alert was to provide plans and advocates with advance notice of the methodology so that CMS could identify any needed changes in advance of the 2013 Call Letter establishing the ratings methodology for the next plan year. As a result of these comments, we are now proposing that two measures be included as display measures, rather than measures included in the star ratings (measures from the Hospital Inpatient Quality Reporting program and the Medication Therapy Management Comprehensive Medication Review measure).

- ***HRSA Facts: Drill Down from Nation-to-Region-to-State-to-County-to-Congressional District***

The integration of the Health Resources and Services Administration (HRSA) Fact Sheets is a new HRSA Data Warehouse initiative that aims to create a user-friendly, integrated series of data-driven fact sheets about HRSA's health care activities (e.g., funding, designations, and job opportunities) at the National, Regional, State, County, and Congressional District levels. The Fact Sheets will be provided as a web-based user interface that allows for improved access to information on multiple geographic areas. This initiative will take the existing stove-piped *HRSA in Your Nation* and *State Fact Sheets* and consolidate them into an integrated platform, which will result in easy navigation as well as accessibility to charts and more detailed data that are not currently available in the existing Fact Sheets. The online tool is scheduled for availability in the Summer of 2013.

- ***Medicare Data to Support Care Coordination for Medicare and Medicaid Enrollees***

In FY 2011, CMS made available a new process for State Medicaid Agencies to request timely Medicare Parts A, B and D data for Medicare-Medicaid enrollees to support care coordination. Having access to Medicare data is an essential tool for states seeking to coordinate care, improve quality, and control costs for Medicare-Medicaid enrollees. States may request the following: Medicare Parts A and B claims, Part D event, and Medicare Parts

A, B, C, and D eligibility and enrollment data. These data are critical to care coordination and partnerships with states, while also increasing the transparency and openness of CMS for external partners. To support and facilitate this effort, CMS is providing ongoing technical assistance, through the Integrated Care Resources Center, to states seeking or newly using these data to coordinate care for Medicare-Medicaid enrollees.

2. POLICIES AND ACTIVITIES TO PROMOTE AVAILABILITY OF DATA RESOURCES

Increased capabilities for supporting transparency of data to the public are emerging from new policies and activities. These include statutory and regulatory authorities that are in place now to create pathways for new data products and services. Additional steps are being taken through administrative and management policies that are guiding programs and agencies to greater transparency.

- ***Prevention and Public Health Fund Reporting***

  Public reporting requirements on funding of prevention and public health fund projects will be a new resource in 2012. Section 220 of the Consolidated Appropriations Act, FY 2012, Public Law 112-74 requires HHS to establish a publicly-accessible website to provide information regarding the uses of prevention and public health funds made available under section 4002 of the Patient Protection and Affordable Care Act (Public Law 111-148) including:

  - A statement indicating the program or activity receiving funds, the Operating Division or office that will administer the funds, the planned uses of the funds, to be posted not later than the day after the transfer is made.
  - Identification (along with a link to the full text) of each funding opportunity announcement, request for proposals for grants, cooperative agreements, or contracts intended to be awarded using such funds, to be posted not later than the day after the announcement or solicitation is issued.
  - Identification of each grant, cooperative agreement, or contract with a value of $25,000 or more awarded using such funds, including the purpose of the award and the identity of the recipient, to be posted not later than five days after the award is made.
  - A report detailing the uses of all funds transferred under section 4002(c) during the fiscal year, to be posted not later than 90 days after the end of the fiscal year.
  - Semi-annual reports from each entity awarded a grant, cooperative agreement, or contract from such funds with a value of $25,000 or more, summarizing the activities undertaken and identifying any sub-grants or sub-contracts awarded (including the purpose of the award and the identity of the recipient), to be posted not later than 30 days after the end of each 6-month period.

This resource will be developed starting in March 2012 with semi-annual reports to follow once the reporting methods are established.

- ***Health System Tracking Project***

The provisions of the Affordable Care Act will impact many different parts of the U.S. health care system at about the same time, and it is important to know whether these changes are making measureable differences in the health and well-being of the US population. In order to ensure a robust system of monitoring and evaluation as well as government transparency and accountability, the Office of the Assistant Secretary for Planning and Evaluation has developed a Health System Tracking Project (HSTP). The Health System Tracking Project is a dynamic, web-based tool that displays data on key health indicators, compiled from across HHS and other federal data sources, along with descriptions of the measures and links to data sources. Good metrics will allow policy analysts inside and outside the government, health reporters, and staffers to understand the degree to which the Affordable Care Act is driving desired changes in health care quality, cost, and access and will enable us to understand the effects of these changes among vulnerable groups.

The project ensures that the public has access to important data about the effects of health reform in an understandable, navigable, and transparent way. Each measure will include an explanation and applicable metadata, which will be displayed along with links to additional information about the data sources. Data will be updated annually on an ongoing basis. The system will include site-wide analytics so that administrators can track civic engagement with the data. These analytics will include trend data on measure visitation and allow us to identify the most visited datasets and track site-wide search trends. A public launch of the tool is anticipated in summer 2012.

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

The Food Safety Modernization Act (FSMA), enacted on January 4, 2011, established a mandated inspection frequency for food facilities that must register under the Bioterrorism Act that is based in part on the inherent risk of facilities. All "high-risk" domestic facilities must be inspected within five years of FSMA enactment and no less than every three years thereafter. All "non high-risk" domestic facilities must be inspected within seven years of enactment and no less than five years thereafter. FDA will make publicly available the criteria that will be used in defining "high risk" and "non high risk" domestic food facilities. In addition, at the end of each fiscal year, the Agency will make available the number of high risk and non high risk inspections for each state.

- ***CMS Data and Information Product Strategy***

The core business at CMS is evolving from a fee-for-service-based payment system to that of a value-based purchaser of care. Additionally, CMS responsibilities are expanding to incorporate stewardship of Affordable Insurance Exchanges under the Affordable Care Act

and the collection of clinical data under the HITECH program. With full implementation of the Affordable Care Act, CMS will play a direct or indirect role in administering health insurance coverage for more than 100 million people across the Medicare, Medicaid, CHIP, and Exchange populations. This will result in data generation and creation on a massive scale, even for an agency that currently processes 1.5 billion Medicare claims per year while collecting over ½ terabyte of data each month from various activities. Further, the type of data that CMS collects is expanding from the traditional administrative elements needed for provider payment purposes to include a richer set of clinical elements and to a broader covered population. The current approach to data release at CMS is guided by the application of multiple statutory authorities, systems that are not optimized for the rapid or cost effective release of data and processes that often frustrate existing data users. CMS data and information products will be a key component in this evolution to a value-based purchaser, and, as such, should become a core business function for CMS. Without timely, relevant data CMS will not be able to define or reward value. Without access to CMS data, the health care system will not successfully transform into one that maximizes health and value. In the future, a properly functioning data and information enterprise will be critical to CMS operations for the Medicare, Medicaid, CHIP and Exchange programs. Indeed the ongoing evolution of these programs will depend on CMS's ability to harness its data and information products. CMS will, in partnership with others, help advance better care, better health and lower costs in the United States through excellence in operations in data collection, analysis and dissemination, enabling ease of access and use for internal and external users. CMS will ensure that data dissemination practices are consistent with beneficiary wishes,concerns and laws that protect beneficiary privacy. CMS will efficiently capture and structure administrative and clinical data and make it available in a wide range of formats to the maximum number of users in a timely fashion. This will promote ongoing transparency and innovation in the development of tools and analyses to improve health and health care, as well as protect CMS programs the trust fund from acts of fraud, waste, and abuse. The work schedule is as follows: mission statements and principles will begin in January 2012, public rollout will begin in February/March 2012, and the plan will be put into operation in March through December 2012.

- ***Medicare Data Sharing for Performance Measurement***

  The Medicare Data Sharing Program for Performance Measurement provides standardized extracts of Medicare claims data to qualified entities to enable them to measure the performance of providers and suppliers in ways that protect patient privacy. Under the Medicare Data Sharing Program, CMS makes standardized extracts of Medicare Parts A, B, and Part D claims data available to qualified entities for the evaluation of performance of providers. Qualified entities must combine the Medicare claims data with claims data from other sources to generate reports and must publicly report measure results. However, public reports generated by qualified entities may only include information on individual providers and suppliers in aggregate form to protect beneficiary privacy and may not be released to the public until the providers have had an opportunity to review them and ask the qualified entity for corrections. The program has strict privacy and security

requirements to protect patients and health care providers as well as misuse of Medicare data may lead to the qualified entity being removed from the program. This program creates a framework for improvements in the quality of care. Major milestones for the program include the release Medicare claims data to qualified entities starting in March 2012 and generating the first public reports generated using combined Medicare claims data and claims data from other sources.

- ***CMS Financial Alignment Initiative***

  In FY 2011, the Medicare-Medicaid Coordination Office, in partnership with the Innovation Center, established a demonstration opportunity for states to align the service delivery and financing between Medicare and Medicaid through the Financial Alignment Initiative. Many states will submit proposals to CMS to participate in this demonstration. In continuing efforts for meaningful stakeholder input, CMS is requiring states to post their proposals for 30 days before officially submitting the proposal to CMS. Once CMS receives each state's proposal, CMS will post it online for 30 days for comment to allow for another round of public comment. Publicly posting the proposals facilitates an open and transparent process and supports the Administration's directive on open government.

- ***Annual Release of Survey Paradata***

  Paradata are the detailed information on the mechanism of how a survey is carried out from the timing of interviews to interview locations to in some cases individual keystrokes on the interviewer's computer. The data provides a wealth of measures on the quality of survey administration and therefore on the quality of a survey's product: its data. The National Center for Health Statistics is conducting this project which represents a major advance in providing public and private survey researchers insight into how the principal health data survey of the Federal Government is conducted. It provides a window – a transparent interface – into the survey that will be invaluable to survey researchers and health policy analysts alike. Access to paradata allows National Health Information Survey data users to conduct methodological studies, such as relating response rate to number of attempts or relating item non-response rates to initial response to interview attempts.

- ***Tobacco Regulation, Education, and Prevention Information – Content Syndication Pilot***

  FDA Center for Tobacco Products will launch an effort to make the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) easier to access, search, and navigate on the web. The development of this more accessible search functionality was tested with stakeholders for ease-of-use and developed in collaboration with plain language experts. The undertaking aligns with the Administration, HHS, and FDA initiative to increase transparency and the recent Plain Language Act. The accessible Tobacco Control Act project provides:

- A searchable version of the law. When launched, the search feature will enable the public to search the act by "Audience," "Type of Tobacco," and "Topic" to find relevant sections of the act. A detailed spreadsheet was created to organize the law to improve search accuracy. Each search results page provides a link to the full statute for complete information.
- A more navigable act. The searchable Tobacco Control Act breaks down the 84 pages of legal language in the law and provides the exact information in a more usable structure with navigation to help the public find information faster.
- An overview of the law, including an appropriate disclaimer that links to the full Act for more information.
- A scrolling timeline of key deliverables of the act, and an infographic timeline including key deliverables, images, and the act's public health rationale.

The next phase will be to map links between the law and FDA actions (e.g., regulations, guidance documents, etc.). Work is ongoing and expected to be online in Spring 2012.

3. PUBLISHING OF NEW OR ENHANCED DATASETS AND TOOLS

Across HHS, agencies and programs are making substantial efforts to provide data and tools to use the information in new ways. Secretary Sebelius announced plans in August 2011 to establish new operating procedures across the agencies that will augment the availability of data through semi-annual reports and publications of new and updated data sets to Healthdata.gov. New advisory committee roles are being established under the National Committee on Vital and Health Statistics (NCVHS) to oversee the uses of data and its publication. Described here are some of the new data resources that are being made publicly available.

- ***Release of Medicare Part C, Part D, and Retiree Drug Subsidy Plan Payment Data***

  CMS is releasing Part C, Part D, and Retiree Drug Subsidy (RDS) plan payment data to better inform the public on how their tax dollars are spent. The release of this data is also in keeping with the President's January 21, 2009, Memorandum on Transparency and Open Government. It is important for these data to be made available for the public to understand expenditures for the Part C, Part D, or RDS programs. The release of these data will facilitate public evaluation of the efficacy of the Medicare Advantage, prescription drug benefit, and RDS programs. The payment data to be released includes average per-person payment amounts for each plan, and average beneficiary risk score information for each plan for payment years 2006 through 2010. In addition, we will release average per-person payment and risk score information by county and plan type (e.g., Health Maintenance Organizations). The data will be posted annually: http://www.cms.gov/Plan-Payment/PPData/list.asp.

- ***National Center for HIV/AIDS, Viral Hepatitis, Sexually Transmitted Diseases, and Tuberculosis Atlas.***

  A new interactive tool developed by CDC's National Center for HIV/AIDS, Viral Hepatitis, Sexually Transmitted Diseases, and Tuberculosis Prevention (NCHHSTP), the NCHHSTP Atlas, will allow users to create maps, charts, and tables using HIV/AIDS, Viral Hepatitis, STD, and TB surveillance data. This new application is a result of a commitment to continue to improve access to public health data from across its programs. This increased access will provide public health partners and the public with the opportunity to use data in new and innovative ways. Having these data together in one user-friendly application will help ensure that program collaboration and service integration efforts have a solid foundation in surveillance and data use, which will help maximize the impact of public health programs and support the wise and efficient use of resources. This current release of the Atlas presents surveillance data for HIV, AIDS, chlamydia, gonorrhea, as well as primary and secondary syphilis. TB and viral hepatitis surveillance data are expected to be added in 2013, allowing for more emphasis on mapping, display, and analyses. By late 2014, NCHHSTP is planning to expand its functionality to provide more dynamic query functions as well as county-level data. More information on the NCHHSTP Atlas can be found at: http://www.cdc.gov/nchhstp/atlas/

- ***HHS Grants Forecast***

  HHS' Grant Forecast is a database of planned grant opportunities proposed by its agencies. Each forecast record contains actual or estimated dates and funding levels for grants that the agency intends to award during the fiscal year. The HHS Grants Forecast database is one of HHS's key communication tools used to alert the public to upcoming grant funding opportunities. While "Forecasted" opportunities are subject to change based on enactment of congressional appropriations, communicating these prospects in advance gives potential recipients the chance to plan ahead for the upcoming application process. Once grant funding opportunities are available for the public to find and apply, they are transferred and posted to grants.gov, for which HHS is the Managing Partner.

- ***Health Indicators Warehouse***

  The Health Indicators Warehouse (HIW) is an HHS resource that supports the principle of transparency by making an increasing amount of high-quality data, data descriptions, related resources, and relevant interventions available from various Operating Divisions of the federal government in a single easily accessible and user-friendly location. The Health Indicators Warehouse (HIW) provides access to high-quality data, improves understanding of a community's health status and health and health care determinants, and facilitates the prioritization of interventions. The purpose of the HIW is to:

  - Provide a single, user-friendly source for national, state, and community health indicators

- Meet needs of multiple population health initiatives
- Facilitate harmonization of indicators across initiatives
- Link indicators with evidence-based interventions
- Serve as the data hub for the HHS Community Health Data Initiative, a flagship HHS Open Government initiative to release data; encourage innovative application development; and catalyze change to improve community health

Since the public launch of the site in early 2011 the system has seen a growing number of users and is now averaging approximately 1,500 visitors per day. The next release of the HIW, version 1.5, in early 2012 will add new indicators from CMS, county-level notifiable disease counts, a large amount of new data for existing indicators, and improvements to the interface display. This release will continue the improvements of the HIW in serving the community of public health indicator users with more and better data more easily accessed. New indicators, and updates to existing indicators, will be added over time with priorities set by an Inter-HHS Agency governance group. In 2012 the HIW will undergo a revision to enhance user features and build additional indicators for measuring health and disease conditions, and providing vast amounts of data for use. A release of version 2 is anticipated in March 2013.

- ***Affordable Care Act Report for "New" Grant Programs***

  This initiative established a routine electronic method for collecting Affordable Care Act grant award information from across HHS by state, program and Catalog of Federal Assistance Number (CFDA). This information is compiled into a single report which is used to inform the public of HHS's Affordable Care Act spending. In the Fall of 2012 there will be a heightened focus on data quality and data integrity to ensure that information posted on the upcoming CFDA website is aligned with the obligation/award data made available to the public post-award.

- ***Monitoring of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies***

  The Centers for Medicare & Medicaid Services (CMS) is releasing broad-view analyses, comparing the impact of the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program on the general Medicare population as well as Medicare beneficiaries likely to use competitive bid equipment based on their health conditions. Section 302 of the Medicare Modernization Act of 2003 (MMA) established requirements for a new Competitive Bidding Program for certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). Under the program, DMEPOS suppliers compete to become Medicare contract suppliers by submitting bids to furnish certain items in competitive bidding areas, and CMS awards contracts to enough suppliers to meet beneficiary demand for the bid items. The new, lower payment amounts resulting from the competition replace the Medicare DMEPOS fee schedule amounts for the bid items in these areas. The program sets more appropriate payment amounts for DMEPOS items while ensuring continued access to quality items and services, which will

result in reduced beneficiary out-of-pocket expenses and savings to taxpayers and the Medicare program. The Medicare Improvements for Patients and Providers Act (MIPPA) requires the competition for Round Two to occur in 2011 in 70 additional metropolitan statistical areas (MSAs) and authorizes competition for national mail order items and services after 2010. The Affordable Care Act of 2010 expands the number of Round Two MSAs from 70 to 91 areas and mandates that all areas of the country are subject either to DMEPOS competitive bidding or payment rate adjustments using competitively bid rates by 2016.

On January 1, 2011, CMS launched the first phase of the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program in nine different areas of the country for nine product categories. In order to protect the interests of potentially affected Medicare beneficiaries and the Medicare trust Fund, CMS performs the following activities:

- Conducts real-time claims analysis to monitor health status for groups of Medicare beneficiaries in competitive bidding areas (CBAs).
- Monitors usage rates and a wide range of health outcomes such as deaths, hospitalizations, emergency room visits, physician visits, admissions to skilled nursing facilities, average number of days spent hospitalized in a month and average number of days in a skilled nursing facility in a month.
- Monitors a "comparator" region for each CBA to examine rates across regions, as a type of control; in general, CBA rates are tracked closely by comparator rates both before and after the implementation of competitive bidding.
- Routinely updates and makes this monitoring information publically available on the CMS website.

Key deliverables and timelines for the project include monthly updates to be posted until first year claims are largely complete (March 2012); updates to be posted quarterly thereafter. The program is scheduled to be phased into 91 additional areas on July 1, 2013, increasing scale of monitoring and information from 9 to 100 total areas. In addition, a national mail order program for diabetic supplies is scheduled to be implemented on July 1, 2013, and monitoring information will then be generated for this national program.

- ***Retailer Compliance Check Inspection Database***

Under the Tobacco Control Act, passed in June 2009, FDA is required to contract with states, where feasible, to conduct inspections of tobacco product retail establishments. To date, FDA has contracted with 37 states and the District of Columbia to conduct these retail compliance check inspections and has conducted over 41,000 inspections. FDA developed a database that shows the results, in a searchable format, of all retail compliance check inspections conducted (http://www.accessdata.fda.gov/scripts/oce/inspections/oce_insp_searching.cfm). The database displays whether a particular establishment has been inspected and whether that

inspection resulted in a Warning Letter or "no violations observed." After an inspection is conducted, the evidence is sent to FDA for review. Once the review is complete, the result of the inspection is added to the database on a monthly basis. This database is searchable by retailer name, city, state, and zip code.

- ***Enterprise-wide Financial Business Intelligence Program***

  This initiative fosters greater integration and transparency of Department-wide data and facilitates greater collaboration across HHS and amongst decision makers to ensure the robust fiscal integrity of data throughout its lifecycle from dollars being appropriated through its commitment, obligation, and expenditure to include providing the proper alerts, performance metrics, and reporting. This is a long-term strategic initiative being implemented over a period of five years to ensure that integrated financial information is easily accessible to decision makers via electronic tools known as "business intelligence tools." In September 2012, documentation of the strategic vision and road map will be developed and by the end of 2012 a business case proposal in support of the long-term strategic initiative will be made available for Departmental consideration and decision.

- ***Self-Referral Disclosure Protocol***

  Section 6409 of the Affordable Care Act requires the Secretary of the Department of Health and Human Services, in cooperation with the Inspector General of the Department of Health and Human Services, to establish a Medicare Self-Referral Disclosure Protocol (SRDP) that sets forth a process to enable providers of services and suppliers to self-disclose actual or potential violations of the physician self-referral statute. It also gives the Secretary the authority to reduce the amount due and owing for violations of the statute. Once settlements are reached, limited information regarding SRDP settlements are published on the CMS website.

- ***BioSense and the Visualize Tarrant County, Texas Public Health Project***

  BioSense is a CMS program that tracks health problems as they evolve and provides public health officials with the data, information and tools needed to better prepare for and coordinate responses to safeguard and improve the health of the American people. The CDC BioSense Program was launched in 2003 to establish an integrated national public health surveillance system for early detection and rapid assessment of potential bioterrorism-related illness.

  The BioSense Project to Visualize Tarrant County Public Health (TCPH) health data collected by the BioSense Network and make available for public health use. Data consists of patient visits to hospital EDs that had the illness Gastro Intestinal, Heat Related, or Upper Respiratory divided by all emergency department visits that occurred for the same time period and in the geographic granularity for which the calculation was made. New data releases are anticipated in late 2013.

- ***Monitoring and Analysis of End-stage Renal Disease Claims***

  On January 1, 2011, the CMS implemented a new payment system for End-stage Renal Disease (ESRD) facilities that bundles payment for dialysis treatments at the dialysis facility and at home and other renal dialysis services including drugs, laboratory tests, and supplies. In order to protect the interests of potentially-affected Medicare beneficiaries and the Medicare Trust Fund, CMS has been performing the following activities:

  - Conducting real-time claims surveillance on all ESRD facilities to monitor a wide range of health outcomes of individuals with ESRD and track changes in their utilization of services.
  - Analyzing data reflecting trends for the three years preceding the implementation of the ESRD PPS.
  - Comparing pre- and post implementation data, e.g., utilization rate of blood transfusions

  CMS plans to call for non-proprietary findings to be made publicly available on the ESRD PPS website in Spring 2012 and will continue the claims analysis through CY 2013 and 2014 with routine updating of the postings.

- ***Expanding the Research Base for Tobacco Product Regulation***

  FDA's Center for Tobacco Products (CTP) and the NIH formed an interagency partnership to foster research relevant to tobacco regulations. As a result of this partnership, CTP and NIH have released and are planning a number of Funding Opportunity Announcements to stimulate research to aid in the development and evaluation of tobacco product regulations. In addition, CTP and NIH are collaborating to fund a number of research projects including a longitudinal cohort study of tobacco users known as the Population Assessment of Tobacco and Health (PATH) Study. CTP reached out to over 40 organizations representing a broad array of scientific disciplines and invited them to attend the meeting. In addition, CTP is webcasting the meeting and inviting organizations to promote that webcast to their membership. Following the workshop, key staff from the CTP are planning symposia at several national conferences to increase awareness of and highlight FDA's tobacco research opportunities and priorities. These initial steps are designed to build better linkages with and increase CTP's visibility among the broader research community.

- ***Import Filer Evaluation Outcomes Initiative***

  Importers, or third parties working on behalf of importers, file information about products offered for import into the United States. FDA conducts evaluations of those filers who submit information electronically to ensure submission accuracy. Under this initiative, FDA will make the filer evaluation outcomes publicly available. FDA is exploring procedures to speed up the evaluation, which gives an incentive for filers to improve their outcomes

quickly. The new procedures are expected to be implemented in September 2013. Additional information promoting transparency of the import filer process can be found at: http://www.fda.gov/ForIndustry/ImportProgram/ucm282834.htm.

4. SMART DISCLOSURE – SUPPORTING A MORE INFORMED PUBLIC

HHS is working to do a better, faster job of informing the public about new policies and regulations. A number of projects are aimed at making information readable in digital formats so they may be incorporated in other information systems and services. Provided here are some of the steps to enable disclosure of information to support consumer decision making.

- ***National Health Interview Survey Early Data Release Project***

  The National Health Interview Survey's Early Release (ER) Program provides very timely estimates of key health and health-related indicators through three online reports. Other products include preliminary microdata files that can be used to determine key factors attributable to health issues at an individual level, which allows analysts to access these ER products as much as nine months before the annual release of NHIS public use microdata files. This initiative focuses on one of the ER reports, entitled "Selected Estimates Based on Data from the National Health Interview Survey," that is released quarterly. That report provides data for 15 key health indicators including:

  - lack of health insurance coverage and type of coverage
  - having a usual place to go for medical care
  - obesity
  - current smoking and alcohol consumption

  Figures including trends and data by race, age and sex are presented. The NHIS is in the field continuously, and annual public use files are released about six months after each calendar year.

- ***Data Resource Center for Child and Adolescent Health***

  This project of the Child and Adolescent Health Measurement Initiative takes survey data collected by the National Center for Health Statistics and transforms it into an easily accessible form aimed at parents, teachers, and others interested in the welfare of children. The mission of the Data Resource Center for Child and Adolescent Health (DRC) is to advance the effective use of public data on the status of children's health and health-related services for children, youth, and families in the United States. The DRC does this by providing hands-on access to national, state, and regional data findings from large population-based surveys. Data are collected from parents and thus contribute a much-needed voice in the drive to improve the quality of health care for children and youth. The DRC provides easily accessible data that do not require statistical expertise. DRC also gives

technical assistance on the use of this data and contributes to the maternal and child health (MCH) field through publications and research on the quality of health care systems for children and children with special health care needs.

- ***Companyprofiles.healthcare.gov***

  The "Rate Review" and "Medical Loss Ratio" features of the Affordable Care Act promote transparency while holding insurers accountable for rate increases and how they spend your premium dollars.

  - Rate Review: The Affordable Care Act brings an unprecedented level of scrutiny and transparency to health insurance rate increases. It ensures that, in every state, proposed increases of ten percent or more will be evaluated by experts to assess whether they are based on reasonable cost assumptions and solid evidence. The review and scrutiny is expected to prevent unjustified premium hikes by insurance companies and to help provide those who buy insurance with greater value for their premium dollar. Additionally, consumers will benefit from greater transparency as they will be able to access online easy-to-understand information about the reasons behind rate increases and why insurers are seeking the increases. These protections allow consumers to know why they are paying the rates that they are. Detailed information about these reviews became available on September 1, 2011 on HealthCare.gov and the website of the Center for Consumer Information & Insurance Oversight.

  - Medical Loss Ratio: Beginning in August, 2012, the law requires that insurance companies publicly report how they spend premium dollars. This will give consumers meaningful information on how their premium dollars are spent, clearly accounting for how much money goes toward actual medical care and activities to improve health care quality versus how much money is spent on administrative expenses like marketing, advertising, underwriting, executive salaries, and bonuses. This new transparency gives consumers information on how their premium dollars have been spent.

PARTICIPATION & COLLABORATION

HHS depends on participation by and collaboration with the public to realize its goals – a statement that is underscored in the Department's Strategic Plan. In fact, citizen participation and collaboration with stakeholders is so central to the operations of the Department that it is featured as one of the key objectives within our Strategic Plan. Goal 2 of the HHS Strategic Plan (Advancing Scientific Knowledge and Innovation) sets forth an entire objective to "Foster Innovation to Create Shared Solutions." [1]

Since the development of our first Open Government Plan, HHS has made enormous strides in promoting and expanding participation and collaboration in departmental activities. This section of the report features a number of new and planned collaboration and participation initiatives that fall broadly into one of seven areas:

1. Using challenge competitions for problem-solving
2. Collaborative consortia, networks and learning communities The creation of collaborative databases, registries, and tools for information sharing.
3. Collaborative metrics development
4. Web-based strategies for enhanced sharing of HHS resources.
5. New approaches for enhancing stakeholder input and feedback.
6. The expanded use of advanced communication technology by our HHS Federal Advisory Committees.

A number of factors contributed to HHS's ability to enhance its collaboration and participation activities. Among them is the introduction of an internal "consulting team" that was formed as part of HHS's broader Community of Practice in 2010. This team worked with a number of agencies to analyze new approaches for fostering collaboration and participation, and has assisted several programs in the launching of new initiatives. Another notable forum that helped to promote collaboration and participation activities across the Department is the HHS Innovation Council. This Council was established in January 2010 and is composed of representatives from across HHS. It meets on a monthly basis to examine best practices and share new approaches to promoting innovation across the Department. In addition to engaging outside experts and sharing internal strategies, the Council's various subcommittees actively develop and disseminate tools and toolkits for innovators throughout HHS to use in promoting collaboration and participation. Finally, the Council has a leading role in working with offices across the HHS to identify barriers and develop creative solutions to overcome them.

One major barrier that the Council identified relates to the use of social media by HHS program and personnel. Social media technologies (e.g. Facebook, Twitter, and electronic chat rooms)

[1] See Strategic Goal 2, Objective B "Foster Innovation to Create Shared Solutions". U.S. Department of Health and Human Services Strategic Plan FY 2010-2015. Available at: http://www.hhs.gov/secretary/about/stratplan_fy2010-15.pdf

are becoming increasingly popular methods of communication that our stakeholders use to exchange information with each other. Yet, access to these technologies has been used inconsistently, with some agencies embracing them, and others blocking access to them. Another important barrier to the effective and appropriate use of these powerful connecting tools is the lack of experience by the workforce. A New Media committee was established across the organization to enhance dissemination of knowledge, share best practices, and advance access to these tools through terms of service agreements. This group is planning to further enhance their work and optimize the ways these tools are used to engage public participation. In March 2012, the HHS Office of the Chief Information Officer published a revised Department-wide social media policy to more pro-actively and uniformly embrace social media technologies. The new social media policy has been significant to the Department's collaboration and participation activities to the point policy has changed from a default of avoidance to now embracing social media technologies.

1. USING CHALLENGE COMPETITIONS FOR PROBLEM-SOLVING

In January 2011, President Obama signed into the law the America COMPETES Reauthorization Act, granting all federal agencies broad authority to conduct challenge competitions to spur innovation, solve tough problems, and advance their core missions (Public Law No. 111-358, 15 U.S.C. 3719). Challenges are open competitions to solve problems in which a prize is awarded only if an eligible contestant satisfies the criteria established for winning a prize for that challenge. It is a powerful "open innovation" tool that can be quite effective at generating new ideas, new technology solutions, and novel approaches. While several agencies conducted challenge competitions before the America COMPETES Reauthorization Act, Section 105 of this legislation has been significant by creating a an additional legal pathway to use appropriated federal funds for support prize incentives.

HHS stands at the forefront of agency implementation efforts. As an example of the framework for challenge competitions that HHS established, Secretary Sebelius delegated the authority to conduct challenge competitions to the Heads of all Operating and Staff Divisions on April 22, 2011. In October 2011, Secretary Sebelius issued a memorandum notifying the Department of the new challenge competition authority provided under the America COMPETES Reauthorization Act, outlining the strategy to optimize the use of challenge competitions, and calling on the heads of Operating and Staff Divisions to forecast their future use of challenge competitions to stimulate innovation in advancing the agency's mission. The memorandum also highlighted the implementation framework established to accelerate the use of well-designed challenge competitions. For example, Secretary Sebelius delegated the authority to conduct challenge competitions to the Heads of all Operating and Staff Divisions. The Department also developed judging guidelines [as required by Section 24(k)(3)] governing principles outlining responsibilities for challenge managers, a financial management policy for challenge competitions, and a vehicle to share best practices across the Department. The full set of policy statements, guidance, and resources are available online at: http://www.hhs.gov/open/initiatives/challenges. The toolkit and guidance documents have

been heralded as model by the Office of Science and Technology Policy. In addition, a number of our Operating and Staff Divisions have hosted their own conferences and created their own training materials to promote the use of challenge competitions for specific Operating and Staff Divisions. For example in July 2011, NIH held a conference entitled, Crowdsourcing: the Art and Science of Open Innovation, that brought together many of the leading experts in challenge competition design.

The most ambitious project launched by any HHS agency under the new challenge competition authority in the America COMPETES Reauthorization Act in FY2011 is the HHS Investing in Innovation (i2) initiative, a new $5 million program to spur innovations in Health Information Technology (Health IT). Led by the Office of the National Coordinator for Health Information Technology (ONC), the core of i2 is a series of challenge competitions to accelerate innovation and adoption of Health IT for improved clinical outcomes and efficient care delivery. Innovation challenges encourage development in priority areas identified by HHS, but also foster significant community building within the development community. Typically 3-6 months in duration, a challenge effort offers a chance for external developers, many new to health care, to provide solutions to key health IT challenges. Innovators who participate in challenges are offered the opportunity to compete against other solution providers and receive detailed feedback on how to improve their innovations. The challenge process offers the opportunity for entrepreneurship in a manner that is catalyzed by federal resources. ONC plans to run a substantial number of challenges in the near future and has allocated funds for more than 30 challenges over the next two years.

Since the launch of our first Open Government plan, HHS has administered nearly 50 challenges, many of which have been listed on challenge.gov. In addition, HHS partnered with a number of outside entities and provided support to their challenge efforts. In a memorandum issued in October 2011 the Secretary requested a challenge forecast from each agency. Based on the inputs received, the Department expects to issue at least 50 challenges in 2012. Nearly every agency – including ASPR, CDC, CMS, FDA, IHS, FDA, NIH, ONC, SAMHSA, and OS – expressed interest in running challenges. Areas of future interest for challenge competitions include:

- new uses of social media tools for reaching HHS stakeholders;
- development of apps and mobile tools to improve public health in priority areas such as suicide prevention;
- reaching persons who have breaks in health coverage; and
- the sharing of best practices in areas such as care coordination, workforce development and training.

Notably, CMS plans a 2012-launch for a large-scale challenge competition to produce and evaluate a shared services solution for states to identify Medicaid provider eligibility.

In 2012 and beyond, the Innovation Council will capitalize on the Department's emerging interest in challenge competitions through continuing to develop guidance documents on

topics such as compliance with the Paperwork Reduction Act (PRA) in challenge competitions, as well developing as clear pathways to let HHS challenge managers obtain the necessary PRA clearances as expeditiously as possible. The Innovation Council is also taking a lead role on promoting training activities. For example, the Council plans to develop an education component on challenge competitions as part of the 2012 Health Data Initiative Forum III: the Health Datapalooza.

2. COLLABORATIVE CONSORTIA, NETWORKS, AND LEARNING COMMUNITIES

HHS is engaged in many collaborative activities with its stakeholders, covering a broad range of health and human service concerns. Over the past two years, since its first Open Government Plan was published, HHS has been building upon its interests in collaboration and co-creation in new ways. These include:

- creating "learning communities" where the experiences of collaborators are used to improve HHS programs;
- establishing training programs that leverage the "real-world" experiences of communities and use field training exercises as opportunities to improve the conditions of communities in need;
- realigning existing departmental programs to create new synergies among existing programs; and
- using new forums for the sharing of pre-competitive data.

Some examples of these activities and their near-term plans for growth include:

- ***Community Health and Service Missions***

  The United States Public Health Service's (USPHS) Community Health and Service Missions (CHASM) program is designed to bridge the chasm of health disparities, protect the health of all Americans, and provide essential human services for those who are least able to help themselves. This program helps underserved and vulnerable populations by fostering collaborations among local, state, tribal, and federal governments with active participation from local volunteers and nongovernmental organizations. CHASM is particularly transformative because it creates the ability to bring in multidisciplinary experts from across federal agencies under one umbrella, enhancing knowledge and services provided. USPHS officers provide expertise in environmental health, epidemiology, toxicology, program administration and development, dental, veterinarian, nursing, primary care, mental health, preventive medicine, and applied public health care. USPHS found that the more involved the community is with determining and addressing their health care needs, the more successful the outcome of the mission.

  CHASM meaningfully and purposefully incorporates technology, in the form of *Responder eLearn*, a web-based public health training platform. *Responder eLearn* is utilized in CHASM in order to increase stakeholder involvement in the development phase through the tool's

community forums, measure outcomes through survey distribution, as well as providing just in time training in the days prior to the mission. CHASM is highly innovative because it provides an avenue for USPHS officers to train for emergency response while also promoting and advancing health infrastructure in underserved communities. This initiative unites multidisciplinary USPHS officers to respond, collaborate, and participate with local, state, tribal, and NGO groups in an effort to address this nation's most pressing public health needs. Upon return, these officers are able to share their newly acquired knowledge and leadership skills with their home agencies, which further facilitate interagency transparency. More information on the CHASM program can be found at: http://dcp.psc.gov/ccmis/CHASM.aspx

In early February 2012, CHASM convened a collaborative meeting with multiple federal agencies to discuss additional opportunities for partnership by identifying overlapping strategic goals that result in reducing health disparities and improving environmental health. One example of this collaboration is the use of USPHS officers to help meet the strategic goals of sister agencies while helping the USPHS meet its goal of emergency response training. In 2012 and beyond, CHASM will advance partnership opportunities with these federal agencies and collaborating in the Federal Interagency Health Equity Team.

- ***Collaboration Network for CMS Partners***

CMS is developing an online collaboration network to support awardees, grant recipients, and other CMS partners who seek a web-based experience to share best practices, learning resources, and trends in the quality of the care they deliver among themselves. Aside from simple file-sharing and discussion threads, the site will allow CMS partners to track their own health care quality metrics. Through regular reports of aggregated anonymous quality metrics (e.g., percent of patients with bedsores over a preceding month) submitted online, users will see their own quality trends and can compare their trends with those of others. Major health care initiatives will use this space including the Partnership for Patients and Accountable Care Organizations (ACOs). CMS established the information technology infrastructure, and anticipate that by mid-2012, the collaboration network will be deployed to support the Pioneer ACOs and 500 Health Centers running a primary care demonstration.

- ***Innovation Pathway - End Stage Renal Disease Innovation Challenge***

FDA's Innovation Pathway is a streamlined review program for innovative medical devices that are intended to address unmet public health needs. Along with shortening the overall time it takes for the development, assessment, and review of breakthrough medical devices, one of the goals of the Innovation Pathway is to create a more collaborative and transparent experience for innovators and FDA working together. The program will introduce new decision tools to help the FDA assess and characterize benefits and risks to patients, and new collaborative ways for the FDA and innovators to share ideas about new device concepts.

In January 2012, FDA's Center for Devices and Radiological Health launched the End Stage Renal Disease Innovation Challenge as a pilot program to test the tools and processes being developed for the Innovation Pathway. Since the launch, the Center has received interest requests from over 30 entities, over a dozen of which submitted completed applications.

Accepted applicants will undergo a "Collaboration Phase" with FDA. During this period, a team will be created consisting of both the FDA review staff and the company experts. This team is charged with collaboratively creating the regulatory pathway forward for the new technology, including identifying key scientific and regulatory hurdles. While FDA will retain the final authority in making all regulatory decisions, the intent is for these key decisions to be reached with agreement from both sides in a collaborative way.

The ESRD challenge was launched in January 2012 and will be ongoing. In March 2012, FDA publically announced the accepted applicants. By December 2012 FDA will complete the Collaboration Phase of the Innovation Pathway with all applicants. By January 2013 the group will publicly share lessons learned from the early ESRD experience. It is also expected that a narrative story will be generated that captures the intent and outcome of the Collaboration Phase for each company, and will be publicly posted on the Innovation Pathway website as case examples.

- ***National Center for Advancing Translational Sciences***

NIH established a new center, the National Center for Advancing Translational Sciences (NCATS), to catalyze the generation of innovative methods and technologies that will enhance the development, testing, and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions. NCATS was created primarily by uniting and realigning existing programs that play key roles in translational science into one focused NIH effort. The decision to establish NCATS was motivated in part by the recognition that the *process* for translating scientific discoveries into new tools and treatments is ripe for innovation. It is well known that developing new diagnostics and therapeutics is a complex, costly, and risk-laden endeavor, demonstrated by the less than 1% of compounds initially tested actually making it into a patient's medicine cabinet. For this reason, NCATS will focus on developing and testing new methods and tools to circumvent the greatest bottlenecks in translational science. By improving the diagnostic and therapeutic development, NCATS will make translational science more efficient, less expensive, and less risky. In this way, NCATS complements — and does not compete with — the work of the private sector and the other NIH Institutes and Centers. To accomplish its mission NCATS creates new synergies among existing programs by focusing on three broad research domains: clinical and translational science activities, rare diseases research and therapeutics, and re-engineering translational sciences. NCATS will also establish and administratively house the *Cures Acceleration Network***,** which was authorized in FY 2012 to advance the development of "high need cures" by funding research projects in new and innovative ways while reducing barriers to translation, in areas the private sector is less likely to pursue. In early 2012, the NCATS leadership hosted a meeting and tour for leaders

of stakeholder constituency groups as well as a webinar in partnership with *FasterCures* for approximately 1,000 NCATS stakeholders.

- ***Pediatrics Formulations Platform***

  This program, which is a collaboration between FDA and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), addresses the need for facilitating formulations for children so that they will take their medicines. Currently there is a lack of commercially available, age-appropriate, oral pediatric dosage forms for several critical diseases. In addition, there is no coherent approach to pediatric formulations development, by industry.

  The Pediatric Formulations Platform initiative seeks to review, categorize, and describe the formulations in a manner that allows others to learn from prior successes and failures through an open-source, publicly available approach. This assessment will be posted on a Pediatric Formulations Platform and made available to sponsors, regulators, scientists, and anyone interested in knowing what approaches were successful for pediatric products with defined chemical characteristics. In addition, this initiative seeks to remove/lessen the technical barriers to production of pediatric formulations by determining and/or developing technologies to formulate medications in appropriate oral pediatric dosage forms, so that they are in an age-appropriate formulation and in the correct dosage amount for the youngest children in an open-source approach. For more information about the Pediatrics Formulations Platform see:
  http://bpca.nichd.nih.gov/collaborativeefforts/initiatives/index.cfm

  Several important milestones have been achieved to date, including an assessment of all commercially available products to determine which have pediatric formulations; and a determination of what technologies are publicly available, how these technologies have been used, and for what types of products. In 2012, FDA staff plan to use prototypical drug products and employ computational methods to characterize their molecular structure. Staff will also determine the best formulations technology for specific drug categories based on information previously identified. In 2013, staff will produce prototype batches of selected drug products with several taste-masking approaches. In 2014, staff will perform bioavailability of prototype products in appropriate preclinical models and standardize the prototype products and perform stability studies to determine shelf-life.

- ***Critical Path Institute Partnership with the Food and Drug Administration***

  FDA established a partnership with the Critical Path Institute (C-Path), an independent, publicly-funded institute, to "Conduct Essential Research to Spur Medical Innovation." C-Path serves as the third-party neutral convener for the collaboration among multiple partners from government, the pharmaceutical industry, academia, patient advocacy groups, and research foundations. Since its founding, five consortia have been established including:

- Coalition Against Major Diseases
- Predictive Safety Testing Consortium
- Polycystic Kidney Disease Consortium
- Critical Path to Tuberculosis Drug Regimens Consortium
- Patient Reported Outcome Consortium

Ideas, expertise, and experience are leveraged to facilitate the development of drug development tools within these consortia. Their efforts demonstrate collaboration and data-sharing in the pre-competitive stages of research and development across multiple stakeholders to optimize drug development paradigms. Activities are ongoing with the expectation that multiple new packages for qualification of drug development tools will be submitted over the next few years. More information for each of these consortia can be found at: http://c-path.org/project-pipeline.cfm

3. COLLABORATIVE DATABASES, REGISTRIES, AND TOOLS FOR INFORMATION SHARING

To foster increased collaboration within HHS, and between HHS and partner organizations, as well as with the public, the Department has focused on the development of a number of platforms and collaboration tools. These include the development and use of tracking and portfolio analysis tools, tools for analysis and visualization, cloud computing, collaborative spaces where information can be securely shared between two or more entities, and shared databases. Provided below are examples of how these new types of collaboration tools and platforms are being initiated across HHS.

- ***Public Health Emergency Medical Countermeasures Enterprise Portfolio Tracking and Coordination Initiative***

  The Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) represents an integrated federal capability to identify, research, develop, acquire, maintain, distribute, dispense, and evaluate critical medical countermeasures (MCMs) such as vaccines, biologics, drugs, and diagnostics to protect and treat the population of the United States in the event of a Chemical, Biological, Radiological, or Nuclear (CBRN) event whether intentional or accidental. To maximize the effectiveness of this resource, the CBRN Medical Countermeasures Portfolio Advisory Committee, which is responsible for providing portfolio analysis and recommendation to PHEMCE leadership, authorized the development of a portfolio tracking system to effectively and efficiently manage our overall investments. Since no such system existed for the PHEMCE arena, this initiative has been crafted to create a capability to enable real-time viewing of the integrated portfolio, conduct analyses, minimize duplication of effort and better anticipate transition points and hand-offs between agencies, and where possible reduce costs and/or development time.

The HHS Assistant Secretary for Preparedness and Response (ASPR) Office of Special Projects in coordination with the agencies involved in the Integrated Portfolio for CBRN MCMs has taken a leading role in developing a cost effective/low risk approach to capture and analyze portfolio data. By using innovative web and cloud technologies the proposed phased approach allows for quick and cost-effective deployment as well as system scalability and security to address current needs and new requirements going forward. The overarching goal of this initiative is to develop a set of PHEMCE common tools including project level tracking, cost, and risk that are based on common business processes and harmonized metrics to use for PHEMCE portfolio tracking and coordination. More information on the PHEMCE Review can be found at: http://www.phe.gov/preparedness/mcm/enterprisereview/Pages/default.aspx

In July 2012, this group will develop a core infrastructure and deliver aggregated analyses and dashboards for the PAC PHEMCE to use for portfolio management. By 2013 PHEMCE expects to move the data-collection component from a stand-alone excel-based application to a globally-accessible web-based user interface. The longer-term goal is to develop an integrated tracking system with other systems that support the financial and risk management components.

- ***Wide-ranging Online Data for Epidemiologic Research***

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 CDC WONDER supports collaboration 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 CDC and their external partners which include state health departments, local cancer registries, the National Cancer Institute (NCI), FDA, the National Aeronautics and Space Administration (NASA), the National Oceanic and Atmospheric Administration (NOAA) and the University of Alabama at Birmingham (UAB) 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 and informatics tools, and improve and enhance the WONDER source code base. More information on the CDC Wonder Program can be found at: http://wonder.cdc.gov/

In 2012-2013, CDC plans to continue collaborations with data stewards in organizations across CDC and their external partners in federal, state and local government, academic and private organizations (as listed above). CDC WONDER also plans to continue collaborative informatics activities with potential partners, such as the Institute for Child Health Policy (ICHP) at the University of Florida College of Medicine, the Administration for Children and Families (ACF), the proposed Integrated Health Disparities Research Coordinating Center at the Houston Department of Health and Human Services, and others.

- ***National Public Health Surveillance/Biosurveillance Registry***

  CDC's National Public Health Surveillance/Biosurveillance Registry for Human Health (NPHSB Registry) is a comprehensive electronic catalog of over 280 CDC public health surveillance and biosurveillance assets related to human health. Launched in December 2012, the Registry provides information to foster collaboration among surveillance subject matter experts, and provides critical information about CDC's surveillance capabilities to decision-makers as they address a wide range of public health preparedness and response issues that depend on effective coordination. The goal is to enable them to better coordinate their efforts to potentially identify and implement appropriate measures for prevention and intervention strategies. The registry is currently located on CDC's intranet and available only to members of the CDC community. Pending the availability of resources, planned improvements to the Registry during 2012-2013 will allow end-users greater access to, and manipulation of, the information in the database to better meet their needs and inquiries. Pending the availability of resources, planned activities during 2013 - 2104 include expanding access to the Registry to our federal, state, and local partners.

4. COLLABORATIVE METRICS DEVELOPMENT

Continuous improvements strategies rely on regularly occurring evaluations to set benchmarks and measure progress. To be effective, consistent metrics must be utilized and compared. The notion of "consistent metrics" can be challenging when multiple stakeholder groups are involved. In several priority areas, the Department has played a lead role in developing common metrics as a tool for measuring our progress towards a stated goal or set of outcomes as well as improving program integrity. Examples of areas in which HHS has taken a lead role in metrics development include:

- ***Single Audit Metrics Initiative***

  The Administration for Children and Families (ACF) carries out a large portion of its mission through grants to non-federal entities including states, Indian tribes, local governments, and non-profit organizations. ACF relies on the "Single Audit" process as a key control over its grant programs to provide assurance that grantees properly administer taxpayer funds consistent with applicable laws and regulations and the terms and conditions of each particular grant. The initiative goal is to hold grantees and ACF program offices accountable to ensure deficiencies identified by Single Audits, which cause an unclean audit opinion, are corrected in a timely manner. Metrics provide a means to gage success in improving ACF program integrity. To achieve this goal, careful analysis of Single Audit findings is performed within and across ACF grant programs, as well as across HHS grantees. More importantly, the use of such metrics may lead to the development of strategies for addressing chronic and pervasive internal control and compliance weaknesses in ACF grant programs and the entities that administer them.

ACF is performing a careful analysis of unclean Single Audit findings across ACF grant programs. Supported by a web-based data collection system, OMB MAX, ACF is identifying those Single Audit findings that pose a risk to ACF programs, working with grantees and auditors to identify root causes, obtaining grantee commitment to strategies to correct materially noncompliant findings, and tracking the grantee's progress in resolving those findings. ACF is developing the Audit Resolution Tracking and Monitoring System, ARTMS, to enhance the Department's ability to meet OMB's challenge for consistency and uniformity in audit resolution and debt management. Through the ACF SharePoint site, ACF is also working to establish a repository of best practices when working with grantee's to resolve findings for ACF staff across its regions. ACF's goal is to achieve 100% clean audit opinions in target programs by FY 2013.

- ***STAR METRICS***

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 NIH, the National Science Foundation (NSF) and the White House Office of Science and Technology Policy (OSTP). Effective January 2012, NIH became the host institution for the STAR METRICS consortium which presently consists of NIH, NSF, EPA, USDA, DOE, and OSTP. STAR METRICS has two levels of activity. The Level I goal is to describe the scientific workforce supported by federal funding. 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. The STAR METRICS initiative began roughly in the second half of 2010, and NIH committed to five years. A formal governance structure was proposed and ratified by agency representatives in January 2012. More information about the STAR METRICS initiative can be found at: https://www.starmetrics.nih.gov

5. WEB-BASED STRATEGIES FOR ENHANCED SHARING OF HHS RESOURCES

The Department is leveraging web-based technologies to improve its interactions with stakeholders. These include strategies such as:

- paperless systems that are customer-focused;
- portals that amalgamate resources in ways that can assist our stakeholders such as patients, provides, and entrepreneurs to effectively utilize HHS products and services;
- real-time information that allows requestors to meaningfully assess the availability of resources;
- new tools for easy, on-line, one-click licensing;
- templates that can be downloaded; and

- syndication tools that allow other organizations to effectively utilize and disseminate HHS-developed or verified content.

- ***Provider Enrollment Improvement Initiative***

  The CMS Center for Program Integrity (CPI) Provider Enrollment Operations Group (PEOG) has made improving customer service a primary goal, and by doing so has begun to change the way providers view and interact with CMS. Provider Enrollment is the registration and verification gateway to the Medicare Program. Provider Enrollment Chain and Ownership System (PECOS) is where the official record of information about that provider and any groups they are associated with is maintained. Provider enrollment also supports claims payment, fraud prevention programs, and law enforcement through the sharing of data.

  The Provider Enrollment Improvement initiative focuses on three primary areas:

  1) *Customer Usability* - Evaluate the user experience from start to finish, simplify the online registration processes, reduce data entry time, and provide tools for large groups and organizations;
  2) *Creation of All Digital Processes* - Remove paper from the enrollment process, leveraging new and existing best practice technology, and allowing increased connectivity for large providers; and
  3) *Increased Communication* - Increasing access and consistency of information and communication with providers, while also increasing access to information for other groups within CMS.

  The CMS Provider Enrollment initiative was launched in 2011. A number of improvements have already been launched this year and will continue through 2012, including:

  - E-Signature (e.g., allowing providers to submit enrollment applications without mailing in a signed signature page);
  - Fast track view (e.g. ability to view and quickly update all enrollment application data from a single screen);
  - Self-service password /username reset (e.g., ability for users to reset their system password or regain username without calling help desk);
  - Searching and Filtering of 3nrollment Records (e.g., ability for PECOS web users to quickly search through their enrollment records);
  - Special screen for state users (e.g. , creation of special screen within PECOS administrative interface that gives state users the ability to quickly view a summary of all enrollment information need by state users on a single screen);
  - Reassignment reporting (e.g., ability for organizational providers such as group clinics who accept reassignments to see the status of all Individual Providers who have reassigned benefits to them);

- Collection of digital documents (e.g., ability to upload supporting documents when submitting an application, removing the need to mail in any additional information); and
- Bulk upload of enrollment applications (e.g. ability for large organizational providers who manage large numbers of enrollments for individual providers to upload hundreds of enrollment applications via an XML form rather than one at a time via the PECOS web interface).

- ***National Institutes of Health Clinical Research Trials and You Initiative***

  NIH recently created a new website, NIH Clinical Research Trials and You to help people learn more about clinical trials, why they matter, and how to participate. Recent research has shown that among the greatest challenges to recruitment of volunteers is the lack of general knowledge about what trials involve, where they are carried out, and who may participate. This site has created a "front porch" for easy entry into all the aspects of clinical trials, bringing together resources from both NIH offices and grantee institutions, such as: information on the basics of clinical trial participation; first hand experiences from actual clinical trial volunteers; explanations from researchers; and links on how to search for a trial or enroll in a research matching program. In addition, health care professionals can read about evidence-based strategies for talking with patients about trials, print audience-tested posters to help promote trials in clinics and offices, and find other educational materials. The site was created by trans-agency cooperation, formative research results, and public and physician participation. An initial version of the website was launched in February 2012. Updates to the site will be made on an ongoing basis, in collaboration with an improved National Library of Medicine clinical trials website. More information about this initiative can be found at: http://clinicalresearchtrials.nih.gov

- ***Electronic Research Materials Catalogue***

  The NIH Office of Technology Transfer (OTT) recently launched the electronic Research Materials catalogue (eRMa) to drive licensing of unpatented materials to companies and support the continued advancement of scientific research in the private sector. The new system will streamline the licensing process by providing a website for companies to find and license unpatented materials using a ready-to-go, one-click license contract, and allowing a company to pay online through Pay.gov. Under the current paper-based system companies must negotiate the terms of the license based upon a model, which can take weeks. The scientist with the materials may no longer have them available by the time the license is complete, and NIH must wait for the paper check to arrive and clear before the materials are sent. This creates unbearable delays of many weeks or months for commercial scientists trying to move projects forward quickly. Sometimes they give up trying. The new site changes this paradigm completely with a searchable catalogue of materials available for licensing, licensing and royalty payment information, and on-line, one-click licensing capability. In addition, the verification of the availability of the research material from the researcher is automated, thereby providing accurate and real time information to the requestor about the availability of materials. The site also automates

the internal routing of the license and provides information to all users on the status of the process. The website provides potential partners with the information necessary to license materials from OTT, including fillable license agreements. The interactive website provides a marketing and licensing option that is designed to expedite the licensing process, decrease transaction costs, and facilitate greater dissemination of research materials. The next version of this site will have even more integration with the staff within OTT to provide them with feedback on the usage of the site as well as provide the ability of licensees to securely communicate with the licensing managers about the research materials. In time, OTT would like to expand the capability to include commercial development licenses in addition to these internal research use licenses.

5. NEW APPROACHES FOR ENGAGING HHS STAKEHOLDER INPUT AND FEEDBACK

Stakeholder input is critical to the ongoing development and improvement of HHS programs. Many HHS agencies are developing new approaches to soliciting stakeholder input and feedback. These include new initiatives to solicit stakeholder feedback at the earliest stages of an initiative, before any action is taken; new strategies for providing ongoing feedback and status updates; and the use of standing forums (as opposed to ad hoc) for interacting with stakeholders. The issue of public participation is so important that HHS established a department-wide task force on public participation in regulatory review and associated activities to explore these issues and develop recommendations.

- ***Public Participation Task Force and Related Initiatives***

  To increase its efforts to promote and develop meaningful public participation, HHS established a Public Participation Task Force which is comprised of members from a number of offices in the Department. The Task Force explores ways to increase interactivity in the public comment process with respect to regulatory review and ongoing regulatory activity, including the use of technology and new media. Some HHS agencies already use these tools to foster public participation in regulatory activities, and other agencies can enhance the regulatory review and development process with increased use of these technologies. The Task Force initiated a Department-wide survey in February 2012 to gain a comprehensive understanding of the regulatory activities and the level of public participation, as well as the tools and methods used to increase public participation.

  Several themes emerged from the survey results and the Task Force's research, including needs to:

  - better educate the public on the regulatory comment process;
  - simplify the comment process;
  - increase access for individuals with disabilities or Limited English Proficiency; and
  - increase public participation in retrospective review.

The Public Participation Task Force submitted a report to the Deputy Secretary in March 2012, which included specific suggestions to promote and develop meaningful public participation in the Department's regulatory processes.

Additionally, the Task Force is developing a comprehensive website devoted to HHS regulations and retrospective review activities. This website will be an interactive, easy-to-navigate, single entry portal allowing users to:

- link to specific regulations;
- find regulations published as proposed and provide comment;
- provide input on the review of any existing regulation;
- read supporting data and other background material; and
- otherwise participate in the regulatory process.

HHS will also post links to its Unified Agenda, as well as information relating to regulatory compliance and enforcement actions.

- ***Promoting Electronic Health Records Adoption through Open Government Approaches***

The Office of the National Coordinator for Health Information Technology (ONC) has enabled dramatic progress in electronic health records (EHR) adoption nationwide using Open Government, collaboration with innovators, and outcomes-oriented regulation. In just three years, ONC has worked with federal partners and private sector stakeholders to establish:

- a clear policy framework for the certification and "meaningful use" of EHRs;
- a competitive market-based program for EHR testing and certification;
- consensus-based standards for medical vocabularies and system interfaces, and technical protocols for securely sending health information over the internet;
- a network of 62 local non-profit "extension centers" that give hands-on assistance to 40% of primary care providers in the United States;
- cooperative agreements for coordination of health information exchange activities in every state;
- a widely used health IT curriculum, competency exams, and a network of 85 university and community college training programs that have enrollment over 20,000 students.

For years technical disagreements and proprietary industry approaches prevented the emergence of widely-implemented standards for health information exchange. The time and effort needed to negotiate each data interchange leads to high costs and low information flow. But top-down promulgation of standards carries significant risk. The ONC's approach is to establish the conditions for accelerated consensus:

- clear objectives (e.g., consensus protocols for sending health information securely over the internet, within 90 days);

- criteria for success (simple enough for "the little guy");
- policy guideposts (no patient identifiers revealed in transit);
- the process (rough consensus and running code) and;
- an open online "wiki."

Over 1,000 private sector experts have volunteered their labor to these collaborative efforts. In February 2012, ONC recognized the first ever consensus standards for laboratory results interfaces, patient summary records for transitions in care, and protocols for sending health data securely over the Internet.

- ***Project Evolve***

  The Substance Abuse and Mental Health Services Administration (SAMHSA) recently launched Project Evolve, a new web consolidation and modernization project. To promote participation and collaboration while still in its developmental stages, Project Evolve actively solicited and incorporated input from the public on key decisions on website organization and how information on the site will be presented. One question that was asked of the public related to what was missing in the agency's initial design of its website (see http://feedback.samhsa.gov/forums/144246-closed-evolve-what-is-missing). In the spirit of transparency, project planning and status updates have been regularly documented on the agency blog (http://blog.samhsa.gov/category/evolve). Using Open Government principals as a foundation for the project helped ensure the final project will align as closely as possible with the needs of the website's visitors. Moreover, integrating these new approaches to engagement and participation into business processes helps SAMHSA increase flexibility and responsiveness to changes in priorities or stakeholders' needs. The website redesign is slated for completion in Spring 2013.

- ***Feedback Project***

  SAMHSA recently launched Feedback Project, using it in concert with its blog to interact with the public and solicit feedback on some of SAMHSA's highest priority projects. These include the drafting of SAMHSA's Strategic Initiative Paper, creating a standard definition of recovery and the ten principles of recovery, SAMHSA's web project – Evolve, and the National Health Communications Conference. In the coming years, SAMHSA will continue to use feedback.samhsa.gov to share new initiatives, gather new ideas, and cultivate a conversation and relationship with SAMHSA's constituency. More information on SAMHSA's Feedback project can be found at: http://feedback.samhsa.gov/forums/148531-help-samhsa-highlight-advances-of-the-behavioral-h

- ***Centers for Medicare & Medicaid Alignment Initiative***

  The CMS Alignment Initiative is an ongoing effort of the Medicare-Medicaid Coordination Office to identify and address conflicting requirements between the Medicare and Medicaid

programs that may create barriers to providing high-quality and cost-effective care for Medicare-Medicaid enrollees. The initial phase of the Alignment Initiative compiled a wide-ranging list of opportunities for statutory, regulatory, and policy alignment in areas identified through numerous discussions with internal and external partners. There were 29 specific areas identified for improved coordination across both programs, which fell into the following categories: care coordination, fee-for-service benefits, prescription drugs, cost sharing, enrollment, and appeals. CMS published this list in the Federal Register on May 16, 2011, and requested public comment to help inform policy and program development. These comments are publicly available on regulations.gov. The Medicare-Medicaid Coordination Office has publicly posted the link to these comments on its webpage which will permit users to link directly to the public comments from the Alignment Initiative and permit a more open and transparent process. Moving forward, CMS will release a public summary providing stakeholders and partners with a broad breadth and scope of the comments received on the Alignment Initiative. Likewise, CMS will continue to host public listening sessions to facilitate a dialogue on better coordination of the Medicare and Medicaid programs on specific alignment opportunities. More information on the CMS Alignment Initiative can be found at: https://www.cms.gov/medicare-medicaid-coordination/07_AlignmentInitiative.asp

- ***International Cooperation on Cosmetics Regulation – Stakeholder Session***

  The International Cooperation on Cosmetics Regulation (ICCR) was founded in 2007 as an international forum for exchanging ideas for how to best maintain global consumer protection in the area of cosmetic products without creating unnecessary obstacles to international trade. FDA's Center for Food Science and Applied Nutrition (CFSAN) is working with counterpart regulatory agencies in Canada, the European Commission, and Japan to host a Stakeholder Session at the upcoming annual ICCR meeting for organizations that are active in the field of cosmetics. The session will provide an opportunity for the exchange of viewpoints among a broad range of participants and to identify potential areas for future work and engagement. FDA will hold a Public Meeting in advance of this event to request information and possible agenda items from interested parties. The annual meeting and ICCR Stakeholder Session are scheduled for July 2012. More information about the ICCR can be found at:
  http://www.fda.gov/Cosmetics/InternationalActivities/ConferencesMeetingsWorkshops/InternationalCooperationonCosmeticsRegulationsICCR/default.htm

- ***Additional Outreach Stakeholder Efforts led by the Food and Drug Administration – Webinars and Liaison and Roundtable Meetings***

  FDA has a number of efforts underway to increase communications with its stakeholders. For example, in an effort to increase collaboration and transparency, the Center for Biologics Evaluation and Research (CBER) established a liaison meeting program whereby the Center meets with external industry organizations on a routine, rather than ad hoc, basis. These meetings are intended to:

- discuss issues of mutual interest to the Center and the requesting organization;
- provide for an exchange of information to allow outside organizations to inform CBER of specific concerns;
- discuss events which have occurred for products of interest; and
- provide information to the external organizations on how the Center operates.

As another example of the agency's outreach efforts, the Center for Food Safety and Applied Nutrition (CFSAN) and the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) are co-sponsoring a webinar in Spring 2012 to acquaint food and nutrition professionals with FDA's regulatory policies related to applied nutrition. This web-based training program will assist nutrition practitioners and educators in understanding regulatory policy issues that are relevant to professional practice.

6. HHS FEDERAL ADVISORY COMMITTEES' OF USE OF ADVANCED COMMUNICATION TECHNOLOGIES

The HHS Federal Advisory Committees (FACs) play a critical role in providing channels allowing the public to engage in federal decision making. There are approximately 270 federal advisory committees that currently provide HHS with advice and strategic input on a broad range of issues. In the winter of 2012, the HHS Office of the Secretary conducted a survey of the HHS FACs to understand how they use advanced communication technologies for both their own work and for purposes of public engagement. Of the 270 FACs surveyed, responses were received from 75. Of the responding FACs, over three quarters (78%) reported using advanced communication technologies in their work. Provided below are highlights of the survey findings:

- Over two thirds of the respondents (68%) reported using advanced communication technologies in their own work. The most widely utilized forms of technology were webcasting technologies (e.g. videocasts or WebEx), followed by electronic voting or ranking capabilities, collaboration tools (e.g. MAX or Microsoft Sharepoint), and E-document software (e.g., paperless office systems). To a lesser extent, committees reported using social networking sites and wikis.

- Over half of the FACs (54%) reported using advanced communication technologies to engage the public in their deliberations. The most widely utilized forms of technology were webcasting technologies (e.g. web-conferencing or video-conferencing). A handful of committees also reported using blogs, social networking sites, twitter, and electronic forums to engage the public. Over half of the respondents (54%) used these technologies for information dissemination to the public; nearly a quarter (22%) used these technologies to engage the public in their deliberations; and 17% used these technologies for information gathering prior to deliberations (e.g. for gaining public perspective on questions to consider).

- Most FACs reported that the use of advanced communication technologies has improved their ability to conduct work and engage the public. Nearly two-thirds (61%) reported an enhanced ability to disseminate information. Other benefits that were noted included: enhanced efficiency in conducting committee work (42%); increased discussions and deliberations among members (32%), increased public (30%); improved diversity among the public input (25%); and FAC members that are better informed of the public's concerns and issues (18%). A number of FACs noted that the overall cost of hosting meetings is reduced as travel expenditures can be reduced and fewer staff resources are needed for travel planning; as materials can be sent electronically, rather than printed; and that member attendance and public participation has increased as a result of virtual meetings.

- We received over 40 comments and examples of the ways in which advanced communication technologies have benefitted FACS. Provided here are examples of them:

  - "The use of Twitter to announce FAC updates and meeting information has allowed us to reach a broader audience; webcasting and archiving the webcasts of our meetings has helped the public to feel more engaged and allowed us a larger cross section of the public to view our FAC activities."

  - We have "used Webex during our last two advisory council meetings. Information technology has opened our meeting to the public and greatly increased participation of the public." In addition, for committee members who have not been able to attend in person, it has allowed them to participate and contribute valuable information and advice during meetings.

  - Our advisory committee "has used webinars for 15 of its 20 public meetings. The use of this technology allowed increased numbers of participants from around the country and the world by providing open and free access to the committee's meetings and deliberations. The online webinar format facilitated timely and efficient meetings of the full committee in a manner that allowed them to deliberate and produce timely recommendations to the Secretary. Further, holding the meeting online as webinars eliminated the expenses commonly associated with in-person meetings."

  - "We frequently webcast our advisory committee meetings. As the public has gotten used to this service and come to rely on it, I find that I hear of more public interest in the meetings. Additionally, several people have contacted me with questions and expressed happiness that they do not need to travel for the meeting in order to see the proceedings."

- FACs cited a number of barriers inhibiting their use of advanced communication technologies. The most widely cited barrier was that access to social media technologies are blocked for FAC members and staff (28%). Other barriers included: unclear agency policies with respect to use of social media (26%) and lack of training or knowledge on how to use these tools (25%). A number of FACs also mentioned the upfront cost and resources (e.g. equipment) and administrative burden associated with webcasting technologies, as well as the lack of in-house technical expertise as significant barriers to the use of advanced communication technologies.

- A number of FACs reported that they would be interested in better understanding and incorporating public priorities in crafting recommendations and policies. Some of the areas noted by FACs include: ensuring that the clinical trials system meets the needs of patients, physical activity guidelines, privacy and security quality measures, employment and health care, and the planning of agency and biomedical community research agendas.

- FACs recommended several actions that HHS could take to improve their use of advanced communication technologies: 1) provide a menu or toolkit of advanced communication tools available to FACs, 2) in cases where tools (such as webcasting) are not available, provide help to ensure low-cost universal access across HHS committees for public input, 3) develop guidelines or best practices for FAC use of social media technologies, and 4) provide training and technical help on the use of advanced communication technologies.

FLAGSHIP INITIATIVES

In its Open Government plan version 2.0, HHS is featuring three flagship initiatives for completion in 2013-14. In the determination of flagship initiatives, the Innovation Council sought projects that were cross-cutting across multiple parts of the organization, featured transparency elements with participation and collaboration components, and/or represented highly innovative approaches to Open Government practices. The Council pursued activities that focused on new approaches to participation and collaboration as a means of strengthening this element of the portfolio. There was also a strong interest in building on the successes that emerged from the Community Health Data Initiative to focus on applications of data, as well as improving the quality of the data and its understandability. HHS will give semi-annual updates on the implementation of these flagship initiatives.

1. Innovation Fellows Program – Promoting Collaboration and Partnerships to Address Important Mission-related Opportunities

This initiative 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 will be launched in early 2012 and aims to have 3 to 5 innovation teams in place by late 2012. The projects will be of 6 to 12 months duration.

With strong assets in place alongside the leadership to create and develop new products, HHS has begun exploring ways to bring entrepreneurial spirit to provide fresh, innovative approaches to agencies. The Innovation Fellows 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.

The HHS Innovation Fellows Program will enable agencies to bring external experts and entrepreneurs on board to work with internal "Host Innovation Fellows" to take on some of the Department's toughest challenges. Host Innovation Fellows are dynamic individuals within HHS who are working to find and scale solutions to the most complex challenges we face. Host Fellows will have the flexibility to experiment, take risks, and converge with like-minded individuals to establish innovation as a key business process and core capability at HHS. "External Innovation Fellows" will be paired with Internal Host Innovation Fellows from within the participating HHS Operating Divisions / Staff Divisions to work on a specific, high-priority project over a period of at least 6 - 12 months. External Fellows will be highly-talented individuals who are equally interested in facilitating the exchange of innovative ideas throughout the Department and pushing the needle forward.

HHS Host Fellows will have the opportunity to work with a team dedicated to rapidly solving high-value problems, with the freedom to iterate and open the doors to co-creation and collaboration. Host Fellows will have the support of senior leadership and resources to develop, test, and implement innovative ideas with External Fellows. For External Fellows, this Fellowship is an opportunity to be paired with an innovative, forward-thinking team at HHS and directly contribute to the mission of the organization. This bi-directional facilitation of innovation is an unparalleled chance to enhance the effectiveness of collaborative learning and move beyond traditional efforts in problem solving. More information about the fellows program can be found at: http://www.hhs.gov/open/initiatives/innovationfellows/index.html

2. New Collaborations to Promote Medical Products Innovation

This thematic area of flagship activity integrates several key areas to improve our nation's approach to innovative new strategies to prevent, diagnose, and treat disease and health conditions. As a composite of several specific initiatives taking place at several HHS agencies, new models of collaboration on innovation pathways for creating new, more effective interventions. Among the various components of this plan are new capabilities addressing unmet public health needs. These include FDA's Innovation Pathway – End Stage Renal Disease Challenge that will introduce new decision tools to help FDA assess and characterize benefits and risks to patients. In a new collaboration model, FDA will use tools and other approaches to foster collaboration with innovators to share ideas about new device concepts. During 2012, this project will complete its collaboration phase with innovators, and in early 2013, FDA will publicly share lessons learned from the process.

Another component of this flagship is an innovative joint FDA-NIH initiative on new pediatric formulations of medical products. This collaboration is designed to address the lack of commercially-available, age-appropriate oral forms of medications for pediatric patients for several critical diseases. The project will use an open-source approach to sharing non-confidential information included in applications to FDA from researchers, regulators, and sponsoring industry through a new platform that promotes networking and collaboration. This project aims to use prototypical drug products and employ computational methods to characterize their molecular structure through standardized testing to produce an open-source, publicly available approach to pediatric oral formulations by 2014.

Collaboration and partnerships opportunities will be key elements underpinning a major new effort underway at NIH to strengthen our nation's medical product pipeline. The National Center for Advancing Translational Sciences is reshaping research capabilities and infrastructure to catalyze a generation of innovative methods and technologies to enhance the development, testing, and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions.

More information about each of these components of this flagship initiative can be found in the participation and collaboration section of this plan. Collectively, these initiatives will

demonstrate new approaches to bringing scientific knowledge together in collaborations that use technology capabilities to foster new ideas and approaches to problem solving. The yield of this Open Government effort will bring innovations in areas of high public health need in 2013 and 2014.

3. Enhanced Data Quality and Usability

Building on the success of efforts to further mobilize the data and information through the Health Data Initiative, new avenues of focused activity on data and information services across HHS will be integrated as a flagship initiative for 2012-2014. The amalgam of programs, strategies, and policies at the heart of many components of HHS are yielding new opportunities for Open Government through better understanding of data and information services derived from them. While our efforts will continue to produce more data and data service technical capabilities, a major thrust of our Open Government plan will be to enhance the quality and usability of the data we publish. The ability to integrate, analyze, and interpret data into useful information services is growing in demand across government and the private sector.

The Health Data Initiative will be enhanced in its service and capabilities for the public through new technology platforms in 2012 that bring new features to enhance access to data and greater opportunity for networking among data users and data providers. The Health Indicators Warehouse will be revised in a new 2.0 version in late 2012 to provide even greater capabilities for machine readable formats enabling machine-to-machine data linkages. These capabilities will further improve the dissemination of information through a wide array of formats. The broader use of application programming interfaces, creation of digital libraries of content, enhancement of metadata directories of our data resources in Healthdata.gov, and use of new tagging methodologies of data elements will increase the efficiency of data transfer, improve the liquidity of data, and further accelerate the use of web services to transfer information to its users. New additions to the collection of linked datasets will provide new insights of information into complex interactions of health and health care services. The redesign of our HHS data catalogue, Healthdata.gov Version 2, will provide many new features for developers, researchers, policy analysts to visualize data in new ways, and have more interactive capabilities to use the data to understand critical problems in health care. This new platform will be open source and opportunities for technology developers to collaborate and participate in the Health Data Initiative by creating modules and applications to further improve the resource will be announced in 2012.

A key area of new datasets and tools in the Health Data Initiative pertains to access of administrative data from CMS. To further support the public's needs, CMS will unveil its Data and Information Product Strategy in mid-2012 that will bring access to new data resources for a wide array of innovative uses. For the first time a designated administrative approach will be in place to offer data users a more complete picture of health care expenditures, use of services, and costs of care at community and provider level. The establishment of data and information services as a core element of organizational business services demonstrates the importance of

data in supporting the transformation of health care delivery into more efficient and higher quality experiences.

The pace of data growth, the complexity of the data sources, and immense dimension of data holdings across HHS are three vectors that contribute to new considerations we are taking with this flagship activity. Generally addressed as "big data," HHS is taking new steps to better manage, store, retrieve, and collect data resources through several initiatives. As part of the National Big Data Initiative, NIH is participating in support of the National Big Data Core Technology Solicitation for research and development activities across the federal government. An array of research program announcements will inspire research, development and application of tools for data acquisition, archiving, retrieval, visualization, integration and management, platform-independent transitional tools for data exchange and for promoting interoperability, and many other capabilities. The National Center for Biomedical Computing consortium supports computing needs from basic research in computational science to providing tools and resources that biomedical and bio-behavioral researchers can use at a variety of levels. NIH also established a Data and Informatics Working Group that is gathering input from a wide array of experts and stakeholders to help address the rapid growth of datasets. Further work is being done on the uses of cloud computing capabilities in research by fostering collaborations with cloud services that will enable researchers to access data more quickly.

While difficult to measure in specific increments, each of these efforts addressing data and information services is expected to improve the speed of knowledge transformation to end users, improve the productivity of HHS programs, and enhance the understanding of data leading to more effective programs administered by HHS. HHS will rely upon strong partnerships with the private sector to promote entrepreneurship and innovations that help in creating value through information services.

SUMMARY

In our work on the initial Open Government plan, the HHS Operating and Staff Divisions leveraged the capabilities of their programs and business processes to collectively improve our capabilities to enhance the benefits of transparency, participation, and collaboration for the public. Most of our initial goals were achieved and many new opportunities to further broaden Open Government processes were discovered. Our administrative practices and planning efforts have accommodated Open Government principles. Our communication efforts through many avenues inside and outside the government have shed new light on how we address mission-related actions. And our use of technology to enhance the principles of Open Government have extended the impact and increased the efficiency of efforts substantially. One key strategy that contributed to our initial success was to embed the principles of Open Government in and across as many processes as possible – from the planning phases of projects, to design and execution, to the evaluation of them. These things we have learned and will now apply in our path forward.

As we take the next steps with the new version of our Open Government plan, observers will note that there is a noticeable continuum from the initial plan. This demonstrates that progress is being made in important ways. There are many new opportunities unfolding, however, where our performance can improve and this plan captures them as well. Readers will also note that we are intentionally placing more emphasis on collaboration and participation efforts with this plan. In the coming months we welcome comments, ideas, and suggestions that can assist us in carrying out the initiatives described throughout this plan. Our hhs.gov/open website will continue to be a place where ideas and reflections on this plan can come together to enable us to succeed in all of aspects of our Open Government endeavors.