United States Department of Health & Human Services

Open Government Progress Report

June 27, 2011

1. Introduction

It has been just over a year since the U.S. Department of Health and Human Services (HHS) first published its Open Government Plan at http://www.hhs.gov/open. Since its publication, HHS has received a wide range of comments and public input that have helped guide the implementation of the plan. HHS has used a variety of new communication strategies, including social media platforms, to engage, inform, and respond to the public. During this period, HHS has made great progress in advancing transparency, collaboration, and participation at the Department, which in turn has helped us to more effectively and efficiently deliver on our mission of promoting the health and well-being of the American people.

This memo highlights some of the most important developments in HHS's Open Government Initiative in four key domain areas: Leadership, Governance and Culture Change at HHS; Transparency and Data Sharing; Participation and Collaboration; and HHS Flagship Initiatives.

2. Leadership, Governance and Culture Change

The promotion of innovation throughout the Department has been a key focus of HHS's leadership, governance and culture change efforts. HHS has sought to promote innovation through the establishment of an interagency Innovation Council to help ensure that innovation efforts are coordinated and infused into the management structure of HHS and through the development of a department-wide contest that celebrates and rewards staff-driven innovations at HHS.

2A. Innovation Council

HHS formed an *Innovation Council* and charged it with the mission of advancing a culture of innovation at HHS. The Council, which contains representatives from every major operating and staff division at HHS, meets monthly to discuss issues of relevance to the Department's Innovation Agenda. The Council oversees HHS's open government efforts, including enhancing collaboration and participation activities at HHS. The Council has actively invited outside stakeholders to participate in these meetings as a way of bringing an external perspective to the dialogue and to provide a forum through which agency leadership can consider private sector, non-profit, and other governmental agency perspectives in its deliberations. Examples of outside speakers who have participated in HHS Innovation Council meetings include: Dwayne Spradlin, CEO of Innocentive; Sanford Lew, Director of the Office of

Innovation in the Social Security Administration, and Darrell West, founding Director of the Center for Technology Innovation at the Brookings Institution.

2B. HHS*innovates* Program

A key early win for the HHS Innovation Council has been the successful launch of a new Secretary's open innovation awards program, HHS*innovates*, which rewards and recognizes promising innovations across HHS. Via an online tool, any HHS employee can nominate an individual or team that has executed a notable change in how HHS works for the better. All employees then vote online for the best innovations, which are sent to the Secretary for her to pick the top winners. To date, HHS has successfully executed two rounds of HHS*innovates* (the first round in Spring 2010 and the second round in Fall 2010). A third round commenced on May 2nd, 2011. Thus far, the competition has led to the identification of nearly 200 exciting innovations at HHS. In each round, approximately 10,000 votes were cast by HHS employees who had viewed and commented on these promising innovations. Thus far, a total of twelve "finalist teams" have been selected by the Secretary for recognition. The recognition ceremonies are made available to the entire HHS community as well as the public via webcast. More information about the contest, including a gallery featuring the winning innovations and archived videos of the awards ceremony can be found at http://www.hhs.gov/open/innovate/index.html. The program has also sparked efforts to scale and disseminate the successful innovations from this program throughout HHS. For example, Text4Baby, a program executed through a public-private partnership that received an HHS*innovates* award, triggered the launch of an HHS Text4Health task force to pursue the utilization of text messaging to improve health in other areas, such as smoking cessation and childhood health.

3. Transparency & Data Sharing

During the past year, HHS has made great strides in its efforts to enhance transparency and data sharing at the Department. Notable highlights include the fulfillment of many of our commitments to release new, high-value data sets and tools, plus the release of substantial additional data assets beyond what we committed to do in our plan; improvements in the quality of HHS financial data made available to the public; and a 53% reduction in our Freedom of Information Act (FOIA) backlog. These efforts are further elaborated on in the following sections.

3A. High Value Data Sets and Tools

Provided below is a table summarizing the current status of the HHS high-value datasets and tools that we committed to release in our Open Government Plan:

Data Set/Tool	Status
CMS Dashboard (inpatient + prescription drug)	Completed
Medicare claim "basic files" for 9 major categories of care services – the first-ever claim-level files available for free public download	Completed
New user interface/analytical tool/APIs for provider quality COMPARE data at data.medicare.gov	Completed
Medicaid State Plan documents	In Progress
New Medicare community-level indicators of prevalence of disease, prevention, health care quality, and utilization of services to be supplied to the Health Data Initiative	Completed
FDA-TRACK	Completed
Summary data from FDA's reportable food registry	Completed
FDA recall data downloadable in XML format	Completed
Administration on Aging Annual National Survey of Older Americans Act – raw data set	Completed
Centers for Disease Control and Prevention BioSense Condition-Specific Data	Completed
Office of the National Coordinator for Health Information Technology Dashboard	October 2011

Below are additional details on the new FDA data assets in particular:

- *Reportable Food Registry:* in Q2 FY 2011, FDA posted new summary aggregate data resulting from the first year of the Reportable Food Registry at http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/RFR/default.htm. The FDA Reportable Food Registry contains information about foods for which there is a reasonable probability that the article of food will cause serious adverse health consequences or death. Regulated industry submits reportable food reports to FDA for possible inclusion in the Registry via an electronic portal. Federal, state, and local government officials may also voluntarily use the electronic portal to report information that may come to them about reportable foods. FDA posts annual reports summarizing certain aggregate data from the Registry online. FDA will continue to design, develop and deploy annual aggregated data reports through information submitted to the Reportable Food Registry.
- *FDA Recalls Website:* FDA has created a new section of the FDA Web site for agency data sets including data sets for recall information. The new section can be found at http://www.fda.gov/AboutFDA/Transparency/OpenGovernment/default.htm. The new section includes all available downloadable data for major recalls from 2009 to present based on information provided by firms in press releases, including

data on the recent Shell Egg recall. The new gateway features data sets in XML format, which allows developers to easily create applications and mashups centered around FDA data. The data may also be available in other formats such as Excel and PDF. This new section became available on September 30, 2010.

In addition, in February 2011, HHS launched a new community on Data.gov, Health.Data.gov, that serves as a one-stop resource containing the following: (a) listing free, publicly available health-related data sets and tools available from HHS and other agencies, (b) an "apps expo" containing examples of health data-powered apps and services, (c) an online forum to discuss health data, and (d) a listing of non-federal open health data sets. HealthData.gov currently lists 241 data sets and tools (190 from HHS), with more being added on a continuous basis. Notable new resources made available through HealthData.gov (in addition to the new high-value data sets and tools listed in the table above) include the Health Indicators Warehouse (at healthindicators.gov), deployed in February 2011 and which contains over 1,170 metrics of community health and health care performance across the country (available for download or accessible via a web services API); Medline Plus Connect, a powerful new service deployed in November 2010 that serves up customized packages of patient education content from the vast Medline Plus library to electronic health records and personal health records; and much, much more.

Three additional data transparency actions over the past year are worthy of note:

- *HealthCare.gov:* HealthCare.gov is a new website launched by HHS in July 2010 that helps consumers take control of their health care -- by putting the power of information at their fingertips. It is the first website to provide a comprehensive catalog of both public and private health insurance options across the U.S. in a single, easy-to-use tool for consumers. Based on your answers to a series of questions, the site automatically produces a personalized menu of insurance options that may be right for you -- drawing on information compiled by HHS on thousands of private health insurance plans (including detailed pricing and benefit information, and never-before-seen information such as the percentage of applications for a given insurance product that are denied) and on every Medicaid, Children's Health Insurance Program, and pre-existing condition insurance plan in the country. HealthCare.gov puts consumers in charge by providing a one-stop resource that takes much of the guesswork and confusion out of finding the right coverage -- making the insurance marketplace more open and transparent than ever before. In addition, the site also provides information that helps consumers find high quality care providers and prevention tips that can help them stay healthy. Since its launch on July 1, 2010, HealthCare.gov has received over 6 million visits, with visitors spending an average of ten minutes on the site, and has won widespread praise for its usefulness as a consumer tool from voices ranging from Consumer Reports to the American Heart Association. The HealthCare.gov team has worked to continually refine and improve the site, with the help of ongoing user input, gathered through "yellow bubbles" that are placed throughout HealthCare.gov, asking if users found a particular page useful, and inviting

suggestions on how to improve it. "Yellow bubble" input is reviewed weekly and utilized to determine how to make HealthCare.gov even more useful.

- *"Blue Button:"* the Blue Button initiative is a joint venture between the US Department of Veterans Affairs (VA), HHS, and US Department of Defense, in which these three agencies have collectively undertaken the simple but powerful action of allowing veterans, Medicare beneficiaries, and members of the military to freely and easily download electronic copies of their own personal health information or claims (by simply hitting a newly installed "Blue Button" on the VA, Medicare, and military's patient/beneficiary websites). Deployed in October 2010, the "Blue Button" capability has already been utilized by over 310,000 unique users (including over 75,000 unique Medicare beneficiaries).

- *Sustainability Efforts and Outcomes:* Executive Order 13514 of October 8, 2009 titled *Federal Leadership in Environmental, Energy, and Economic Performance* set sustainability goals and planning requirements for federal agencies. Additionally, it established a policy requiring agencies' efforts and outcomes in implementing the order to be transparent and disclosed on publicly available federal websites. In 2010 HHS developed its first Strategic Sustainability Performance Plan (SSPP) for implementing the order and issued an updated SSPP in June 2011, which described HHS's 2010 outcomes, planned efforts and related transparency initiatives. These initiatives included publication of the SSPP and a scorecard showing progress in meeting sustainability goals on the publicly accessible HHS and OPDIV internet websites and social media platforms, and using other established Open Government initiatives such as *HHSinnovates* to incentivize innovations needed to meet sustainability goals. These sustainability initiatives were developed concurrently with the HHS Open Government Plan and will be fully integrated into the Plan in 2011.

3B. Enhancing Financial Data Quality

HHS has made tremendous progress in meeting the goals of the HHS Open Government Financial Data Quality Plan. Since the launch of Open Gov in December 2009, the Office of Grants and Acquisition Policy and Accountability within the Assistant Secretary for Financial Resources has partnered with HHS awarding agencies, OMB, government-wide taskforces and workgroups, and the public to make HHS data more useful, complete, accurate, and timely. Key highlights of our progress on the Open Gov Financial Data Quality Update include:

Improving Financial Data Quality posted to the Web

- Completed a 2011 assessment to certify the accuracy and completeness of contract data submitted to the Federal Procurement Database-Next Generation system.

- Instituted new policy and procedures for reviewing Recovery Act data released to the public and the Recovery Act Transparency Board including leveraging SharePoint technology to reduce burden and cost for data quality reviews.

Engaging the Public in New Participation and Collaboration Efforts

- Met with the Sunlight Foundation to discuss concerns for USASpending.gov data quality and to open dialogue for defining appropriate metrics for performance.
- Developed new functionality for the NEW Tracking Accountability in Government Grants System (TAGGS) web-site at http://taggs.hhs.gov/ to solicit public feedback and to track, monitor, and evaluate data quality recommendations and comments from the user community.

Improving and Increasing Transparency and Accountability of Federal Funds

- Closed identified data quality gaps for CMS Medicare Prescription Drug Coverage, Hospital Insurance, and Supplementary Medical Insurance programs submitting over $1 trillion dollars in spending data to USASpending.gov.
- Performed a large scale re-design of the TAGGS web-site at http://taggs.hhs.gov/ to provide the public better tools for accessing HHS grant data. Features of the web-site include updated search capability; improved navigation, look, and feel; and increased spending reports.

3C. Freedom of Information Act Excellence

Throughout 2010, HHS achieved major FOIA backlog reductions. After several components launched backlog reduction projects, HHS's total backlog decreased by over 53 percent. Across HHS, the major operating components continue to evaluate their FOIA processes and to look for areas to improve. Several offices are considering a joint collaboration involving information technology, and evaluating how it can be utilized to enhance FOIA request processing to make it faster, easier, and more user-friendly.

HHS has undertaken a number of initiatives in its Freedom of Information Act (FOIA) operations in line with the Open Government plan. For example, FOIA Officers and other officials have taken steps to inform HHS staff members of the President's and the Attorney General's policy concerning the presumption of openness through distribution of the memoranda and continued training in its application. One major effort was the first Department-wide FOIA conference, which included training for junior staff, and more advanced subjects and discussion for the HHS' FOIA Officers and senior staff.

A number of HHS operating components report renewed efforts to instill the spirit of openness in their daily processing of FOIA requests. The FOIA offices are working with program staff to increase proactive disclosures by identifying materials responsive to FOIA requests. HHS now posts a variety of information that used to be

available only by making a FOIA request, including Office of the Inspector General reports, audits, and testimony; various community health center information; and a broad variety of FDA reports and Advisory Committee Meeting minutes.

4. Featured Participation and Collaboration Activities

Furthering our ability to engage HHS stakeholders has been a major thrust of HHS's participation and collaboration activities. An important focus of the Department's activities has centered on the promotion of a new Congressionally-authorized policy tool – the prize & challenge mechanism – through which federal agencies can provide incentives to external stakeholders to assist in developing, testing, and implementing creative solutions to pressing problems

In addition, HHS has sought to leverage new social media technologies, such as text messaging, content syndication, twitter feeds, and ideation tools to better engage our partners. These efforts have particularly helped to improve HHS's ability to connect with and provide useful information to stakeholders. Described below are updates on three exciting newly launched activities: product safety text messaging pilot; social media tools for tobacco regulations; and the tobacco content syndication pilot.

4A. Stakeholder Engagement through Prizes and Challenges

Through the coordinating efforts of its Innovation Council, HHS has embraced the notion of engaging HHS stakeholders through prize and challenge competitions to help the Department in solving its most pressing problems. To date, HHS has launched or participated in approximately 20 challenge contests, all of which are available to the public through the Challege.Gov site at http://challenge.gov/HHS. These contests have helped to identify and recognize new approaches to program recruitment; lead to the development of inspirational videos about real-life confrontations with drug abuse and addiction; inspire communication materials about new approaches to healthy living; promote the development of mobile and wireless applications that help consumers find the best care providers, and foster the development of prototype web and mobile communication technology applications to enable communities' use of population data for cancer prevention and control. In many of these cases, HHS has been able to gather novel approaches that it did not have the capacity to develop internally.

The Innovation Council is actively developing guidance and educational materials for HHS program managers who wish to engage the public and other stakeholders in helping the Department to solve mission-relevant problems. Simultaneously, the Council is working with the HHS Office of General Council to clarify and resolve important legal and policy issues related to the development and execution of challenges.

4B. Product Safety Text Message Pilot

The MedWatch Mobile Pilot began March 11, 2010 and was completed October 14, 2010. The purpose of the project was to determine the acceptability by healthcare professionals, patients, and other members of the public of using text messaging to receive MedWatch Safety Alerts. The content of the text messages consisted of alerts that provided timely new safety information on human drugs, medical devices, vaccines and other biologics, dietary supplements, and cosmetics. The alerts contained actionable information that may have impacted both treatment and diagnostic choices for healthcare professionals and patients.

The pilot was evaluated by presenting text messaging subscribers with a series of questions to determine the effectiveness and usefulness of the messages as well as users' satisfaction and message delivery preference.

Over 1,900 individuals subscribed during the pilot; however, there were few respondents to the evaluation questions. Although a large majority of respondents were satisfied with the pilot, additional studies are needed to evaluate if text messaging would be widely preferred among the target audiences.

4C. Social Media Tools for Tobacco Regulations

The Food and Drug Administration is using social media tools to increase awareness and engage stakeholders about new tobacco control regulations. On June 22, 2010 the Center for Tobacco Products (CTP) launched the *Break the Chain of Tobacco Addition campaign* to raise the awareness of tobacco retailers on the front lines of this issue as well as consumers, the tobacco industry, and community tobacco control advocates about new tobacco product regulations and their purpose. The campaign features both traditional campaign materials and open government technologies to maximize the impact of the campaign with our audiences and better reach our communication objectives. The tools are notable because they provide portable content, encourage participation, leverage networks, and provide information in multiple formats.

The campaign has been successful in meeting FDA's primary communication goals. For instance, in a few months, FDA received almost 50,000 visits to the website. The agency also found that almost 90% of the text messaging subscribers were satisfied or very satisfied with our text messaging project. Likewise, about 88% of the subscribers thought the messages were effective or very effective in meeting their needs. The campaign had almost 4,000 Twitter subscribers. This campaign is continuing and FDA is working on making data-driven enhancements to the social media components and developing deeper evaluation strategies to assess usability, content effectiveness and impact.

4D. Tobacco Content Syndication Pilot

FDA also launched a pilot content syndication project last year in collaboration with the Centers for Disease Control and Prevention. The goal was to more widely disseminate important health and regulation information while delivering resource-strapped partners and health groups free, timely, relevant, and accurate web content. Partners benefit as they can now provide free tobacco-related web content and open up resources for other efforts.

FDA invested in content syndication to broadly share online health information and meet growing audience demand for up-to-date reliable health-related content across the web. Syndication allows multiple partners to subscribe to and automatically display up-to-date content on their webpages. The groups providing this content benefit by strategically reaching new audiences and increasing exposure to and reach of messages. The websites displaying syndicated content benefit by utilizing a low-cost, simple way to add reliable content without losing visitors by linking to outside websites. In addition, syndication helps meet the Open Government Initiative by improving health information dissemination by collaborating to improve reach, access and trust of health messages and allowing for strategic placement of content on partner websites.

Bringing this technology to the FDA requires new technology and CDC and FDA are working to develop and implement business requirements, technologies and research requirements. In addition to the technological components of the project, both agencies are working to develop a data-driven strategy for developing, disseminating and evaluating the content used in the syndication project.

4E. Direct Project Collaborative

In response to a physician's observation at a public hearing that there was no easy, secure way for him to send a patient's information from his electronic health record software application to another doctor's electronic health record software application, the Department of Health and Human Services launched the Direct Project – an initiative to develop a way to help health care providers send electronic information to each other in a way that is both secure and extremely easy to do. HHS's Office of the National Coordinator for Health IT decided to execute this project via an open innovation approach that delivered spectacular results. As opposed to convening a wholly internal team to solve the problem, HHS instead posed the problem as a public challenge, launched in March 2010, and invited all willing participants to join a Direct Project Collaborative that would work to develop an answer to the problem via a public wikispace and forums, open and visible to all. Over 60 companies and organizations joined the collaborative. In three months, they hammered out a solution: a protocol for secure health care email over the Internet. The Collaborative executed the first production transactions using this protocol in January 2011. By March 2011, nearly 70 companies representing over 90% of the U.S. electronic health

record market had committed to enabling their products to interact with others using the Direct email protocol.

5. HHS Flagship Initiatives

In the HHS Open Government Plan, we identified key activities that represented new strategies and approaches to serve the public's information needs and access points. We identified 5 "flagship initiatives" last year and each of these has made substantial progress. Provided here is an update on the progress of each of the flagship initiatives with a look to their future developments.

5A. Health Data Initiative

In March 2010, HHS took the first steps toward promoting the uses of HHS-developed data from surveys, administrative processes, and other sources and promoted its use to the public. Underpinning this initiative is the recognition that there are vast needs for information by consumers, health care providers, policy makers and others to guide decisionmaking in many aspects of health and health care. This effort was established a "health data ecosystem" in which data resources were integrated into electronic platforms aimed at consumer health, community health and health care users.

In June 2010, a conference was held with the Institute of Medicine to showcase more than 20 new applications that were developed to use HHS data and inform decisionmaking. This sparked a major effort for data production, applications development, and uses. Across HHS, major efforts were committed to helping organize already existing data and tools with links to one common website. This effort to facilitate data transparency has yielded more than 230 datasets and tools that can now be found on a common website known as HealthData.gov. Healthdata.gov, the common site for identifying data resources, has many Web 2.0 features that enable users to see ratings and rankings and comments from other data users. A linkage to an "apps expo" provides interested parties with examples of how others have used the data.

HHS also unveiled an additional new resource known as the Health Indicators Warehouse (healthindicators.gov) with many new automated download features to support computer-to-computer linkages of data resources. In this warehouse are more than 1170 indicators of all sorts of health status indicators, administrative data, and others that are now being widely used by application developers, researchers, policy makers and others. Cumulatively, these new data resources are shining a light on major issues in health and health care – such as differences in quality of care, outcomes, and incidence of disease and conditions. This year, expanded efforts are being made to bring information on health and social services in various community resources into HealthData.gov as well. With the expansion of the focus from

community level data to more broad and diverse sources, HHS now refers to these collective activities as the "Health Data Initiative."

To further promote the use of health data, HHS has partnered with a number of non-governmental organizations to hold challenges and competitions to inspire new developers to create tools and resources that use HHS data. Additionally, events that bring data experts and technology developers together, called 'code-a-thons' have yielded new ideas and applications of health data. Over the last year, more than 30 of these events have been held and yielded an impressive array of technologies to further integrate uses of data into health and health care decision making.

In June 2011, the second annual Health Data Initiative Forum was held in conjunction with the Institute of Medicine. Over 75 new applications were submitted in response to the meeting sponsors' solicitation, and nearly four dozen of the most promising new applications and services that have been developed using HHS data were showcased at the meeting. Additional efforts are now focused on use cases for how data can be used to address issues such as patient safety, obesity, regional differences in health outcomes, etc. The Health Data Initiative is beginning to engage a wide array of partnerships with foundations, philanthropy, private industry, health care delivery networks, academia, and state and local governments. This effort is continuing to promote the uses of data in a broad array of ways that creates value for the users.

5B. Centers for Medicare & Medicaid (CMS) Dashboard

The Centers for Medicare & Medicaid Services (CMS) has developed a series of dashboards, which are exciting new web applications that allow the public to visualize and analyze Medicare spending with unprecedented ease and clarity. By simplifying and making data more accessible through dashboards, the CMS aims to facilitate the ability of researchers and policymakers to ask questions and quickly obtain answers, thus helping to accelerate efforts to improve the nation's health care delivery and payment systems.

To date, CMS has developed two dashboards that are available to the public on the CMS website at https://www.cms.gov/Dashboard/01_Overview.asp#TopOfPage. Both dashboards have demonstrated success as evidenced by recently released metrics:

- The Medicare Inpatient Hospital Dashboard offers statistical views of the Inpatient Prospective Payment System (IPPS) data as it relates to claims payment and volume as collected by CMS. This external-facing dashboard has had 1,495 hits since January 2011 and is currently available and refreshed the second Monday of each month.

- The Medicare Prescription Drug Benefit Dashboard BETA is a beta release and offers statistical views of the Prescription Drug Event (PDE) data as it relates to

drug costs and utilization as collected by CMS. Currently, HHS is planning to add the 2009 data in June; future releases may contain additional CMS Program data. This external facing dashboard has had 1,297 hits since January 2011 and is currently available and refreshed annually after reconciliation occurs in June.

In addition to these dashboards, CMS is in the process of developing two additional public-facing dashboards: the Physician Supplier (Part B) Dashboard and the CMS Enrollment Dashboard. The CMS is projecting a Fall 2011 release for both dashboards.

5C. FDA Transparency Initiative

Since June 2010, FDA has made substantial progress towards the goals of its Transparency Initiative. Among other things, FDA has issued two major reports proposing new disclosure initiatives and launched a second website (*FDA Basics for Industry*), in addition to its initial *FDA Basics* website. Below, we provide updated information on each of the 3 phases of the Transparency Initiative identified in the 2010 report.

Phase I: FDA Basics

This resource now includes (1) 156 questions and answers about FDA and the products that the agency regulates, (2) eight short videos that explain various agency activities and (3) conversations with 14 agency officials about the work of their offices. The site has received over 1.2 million visits since launch. The videos have received over 20,422 views, and the agency has received over 9,000 comments and ratings from the public. Feedback provided by the public is used to update the resource. There is now a section of FDA Basics that allows visitors to see the number of comments and ratings as well as the average score of ratings per product category (accessible online at http://www.fda.gov/AboutFDA/Transparency/Basics/ucm1176986.htm). Visitors can also see the web traffic to this section by month in this metrics section.

Each month, senior officials from FDA product centers and offices host 30 minute online sessions about a specific topic and answer questions from the public about that topic. So far, FDA has hosted 13 webinars with the average number of attendees being around 200.

Phase 2: Public Disclosure

On May 19, 2010, FDA issued a draft set of 21 proposals for disclosing information on a range of topics, including adverse event reporting, enforcement actions and letters, import procedures, inspections, as well as the existence, status, and content of product applications, and recalls (report accessible online at http://www.fda.gov/AboutFDA/Transparency/PublicDisclosure/default.htm). FDA received 145 public comments on the draft proposals. FDA has reviewed the

comments, and has conducted resource, legal, and priority assessments to determine which proposals to implement and in what order. FDA has implemented 4 of the proposals, including the launch of a database providing information about all the inspections related to marketed products that the agency has conducted, and has announced plans to implement 3 more before the end of the year.

Phase 3: Transparency to regulated industry

On January 6, 2011, after holding 3 listening sessions with industry and receiving written comments, FDA released a report containing 19 action items and five draft proposals to improve transparency to regulated industry (accessible online at http://www.fda.gov/downloads/AboutFDA/Transparency/TransparencytoRegulatedIndustry/PhaseIIITransparencyReport/UCM239088.pdf), including a web-based resource called *FDA Basics for Industry* to provide basic information about the regulatory process, including information that is frequently requested by industry. FDA sought public comment on the report. The comment period closed on March 6, 2011.

On the same day that the report was released, FDA launched *FDA Basics for Industry*. This resource includes: easier access to frequently requested content including guidance documents, information about the review process, and registration and listing information; links to training modules for industry, such as the Center for Devices and Radiological Health's CDRH Learn educational tool; answers to questions frequently asked by industry including a rating system so visitors can rate the helpfulness of the answers; and an interactive flowchart that helps industry determine whether or not their product is regulated by FDA.

Since launch, *FDA Basics for Industry* has received over 68,000 visits.

5D. FDA TRACK

FDA-TRACK adheres to values that comprise its name – **T**ransparency, **R**esults, **A**ccountability, **C**redibility and **K**nowledge-sharing. FDA's senior leaders continue to be committed to making FDA-TRACK successful and sustainable, and ultimately a model for open government at the federal level. Below are some updates on planned continuous improvements since the April 2010 launch:

Alignment of FDA-TRACK measures to the annual agency performance measures such as those required by the Government Performance and Results Act of 1993 (GPRA)

FDA has completed the alignment of our GPRA measures to FDA-TRACK measures. Although some of our annual measures are directly tracked on FDA-TRACK, there are some that are not (since these measures are longer term annual measures, as opposed to monthly FDA-TRACK measures). FDA is in the process of addressing

this issue and developing monthly indicators to better align to annual long-term measures.

Alignment of FDA-TRACK measures to individual employee performance plans

The Commissioner's FY11 SES plan includes as an element the alignment of FDA-TRACK program measures to program outcomes and this element cascades down to senior executives across the agency. Additionally, Center and Office Directors have begun to align more program-specific strategic priorities with FDA-TRACK goals, which are also incorporated into individual performance plans where applicable. For example, our Center for Devices and Radiological Health (CDRH) has a 2011 Strategic Priority initiative to enhance the efficiency and clarity of the medical device and radiation-emitting product recall processes. CDRH tracks the specific milestones and progress as a key project within the CDRH compliance dashboard in FDA-TRACK, and the milestones are included in the Office of Compliance Director's FY11 SES plan.

Improvements to FDA-TRACK data management and reporting software

In late 2010, FDA released a Request for Information (RFI) for potential business intelligence platforms and data warehousing capabilities to better support FDA-TRACK data management, analytics, and reporting. FDA has completed an evaluation of all the RFIs and is in the system demonstration stage.

FDA began publishing public briefing summaries on the FDA-TRACK website (www.fda.gov/fdatrack) in January 2011. In addition to the data updates, the public can now read (as well as submit comments on) summaries of progress and accomplishments discussed internally at the quarterly briefings. Other enhancements to facilitate public access since the April 2010 launch include: a "Search FDA-TRACK" function; monthly "FDA-TRACK Updates" email subscription feature; redesign of our home page, which now features monthly updates, Spotlight of the Month, and upcoming changes.

Improvements to measures based on public input and experience so that measures can be more closely tied to the public health mission of the agency

FDA conducts real-time monitoring of the FDA-TRACK email account (FDATRACK@fda.hhs.gov) and integrates public feedback where appropriate. The public can also submit feedback via the FDA Transparency Blog.

Internally, FDA regularly analyzes, evaluates, and enhances existing measures and data results during quarterly briefings to ensure the information tracked is meaningful and more closely tied to program goals and, ultimately, public health outcomes. To date, the agency conducts about 20 briefings every quarter, for almost 80 briefings since the April 2010 launch. FDA publishes updates to measures and performance data every month on the FDA-TRACK website.

FDA has identified and implemented five new cross-cutting TRACK programs focusing on Advisory Committees vacancies, Freedom of Information Act (FOIA) backlog, Office of Regulatory Affairs (ORA) Lab Throughput, FDA's efforts to reduce the rate of Salmonella Enteritidis (SE) illness in shell eggs, and implementing FDA components of Health Care Reform. Several more are underway, including a program to track FDA's implementation of its Medical Counter-Measures program.

In July 2010, FDA implemented a monthly FDA-TRACK Updates email subscription to keep the public informed of updates and provide additional venues for submitting feedback. Currently, FDA-TRACK has almost 8,000 subscribers and continues to grow (on average, 25% every month).

Implementation of improvements to FDA-TRACK performance data analysis to enable better predictive outcomes and other quantitative data-based decision making

FDA is assessing sophisticated analytic capabilities as part of its current RFI and market research on business intelligence and data warehousing platforms. As FDA-TRACK accumulates data, predictive analysis and other quantitative and qualitative-based decision making continues to strengthen. To date, the agency has implemented over 600 performance measures and 100 key projects.

A sample of significant accomplishments from the first year has been published on the FDA-TRACK website, and will be updated on a regular basis. Accomplishments include:

- Reduced advisory committee vacancy rate by 25%
- Successfully piloted an electronic lot release submission program to increase efficiency and effectiveness of releasing H1N1 vaccines to the public
- Exceeded annual target by 10% for first year implementation of Quality by Design for new drug applications
- Increased medical device reporting participation rates of hospitals in the Medical Product Safety Network (MedSun) by over 70%
- Developed and implemented measures to track FDA’s implementation of the Egg Safety Rule (Egg-TRACK), and ultimately reduce the rate of SE illness from shell eggs
- Eliminated and sustaining a zero backlog of generic new animal drug applications from over 130 applications.

5E. HHS Excellence in Freedom of Information Act (FOIA) Initiative

As discussed in Section 3B of this report, a number of HHS operating components are working with program staff to increase proactive disclosures by identifying materials responsive to FOIA requests. As a result of these efforts, HHS has achieved major FOIA backlog reductions during 2010. One notable example is the FDA, which is

actively participating in all aspects of the HHS FOIA initiative through tracking the number of incoming requests, number of processed requests, and number of pending/backlogged requests and providing weekly reports to HHS FOIA.

As a result of these efforts, FDA's FOIA backlog has decreased 11.3% since the end of FY10 (from 4691 pending requests to 4161). This brings the total reduction over the last four years to about 80%.

Currently, while most agency components are responding to most or all requests within the statutory timeframe of 20 days, there remain significant backlogs in the two components that receive the highest number of complex FOIA requests. The two components with the highest backlogs are continuing to review their procedures to identify strategies for backlog reduction. For example, additional staff training has been provided; workload queues have been rebalanced in order to respond to more requests within 20 days; and additional administrative support has been offered through headquarters (Division of Freedom of Information).

Going forward, FDA will continue to focus on the components with the largest backlogs. These components will continue to review SOPs and provide additional staff training. FDA will also continue to enhance transparency by posting high-profile records to the agency's internet website, which may have the effect of reducing the number of incoming FOIA requests. In addition, Division of Freedom of Information will continue to provide administrative support to assist components handling large volumes of FOIA requests. Finally, FDA is making enhancements to its existing FOIA tracking database that could assist with workload monitoring and backlog reduction.

6. Summary – Continuing to Build on the Open Government Momentum

This report summarizes a small number of the events, capabilities, resources, and other enhancements that represents the work at HHS over the past year to focus on Open Government strategies. A key strategy from the beginning has been to integrate the principles of open government – participation, collaboration, and transparency – into each program and initiative when possible. Across HHS, through the vision and leadership of Secretary Sebelius, greater dialogue and awareness of the importance of these principles have occurred. In the next year, additional milestones and projects will be undertaken to reinforce the positive changes that have occurred. Throughout the year, we will continue to promote these changes in our communications and all aspects of the work that is done on behalf of the American people.