to pay the deductibles and coinsurance for dually-eligible beneficiaries.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This notice will not have a substantial effect on State or local governments.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance)

Dated: September 9, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 29, 2010.

Kathleen Sebelius,

Secretary.

[FR Doc. 2010–28251 Filed 11–4–10; 2:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Secretary's Advisory Committee on Heritable Disorders in Newborns and Children; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Secretary's Advisory Committee on Heritable Disorders in Newborns and Children.

Dates and Times: January 27, 2011, 8:30 a.m. to 5 p.m. January 28, 2011, 8:30 a.m. to 3:30 p.m.

Place: Renaissance Washington, DC Dupont Circle Hotel, 1143 New Hampshire Avenue, NW., Washington, DC 20037.

Status: The meeting will be open to the public with attendance limited to space availability. Participants are asked to register for the meeting by going to the registration Web site at *http://altarum.cvent.com/event/SACHDNC012011.* The registration deadline is Tuesday, January 25, 2011. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations should indicate their needs on the registration Web site. The deadline for special accommodation requests is Friday, January 21, 2011. If there are technical problems gaining access to the Web site, please contact Maureen Ball, Meetings Coordinator at *conferences@altarum.org.*

Purpose: The Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (Advisory Committee) was established to advise and guide the Secretary regarding the most appropriate application of universal newborn screening tests, technologies, policies, guidelines and programs for effectively reducing morbidity and mortality in newborns and children having or at risk for heritable disorders. The Advisory Committee also provides advice and recommendations concerning the grants and projects authorized under the Public Health Service Act, 42 U.S.C. 300b–10, (Heritable Disorders Program) as amended in the Newborn Screening Saves Lives Act of 2008.

Agenda: The meeting will include: (1) Presentations from the following Advisory Committee workgroups: Communications, Health Information Technology, and Evidence Review; (2) a report from a National Survey of Recent and Prospective Mothers about Newborn Screening; and (3) presentations on the continued work and reports of the Advisory Committee's subcommittees on laboratory standards and procedures, follow-up and treatment, and education and training. Proposed Agenda items are subject to change as priorities dictate. You can locate the Agenda, Committee Roster and Charter, presentations, and meeting materials at the home page of the Advisory Committee's Web site at *http://www.hrsa.gov/heritabledisorderscommittee/.*

Public Comments: Members of the public can present oral comments during the public comment periods of the meeting, which are scheduled for both days of the meeting. Those individuals who want to make a comment are requested to register online by Tuesday, January 25, 2011, at *http://altarum.cvent.com/event/SACHDNC012011.* Requests will contain the name, address, telephone number, and any professional or business affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The list of public comment participants will be posted on the Web site. Written comments should be e-mailed via e-mail no later than Tuesday, January 25, 2011, for consideration. Comments should be submitted to Maureen Ball, Meetings Coordinator, Conference and Meetings Management, Altarum Institute, 1200 18th Street, NW., Suite 700, Washington, DC 20036, *telephone:* 202 828–5100; *fax:* 202 785–3083, or *e-mail: conferences@altarum.org.*

Contact Person: Anyone interested in obtaining other relevant information should write or contact Alaina M. Harris, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A–19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–0721, *aharris@hrsa.gov.* More information on the Advisory Committee is available at *http://mchb.hrsa.gov/heritabledisorderscommittee.*

Dated: November 2, 2010.

Robert Hendricks,

Director, Division of Policy and Information Coordination.

[FR Doc. 2010–28188 Filed 11–8–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0369]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: Under the Food and Drug Administration Modernization Act of 1997 (Modernization Act), the Food and Drug Administration (FDA) is required to report annually in the **Federal Register** on the status of postmarketing requirements and commitments required of, or agreed upon by, holders of approved drug and biological products. This notice is the Agency's report on the status of the studies and clinical trials that applicants have agreed to or are required to conduct.

FOR FURTHER INFORMATION CONTACT: Cathryn C. Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6464, Silver Spring, MD 20993–0002, 301–796–0700; or

Robert Yetter, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1400 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Modernization Act

Section 130(a) of the Modernization Act (Pub. L. 105–115) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding a new provision requiring reports of certain postmarketing studies, including clinical trials, for human drug and biological products (section 506B of the FD&C Act (21 U.S.C. 356b)). Section 506B of the FD&C Act provides FDA with additional authority to monitor the progress of a postmarketing study or clinical trial that an applicant has been required to or has agreed to conduct by requiring the applicant to submit a report annually providing information

on the status of the postmarketing study/clinical trial. This report must also include reasons, if any, for failure to complete the study/clinical trial. These studies and clinical trials are intended to further define the safety, efficacy, or optimal use of a product and therefore play a vital role in fully characterizing the product.

Under the Modernization Act, commitments to conduct postmarketing studies or clinical trials included both studies/clinical trials that applicants agreed to conduct as well as studies/clinical trials that applicants were required to conduct under FDA regulations.[1]

B. The Food and Drug Administration Amendments Act of 2007

On September 27, 2007, the President signed Public Law 110–85, the Food and Drug Administration Amendments Act of 2007 (FDAAA). Section 901, in Title IX of FDAAA, created a new section 505(o) of the FD&C Act authorizing FDA to require certain studies and clinical trials for human drug and biological products approved under section 505 of the FD&C Act or section 351 of the Public Health Service Act. Under FDAAA, FDA has been given additional authority to require applicants to conduct and report on postmarketing studies and clinical trials to assess a known serious risk, assess signals of serious risk, or identify an unexpected serious risk related to the use of a product. This new authority became effective on March 25, 2008. FDA may now take enforcement action against applicants who fail to conduct studies and clinical trials required under FDAAA, as well as studies and clinical trials required under FDA regulations (*see* sections 505(o)(1), 502(z), and 303(f)(4) of the FD&C Act; 21 U.S.C. 355(o)(1), 352(z), and 333(f)(4)).

Although regulations implementing the Modernization Act postmarketing authorities use the term "postmarketing commitment" to refer to both required studies and studies applicants agree to conduct, in light of the new authorities enacted in FDAAA, FDA has decided it is important to distinguish between enforceable postmarketing requirements and unenforceable postmarketing commitments. Therefore, in this notice and report, FDA refers to studies/clinical trials that an applicant is required to conduct as "postmarketing requirements" (PMRs) and studies/clinical trials that an applicant agrees to but is not required to conduct as "postmarketing commitments" (PMCs). Both are addressed in this notice and report.

C. FDA's Implementing Regulations

On October 30, 2000 (65 FR 64607), FDA published a final rule implementing section 130 of the Modernization Act. This rule modified the annual report requirements for new drug applications (NDAs) and abbreviated new drug applications (ANDAs) by revising § 314.81(b)(2)(vii) (21 CFR 314.81(b)(2)(vii)). The rule also created a new annual reporting requirement for biologics license applications (BLAs) by establishing § 601.70 (21 CFR 601.70). The rule described the content and format of the annual progress report, and clarified the scope of the reporting requirement and the timing for submission of the annual progress reports. The rule became effective on April 30, 2001. The regulations apply only to human drug and biological products that are approved under NDAs, ANDAs, and BLAs. They do not apply to animal drugs or to biological products regulated under the medical device authorities.

The reporting requirements under §§ 314.81(b)(2)(vii) and 601.70 apply to PMRs and PMCs made on or before the enactment of the Modernization Act (November 21, 1997), as well as those made after that date. Therefore, studies and clinical trials required under FDAAA are covered by the reporting requirements in these regulations.

Sections 314.81(b)(2)(vii) and 601.70 require applicants of approved drug and biological products to submit annually a report on the status of each clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology study/clinical trial that is required by FDA or that they have committed to conduct either at the time of approval or after approval of their NDA, ANDA, or BLA. The status of PMCs concerning chemistry, manufacturing, and production controls and the status of other studies/clinical trials conducted on an applicant's own initiative are not required to be reported under §§ 314.81(b)(2)(vii) and 601.70 and are not addressed in this report. It should be noted, however, that applicants are required to report to FDA on these commitments made for NDAs and ANDAs under § 314.81(b)(2)(viii). Furthermore, section 505(o)(3)(E) of the FD&C Act as amended by FDAAA requires that applicants report periodically on the status of each required study/clinical trial and each study/clinical trial "otherwise undertaken * * * to investigate a safety issue * * *."

According to the regulations, once a PMR has been required or a PMC has been agreed upon, an applicant must report on the progress of the PMR/PMC on the anniversary of the product's approval until the PMR/PMC is completed or terminated and FDA determines that the PMR/PMC has been fulfilled or that the PMR/PMC is either no longer feasible or would no longer provide useful information. The annual progress report must include a description of the PMR/PMC, a schedule for completing the PMR/PMC, and a characterization of the current status of the PMR/PMC. The report must also provide an explanation of the PMR/PMC status by describing briefly the progress of the PMR/PMC. A PMR/PMC schedule is expected to include the actual or projected dates for the following: (1) Submission of the final protocol to FDA, (2) completion of the study/clinical trial, and (3) submission of the final report to FDA. The status of the PMR/PMC must be described in the annual report according to the following definitions:

- *Pending:* The study/clinical trial has not been initiated (*i.e.,* no subjects have been enrolled or animals dosed), but does not meet the criteria for delayed (*i.e.,* the original projected date for initiation of subject accrual or initiation of animal dosing has not passed);
- *Ongoing:* The study/clinical trial is proceeding according to or ahead of the original schedule;
- *Delayed:* The study/clinical trial is behind the original schedule;
- *Terminated:* The study/clinical trial was ended before completion, but a final report has not been submitted to FDA; or
- *Submitted:* The study/clinical trial has been completed or terminated, and a final report has been submitted to FDA.

Databases containing information on PMRs/PMCs are maintained at the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).

II. Summary of Information From Postmarketing Status Reports

This report, published to fulfill the annual reporting requirement under the Modernization Act, summarizes the

[1] Before passage of FDAAA, FDA could require postmarketing studies and clinical trials under the following circumstances: To verify and describe clinical benefit for a human drug approved in accordance with the accelerated approval provisions in section 506(b)(2)(A) of the FD&C Act (21 U.S.C. 356(b)(2)(A); 21 CFR 314.510 and 601.41); for a drug approved on the basis of animal efficacy data because human efficacy trials are not ethical or feasible (21 CFR 314.610(b)(1) and 601.91(b)(1)); and for marketed drugs that are not adequately labeled for children under section 505B of the FD&C Act (Pediatric Research Equity Act (21 U.S.C. 355c; Public Law 108–155)).

status of PMRs and PMCs as of September 30, 2009. If a requirement or commitment did not have a schedule, or a postmarketing progress report was not received in the previous 12 months, the PMR/PMC is categorized according to the most recent information available to the Agency.[2]

Information in this report covers any PMR/PMC that was made, in writing, at the time of approval or after approval of an application or a supplement to an application, including PMRs required under FDAAA (section 505(o)(3) of the FD&C Act), PMRs required under FDA regulations (*e.g.,* PMRs required to demonstrate clinical benefit of a product following accelerated approval (see footnote 1 of this document)), and PMCs agreed to by the applicant.

Information summarized in this report includes the following: (1) The number of applicants with open (uncompleted) PMRs/PMCs, (2) the number of open PMRs/PMCs, (3) the status of open PMRs/PMCs as reported in § 314.81(b)(2)(vii) or § 601.70 annual reports, (4) the status of concluded PMRs/PMCs as determined by FDA, and (5) the number of applications with open PMRs/PMCs for which applicants did not submit an annual report within 60 days of the anniversary date of U.S. approval.

Additional information about PMRs/PMCs submitted by applicants to CDER and CBER is provided on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm.* Neither the Web site nor this notice include information about PMCs concerning chemistry, manufacturing, and controls. It is FDA policy not to post information on the Web site until it has been reviewed for accuracy. Numbers published in this notice cannot be compared with the numbers resulting from searches of the Web site because this notice incorporates totals for all PMRs/PMCs in FDA databases, including PMRs/PMCs undergoing review for accuracy. In addition, the report in this notice will be updated annually while the Web site is updated quarterly (*i.e.,* in January, April, July, and October).

Many applicants have more than one approved product and for many products there is more than one PMR or PMC. Specifically, there were 163 unique applicants with 242 NDAs/ANDAs that had open PMRs/PMCs. There were 59 unique applicants with 91 BLAs that had open PMRs/PMCs.

Annual status reports are required to be submitted for each open PMR/PMC within 60 days of the anniversary date of U.S. approval of the original application. In fiscal year 2009 (FY09), 25 percent (48/193) of NDA/ANDA and 34 percent (31/91) of BLA annual status reports were not submitted within 60 days of the anniversary date of U.S. approval of the original application. Of the annual status reports due but not submitted on time, 100 percent of the NDA/ANDA and 45 percent (14/31) of the BLA reports were submitted before the close of FY09 (September 30, 2009).

Most PMRs are progressing on schedule (91.5 percent for NDAs/ANDAs; 92 percent for BLAs). Most PMCs are also progressing on schedule (89 percent for NDAs/ANDAs; 75 percent for BLAs). Most of the PMCs that are currently listed in the database were developed before the postmarketing requirements section of FDAAA took effect.[3]

III. About This Report

This report provides six separate summary tables. The tables distinguish between PMRs and PMCs and between on-schedule and off-schedule PMRs and PMCs according to the original schedule milestones. On-schedule PMRs/PMCs are categorized as pending, ongoing, or submitted. Off-schedule PMRs/PMCs that have missed one of the original milestone dates are categorized as delayed or terminated. The tables include data as of September 30, 2009.

Table 1 of this document provides an overall summary of the data on all PMRs and PMCs. Tables 2 and 3 of this document provide detail on PMRs. Table 2 provides additional detail on the status of on-schedule PMRs.

Table 1 shows that most PMRs (91.5 percent for NDAs/ANDAs and 92 percent for BLAs) and most PMCs (89 percent for NDAs/ANDAs and 75 percent for BLAs) are on schedule. Overall, of the PMRs that are pending (*i.e.,* have not been initiated), 83 percent were created within the past 3 years. Table 2 shows that 62 percent of pending PMRs for drug and biological products are in response to the Pediatric Research and Equity Act (PREA), under which FDA requires sponsors to study new drugs, when appropriate, for pediatric populations. Under section 505B(a)(3) of the FD&C Act, the initiation of these studies generally is deferred until required safety information from other studies has first been submitted and reviewed. PMRs for products approved under the animal efficacy rule (21 CFR 314.600 for drugs; 21 CFR 601.90 for biological products) can be conducted only when the product is used for its indication as a counterterrorism measure. In the absence of a public health emergency, these studies/clinical trials will remain pending indefinitely. The next largest category of pending PMRs for drug and biological products (35 percent) comprises those studies/clinical trials required by FDA under FDAAA, which became effective on March 25, 2008.

Table 3 provides additional detail on the status of off-schedule PMRs. The majority of off-schedule PMRs (which account for 8.5 percent of the total for NDAs/ANDAs and 9 percent for BLAs) are delayed according to the original schedule milestones (94 percent (31/33) for NDAs/ANDAs; 88 percent (7/8) for BLAs). In certain situations, the original schedules may have been adjusted for unanticipated delays in the progress of the study/clinical trial (*e.g.,* difficulties with subject enrollment in a trial for a marketed drug or need for additional time to analyze results). In this report, study/clinical trial status reflects the status in relation to the original study/clinical trial schedule regardless of whether FDA has acknowledged that additional time may be required to complete the study/clinical trial.

Tables 4 and 5 of this document provide additional detail on the status of PMCs. Table 4 provides additional detail on the status of on-schedule PMCs. Pending PMCs comprise 52 percent (449/867) of the on-schedule NDA and ANDA PMCs and 34 percent (82/244) of the on-schedule BLA PMCs.

Table 5 provides additional details on the status of off-schedule PMCs. The majority of off-schedule PMCs (which account for 11 percent for NDAs/ANDAs and 25 percent for BLAs) are delayed according to the original schedule milestones (90 percent (100/111) for NDAs/ANDAs; 98 percent (79/81) for BLAs). As noted above, this report reflects the original due dates for study/clinical trial results and does not reflect discussions between the Agency and the sponsor regarding studies/clinical trials that may require more time for completion.

Table 6 of this document provides details about PMRs and PMCs that were concluded in the previous year. Most concluded PMRs and PMCs were fulfilled (60 percent of NDA/ANDA PMRs and 56 percent of BLA PMRs; 79

[2] Although the data included in this report do not include a summary of reports that sponsors have failed to file by their due date, the Agency notes that it may take appropriate regulatory action in the event reports are not filed on a timely basis.

[3] There are existing PMCs established before FDAAA that might meet current FDAAA standards for required safety studies/clinical trials under section 505(o)(3)(B) of the FD&C Act (21 U.S.C. 355(o)(3)(B)). Under section 505(o)(3)(c), the Agency may convert pre-existing PMCs into PMRs if it becomes aware of new safety information.

percent of NDA/ANDA PMCs and 82 percent of BLA PMCs). Compared to FY08, in FY09 there has been a significant increase in the number of concluded PMRs and the number of concluded PMCs for drug and biological products.

TABLE 1—SUMMARY OF POSTMARKETING REQUIREMENTS AND COMMITMENTS

[Numbers as of September 30, 2009]

	NDA/ANDA (% of total PMR or % of total PMC)	>BLA (% of total PMR or % of total PMC)[1]
Number of open PMRs	405	96
On-schedule open PMRs (see table 2 of this document)	372 (91.5%)	88 (92%)
Off-schedule open PMRs (see table 3 of this document)	33 (8.5%)	8 (9%)
Number of open PMCs	978	325
On-schedule open PMCs (see table 4 of this document)	867 (89%)	244 (75%)
Off-schedule open PMCs (see table 5 of this document)	111 (11%)	81 (25%)

[1] On October 1, 2003, FDA completed a consolidation of certain therapeutic products formerly regulated by CBER into CDER. Consequently, CDER now reviews many BLAs. Fiscal year statistics for postmarketing requirements and commitments for BLAs reviewed by CDER are included in BLA totals in this table.

TABLE 2—SUMMARY OF ON-SCHEDULE POSTMARKETING REQUIREMENTS

[Numbers as of September 30, 2009]

On-schedule open PMRs	NDA/ANDA (% of total PMR	BLA (% of total PMR)[1]
Pending (by type):		
Accelerated approval	6	4
PREA[2]	185	26
Animal efficacy[3]	2	0
FDAAA safety (since March 25, 2008)	85	35
Total	278 (68.5%)	65 (68%)
Ongoing:		
Accelerated approval	16	5
PREA[2]	23	5
Animal efficacy[3]	0	0
FDAAA safety (since March 25, 2008)	19	9
Total	58 (14%)	19 (20%)
Submitted:		
Accelerated approval	8	0
PREA[2]	23	4
Animal efficacy[3]	0	0
FDAAA safety (since March 25, 2008)	5	0
Total	36 (9%)	4 (4%)
Combined total	372 (91.5%)	88 (92%)

[1] *See* note 1 for table 1 of this document.

[2] Many PREA studies have a pending status. PREA studies are usually deferred because the product is ready for approval in adults. Initiation of these studies also may be deferred until additional safety information from other studies has first been submitted and reviewed.

[3] PMRs for products approved under the animal efficacy rule (21 CFR 314.600 for drugs; 21 CFR 601.90 for biological products) can be conducted only when the product is used for its indication as a counterterrorism measure. In the absence of a public health emergency, these studies/clinical trials will remain pending indefinitely.

TABLE 3—SUMMARY OF OFF-SCHEDULE POSTMARKETING REQUIREMENTS

[Numbers as of September 30, 2009]

Off-schedule open PMRs	NDA/ANDA (% of total PMR)	BLA (% of total PMR)[1]
Delayed		
Accelerated approval	3	2
PREA	28	5
Animal efficacy	0	0
FDAAA safety (since March 25, 2008)	0	0
Total	31 (8%)	7 (12%)
Terminated	2 (0.5%)	1 (1%)

TABLE 3—SUMMARY OF OFF-SCHEDULE POSTMARKETING REQUIREMENTS—Continued

[Numbers as of September 30, 2009]

Off-schedule open PMRs	NDA/ANDA (% of total PMR)	BLA (% of total PMR) [1]
Combined total	33 (8.5%)	8 (9%)

[1] *See* note 1 for table 1 of this document.

TABLE 4—SUMMARY OF ON-SCHEDULE POSTMARKETING COMMITMENTS

[Numbers as of September 30, 2009]

On-Schedule Open PMCs	NDA/ANDA (% of total PMC)	BLA (% of total PMC) [1]
Pending	449 (46%)	82 (25%)
Ongoing	147 (15%)	84 (26%)
Submitted	271 (28%)	78 (24%)
Combined total	867 (89%)	244 (75%)

[1] *See* note 1 for table 1 of this document.

TABLE 5—SUMMARY OF OFF-SCHEDULE POSTMARKETING COMMITMENTS

[Numbers as of September 30, 2009]

Off-Schedule Open PMCs	NDA/ANDA (% of total PMC)	BLA (% of total PMC) [1]
Delayed	100 (10%)	79 (24%)
Terminated	11 (1%)	2 (1%)
Combined total	111 (11%)	81 (25%)

[1] *See* note 1 for table 1 of this document.

TABLE 6—SUMMARY OF CONCLUDED POSTMARKETING REQUIREMENTS AND COMMITMENTS

[October 1, 2008 to October 1, 2009]

	NDA/ANDA (% of total)	BLA (% of total) [1]
Concluded PMRs:		
Requirement met (fulfilled)	28 (60%)	5 (56%)
Requirement not met (released and new revised requirement issued)	7 (15%)	2 (22%)
Requirement no longer feasible or product withdrawn (released)	12 (25%)	2 (22%)
Total	47	9
Concluded PMCs:		
Commitment met (fulfilled)	259 (79%)	32 (82%)
Commitment not met (released and new revised requirement/commitment issued)	21 (6%)	0
Commitment no longer feasible or product withdrawn (released)	48 (15%)	7 (18%)
Total	328	39

[1] *See* note 1 for table 1 of this document.

Dated: November 3, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–28193 Filed 11–8–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 75 FR 61157–61160 dated October 4, 2010).

This notice reflects organizational changes to the Health Resources and Services Administration. Specifically, this notice updates the Office of Information Technology (RB5) functional statement to better align functional responsibility, improve the management and delivery of information technology services, improve management and