within 100 days of receipt of the filed PMA application to discuss the review status of the application. With the concurrence of the applicant, a different schedule may be established. Prior to this meeting, FDA must inform the applicant in writing of any identified deficiencies and what information is required to correct those deficiencies. FDA must also promptly notify the applicant if FDA identifies additional deficiencies or of any additional information required to complete Agency review.

Recordkeeping

§ 814.82(a)(5) and (a)(6)—Maintenance of Records

The recordkeeping burden under this section requires the maintenance of records, used to trace patients and the organization and indexing of records into identifiable files to ensure the device's continued safety and effectiveness. These records are required of all applicants who have an approved PMA.

PMAs have been required since 1976, and there are 556 active PMAs that could be subject to these requirements, based on actual FDA data, and approximately 25 new PMAs are approved every year. The aggregate burden for the estimated 600 PMA holders of approved original PMAs for the next few years is estimated to be 10,200 hours.

The applicant determines which records should be maintained during product development to document and/or substantiate the device's safety and effectiveness. Records required by the current good manufacturing practices for medical devices regulation (21 CFR part 820) may be relevant to a PMA review and may be submitted as part of an application. In individual instances, records may be required as conditions of approval to ensure the device's continuing safety and effectiveness.

In the **Federal Register** of July 23, 2013 (78 FR 44128), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR or FD&C act section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Research conducted outside the United States (814.15(b))	25	1	25	2	50
PMA application (814.20)	40	1	40	668	26,720
PMA amendments and resubmitted PMAs (814.37(a)–(c) and (e))	120	1	120	167	20,040
PMA supplements (814.39(a))	650	1	650	60	39,000
Special PMA supplement—changes being affected (814.39(d))	80	1	80	6	480
30-day notice (814.39(f))	1,500	1	1,500	16	24,000
Postapproval requirements (814.82(a)(9))	230	1	230	135	31,050
Periodic reports (814.84(b))	600	1	600	10	6,000
Agreement meeting (520(g)(7))	3	1	3	50	150
Expedited review request (515(d)(5) of the FD&C Act)	5	1	5	10	50
Determination Meeting (513(1)(3)(D) of the FD&C Act)	5	1	5	50	250
Panel meeting (515(c)(3) of the FD&C Act)	10	1	10	30	300
Day 100 meeting (515(d)(3) of the FD&C Act)	10	1	10	10	100
Total					148,190

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Maintenance of records (814.82(a)(5) and (a)(6))	600	1	600	17	10,200

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–25960 Filed 10–30–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Discretionary Grant Funds

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice of Deviation: Non-Competitive Expansion Supplement Funds to the Healthcare Systems Bureau (HSB).

SUMMARY: HRSA will be issuing a non-competitive award to the Children's Hospital of Alabama's Regional Poison Control Center. The 11-month award for $126,144 will be made available in the form of a supplement to grant funds to the organization's current grant, H4BHS15500. Effective October 1, 2013, the Regional Poison Control Center will be Alabama's sole poison control center. The center's responsibility to provide poisoning triage and treatment to half the state will be expanded to the entire state. The grant supplement will allow

HSB to maintain its mandate to provide grant support to the poison center and ensure ready access to poison control center services.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: Children's Hospital of Alabama's Regional Poison Control Center (Grant #H4BHS15500).

Amount of the Non-Competitive Award: $126,144.

CFDA Number: 93.253.

Period of Supplemental Funding: 10/1/2013—8/31/2014.

Authority: SECTION 1273 of the Public Health Service Act, (42 U.S.C. 300d—73), as amended by the Poison Center Support, Enhancement, and Awareness Act of 2008.

Justification: HSB is legislatively mandated to fund poison centers; establish and maintain a single, national toll-free number (800–222–1222) to ensure universal access to poison center services; and implement a nationwide media campaign to educate the public and health care providers about poison prevention, poison center services, and the toll-free number.

To meet the legislative mandate, HSB funds the Poison Center Support and Enhancement Grant Program (H4B) CFDA 93.253. Grantees are funded based on population. The Children's Hospital of Alabama's Regional Poison Control Center (H4BHS11550) was funded at $874,061 for a 5-year project period that is due to end August 31, 2014. The funding was based on providing services to 50 percent of Alabama's population. Beginning October 1, 2013, the grantee will be responsible for providing poison center services to the state's entire population.

HSB proposes this deviation to provide a single supplement of funds in the amount of $126,144 to support the grantee's ability to provide poison center services to the state's entire population with the least amount of disruption.

FOR FURTHER INFORMATION CONTACT: Elisa Gladstone, Director, Division of Poison Control and Healthcare Facilities, Healthcare Systems Bureau, Health Resources and Services Administration, Room 10–105, Rockville, Maryland 20857; (301) 594–4394; *Egladstone@hrsa.gov.*

Dated: October 24, 2013.

Mary K. Wakefield,

Administrator.

[FR Doc. 2013–25890 Filed 10–30–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on Nurse Education and Practice; Notice of Meeting

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

Name: National Advisory Council on Nurse Education and Practice (NACNEP).

Dates and Times: November 7, 2013, 9:00 a.m.–5:00 p.m. Eastern Standard Time; November 8, 2013, 9:00 a.m.–5:00 p.m. Eastern Standard Time.

Place: Webinar Format.

Status: This advisory council meeting will be open to the public.

Purpose: The purpose of this meeting is to identify the key issues facing nursing workforce development to respond to the Affordable Care Act and health care system redesign, and to formulate policy recommendations for Congress and the Secretary to ensure the nursing workforce is ready to meet these challenges. The objectives of the meeting are:

(1) To articulate the key challenges facing nursing workforce development in meeting the health care needs of the nation; (2) to develop goals and priorities for Council action to address these challenges; and (3) to develop recommendations on the activities, initiatives, and partnerships that are critical to advancing twenty-first century public health education and practice models needed to promote the health of the public. This meeting will form the basis for NACNEP's mandated Twelfth Annual Report to the Secretary of Health and Human Services and Congress. The meeting will include presentations and discussion focused around the purpose and objectives of this meeting. The logistical challenges of scheduling this meeting hindered an earlier publication of this meeting notice.

Agenda: The Agenda will be available on the NACNEP Web site, noted below, one day prior to the meeting. Agenda items are subject to change as priorities dictate.

For Further Information Contact: Further information regarding NACNEP including the roster of members, Reports to Congress, and minutes from previous meetings is available at the following Web site: *http://www.hrsa.gov/advisorycommittees/bhpradvisory/nacnep/index.html.* Members of the public and interested parties may request to participate in the meeting by contacting our Staff Assistant, Jeanne Brown, to obtain access information. Access is by invitation only and will be granted on a first come, first served basis. Space is limited.

For additional information regarding NACNEP, please contact Jeanne Brown, Staff Assistant, National Advisory Council on Nurse Education and Practice, Parklawn Building, Room 9–61, 5600 Fishers Lane, Rockville, Maryland 20857; email at *reachDN@hrsa.gov;* or telephone at (301) 443–5688.

Dated: October 24, 2013.

Jackie Painter,

Deputy Director, Division of Policy and Information Coordination.

[FR Doc. 2013–25891 Filed 10–30–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Human Genome Research Institute Special Emphasis Panel, October 17, 2013, 08:00 a.m. to October 17, 2013, 06:00 p.m., Renaissance Arlington Capital View Hotel, 2800 South Potomac Ave., Studio E, Arlington, VA 22202 which was published in the **Federal Register** on September 11, 2013, 78 FR 55752.

The October 17, 2013 meeting has been changed to December 19, 2013. The meeting is closed to the public.

Dated: October 25, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25875 Filed 10–30–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Kidney, Nutrition, Obesity and Diabetes Study Section, October 10, 2013, 8:00 a.m. to October 11, 2013, 12:30 p.m., Melrose Hotel, 2430 Pennsylvania Ave. NW., Washington, DC 20037 which was published in the **Federal Register** on September 17, 2013, 78 FR 180, Pgs. 57169–57170.

The meeting will be held at National Institutes of Health, 6701 Rockledge Dr., Bethesda, MD 20892. The meeting will start on December 5, 2013 at 09:30 a.m. and end on December 6, 2013 at 1:00 p.m. The meeting is closed to the public.

Dated: October 25, 2013.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25886 Filed 10–30–13; 8:45 am]

BILLING CODE 4140–01–P