the submission of periodic reports under § 814.84.

Collecting or transfusing facilities and manufacturers have certain responsibilities under the Federal regulations. For example, collecting or transfusing facilities are required to maintain records of any reports of complaints of adverse reactions (21 CFR 606.170), while the manufacturer is responsible for conducting an investigation of each event that is reasonably known to the manufacturer and evaluating the cause of the event (§ 803.50(b)). In addition, manufacturers of medical devices are required to submit to FDA individual adverse event reports of death, serious injury, and malfunctions (§ 803.50).

In the special control guidance document, FDA recommends that manufacturers include in their three annual reports a summary of adverse reactions maintained by the collecting or transfusing facility or similar reports of adverse events collected in addition to those required under the MDR regulation. The MedWatch medical device reporting code instructions (*http://www.fda.gov/cdrh/mdr/373.html*) contains a comprehensive list of adverse events associated with device use, including most of those events that we recommend summarizing in the annual report.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Reporting Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Annual Report	4	1	4	5	20

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

Based on FDA records, there are approximately four manufactures of automated blood cell separator devices. We estimate that the manufacturers will spend approximately 5 hours preparing and submitting the annual report.

Other burden hours required for § 864.9245 are reported and approved under OMB control number 0910–0120 (premarket notification submission 501(k), 21 CFR part 807, subpart E), and OMB control number 0910–0437 (MDR).

Dated: February 20, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–4315 Filed 2–27–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Part C Early Intervention Services Grant

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of non-competitive program expansion supplemental award.

SUMMARY: The Health Resources and Services Administration (HRSA) will be providing temporary critical HIV medical care and treatment services through the Greenwood Leflore Hospital (GLH) Magnolia Medical Clinic to avoid a disruption of HIV clinical care to clients in Bolivar, Sunflower and Washington Counties in Mississippi.

SUPPLEMENTARY INFORMATION: Intended recipient of the award: GLH Magnolia Medical Clinic, Greenwood, Mississippi.

Amount of the Award: $73,125 to ensure ongoing clinical services to the target population.

Authority: Section 2651 of the Public Health Service Act, 42 U.S.C. 300ff–51.

CFDA Number: 93.918.

Period of Support: The period of supplemental support is from April 1, 2009 to June 30, 2009.

Justification for the Exception to Competition:

Critical funding for HIV medical care and treatment services to clients in Bolivar, Sunflower and Washington Counties in Mississippi will be continued through a non-competitive program expansion supplement to an existing grant award to the GLH Magnolia Medical Clinic in Greenwood, Mississippi. This is a temporary award because the previous grant recipient serving this population notified HRSA that it would not continue in the program. GLH Magnolia Medical clinic is the best qualified grantee for this supplement since it serves many of the former grantee's patients and is the closest Part C Ryan White HIV/AIDS Program to the former grantee. Further funding beyond June 30, 2009 for this service area will be competitively awarded during the next Part C HIV Early Intervention Service competing application process for FY 2009.

FOR FURTHER INFORMATION CONTACT: Kathleen Treat, via email *ktreat@hrsa.gov*, or via telephone, 301–443–0493.

Dated: February 22, 2009.

Elizabeth M. Duke,

Administrator.

[FR Doc. E9–4277 Filed 2–27–09; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2008–0333]

Delaware River and Bay Oil Spill Advisory Committee; Meeting

AGENCY: Coast Guard, DHS.

ACTION: Notice of meeting.

SUMMARY: The Delaware River and Bay Oil Spill Advisory Committee (DRBOSAC) will meet in Philadelphia, PA to discuss various issues to improve oil spill prevention and response strategies for the Delaware River and Bay. This meeting will be open to the public.

DATES: The Committee will meet on Wednesday, March 18, 2009, from 10 a.m. to 1 p.m. Written material and requests to make oral presentations should reach the Coast Guard on or before March 11, 2009. Requests to have a copy of your material distributed to each member of the committee should reach the Coast Guard on or before March 11, 2009.

ADDRESSES: The Committee will meet at Coast Guard Sector Delaware Bay, 1 Washington Ave., Philadelphia, PA 19147. Send written material and requests to make oral presentations to Gerald Conrad, liaison to the Designated Federal Officer (DFO) of the DRBOSAC, at the address above. This notice and