facility is spacious, registration will be on a first-come, first-served basis. Non-U.S. citizens are subject to additional security screening, and should register as soon as possible.

If you need special accommodations because of a disability, please contact Kathryn O'Callaghan at least 7 days before the public workshop.

IV. Where Can I Find Out More About This Public Workshop?

Background information on the public workshop, registration information, the agenda, information about lodging, and other relevant information will be posted, as it becomes available, on the Internet at *http://www.AdvaMed.org* and *http://www.fda.gov/cdrh/dsma/workshop.html*.

Dated: November 19, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–28169 Filed 11–25–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Patient Navigator Outreach and Chronic Disease Prevention Demonstration Program Patient Data Collection Form—NEW

The purpose of the Patient Navigator Outreach and Chronic Disease Prevention (PN) Demonstration Program is to promote model ''patient navigator'' programs to improve health care outcomes for individuals with cancer and/or other chronic diseases, with a specific emphasis on health disparity populations. This program aims to coordinate comprehensive health services for patients in need of chronic disease care and management through enhanced chronic disease management provided by patient navigators.

In order to describe successful PN program models and make recommendations on the ability of such programs to improve patient outcomes, data is needed at the individual patient, patient navigator, and PN program levels. This information includes:

- Sociodemographics of patients (*e.g.*, insurance status, income, education level, gender, age, race and ethnicity, primary language, number of family dependents) served;
- Patient access barriers to standard chronic disease care (*e.g.*, access to pharmaceuticals, distance of patient's home from health care facilities utilized, primary mode of transportation to health care facilities utilized, cultural and linguistic barriers as well as literacy levels);
- Health care service utilization (*e.g.*, screening rates, compliance rate for appointments and follow-up exams, time interval between diagnosis or referral and resolution date);
- Patient health status (*e.g.*, type and stage of diagnosis, chronic disease status, final outcome or result); and
- Patient navigation data (*e.g.*, type of navigator, patient navigation training plans and outcomes, point at which patient navigator was brought into the process, number of patients referred, how patient barriers were resolved, patient satisfaction, follow-up outcomes—such as number of uninsured who get health coverage).

This information will be collected from patients or their designated caregiver, patient navigators, and PN program administrators. Maintaining confidentiality of patient medical information is a concern and thus all personal information will be de-identified to protect the confidentiality of all patients. Data collection and disclosure processes will abide by Health Insurance Portability and Accountability Act (HIPPA) Privacy Rule provisions and procedures. The estimated annual burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Navigated Patient [1] Data Intake Form	6,000	1	6,000	0.5	3,000
Navigated Patient Satisfaction Survey	6,000	1	6,000	0.25	1,500
SubTotal—Patient Burden	6,000	2	1,2000	0.75	4,500
Patient Navigator Survey	30	1	30	0.25	7.5
Patient Navigator Encounter/Tracking Log [2]	30	750	22,500	0.25	5,625
SubTotal—Patient Navigator Burden	30	751	22,530	0.5	5,632.5
Grantee PN Administrative Records [3]	6	1	6	0.5	3
Medical Record and Clinic Data [4]	6	2,000	12,000	2	24,000
SubTotal—Grantee Burden	12	2,001	12,012	2.5	24,006
Total Average Annual Burden	6,052	2,754	54,052	3.75	36,016

[1] Estimated number of navigated patients per year based on applications was rounded to 6000. See table below for projected numbers navigated by Grantee.

[2] Assumes 5 log entries of PN activities per patient.

[3] Includes administrative data related to PN recruitment, hiring, and training.
[4] Includes medical record abstraction and clinic database abstraction on individual patients (note: decreased to 2 hours per patient).

	Over 2 yrs	Annual
Goodwin	400	200
Lutheran	650	325
Northeast	6,000	3,000
Palmetto	3,000	1,500
South Broward	2,200	1,100
Texas Tech	500	250
Total	12,750	6,375

E-mail comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: November 20, 2008.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E8–28048 Filed 11–25–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (''the Program''), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place, NW., Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 11C–26, Rockville, MD 20857; (301) 443–6593.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.*, provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated his responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at Section 2114 of the PHS Act or as set forth at 42 CFR 100.3, as applicable. This Table lists for each covered childhood vaccine the conditions which may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that the Secretary publish in the **Federal Register** a notice of each petition filed. Set forth below is a list of petitions received by HRSA on January 2, 2008, through June 30, 2008.

Section 2112(b)(2) also provides that the special master ''shall afford all interested persons an opportunity to submit relevant, written information'' relating to the following:

1. The existence of evidence ''that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,'' and

2. Any allegation in a petition that the petitioner either:

(a) ''Sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Table but which was caused by'' one of the vaccines referred to in the Table, or

(b) ''Sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine'' referred to in the Table.

This notice will also serve as the special master's invitation to all interested persons to submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the U.S. Court of Federal Claims at the address listed above (under the heading ''For Further Information Contact''), with a copy to HRSA addressed to Director, Division of Vaccine Injury Compensation Program, Healthcare Systems Bureau, 5600 Fishers Lane, Room 11C–26, Rockville, MD 20857. The Court's caption (Petitioner's Name v. Secretary of Health and Human Services) and the docket number assigned to the petition should be used as the caption for the written submission. Chapter 35 of title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.

List of Petitions

1. Alex and Steven Padula on behalf of William Padula, Miami, Florida, Court of Federal Claims Number 08–0001V.

2. Gary Moraga, Santa Rosa, California, Court of Federal Claims Number 08–0002V.

3. Shayna Tatum and Donnell Villa on behalf of Michael Villa, Hawthorne, California, Court of Federal Claims Number 08–0008V.

4. Matt Daniels, Broderline, New Hampshire, Court of Federal Claims Number 08–0009V.

5. Rhonda Kay Rossi, Glendale, Arizona, Court of Federal Claims Number 08–0010V.

6. December and Danny Ledet on behalf of Dane Paul Ledet, Baton Rouge, Louisiana, Court of Federal Claims Number 08–0013V.

7. Megan and Shawn Brewer on behalf of Renee Brewer, Ft. Sill, Oklahoma, Court of Federal Claims Number 08–0014V.

8. Peter J. Dawson, Clifton Springs, New York, Court of Federal Claims Number 08–0016V.