

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Gastrointestinal Drugs Advisory Committee; Cancellation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is canceling the meeting of the Gastrointestinal Drugs Advisory Committee scheduled for April 12, 2000. This meeting was announced in the **Federal Register** of February 17, 2000 (65 FR 8180).

FOR FURTHER INFORMATION CONTACT: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12538.

Dated: March 28, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)-443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Healthcare Integrity and Protection Data Bank for Final Adverse Information on Health Care Providers, Suppliers, and Practitioners—(OMB 0915-0239)—**EXTENSION**

Section 221(a) of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 specifically directs the Secretary to establish a national health care fraud and abuse data collection program for the reporting and disclosure

of certain final adverse actions taken against health care providers, suppliers, and practitioners. A final rule was published October 26, 1999 in the **Federal Register** to implement the statutory requirements of section 1128E of the Social Security Act (The Act) as added by Section 221(a) of HIPAA. The Act requires the Secretary to implement the national health care fraud and abuse data collection program. This data bank is known as the Healthcare Integrity and Protection Data Bank (HIPDB). It contains the following types of information: (1) Civil judgments against a health care provider, supplier, or practitioner in Federal or State court related to the delivery of a health care item or service; (2) Federal or State criminal convictions against a health care provider, supplier, or practitioner related to the delivery of a health care item or service; (3) Actions by Federal or State agencies responsible for the licensing and certification of health care providers, suppliers, or practitioners; (4) Exclusion of a health care provider, supplier, or practitioner from participation in Federal or State health care programs; and (5) Any other adjudicated actions or decisions that the Secretary shall establish by regulations. Access to this data bank is limited to Federal and State Government agencies and health plans.

The Estimated Response Burden Is As Follows

Regulation citation	Number of respond.	Respon. per respond.	Total respon.	Hrs. per respon.	Total burden hours
61.6 Errors & Omissions	1,200	1	1,200	25 min	500
61.6 Revisions/appeal status	1,000	1	1,000	75 min	1,250
61.7 Licensure actions:					
Disclosure by State licensing boards	1,836	22	40,400	75 min	50,500
Reporting by State Licensing Authorities	216	187	40,400	15 min	10,100
61.8 Reporting of State criminal convictions	54	13	700	75 min	875
61.9 Reporting of Civil Judgments	62	8	500	75 min	625
61.11 Reporting of adjudicated actions/decisions.	66	12	800	75 min	1,000
61.12 Access to data (queries/self queries):					
State licensure Boards	1,000	75	75,000	5 min	6,250
State certification agencies	54	3	162	5 min.	14
States/district attorneys & law enforcement	2,000	25	50,000	5 min	4,166
State Medicaid fraud units	47	50	2,350	5 min	196
Health plans	2,500	400	1,000,000	5 min	83,333
Health care providers, suppliers and practitioners (self query).	60,000	1	60,000	25 min	25,000
Entity registration	5,000	1	5,000	30 min	2,500
Entity registration update	250	1	250	15 min.	62
Authorized agent designation	100	1	100	10 min.	16
Authorized agent designation update	5	1	5	5 min	0.42
61.15 Disputed reports/secretarial review.					
Initial request	750	1	750	10 min	125
Request for secretarial review	37	1	37	480 min	296
Total	76,177	1,278,654	186,808

Other Forms Used in the Management of the HIPDB Include the Following:

Form name	Number of re- spond.	Respon. per re- spond.	Total respon.	Hrs. per respon.	Total burden hours
Account discrepancy	2,000	1	2,000	5 min	166
Electronic funds transfer author- ization.	850	1	850	5 min.	70
Entity reactivation	500	1	500	15 min	125
Total	3,350	3,350	361

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Wendy A. Taylor, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: March 29, 2000.

James J. Corrigan,

Associate Administrator for Management and Program Support.

[FR Doc. 00-8479 Filed 4-5-00; 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) 219-9657. For information on HRSA’s role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers

Lane, Room 8A-46, 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 her 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 will 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 after 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 April 1, 1999, through September 27, 1999.

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 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, Bureau of Health Professions, 5600 Fishers Lane, Room 8-05, 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. Anita Szpotowicz on behalf of Andrew Szpotowicz, Cleveland, Ohio,