

agency's regulations and has been cited by the Commonwealth as the key penalty provision for cases involving immediate jeopardy. However, this must be compared with 42 CFR 493.1834(d)(2) which allows HCFA to impose a penalty amount from \$3,050 to \$10,000 per day of noncompliance or per violation for condition level deficiencies that represent immediate jeopardy.

Lastly, with the exception of information provided concerning cases of immediate jeopardy, the Commonwealth cannot be said to have submitted comprehensible documentation of what actions are taken when less severe deficiencies are not corrected.

In summary, while I disagree with HCFA's initial determination that the Commonwealth did not demonstrate an ability to take enforcement action in cases of immediate and serious jeopardy, I concur with their assessment that the Commonwealth did not adequately explain certain key aspects of their enforcement proceedings. I find that the Commonwealth has not demonstrated the existence of regulations to ensure the timely investigation of and correction of deficiencies. I also find that the amount of civil monetary penalties that the Commonwealth may assess in cases of immediate and serious jeopardy is insufficient when compared to the CLIA regulations. For these reasons, I find that the Commonwealth has failed to document the existence of regulations equal to or more stringent than § 493.1820 of the CLIA regulations.

3. *Laboratory Registry.* Section 493.1850 of the regulations requires HCFA to make available once a year specific information that is useful in evaluating the performance of laboratories. The regulation explicitly mandates that this information include a list of laboratories convicted under laws relating to fraud and abuse, false billing, or kickbacks. In its initial determination, HCFA found that the Commonwealth did not evidence the existence of a regulation or law that would require it to make available to physicians and the public, via HCFA, a list of laboratories convicted of fraud and abuse, false billing, or kickbacks, under Puerto Rican law.¹¹

The Commonwealth in its Position Paper indicates that it does not have any information about any laboratory convicted under Puerto Rican laws

sanctioning fraud and abuse, false billing or kickbacks. (Position Paper, p. 34). As concerns its future duty to report pursuant to § 493.1850, the Commonwealth "guarantees" submission of such information and the future amendment of its regulations, if necessary. (Position Paper, p. 34).

We are unsure of how one should interpret the Commonwealth's lack of information in this regard. One interpretation is that there have been no laboratories in the Commonwealth of Puerto Rico have been convicted of fraud and abuse, false billing or kickbacks. Another interpretation is that the Secretary does not obtain information or maintain a record of the disposition of fraud and abuse, false billing or kickback cases involving laboratories.

In any event, to the extent that the CLIA regulations specifically require disclosure of this information to the public, any State seeking exemption from CLIA must show the existence of a corresponding reporting mechanism. As conceded by the Commonwealth, it does not currently have regulations that require it to collect and submit this data to HCFA. Without such current regulations, I have no alternative but to concur with the initial determination reached by HCFA. For the above-noted reasons, I find that the Commonwealth has failed to demonstrate the existence of a regulation equal to or more stringent than the CLIA regulation requiring laboratory registry.

IV. Findings

After undertaking an exhaustive and complete review of the documentation submitted by the Commonwealth in connection with its application for exemption, HCFA determined that Puerto Rico did not satisfy the requirements of § 493.513(a)(1) and could not be granted exemption from CLIA. I have considered the record, supplementary information provided by the Commonwealth, the Position Paper and testimony in preparing this decision. I hereby make the following findings:

1. Section 493.513 of the regulations sets forth the general requirements for States seeking exemption from CLIA program requirements.

2. Subsection 493.513(a)(1) provides that HCFA may grant a State exemption from CLIA if the State has in effect laws that provide for requirements equal to or more stringent than CLIA condition-level requirements.

3. The application for exemption and supporting documentation submitted by the Commonwealth of Puerto Rico was evaluated by HCFA using this standard.

4. In fourteen instances involving condition-level requirements, HCFA properly determined that the Commonwealth was unable to demonstrate the existence of laws providing for requirements equal to or more stringent than the CLIA regulations. These deficiencies have been thoroughly discussed in this decision.

Legal Conclusion

For the reasons discussed herein, and based upon the above-referenced findings of fact, I conclude that the initial determination reached by HCFA to deny the Commonwealth of Puerto Rico's application for exemption from CLIA was consistent with the applicable laws and regulations. It is recommended that the initial determination denying the Commonwealth's application for CLIA exemption be affirmed.

Dated: September 27, 1996.

Richard W. Besdine,
Hearing Officer, Health Care Financing
Administration.

[FR Doc. 97-2761 Filed 2-4-97; 8:45 am]

BILLING CODE 4120-03-P

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 generally, contact the Clerk, United States Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 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 8A35, Rockville, MD 20857, (301) 443-6593.

¹¹ See also § 493.513(d), which requires exempted States to provide HCFA with certain information, including license approvals, revocations, sanctions and withdrawals.

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 partial list of petitions received by HRSA on October 10, 1996 through December 30, 1996.

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. Sarah Jean Busby on behalf of Payton Elizabeth Helms, Kennett, Missouri, Court of Federal Claims Number 96-0628 V
2. Kimberly Berg on behalf of Ryan Berg, Deceased, Salt Lake City, Utah, Court of Federal Claims Number 96-0630 V
3. Alberta Wagner and Derrick Shaw on behalf of Eric N. Shaw, Kingstree, South Carolina, Court of Federal Claims Number 96-0638 V
4. Elizabeth Watson, Waldorf, Maryland, Court of Federal Claims Number 96-0639 V
5. Tina and Gene Albert Simpson on behalf of Gene Albert Simpson, Jr., English, Indiana, Court of Federal Claims Number 96-0643 V
6. Nicholas Francis DeLouis on behalf of Amanda Rachel Ingebretson, San Antonio, Texas, Court of Federal Claims Number 96-0655 V
7. Catherine Colluro, Woodmere, New York, Court of Federal Claims Number 96-0662 V
8. Kathleen Kurtzhall, Glens Falls, New York, Court of Federal Claims Number 96-0669 V
9. Teary Evaline Gardner, North Fort Myers, Florida, Court of Federal Claims Number 96-0679 V

10. Kristen Matheny on behalf of Kaitlyn Rose Matheny, Woodford, Illinois, Court of Federal Claims Number 96-0722 V
11. Jane and Stephen Miller on behalf of Sarah Miller, Boulder, Colorado, Court of Federal Claims Number 96-0727 V
12. Joanne DeRobertis on behalf of Dean Wesley DeRobertis, Deceased, West Chester, Pennsylvania, Court of Federal Claims Number 96-0746 V
13. Michelle Kelleher on behalf of Jennifer Dawn Bieliauskas, Jersey City, New Jersey, Court of Federal Claims Number 96-0747 V
14. Michelle Emmer-Gilbank on behalf of Dakota Emmer, Deceased Baraboo, Wisconsin, Court of Federal Claims Number 96-0761 V
15. Susan and Gaylen Weil on behalf of Anthony Duane Weil, Shenandoah, Iowa, Court of Federal Claims Number 96-0762 V
16. Breggett and Terrence Rideau on behalf of Terrence Carl Rideau, Bedford, Texas, Court of Federal Claims Number 96-0765 V
17. Angela and Aaron Hill on behalf of Arielle Hill, Jacksonville, Florida, Court of Federal Claims Number 96-0783 V
18. Mary Zwinn on behalf of Kaitlyn Zwinn, LaGrange, Illinois, Court of Federal Claims Number 96-0785 V
19. Angela Ward and Duane Booden on behalf of Alysa Booden, Deceased, Andrews Air Force Base, Maryland, Court of Federal Claims Number 96-0789 V
20. Patricia and Michael Sawinski on behalf of Kaitlyn Sawinski, Melrose Park, Illinois, Court of Federal Claims Number 96-0796 V
21. Carmen Heller on behalf of Isaiah Jones, Deceased, Cuyahoga Falls, Ohio, Court of Federal Claims Number 96-0797 V
22. Tawny and Robert Buck on behalf of Quincy Mason Buck, Wrangell, Alaska, Court of Federal Claims Number 96-0802 V
23. Chatie Bantug Cruz, San Diego, California, Court of Federal Claims Number 96-0820 V.

Dated: January 30, 1997.

Ciro V. Sumaya,

Administrator.

[FR Doc. 97-2867 Filed 2-4-97; 8:45 am]

BILLING CODE 4160-15-P

Health Professions Preparatory, Pregraduate and Indian Health Professions Scholarship Programs

AGENCY: Indian Health Service, HHS.

ACTION: Standing Notice of Availability of Funds for Health Professions