

operational issues relevant to pharmaceutical manufacturers.

13. The OIG believes it is generally not advisable for the compliance function to be subordinate to the pharmaceutical manufacturer's general counsel, or comptroller or similar financial officer. Separation of the compliance function helps to ensure independent and objective legal reviews and financial analysis of the company's compliance efforts and activities. By separating the compliance function from the key management positions of general counsel or chief financial officer (where the size and structure of the pharmaceutical manufacturer make this a feasible option), a system of checks and balances is established to more effectively achieve the goals of the compliance program.

14. For companies with multiple divisions or regional offices, the OIG encourages coordination with each company location through the use of a compliance officer located in corporate headquarters who is able to communicate with parallel compliance liaisons in each division or regional office, as appropriate.

15. As part of its commitment to compliance, a pharmaceutical manufacturer should carefully consider whether to hire or do business with individuals or entities that have been sanctioned by the OIG. The List of Excluded Individuals and Entities can be checked electronically and is accessible through the OIG's Web site at: <http://oig.hhs.gov>.

16. There are many approaches the compliance officer may enlist to maintain the vitality of the compliance program. Periodic on-site visits of regional operations, bulletins with compliance updates and reminders, distribution of audiotapes, videotapes, CD ROMs, or computer notifications about different risk areas, lectures at management and employee meetings, and circulation of recent articles or publications discussing fraud and abuse are some examples of approaches the compliance officer may employ.

17. The compliance committee benefits from having the perspectives of individuals with varying responsibilities and areas of knowledge in the organization, such as operations, finance, audit, human resources, legal, and sales and marketing, as well as employees and managers of key operating units. The compliance officer should be an integral member of the committee. All committee members should have the requisite seniority and comprehensive experience within their respective departments to recommend and implement any necessary changes to policies and procedures.

18. In some cases, employees sue their employers under the False Claims Act's *qui tam* provisions after a failure or apparent failure by the company to take action when the employee brought a questionable, fraudulent, or abusive situation to the attention of senior corporate officials. Whistleblowers must be protected against retaliation, a concept embodied in the provisions of the False Claims Act. See 31 U.S.C. 3730(h).

19. Instances of noncompliance must be determined on a case-by-case basis. The

existence or amount of a *monetary* loss to a federal health care program is not solely determinative of whether the conduct should be investigated and reported to governmental authorities. In fact, there may be instances where there is no readily identifiable monetary loss, but corrective actions are still necessary to protect the integrity of the health care program.

20. Appropriate federal and state authorities include the OIG, the Criminal and Civil Divisions of the Department of Justice, the U.S. Attorney in relevant districts, the Food and Drug Administration, the Federal Trade Commission, the Drug Enforcement Administration and the Federal Bureau of Investigation, and the other investigative arms for the agencies administering the affected federal or state health care programs, such as the state Medicaid Fraud Control Unit, the Defense Criminal Investigative Service, the Department of Veterans Affairs, HRSA, and the Office of Personnel Management (which administers the Federal Employee Health Benefits Program).

21. In contrast, to qualify for the "not less than double damages" provision of the False Claims Act, the provider must provide the report to the government within 30 days after the date when the provider first obtained the information. 31 U.S.C. 3729(a).

22. Some violations may be so serious that they warrant immediate notification to governmental authorities prior to, or simultaneous with, commencing an internal investigation. By way of example, the OIG believes a provider should report misconduct that: (1) Is a clear violation of administrative, civil, or criminal laws; (2) has a significant adverse effect on the quality of care provided to federal health care program beneficiaries; or (3) indicates evidence of a systemic failure to comply with applicable laws or an existing corporate integrity agreement, regardless of the financial impact on federal health care programs.

23. The OIG has published criteria setting forth those factors that the OIG takes into consideration in determining whether it is appropriate to exclude an individual or entity from program participation pursuant to 42 U.S.C. 1320a-7(b)(7) for violations of various fraud and abuse laws. See 62 FR 67392 (December 24, 1997).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

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

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these

documents, call the SAMHSA Reports Clearance Officer on (301) 443-7978.

National Evaluation of the Comprehensive Community Mental Health Services for Children and Their Families Program: Phase Three—(OMB No. 0930-0209, revision)—SAMHSA's Center for Mental Health Services is conducting Phase III of the national evaluation of the Comprehensive Community Mental Health Services for Children and Their Families Program. Phase III collects data on child mental health outcomes, family life, and service system development and performance. Data are being collected on 22 funded systems of care, and approximately 5,100 children and families. Data collection for this evaluation will be conducted over a 5½-year period.

The core of service system data are currently collected every 18 months throughout the evaluation period. Service delivery and system variables of interest include the following: Maturity of system of care development, adherence to the system of care program model, and client service experience. The length of time that individual families will participate in the study ranges from 18 to 36 months depending on when they enter the evaluation.

Child and family outcomes of interest will be collected at intake and during subsequent follow-up sessions at six-month intervals. The outcome measures include the following: Child symptomatology and functioning, family functioning, material resources, and caregiver strain. In addition, a treatment effectiveness study will examine the relative impact of an evidence-based treatment within one system of care.

The average annual respondent burden is estimated below. The estimate reflects the average number of respondents in each respondent category, the average number of responses per respondent per year, the average length of time it will take for each response, and the total average annual burden for each category of respondent, and for all categories of respondents combined.

This revision to the currently approved information collection activities involves: (1) Extension of the data collection period for an additional 18 months to cover an additional sixth year of grant funding in the 22 currently funded systems of care (and a six-month no-cost extension for the evaluation), (2) the addition of a family-driven study to assess the extent of family involvement in service planning, (3) the elimination of the longitudinal comparison study and the addition of a treatment effectiveness study in two sites

including assessment of outcomes, treatment fidelity and interaction of the treatment with the larger system of care, (4) the addition of a sustainability study to assess the capacity of funded communities to continue system of care

service provision after the termination of grant funding, (5) the addition of a wraparound fidelity study to assess the implementation of wraparound services delivery in the context of a system of care. Although the data collection

period is being extended for an additional 18 months, the total average annual burden is reduced because the total number of responses for each individual remains the same.

Respondent	Number of respondents	Number of responses/respondent	Average burden/response	Total average annual burden
	Currently approved			120,046
Caregiver	5,107	1.00	2.16	11,031
Youth	3,064	1.01	0.84	2,600
Provider	462	0.54	1.53	382
New total				14,012

¹Annual burden.

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

Dated: April 29, 2003.

Richard Kopanda,

Executive Officer, SAMHSA.

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DEPARTMENT OF HOMELAND SECURITY

Bureau of Citizenship and Immigration Services

[CIS No. 2269-03]

RIN 1615-AA04

Extension of the Designation of Honduras Under Temporary Protected Status Program; Automatic Extension of Employment Authorization Documentation for Hondurans

AGENCY: Bureau of Citizenship and Immigration Services, Homeland Security.

ACTION: Notice.

SUMMARY: The designation of Honduras under the Temporary Protected Status (TPS) Program will expire on July 5, 2003. This notice extends the Secretary of Homeland Security's designation of Honduras for 18 months until January 5, 2005, and sets forth procedures necessary for nationals of Honduras (or aliens having no nationality who last habitually resided in Honduras) with TPS to re-register and to apply for an extension of their employment

authorization documentation for the additional 18-month period. Re-registration is limited to persons who registered under the initial designation (which ended on August 20, 1999) and also timely re-registered under the extensions of designation. Certain nationals of Honduras (or aliens having no nationality who last habitually resided in Honduras) who previously have not applied for TPS may be eligible to apply under the late initial registration provisions.

Given the large number of Hondurans affected by this notice, the Department of Homeland Security (DHS) recognizes that many re-registrants will not receive their new Employment Authorization Documents (EADs) until after their current EADs expire on July 5, 2003. Accordingly, this notice automatically extends, until December 5, 2003, the validity of EADs issued pursuant to the Honduras TPS program, and explains how TPS beneficiaries or their employers may determine which EADs are automatically extended.

EFFECTIVE DATES: The extension of Honduras's TPS designation is effective July 5, 2003, and will remain in effect until January 5, 2005. The 60-day re-registration period begins May 5, 2003 and will remain in effect until July 7, 2003.

FOR FURTHER INFORMATION CONTACT: Naheed Qureshi, Department of Homeland Security, Bureau of Citizenship and Immigration Services, 425 "I" Street, NW., Room 3040, Washington, DC 20536, telephone (202) 514-4754.

SUPPLEMENTARY INFORMATION:

What Authority Does the Secretary of the Department of Homeland Security Have To Extend the Designation of Honduras Under the TPS Program?

On March 1, 2003, the Immigration and Naturalization Service (INS) transferred from the Department of Justice to the Department of Homeland Security (DHS) pursuant to the Homeland Security Act of 2002, Public Law 107-296. The responsibilities for administering the TPS program were transferred to the Bureau of Citizenship and Immigration Services (BCIS).

Under section 244 of the Immigration and Nationality Act (the Act), 8 U.S.C. 1254a, the Secretary of DHS, after consultation with appropriate agencies of the Government, is authorized to designate a foreign state or (part thereof) for TPS. The Secretary of DHS may then grant TPS to eligible nationals of that foreign state (or aliens having no nationality who last habitually resided in that state).

Section 244(b)(3)(A) of the Act requires the Secretary of DHS to review, at least 60 days before the end of the TPS designation or any extension thereof, the conditions in a foreign state designated under the TPS program to determine whether the conditions for a TPS designation continue to be met and, if so, the length of an extension of TPS. (8 U.S.C. 1254a(b)(3)(A)). If the Secretary of DHS determines that the foreign state no longer meets the conditions for TPS designation, he shall terminate the designation, as provided in section 244(b)(3)(B) of the Act (8 U.S.C. 1254a(b)(3)(B)). Finally, if the Secretary of DHS does not make the required determination prior to the 60-day period prescribed by statute, section 244(b)(3)(C) of the Act provides for an automatic extension of TPS for an additional period of 6 months (or, in the