

containing petroleum; and 40 CFR 281.39 Lender Liability.

Additionally, the Missouri UST program has adequate enforcement of compliance, as described at 40 CFR 281.40 Requirements for compliance monitoring program and authority; 40 CFR 281.41 Requirements for enforcement authority; 40 CFR 281.42 Requirements for public participation; and 40 CFR 281.43 Sharing of information.

On May 5, 2004 (69 FR 25053), EPA published a tentative decision announcing its intent to grant Missouri final approval. Further background on the tentative decision to grant approval is available by contacting Linda Garwood, EPA Region 7, ARTD/USTB, 901 North 5th Street, Kansas City, Kansas, 66101, (913) 551-7268, or by e-mail at [garwood.linda@epa.gov](mailto:garwood.linda@epa.gov).

Along with the tentative determination, EPA announced the opportunity for public comment. All comments needed to be received at EPA by June 4, 2004. Also, EPA provided notice that a public hearing would be provided but only if significant public interest on substantive issues was shown. EPA did not receive any significant comments and no public hearing was held.

### III. Decision

EPA concludes that the State of Missouri's application for final approval meets all the statutory and regulatory requirements established by Subtitle I of RCRA. Accordingly, Missouri is granted final approval to operate its UST program. The State of Missouri now has responsibility for managing all regulated UST facilities within its borders and carrying out all aspects of the UST program, except with regard to Indian lands, where EPA will retain and otherwise exercise regulatory authority. Missouri also has primary enforcement responsibility, for the USTs it regulates, although EPA retains the right to conduct inspections under section 9005 of RCRA, 42 U.S.C. 6991d, and to take enforcement actions under section 9006 of RCRA, 42 U.S.C. 6991e.

#### *Statutory and Executive Order Review*

The Office of Management and Budget (OMB) has exempted this action from the requirements of Executive Order 12866 (58 FR 51735, October 4, 1993), and therefore this action is not subject to review by OMB. For this reason, this action is also not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001). This action authorizes State requirements for the

purpose of RCRA 9004 and imposes no additional requirements beyond those imposed by State law. Accordingly, the Administrator certifies that this action will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this action authorizes pre-existing requirements under State law and does not impose any additional enforceable duty beyond that required by State law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104-4).

This action also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely authorizes State requirements as part of the State underground storage tank program without altering the relationship or the distribution of power and responsibilities established by RCRA. This action also is not subject to Executive Order 13045 "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because it is not economically significant.

Under RCRA 9004, EPA grants approval of a State's program as long as the State meets the criteria required by RCRA. It would thus be inconsistent with applicable law for EPA, when it reviews a State program application, to require the use of any particular voluntary consensus standard in place of another standard that otherwise satisfies the requirements of RCRA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement

Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this document and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

### List of Subjects in 40 CFR Part 281

Environmental protection, Administrative practice and procedure, Hazardous materials, Intergovernmental relations, Reporting and recordkeeping requirements.

**Authority:** This notice is issued under the authority of Section 9004 of the Solid Waste Disposal Act as amended 42 U.S.C. 6912(a), 6926, 6974(b).

Dated: September 13, 2004.

**James B. Gulliford,**

*Regional Administrator, Region 7.*

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**BILLING CODE 6560-50-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

### Office of Inspector General

### 45 CFR Part 61

**RIN 0991-AB31**

### Health Care Fraud and Abuse Data Collection Program: Technical Revisions to Healthcare Integrity and Protection Data Bank Data Collection Activities

**AGENCY:** Office of Inspector General (OIG), HHS.

**ACTION:** Final rule.

**SUMMARY:** The rule finalizes technical changes to the Healthcare Integrity and Protection Data Bank (HIPDB) data collection reporting requirements by clarifying the types of personal numeric identifiers that may be reported to the data bank in connection with adverse actions. The rule clarifies that in lieu of a Social Security Number (SSN), an individual taxpayer identification number (ITIN) may be reported to the data bank when, in those limited

situations, an individual does not have an SSN.

**DATES:** The regulations amending 45 CFR part 61 became effective on July 19, 2004.

**FOR FURTHER INFORMATION CONTACT:** Joel Schaer, Office of External Affairs, (202) 619-0089.

#### **SUPPLEMENTARY INFORMATION:**

### **I. Background**

#### *A. The Healthcare Integrity and Protection Data Bank (HIPDB)*

Section 221(a) of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law 104-91, required the Department, acting through the Office of Inspector General, to establish a health care fraud and abuse control program to combat health care fraud and abuse (section 1128C of the Social Security Act (the Act)). Among the major steps in this program has been the establishment of a national data bank to receive and disclose certain final adverse actions against health care providers, suppliers, or practitioners, as required by section 1128E of the Act, in accordance with section 221(a) of HIPAA. The data bank, known as the Healthcare Integrity and Protection Data Bank (HIPDB), is designed to collect and disseminate the following types of information regarding final adverse actions: (1) Civil judgments against health care providers, suppliers, or practitioners in Federal or State court that are 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) final adverse 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 establishes by regulation.

#### **1. Data Elements To Be Reported to the HIPDB**

Section 1128E(b)(2) of the Act cited a number of required elements or types of data that must be reported to the HIPDB. These elements include: (1) The name of the individual or entity; (2) a taxpayer identification number; (3) the name of any affiliated or associated health care entity; (4) the nature of the final adverse action and whether the action is on appeal; (5) a description of the acts or omissions, or injuries, upon which a final adverse action is based; and (6) any

other additional information deemed appropriate by the Secretary. With respect to this last element, we have exercised this discretion to add additional reportable data elements reflecting much of the information that is already routinely collected by the Federal and State reporting agencies.

Final regulations implementing the HIPDB were published in the **Federal Register** on October 26, 1999 (64 FR 57740). In those final regulations, for an individual (1) who is the subject of a civil judgment or criminal conviction related to the delivery of a health care item or service; or (2) who is the subject of a licensure action taken by Federal or State licensing and certification agencies, an adjudicated action or decision, or an individual excluded from participation in a Federal or State health care program, the current HIPDB systems of records contain, among other things, the individual's full name, other names used (if known), and his or her SSN. We specifically indicated that use of personal identifiers, such as SSNs and Federal Employer Identification Numbers (FEINs), in the collection and reporting to the HIPDB:

- Provides explicit matching of specific adverse action reports to and from the data bank;
- Provides a greater confidence level in the system's matching algorithm and maximizes the system's ability to prevent the erroneous reporting and disclosure of health care providers, suppliers and practitioners; and
- Strengthens States' ability to detect individuals who move from State to State without disclosure or discovery of previous damaging performance.

However, in addressing the list of "mandatory" data elements that must be reported to the data bank in connection with adverse actions, the final regulations inadvertently omitted reference to the reporting of an ITIN to the data bank when, in those limited situations, an individual does not have an SSN.

#### **2. Tax Identification Numbers as Defined by the Internal Revenue Code**

As indicated above, HIPAA requires "the name and TIN (as defined in section 7701(a)(41) of the Internal Revenue Code (IRC) of 1986) of any health care provider, supplier, or practitioner who is the subject of a final adverse action" to be reported to the data bank. Section 7701(a)(41) of the IRC does not specifically define TIN, but instead refers to section 6109 of the Code. Section 6109(d) states that an individual's SSN is the tax identifying number for an individual, except as otherwise specified in regulations by the

Secretary of the Treasury. In turn, the Department of the Treasury regulations set forth at 26 CFR 301.6109-1(a)(ii)(B) provide for the issuance of an ITIN for individuals who are not eligible for an SSN.

#### *C. Technical Revisions to 45 CFR Part 61*

The HIPDB regulations at 45 CFR part 61 required the SSN on reports of adverse actions on individuals. Although the SSN meets the statutory requirement of a TIN, we believed that the inclusion of the ITIN, which is also a TIN, is consistent with the statutory requirements of HIPAA. Most reportable final adverse actions are taken against individual health care practitioners who are permitted to work in the United States. Non-citizens in the United States with permission to work are eligible for SSNs. However, we had become aware that there are non-citizens who do not have permission to work in the United States, but who do have ITINs assigned by the Internal Revenue Service (IRS) for tax purposes<sup>1</sup> and hold valid State health care licenses. One example would be a foreign physician who does not practice in the United States, but desires to have a State license as a qualification of his or her ability to practice medicine. We believed that there may be very limited incidences where reportable adverse actions, particularly licensing actions, may be taken against these health care practitioners, such as an adverse licensing action taken by a medical licensing authority in a foreign country that is then reported to a State medical licensing board which then revokes the State medical license of the foreign physician. However, if the physician does not have a SSN, the State medical licensing authority is currently unable to report the action. We believed that the revision of the HIPDB regulations to include the collection of the ITIN for individuals who do not have SSNs, but have been assigned an ITIN, would enable the data bank to receive reports that it could not receive.

### **II. Summary of Provisions of the Interim Final Rule With Comment Period**

In order to allow for the collection and dissemination of all appropriate information to and from the data bank, on June 17, 2004, we published in the **Federal Register** (69 FR 33866) an interim final rule with comment period that revised §§ 61.7, 61.8, and 61.10 of

<sup>1</sup> These individuals can use previously IRS assigned ITINs, although they cannot qualify for an ITIN solely for licensing purposes.

the HIPDB regulations at 45 CFR part 61 to indicate that for the reporting of (1) licensure actions taken by Federal and State licensing and certification agencies, (2) Federal or State criminal convictions related to the delivery of a health care item or service, or (3) exclusions from participation in Federal or State health care programs:

- If the subject is an individual, entities must report either the SSN or ITIN;
- If the subject is an organization, entities must report the FEIN, or SSN or ITIN when used by the subject as a TIN; and
- If the subject is an organization, entities should report, if known, any FEINs, SSNs or ITINs used.

These revisions in the interim final rule also allowed the reporting of ITINs, by reference, to the reports required in §§ 61.9 and 61.11.

In addition, the interim final rule noted that while the inclusion of a SSN or ITIN was a necessary reporting element in reporting adverse actions to the HIPDB, the Social Security Administration and the Internal Revenue Service are not required to assign a SSN or an ITIN, respectively, to those individuals who do not otherwise qualify for such identification numbers.

### III. Analysis of and Responses to Public Comments

We received no public comments in response to the June 17, 2004 interim final rule.

### IV. Provisions of the Final Regulations

The provisions of this final rule are identical to the provisions of the June 17, 2004 interim final rule.

### V. Regulatory Impact Statement

#### A. Regulatory Analysis

We have examined the impacts of this technical rule revision as required by Executive Order 12866, the Regulatory Flexibility Act (RFA) of 1980, the Unfunded Mandates Reform Act of 1995, and Executive Order 13132.

#### 1. Executive Order 12866

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulations are necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). A regulatory impact analysis must be prepared for major rules with economically significant effects (\$100 million or more in any given year). This is not a major rule as defined at 5 U.S.C. 804(2), and it is not

economically significant since this technical revision will not have a significant effect on program expenditures and there will be no additional substantive cost through codification of this change. Specifically, the revisions to 45 CFR part 61 set forth in this rule are technical in nature and are designed to further clarify statutory requirements. The economic effect of these revisions will impact only those limited few individuals or organizations that are that subject of an adverse action reportable to the data bank. As such, we believe that the aggregate economic impact of this technical revision to the regulations will be minimal and have no appreciable effect on the economy or on Federal or State expenditures.

#### 2. Regulatory Flexibility Act

The RFA and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most providers are considered to be small entities by having revenues of \$6 million to \$29 million or less in any one year. For purposes of the RFA, most physicians and suppliers are considered to be small entities. In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural providers. This analysis must conform to the provisions of section 604 of the RFA.

We anticipate that the number of individuals who do not have permission to work in the United States but who have ITINs, who hold valid State health care licenses, and who will be the subject of a report to the HIPDB will be minimal. Even in those very limited incidences where reportable adverse actions, such as licensing actions, may be taken against a health care practitioner, we believe that the aggregate economic impact of this technical revision will be minimal since it is the nature of the conduct and not the size or type of the entity that would result in the violation and the need to report the adverse action to the HIPDB. As a result, we have concluded that this technical rule should not have a significant impact on the operations of a substantial number of small or rural providers, and that a regulatory flexibility analysis is not required for this rulemaking.

#### 3. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. As indicated, these technical revisions comport with statutory intent and clarify the legal authorities for reporting information to the data bank against those who have acted improperly against the Federal and State health care programs. As a result, we believe that there are no significant costs associated with these revisions that would impose any mandates on State, local, or tribal governments, or the private sector that will result in an expenditure of \$110 million or more (adjusted for inflation) in any given year, and that a full analysis under the Unfunded Mandates Reform Act is not necessary.

#### 4. Executive Order 13132

Executive Order 13132, Federalism, establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirements or costs on State and local governments, preempts State law, or otherwise has Federalism implications. In reviewing this rule under the threshold criteria of Executive Order 13132, we have determined that this rule will not significantly affect the rights, roles, and responsibilities of State or local governments.

#### B. Paperwork Reduction Act

The provisions of this rulemaking impose no express new reporting or recordkeeping requirements on reporting entities. As indicated, this additional reportable data element reflects information that is already routinely collected by the Federal and State reporting agencies on health care providers, suppliers and practitioners, and imposes no new reporting burden beyond the data element fields already approved by OMB.

#### List of Subjects in 45 CFR Part 61

Billing and transportation services, Durable medical equipment suppliers and manufacturers, Health care insurers, Health maintenance organizations, Health professions, Home health care agencies, Hospitals, Penalties, Pharmaceutical suppliers and manufacturers, Privacy, Reporting and recordkeeping requirements, Skilled nursing facilities.

# **PART 61—HEALTHCARE INTEGRITY AND PROTECTION DATA BANK FOR FINAL ADVERSE INFORMATION ON HEALTH CARE PROVIDERS, SUPPLIERS AND PRACTITIONERS**

■ Accordingly, the interim final rule with comment period amending 45 CFR part 61, which was published on June 17, 2004 in the **Federal Register** at 69 FR 33866–33869 is adopted as a final rule without change.

Dated: August 23, 2004.

**Lewis Morris,**

*Chief Counsel to the Inspector General.*

Approved: September 15, 2004.

**Tommy G. Thompson,**

*Secretary.*

[FR Doc. 04–21204 Filed 9–20–04; 8:45 am]

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## **DEPARTMENT OF THE INTERIOR**

### **Fish and Wildlife Service**

#### **50 CFR Part 17**

RIN 1018–AI14

### **Endangered and Threatened Wildlife and Plants; Final Rule To Remove the Tinian Monarch From the Federal List of Endangered and Threatened Wildlife**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Final rule.

**SUMMARY:** Under the authority of the Endangered Species Act (Act) of 1973, as amended (16 U.S.C. 1531 *et seq.*), we, the U.S. Fish and Wildlife Service, remove the Tinian monarch (*Monarcha takatsukasae*) from the Federal List of Endangered and Threatened Wildlife. This determination is based on thorough review of all available information, which indicates that this species has increased in number or is stable, and that the primary listing factor, loss of habitat, has been ameliorated.

The Tinian monarch (monarch) is a forest bird endemic to the island of Tinian in the Mariana archipelago in the western Pacific Ocean. The monarch was listed as endangered on June 2, 1970 (35 FR 8491), because its population was thought to be critically low due to the destruction of native forests by pre-World War II (WW II) agricultural practices, and by military activities during WWII. We conducted forest bird surveys on Tinian in 1982, which resulted in a population estimate of 39,338 monarchs. Based on the results of this survey, the monarch was downlisted to threatened on April 6, 1987 (52 FR 10890). A study of monarch

breeding biology in 1994 and 1995 resulted in a population estimate of approximately 52,904 birds. In 1996, a replication of the 1982 surveys yielded a population estimate of 55,721 birds. The 1996 survey also found a significant increase in forest density since 1982, indicating an improvement in monarch habitat quality. This final rule removes the Tinian monarch from the Federal List of Endangered and Threatened Wildlife, thereby removing all protections provided by the Act.

**DATES:** This rule is effective September 21, 2004.

**ADDRESSES:** The administrative file for this rule is available for inspection, by appointment, during normal business hours at the U.S. Fish and Wildlife Service, Pacific Islands Fish and Wildlife Office, 300 Ala Moana Boulevard, Room 3–122, Box 50088, Honolulu, Hawaii 96850.

**FOR FURTHER INFORMATION CONTACT:** Eric VanderWert, Pacific Islands Fish and Wildlife Office, at the above address (telephone 808/792–9400; facsimile 808/792–9581).

#### **SUPPLEMENTARY INFORMATION:**

##### **Background**

Tinian is a small [101 square kilometers (38 square miles)] island in the Commonwealth of the Northern Mariana Islands (CNMI), and is located three islands to the north of Guam. The human population of Tinian was estimated at 3,540 during a census in 2000. The majority of residents live in the island's only town of San Jose at the southwestern edge of the island. The northern 71 percent of the island is leased to the U.S. Department of Defense (USDOD) for defense purposes. The remaining 29 percent of the island is divided between leased public property (67 percent), privately owned property (26 percent), and other public property (7 percent) (Deborah Fleming, CNMI Division of Public Lands, pers. comm. 1999). Approximately 10 percent of the island is devoted to agriculture, while another 30 to 50 percent is used for cattle grazing (Engbring *et al.* 1986; Belt-Collins 1994).

The monarch, or Chuchurican Tinian in Chamorro, was described by Takatsukasa and Yamashina (1931). It is a small (15 centimeters [6 inches]) forest bird in the monarch flycatcher family (Monarchidae), and has light rufous underparts, olive-brown upperparts, dark brown wings and tail, white wing bars, and a white rump and undertail coverts (Baker 1951). The monarch currently is found only on the island of Tinian, but examination of museum specimens by Peters (1996) suggested a

now extirpated population may have occurred on the island of Saipan, just north of Tinian. The monarch also was reported from the tiny island of Agiguan just south of Tinian in the early 1950's, but some authorities discount this report as an error (Engbring *et al.* 1986).

Heavy disturbance of Tinian's native forests began in the 18th century when the Spaniards used Tinian as a supply island for Guam, and maintained large herds of cattle and other ungulates on the island (Fosberg 1960). In 1926, a Japanese company leased the entire island and cleared additional forested lands for sugarcane production (Belt-Collins 1994). During WW II, the sugarcane plantations and most remaining native vegetation were destroyed by military campaigns and military construction (Baker 1946). After the war, the USDOD may have seeded the island with tangantangan (*Leucaena leucocephala*), a rapidly growing tree that is not native to the Marianas, to slow erosion (U.S. Fish and Wildlife Service [USFWS] 1995; 1996). Currently, the vegetation on Tinian is highly disturbed, with tangantangan thickets being the most abundant habitat type (Fosberg 1960; Engbring *et al.* 1986; Falanruw *et al.* 1989). Engbring *et al.* (1986) estimated that 38 percent of Tinian was dominated by tangantangan, while Falanruw *et al.* (1989) estimated that 54 percent of the island was covered in secondary vegetation, which included tangantangan thickets. Only 5 to 7 percent of the island is estimated to support native forest, which is restricted to steep limestone escarpments (Engbring *et al.* 1986; Falanruw *et al.* 1989).

The monarch inhabits a variety of forest types on Tinian, including native limestone forest dominated by figs (*Ficus* species [spp.]) *Elaeocarpus joga*, *Mammea odorata*, *Guamia mariannae*, *Cynometra ramiflora*, *Aglaia mariannensis*, *Premna obtusifolia*, *Pisonia grandis*, *Ochrosia mariannensis*, *Neisosperma oppositifolia*, *Intsia bijuga*, *Melanolepis multiglandulosa*, *Eugenia* spp., *Pandanus* spp., *Artocarpus* spp., and *Hernandia* spp.; secondary vegetation consisting primarily of the non-natives *Acacia confusa*, *Albizia lebbbeck*, *Casuarina equisetifolia*, *Cocos nucifera*, and *Delonix regia*, with some native species mixed in; and nearly pure stands of introduced tangantangan (Engbring *et al.* 1986; USFWS 1996).

The monarch was listed as endangered in 1970 (35 FR 8491) under the authority of the Endangered Species Conservation Act of 1969 (16 U.S.C. 668cc). The monarch's status remained as endangered under the Act. The decision to list the monarch as