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.

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 government, 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).


James B. Gulliford,
Regional Administrator, Region 7.

[FR Doc. 04–21183 Filed 9–20–04; 8:45 am]

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.


FOR FURTHER INFORMATION CONTACT: Joel Schaefer, 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 TIN 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–(a)(2)(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 ¹ 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

¹ These individuals can use previously IRS assigned ITINs, although they cannot qualify for an ITIN solely for licensing purposes.
defined at 5 U.S.C. 804(2), and it is not 
given year). This is not a major rule as 
effects ($100 million or more in any 
rules with economically significant 
analysis must be prepared for major 
economic, environmental, public health, 
et benefits (including potential 
of available regulatory alternatives and, 
and 
• If the subject is an organization, 
entities should report, if known, any 
and 
• If the subject is an organization, 
that are that subject of an adverse action 
and have no appreciable effect on the economy or on 
Federal or State expenditures.

1. Executive Order 12866

We have examined the impacts of this 
total costs by having revenues of $6 
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 
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 
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.


Lewis Morris,
Chief Counsel to the Inspector General.


Tommy G. Thompson,
Secretary.

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

BILLING CODE 4152–01–P

DEPARTMENT OF THE INTERIOR
Fish and Wildlife Service

50 CFR Part 17
RIN 1018–A114

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.

ADDRESS: 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 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.

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