

of this section in that business entity's tax jurisdiction of residence on the income derived by the permanent establishment.

(v) *Certain transportation income.* If a constituent entity of a U.S. MNE group derives income from international transportation or transportation in inland waterways that is covered by income tax convention provisions that are specific to such income and under which the taxing rights on such income are allocated exclusively to one tax jurisdiction, then the U.S. MNE group should report the information required under paragraph (d)(2) of this section with respect to such income for the tax jurisdiction to which the relevant income tax convention provisions allocate these taxing rights.

(e) *Reporting of financial amounts.*—
(1) *Reporting in U.S. dollars required.* All amounts furnished under paragraph (d)(2) of this section, other than paragraph (d)(2)(viii) of this section, must be expressed in U.S. dollars. If an exchange rate is used other than in accordance with U.S. generally accepted accounting principles for conversion to U.S. dollars, the exchange rate must be indicated.

(2) *Sources of financial amounts.* All amounts furnished under paragraph (d)(2) of this section, other than paragraph (d)(2)(viii) of this section, should be based on applicable financial statements, books and records maintained with respect to the constituent entity, or records used for tax reporting purposes.

(f) *Time and manner for filing.* Returns on Form XXXX, *Country-by-Country Report*, required under paragraph (a) of this section for a taxable year will be filed with the ultimate parent entity's income tax return for the taxable year on or before the due date (including extensions) for filing that person's income tax return.

(g) *Maintenance of records.* The U.S. person filing Form XXXX, *Country-by-Country Report*, as an ultimate parent entity of a U.S. MNE group must maintain records to support the information provided on Form XXXX, *Country-by-Country Report*. However, the U.S. person is not required to have or maintain records that reconcile the amounts provided on Form XXXX, *Country-by-Country Report*, with the tax returns of any tax jurisdiction or applicable financial statements.

(h) *Exceptions to furnishing information.* A U.S. person that is an ultimate parent entity of a U.S. MNE group is not required to report information under this section for an annual accounting period described in paragraph (c) of this section if the

annual revenue of the U.S. MNE group for the immediately preceding annual accounting period was less than \$850,000,000.

(j) *Effective/applicability dates.* The rules of this section apply to taxable years of ultimate parent entities of U.S. MNE groups that begin on or after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register** and that include annual accounting periods determined under section 6038(e)(4) of all foreign constituent entities and taxable years of all domestic constituent entities beginning on or after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

John Dalrymple,
Deputy Commissioner for Services and Enforcement.

[FR Doc. 2015–32145 Filed 12–21–15; 4:15 pm]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 171

[EPA–HQ–OPP–2011–0183; FRL–9940–59]

RIN 2070–AJ20

Pesticides; Certification of Pesticide Applicators; Second Extension of the Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of comment period.

SUMMARY: EPA issued a proposed rule in the **Federal Register** of August 24, 2015, concerning certification of applicators of restricted use pesticides. This document extends the comment period to January 22, 2016. The comment period is being extended to provide additional time for commenters to prepare their responses.

DATES: The comment period for the proposed rule published August 24, 2015, at 80 FR 51356, is extended. Comments, identified by docket identification (ID) number EPA–HQ–OPP–2011–0183, must be received on or before January 22, 2016.

ADDRESSES: Follow the detailed instructions provided under **ADDRESSES** in the **Federal Register** document of August 24, 2015 (80 FR 51356) (FRL–9931–83).

FOR FURTHER INFORMATION CONTACT: Michelle Arling, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania

Ave. NW., Washington, DC 20460; telephone number: (703) 308–5891; email address: arling.michelle@epa.gov.

SUPPLEMENTARY INFORMATION: This document extends the public comment period established in the **Federal Register** document of November 18, 2015 (80 FR 72029) (FRL–9936–82), which extended the comment period originally set in the **Federal Register** document of August 24, 2015. In the November 18, 2015 document, comments were required to be submitted by December 23, 2015. EPA is hereby extending the comment period to January 22, 2016.

To submit comments, or access the docket, please follow the detailed instructions provided under **ADDRESSES** in the **Federal Register** document of August 24, 2015. If you have questions, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

List of Subjects in 40 CFR Part 171

Environmental protection, Administrative practice and procedure, Certified applicator, Commercial applicator, Indian Country, Indian Tribes, Noncertified applicator, Pesticides and pests, Private applicator, Reporting and recordkeeping requirements, Restricted use pesticides.

Dated: December 21, 2015.

Oscar Morales,
Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2015–32457 Filed 12–22–15; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

Solicitation of New Safe Harbors and Special Fraud Alerts

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

ACTION: Notice of intent to develop regulations.

SUMMARY: In accordance with section 205 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), this annual document solicits proposals and recommendations for developing new, and modifying existing, safe harbor provisions under the Federal anti-kickback statute (section 1128B(b) of the Social Security Act), as well as developing new OIG Special Fraud Alerts.

DATES: To ensure consideration, public comments must be delivered to the

address provided below by no later than 5 p.m. on February 22, 2016.

ADDRESSES: In commenting, please refer to file code OIG-124-N. Because of staff and resource limitations, we cannot accept comments by facsimile (fax) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific recommendations and proposals through the Federal eRulemaking Portal at <http://www.regulations.gov>.

2. *By regular, express, or overnight mail.* You may send written comments to the following address: Patrice Drew, Office of Inspector General, Regulatory Affairs, Department of Health and Human Services, Attention: OIG-124-N, Room 5541C, Cohen Building, 330 Independence Avenue SW., Washington, DC 20201. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver, by hand or courier, your written comments before the close of the comment period to Patrice Drew, Office of Inspector General, Department of Health and Human Services, Cohen Building, Room 5541C, 330 Independence Avenue SW., Washington, DC 20201. Because access to the interior of the Cohen Building is not readily available to persons without Federal Government identification, commenters are encouraged to schedule their delivery with one of our staff members at (202) 619-1368.

For information on viewing public comments, please see the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Patrice Drew, Regulatory Affairs Liaison, Office of Inspector General, (202) 619-1368.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on recommendations for developing new or revised safe harbors and Special Fraud Alerts. Please assist us by referencing the file code OIG-124-N.

Inspection of Public Comments: All comments received before the end of the comment period are available for viewing by the public. All comments will be posted on <http://www.regulations.gov> after the closing of the comment period. Comments received timely will also be available for public inspection as they are received at Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue SW., Washington, DC 20201, Monday

through Friday from 10 a.m. to 5 p.m. To schedule an appointment to view public comments, phone (202) 619-1368.

I. Background

A. OIG Safe Harbor Provisions

Section 1128B(b) of the Social Security Act (the Act) (42 U.S.C. 1320a-7b(b)) provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration to induce or reward business reimbursable under the Federal health care programs. The offense is classified as a felony and is punishable by fines of up to \$25,000 and imprisonment for up to 5 years. OIG may also impose civil money penalties, in accordance with section 1128A(a)(7) of the Act (42 U.S.C. 1320a-7a(a)(7)), or exclusion from the Federal health care programs, in accordance with section 1128(b)(7) of the Act (42 U.S.C. 1320a-7(b)(7)).

Because the statute, on its face, is so broad, concern has been expressed for many years that some relatively innocuous commercial arrangements may be subject to criminal prosecution or administrative sanction. In response to the above concern, section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100-93 section 14, the Act, section 1128B(b), 42 U.S.C. 1320a-7b(b), specifically required the development and promulgation of regulations, the so-called “safe harbor” provisions, specifying various payment and business practices that, although potentially capable of inducing referrals of business reimbursable under the Federal health care programs, would not be treated as criminal offenses under the anti-kickback statute and would not serve as a basis for administrative sanctions. OIG safe harbor provisions have been developed “to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial and innocuous arrangements” (56 FR 35952, July 29, 1991). Health care providers and others may voluntarily seek to comply with these provisions so that they have the assurance that their business practices will not be subject to liability under the anti-kickback statute or related administrative authorities. The OIG safe harbor regulations are found at 42 CFR part 1001.

B. OIG Special Fraud Alerts

OIG has also periodically issued Special Fraud Alerts to give continuing guidance to health care providers with respect to practices OIG finds

potentially fraudulent or abusive. The Special Fraud Alerts encourage industry compliance by giving providers guidance that can be applied to their own practices. OIG Special Fraud Alerts are intended for extensive distribution directly to the health care provider community, as well as to those charged with administering the Federal health care programs.

In developing Special Fraud Alerts, OIG has relied on a number of sources and has consulted directly with experts in the subject field, including those within OIG, other agencies of the Department, other Federal and State agencies, and those in the health care industry.

C. Section 205 of the Health Insurance Portability and Accountability Act of 1996

Section 205 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191 section 205, the Act, section 1128D, 42 U.S.C. 1320a-7d, requires the Department to develop and publish an annual document in the **Federal Register** formally soliciting proposals for modifying existing safe harbors to the anti-kickback statute and for developing new safe harbors and Special Fraud Alerts.

In developing safe harbors for a criminal statute, OIG is required to thoroughly review the range of factual circumstances that may fall within the proposed safe harbor subject area so as to uncover potential opportunities for fraud and abuse. Only then can OIG determine, in consultation with the Department of Justice, whether it can effectively develop regulatory limitations and controls that will permit beneficial and innocuous arrangements within a subject area while, at the same time, protecting the Federal health care programs and their beneficiaries from abusive practices.

II. Solicitation of Additional New Recommendations and Proposals

In accordance with the requirements of section 205 of HIPAA, OIG last published a **Federal Register** solicitation notice for developing new safe harbors and Special Fraud Alerts on December 30, 2014 (79 FR 78376). As required under section 205, a status report of the public comments received in response to that document is set forth in Appendix F of OIG’s Fall 2015 Semiannual Report.¹ OIG is not seeking additional public comment on the

¹ The OIG *Semiannual Report to Congress* can be accessed through the OIG Web site at <http://oig.hhs.gov/publications/semiannual.asp>.

proposals listed in Appendix F at this time. Rather, this document seeks additional recommendations regarding the development of new or modified safe harbor regulations and new Special Fraud Alerts beyond those summarized in Appendix F.

A detailed explanation of justifications for, or empirical data supporting, a suggestion for a safe harbor or Special Fraud Alert would be helpful and should, if possible, be included in any response to this solicitation.

A. Criteria for Modifying and Establishing Safe Harbor Provisions

In accordance with section 205 of HIPAA, we will consider a number of factors in reviewing proposals for new or modified safe harbor provisions, such as the extent to which the proposals would affect an increase or decrease in:

- Access to health care services,
- the quality of health care services,
- patient freedom of choice among health care providers,
- competition among health care providers,
- the cost to Federal health care programs,
- the potential overutilization of health care services, and
- the ability of health care facilities to provide services in medically underserved areas or to medically underserved populations.

In addition, we will also consider other factors, including, for example, the existence (or nonexistence) of any potential financial benefit to health care professionals or providers that may take into account their decisions whether to (1) order a health care item or service or (2) arrange for a referral of health care items or services to a particular practitioner or provider.

B. Criteria for Developing Special Fraud Alerts

In determining whether to issue additional Special Fraud Alerts, we will consider whether, and to what extent, the practices that would be identified in a new Special Fraud Alert may result in any of the consequences set forth above, as well as the volume and frequency of the conduct that would be identified in the Special Fraud Alert.

Dated: December 16, 2015.

Daniel R. Levinson,
Inspector General.

[FR Doc. 2015-32267 Filed 12-22-15; 8:45 am]

BILLING CODE 4152-01-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS-R8-ES-2014-0007;
FXES1113090000-156-FF09E42000]

RIN 1018-AY82

Endangered and Threatened Wildlife and Plants; Withdrawal of Proposed Rule To Reclassify the Arroyo Toad as Threatened

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; withdrawal.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), withdraw the proposed rule to reclassify the arroyo toad (*Anaxyrus californicus*) as threatened under the Endangered Species Act of 1973, as amended (Act). This withdrawal is based on our conclusion that the types of threats to the arroyo toad remain the same as at the time of listing and are ongoing, and new threats have been identified. Some conservation efforts are ongoing in most populations to help manage and reduce impacts to arroyo toads from many ongoing threats; however, the species has not yet responded to an extent that would allow a change in listing status. The intent of the reclassification criteria in the recovery plan (Service 1999) has not been met. We have therefore determined that reclassification of this species is not appropriate at this time.

DATES: The March 27, 2014 (79 FR 17106), proposed rule to reclassify the arroyo toad as threatened is withdrawn as of December 23, 2015.

ADDRESSES: This withdrawal, comments on our March 27, 2014, proposed rule (79 FR 17106), and supplementary documents are available on the Internet at <http://www.regulations.gov> at Docket No. FWS-R8-ES-2014-0007. Comments and materials received, as well as supporting documentation used in the preparation of this withdrawal, are also available for public inspection, by appointment, during normal business hours at: U.S. Fish and Wildlife Service, Ventura Fish and Wildlife Office, 2493 Portola Road, Suite B, Ventura, CA 93003; telephone 805-644-1766; or facsimile 805-644-3958.

FOR FURTHER INFORMATION CONTACT: Stephen P. Henry, Field Supervisor, Ventura Fish and Wildlife Office (see **ADDRESSES**). If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800-877-8339.

SUPPLEMENTARY INFORMATION:

Previous Federal Actions

Please refer to the proposed reclassification rule for the arroyo toad (79 FR 17106; March 27, 2014) for a detailed description of the Federal actions concerning this species that occurred prior to publication of the proposed reclassification rule. We accepted submission of new information and comments on the proposed reclassification for a 60-day comment period, ending May 27, 2014. In order to ensure that the public had an adequate opportunity to review and comment on our proposed rule, we reopened the comment period for an additional 30 days on October 17, 2014 (79 FR 62408).

Background

A scientific analysis was completed and presented in detail within the arroyo toad species report (Service 2014, entire), which was available on <http://www.regulations.gov> at Docket Number FWS-R8-ES-2014-0007 after the publication of the proposed reclassification. The species report was updated to include the information we received from public and peer review comments, and the final species report (Service 2015, entire) is available at <http://www.regulations.gov> at Docket Number FWS-R8-ES-2014-0007. The species report was prepared by Service biologists to provide thorough discussion of the species' ecology, biological needs, and an analysis of the threats that may be impacting the species. The species report includes discussion of the species' life history, taxonomy, habitat requirements, range, distribution, abundance, threats, and progress towards recovery. This detailed information is summarized in the following paragraphs of this Background section and the Summary of Factors Affecting the Species section.

Arroyo toads are found in low gradient, medium-to-large streams and rivers with intermittent and perennial flow in coastal and desert drainages in central and southern California, and Baja California, Mexico. Arroyo toads occupy aquatic, riparian, and upland habitats in the remaining suitable drainages within its range. Arroyo toads are breeding habitat specialists that need slow-moving streams that are composed of sandy soils with sandy streamside terraces (Sweet 1992, pp. 23-28). Reproduction is dependent upon the availability of very shallow, still, or low-flow pools in which breeding, egg-laying, and tadpole development occur. Suitable habitat for arroyo toads is created and maintained by periodic flooding and scouring that modify