By direction of the Commission.

April J. Tabor,

Secretary.

[FR Doc. 2020–13109 Filed 6–17–20; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3077]

Agency Information Collection Activities; Proposed Collection; Comment Request; Obtaining Information To Understand Challenges and Opportunities Encountered by Compounding Outsourcing Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with FDA research in obtaining information from pharmacists and other management at outsourcing facilities as well as at related compounding businesses to support a comprehensive analysis of the outsourcing facility sector that will inform ongoing FDA work in this area.

DATES: Submit either electronic or written comments on the collection of information by August 17, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 17, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 17, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–N–3077 for ''Agency Information Collection Activities; Obtaining Information to Understand Challenges and Opportunities Encountered by Compounding Outsourcing Facilities.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice

of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Obtaining Information To Understand Challenges and Opportunities Encountered by Compounding Outsourcing Facilities

OMB Control Number 0910–0883—Extension

This information collection supports Agency-sponsored research. Drug compounding is generally the practice of combining, mixing, or altering ingredients of a drug to create a medication tailored to the needs of an individual patient. Although compounded drugs can serve an important medical need for certain patients when an approved drug is not medically appropriate, they also present a risk to patients. Compounded drugs are not FDA-approved. Therefore, they do not undergo premarket review by FDA for safety, effectiveness, and quality. Since compounded drugs are subject to a lower regulatory standard than approved drugs, Federal law places conditions on compounding that are designed to protect the public health.

The Drug Quality and Security Act of 2013 (Pub. L. 113–54) created ''outsourcing facilities''—a new industry sector of drug compounders held to higher quality standards to protect patient health. Outsourcing facilities are intended to offer a more reliable supply of compounded drugs needed by hospitals, clinics, and other providers. Five years since its creation, this domestic industry is still relatively small and is experiencing growth and market challenges. In addition, FDA continues to find concerning quality and safety problems during inspections.

To help this industry meet its intended function, FDA intends to engage in several initiatives to address challenges and support compliance and advancement. One initiative includes conducting indepth research to understand better the challenges and opportunities encountered by the outsourcing facility sector in a number of different areas. These include: Operational barriers and opportunities related to the outsourcing facility market and business viability; knowledge and operational barriers and opportunities related to compliance with Federal policies and good quality drug production; and barriers and opportunities related to outsourcing facility interactions with FDA.

The results of this research will be used by FDA to develop a comprehensive understanding of the outsourcing facility sector, its challenges, and opportunities for advancement. The information will be essential to help identify knowledge and information gaps, operational barriers, and views on interactions with FDA. The research results will inform FDA's future approaches to communication, education, training, and other engagement with outsourcing facilities to address challenges and support advancement.

Researchers will engage pharmacists, staff, and management from outsourcing facilities and similar compounding businesses. Researchers may use surveys, interviews, and focus groups to obtain information concerning challenges and opportunities encountered by outsourcing facilities. Within this context, the following questions or similar, related questions may be posed:

1. What financial and operational considerations inform outsourcing facility operational and business model decisions?

2. What factors impact the development of a sustainable outsourcing facility business?

3. What financial and operational considerations inform outsourcing facility product decisions?

4. Do outsourcing facilities understand the Federal legislative and regulatory policies that apply to them? What, if any, knowledge gaps need to be addressed?

5. What challenges do outsourcing facilities face when implementing Federal current good manufacturing practice (CGMP) requirements?

6. How do outsourcing facilities implement quality practices at their facilities?

7. How is CGMP and quality expertise developed by outsourcing facilities? How do they obtain this knowledge, and what training do they need?

8. What are the economic consequences of CGMP non-compliance/product failures for outsourcing facilities?

9. What are outsourcing facility management and staff views on current interactions with FDA? How do they want the interactions to change?

10. What are outsourcing facilities' understanding of how to engage with FDA during and following an inspection?

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Surveys, focus groups, and interviews	300	2	600	1	600

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: June 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–13086 Filed 6–17–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Injury Prevention Program; Tribal Injury Prevention Cooperative Agreement Program (TIPCAP)

Announcement Type: New/Competing Continuation

Funding Announcement Number: HHS–2020–IHS–IPP–0001

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.284

Key Dates

Application Deadline Date: October 1, 2020

Earliest Anticipated Start Date: December 1, 2020

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS), Office of Environmental Health and Engineering, Division of Environmental Health Services, Injury Prevention Program (IPP) is accepting applications for the Tribal Injury Prevention Cooperative Agreement Program. This program is authorized under: 25 U.S.C. 13, Snyder Act, and Indian Health Care Improvement Act at 25 U.S.C. 1621b, 25 U.S.C. 1603(11), and 25 U.S.C. 1665a(c)(1)(J). This program is described in the Assistance Listings located at *https://beta.sam.gov* (formerly known as Catalog of Federal Domestic Assistance) under 93.284.

Background

The mission of the IHS Injury Prevention Program is to raise the health status of American Indian/Alaska Native (AI/AN) people to the highest possible level by decreasing the incidence of severe injuries and death to the lowest possible level, and by increasing the ability of Tribes to address their injury problems.

The IHS IPP categorizes injuries by intent and type. Unintentional injury types are falls, burns, drowning, poisoning, and motor vehicle related injuries. Unintentional injuries are the leading cause of death for AI/AN people between the ages of 1 and 44 years.

Intentional injury types are suicide and violence related injuries, and are also a leading cause of death. Considering only injury-specific causes of death, suicide is the third leading injury cause of death among all AI/AN. Depending on the injury type, AI/AN experience injury mortality rates that are 2.5 to 8.7 times higher than the U.S. all races rates. (Trends in Indian Health 2017 Edition, IHS, Division of Program Statistics).

Purpose

The purpose of this IHS cooperative agreement is to address the disparity in injury rates by encouraging Tribes to implement focused, community-based injury prevention programs and projects using evidence-based strategies. Injury prevention evidence-based strategies are prevention methods that have been scientifically evaluated and proven to prevent injuries, including strategic changes to the environment (for example, roadways, elder homes for fall hazards, smoke alarms) and strategies to promote behavior change (such as car seat use, float coat use). Injury prevention programs and projects are most effective when based on these model practices. The use of well-planned, promising, and innovative injury prevention strategies is also recommended.

Nationally, the leading causes of AI/AN unintentional injury deaths are due to motor vehicle crashes (Trends in Indian Health 2017 Edition, IHS, Division of Program Statistics) and falls are a leading cause of hospitalization for older adults (ages 55+) in several IHS Areas. Motor vehicle related injuries and elder falls are priority areas of the IHS IPP. To view IHS IPP supported evidence-based and promising strategies visit the IHS IPP website (*https://www.ihs.gov/InjuryPrevention/*) or Selected Evidence-based Strategies for Preventing Injuries (*https://www.ihs.gov/sites/injuryprevention/themes/responsive2017/display_objects/documents/IHS_IPP_Evidence-based_Strategies.pdf*). The IHS IPP will accept applications for programs addressing the following injury types:

Unintentional Injuries

- Motor vehicle related
- Falls
- Burns
- Drowning
- Poisoning

Intentional Injuries

- Suicide
- Violence related

This cooperative agreement opportunity is available to any eligible applicant regardless of whether or not they have previously received IHS IPP Part I or II funding. The IHS will accept applications in either of the two following categories:

Part I—Injury Prevention Programs: 2,500 minimum population requirement

Part II—Evidence-based strategies or promising and innovative projects: No minimum population requirement

Part I—Injury Prevention Programs

Part I applicants must meet the IHS minimum user population of 2,500. IHS user population is defined as AI/AN people who have utilized services funded by the IHS at least once during the last three-year period. This requirement allows the IHS IPP to reach a large number of AI/AN people with the limited amount of available funding. Additionally, it is important for the determination of reliable outcomes. In order to have the statistical power needed to detect differences of relatively small events in a small community, such as annual motor vehicle crashes with an injury or death, it is necessary that there be an adequate sample size. The minimum sample size needed was determined to be 2,500 persons.

Part II—Evidence-Based Strategies or Promising and Innovative Strategy Projects

There is no IHS user population requirement.

II. Award Information

Funding Instrument

Cooperative Agreement

Estimated Funds Available

The total funding identified for fiscal year (FY) 2020 is approximately $1,900,000. Individual award amounts for the Part I first budget year are anticipated to be from $80,000 up to $125,000 and the Part II first budget year awards are anticipated to be from $20,000 up to $32,000. The funding available for competing and subsequent continuation awards issued under this announcement is subject to the availability of funds and budgetary priorities of the Agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

Approximately 24 awards will be issued under this program announcement. Applicants may apply for more than one of the areas of funding but only one will be awarded.

Part I—Five-Year Injury Prevention Programs: Up to $125,000 will be awarded to each successful applicant each year (up to 12 awards).