

against unfounded or unproven allegations, convictions may be more difficult to obtain in these types of fraud cases. Perpetrators of these increasingly prevalent fraud schemes are employing new technological means, and, as noted above, are seeking new forms of payment which make them difficult to identify and convict. As Calvin A. Shivers, the Assistant Director, Criminal Investigative Division, Federal Bureau of Investigation noted in his June 2020 testimony before the U.S. Senate Judiciary Committee:

With the rise in the use of virtual assets and encrypted devices and applications, the interconnectivity of communication platforms and the ever-changing landscape of emerging payment systems, the world is more connected today than ever. This also means it has become increasingly difficult to track illicit finance flows and identify the criminal actors behind them.<sup>33</sup>

Consequently, we are exploring whether and how we might change the evidentiary standard in our regulations for showing a loss of income-producing property due to criminal fraud or theft by a third party.

*What is the purpose of this ANPRM?*

We are seeking information on whether and how we should update our regulations to provide for relief in cases where beneficiaries are victims of criminal fraud or theft and their incomes are affected, but no criminal convictions (or arrest) may have taken place.

We seek to aid beneficiaries adversely affected by fraud that has affected their IRMAA status, while maintaining our commitment to safeguard the public funds in our trust. Our current regulations safeguard against unfounded or unproven allegations by requiring evidence of fraud or loss, but may not address all situations. We are seeking input from the public to more fully understand the new forms of fraudulent activity affecting beneficiaries, to better understand the types of evidence of fraudulent activities such victims can present, to learn more about the types of financial transactions beneficiaries have engaged in as a result of fraud, and to determine how we might revise our rules to better assist victim-beneficiaries.

<sup>33</sup> COVID-19 Fraud: Law Enforcement's Response to Those Exploiting the Pandemic U.S. Senate Judiciary Committee (Statement of Calvin A. Shivers, Assistant Director, Criminal Investigative Division, Federal Bureau of Investigation June 9, 2020) available at: <https://www.fbi.gov/news/testimony/covid-19-fraud-law-enforcements-response-to-those-exploiting-the-pandemic>.

*What We Will Consider When We Decide Whether To Propose Revisions to Our Rules*

We will consider the public comments and any research or data identified in response to this solicitation. We will also consider any information we obtain through research or other activities intended to inform our policy decisions in this area.

*What should the public comment about?*

We are specifically asking the public to provide us with comments on the following topics related to this ANPRM:

- *Types of fraud that can affect IRMAA status*—We seek to learn more about the types of scams the public is experiencing, including how affected persons were contacted; what was the technique employed by the scammer; what kinds of property were targeted; what kinds of financial transactions did affected persons engage in as a result of the fraud; whether affected persons experienced an increase in taxable income as a result; how much of a monetary loss if any did affected persons sustain; were there any arrests or convictions; what was the experience with law enforcement; *etc.*). As noted above, *please be certain not to include any personally identifiable information in your comments*;

- *Types of evidence*—What types of evidence should we seek from affected beneficiaries to demonstrate that the loss was due to criminal fraud or theft? How can we best balance evidentiary needs with the burden evidence requirements impose on affected beneficiaries? We are seeking information about forms of convincing evidence that would be common among such victims.

How should we determine whether a loss of income-producing property due to alleged criminal fraud or theft is “a result of the ordinary risk of investment,” and thus may not be considered under existing regulations [20 CFR 418.1205(e).]

*Consideration of and Response to Public Comments*

We will consider all relevant public comment we receive in response to this ANPRM. If we decide to propose specific revisions to our rules, we will publish a notice of proposed rulemaking in the **Federal Register**, and you will have a chance to comment on any revisions we propose.

#### List of Subjects in 20 CFR Part 418

Administrative practice and procedure, Aged, Blind, Disability benefits, Medicare subsidies, Public assistance programs, Reporting and

recordkeeping requirements, Supplemental Security Income (SSI).

The Acting Commissioner of Social Security, Kilolo Kijakazi, having reviewed and approved this document, is delegating the authority to electronically sign this document to Faye I. Lipsky, who is the primary Federal Register Liaison for the Social Security Administration, for purposes of publication in the **Federal Register**.

**Faye I. Lipsky,**

*Federal Register Liaison, Office of Legislative and Congressional Affairs, Social Security Administration.*

[FR Doc. 2021-25364 Filed 11-22-21; 8:45 am]

**BILLING CODE 4191-02-P**

## DEPARTMENT OF THE INTERIOR

### 25 CFR Part 1000

[222A2100DD/AAK001030/  
AOA501010.999900 253G]

#### Self-Governance PROGRESS Act Negotiated Rulemaking Committee Establishment; Proposed Membership

**AGENCY:** Office of the Assistant Secretary—Indian Affairs, Interior.

**ACTION:** Proposed membership of Committee, notification of intent to establish committee, and nominations.

**SUMMARY:** The U.S. Department of the Interior (DOI) is announcing the proposed members to form the Self-Governance PROGRESS Act Negotiated Rulemaking Committee (Committee). The Committee will advise the Secretary of the Interior (Secretary) on a proposed rule to implement the Practical Reforms and Other Goals To Reinforce the Effectiveness of Self-Governance and Self-Determination for Indian Tribes Act of 2019 (PROGRESS Act) to revise the regulations on Tribal Self-Governance Annual Funding Agreements Under the Tribal Self-Governance Act Amendments to the Indian Self-Determination and Education Act. This document solicits comments on the proposed membership and the proposal to establish the Committee and invites additional nominations for Committee members who will adequately represent the interests that are likely to be significantly affected by the proposed rule. The Secretary also proposes to appoint Federal representatives to the Committee as listed.

**DATES:** Comments must be submitted no later than December 23, 2021.

**ADDRESSES:** Send comments and nominations to the Designated Federal Officer, Vickie Hanvey, by any of the following methods:

- (Preferred method) Email to: [consultation@bia.gov](mailto:consultation@bia.gov);
- Mail, hand-carry or use an overnight courier service to the Designated Federal Officer, Ms. Vickie Hanvey, Office of the Assistant Secretary—Indian Affairs, 1849 C Street NW, Mail Stop 4660, Washington, DC 20240.

**FOR FURTHER INFORMATION CONTACT:** The Designated Federal Officer, Ms. Vickie Hanvey, Program Policy Analyst, Office of Self-Governance, Office of the Assistant Secretary—Indian Affairs; telephone: (918) 931–0745; email: [Vickie.Hanvey@bia.gov](mailto:Vickie.Hanvey@bia.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On October 21, 2020, the PROGRESS Act was signed into law and amends subchapter I of the Indian Self-Determination and Education Assistance Act (ISDEAA), 25 U.S.C. 5301 *et seq.*, which addresses Indian Self-Determination, and subchapter IV of the ISDEAA, which addresses DOI’s Tribal Self-Governance Program. The PROGRESS Act calls for a negotiated rulemaking committee to be established under 5 U.S.C. 565, with membership consisting only of representatives of Federal and Tribal governments, with the Office of Self-Governance serving as the lead agency for the DOL. The PROGRESS Act also authorizes the Secretary to adapt negotiated rulemaking procedures to the unique context of the self-governance relationship between the United States and Indian Tribes. The purpose of the Committee is to serve as an advisory committee under the Federal Advisory Committee Act (FACA) and the Negotiated Rulemaking Act (NRA). The Committee will use a negotiated rulemaking process to develop regulations for implementation of the PROGRESS Act to amend, delete, and add provisions to the existing regulations at 25 CFR part 1000, Annual Funding Agreements Under the Tribal

Self-Government Act Amendments to the Indian Self-Determination and Education Act, which addresses Tribal Self-Governance compacts.

**II. Proposed Work of the Committee**

The objectives of the Committee are to represent the interests that will be significantly affected by the final regulations, negotiate in good faith, and reach consensus, where possible, on recommendations to the Secretary for the proposed regulations.

The Committee will be charged, consistent with subchapter IV regarding the Tribal Self-Governance Program, with developing proposed regulations to implement the PROGRESS Act’s provisions regarding the DOI’s Self-Governance Program. The proposed regulations will be considered by the Secretary and subject to government-to-government consultation.

The Committee will be expected to meet approximately 3–5 times and each meeting is expected to last multiple hours for a consecutive 2–3 days each. The initial meeting will be held by teleconference and/or web conference; later meetings may be held either virtually or in person. The Committee’s work is expected to occur over the course of 6–12 months, and it is the Secretary’s intent to publish the proposed rule for notice and comment by 2022 (within 18 months of the anticipated date of the Committee’s establishment). However, the Committee may continue its work for up to two years. The Office of Self-Governance has dedicated resources required to: ensure the Committee is able to conduct meetings, provide technical assistance, and provide any additional support required to fulfill the Committee’s responsibilities.

**III. Proposed Tribal Committee Members**

On February 1, 2021, the Office of Assistant Secretary—Indian Affairs (AS–IA) published a **Federal Register** notice of intent (86 FR 7656) requesting

comments and nominations for Tribal representatives for the Committee. The comment period for that notice of intent closed March 3, 2021.

Within the notice, AS–IA solicited comments on the proposal to establish the Committee, including comments on any additional interests not identified. AS–IA solicited nominations from Indian Tribes and Tribal organizations as defined in section 4(I) of the Indian Self-Determination and Education Assistance Act that are currently participating in the Tribal Self-Governance Program and those that are not currently participating in, but are interested in participating in, the Tribal Self-Governance Program and who would be affected by the final rule. AS–IA requested that these Tribes and Tribal organizations nominate representatives to serve on the Committee.

The Secretary has selected 14 Tribal representatives (7 Primary, 7 Alternate) for the Committee and 12 Federal representatives (6 Primary, 6 Alternate) for the Committee, for a proposed total of 26 members (13 Primary, 13 Alternate). Primary representatives are voting members. Both primary and alternate representatives are expected to attend all meetings. Alternate representatives are to remain abreast of discussions and to be prepared to vote in the event the Primary is unavailable. The Designated Federal Officer (DFO) and Alternate DFO are considered non-members of the Committee. The proposed Committee was selected based upon nominations submitted through the process identified in the **Federal Register** (85 FR 7656) dated February 1, 2021, under the “Nominations” section. The Secretary did not consider nominations that were received in any other manner or were received after the deadline.

The Secretary proposes the following 14 Tribal representatives for the Committee:

Proposed committee member	Affiliation
W. Ron Allen, Chairman/CEO .....	Jamestown S’Klallam Tribe.
Melanie Benjamin, Chief Executive .....	Mille Lacs Band of Ojibwe.
Richard Peterson, President .....	Central Council Tlingit and Haida Indian Tribes of Alaska.
Michael Dolson, Councilman .....	The Confederated Salish and Kootenai Tribes of the Flathead Nation.
Melanie Fourkiller, Director of Self-Governance .....	Choctaw Nation of Oklahoma.
Russel (Buster) Attebery, Chairman .....	Karuk Tribe.
Karen Fierro, Self-Governance Director .....	Ak-Chin Indian Community.

The Secretary proposes the following alternate Tribal representatives for the Committee:

Proposed alternate committee member	Affiliation
Sandra Sampson, Board Treasurer .....	Confederated Tribes of the Umatilla Indian Reservation.
Jennifer Webster, Councilwoman .....	Oneida Nation.
Gerry Hope, Transportation Director, Former Tribal Leader .....	Sitka Tribe of Alaska.
Jody LaMere, Councilwoman .....	Chippewa Cree Tribe of the Rocky Boy's Reservation.
Jacklyn King, Secretary .....	Sac and Fox Nation.
Will Micklin, Second Vice President .....	Central Council Tlingit and Haida Indian Tribes of Alaska.
Annette Bryan, Council Member .....	Puyallup Tribe of Indians.

#### IV. Proposed Federal Committee Members

Office of Self-Governance. The Secretary proposes the following 12 Federal representatives for the Committee:

The Designated Federal Officer for the Committee will be Ms. Vickie Hanvey,

Name	Affiliation
Sharee Freeman, Director .....	Office of Self-Governance, Assistant Secretary—Indian Affairs.
Bryan Shade, Attorney-Advisor .....	Branch of Self-Governance and Economic Development, Office of the Solicitor.
Vicki Cook, Native American and International Affairs Office .....	Bureau of Reclamation.
Bryon Loosle, Division Chief .....	National Conservation Lands, Bureau of Land and Minerals Management.
Scott Aikin, National Native American Programs Coordinator .....	U.S. Fish and Wildlife Service Head Quarters.
Rose Petoskey, Senior Counselor to the Assistant Secretary—Indian Affairs.	Office of the Assistant Secretary—Indian Affairs.

The Secretary proposes the following alternate Federal representatives for the Committee:

Name	Affiliation
Matt Kallappa, Northwest Field Office Manager .....	Office of Self-Governance, Assistant Secretary—Indian Affairs.
Jody Schwarz, Attorney-Advisor .....	Branch of Self-Governance and Economic Development, Office of the Solicitor.
Kelly Titensor, Native American Affairs Advisor .....	Bureau of Reclamation.
C. Dave Johnson, Tribal Liaison .....	Bureau of Land and Minerals Management.
Dorothy FireCloud, Native American Affairs Liaison .....	National Park Service.
Samuel Kohn, Senior Counselor to the Assistant Secretary—Indian Affairs.	Office of the Assistant Secretary—Indian Affairs.

#### V. Comments

The Secretary solicited comments on the proposal to establish the Committee and received seven written responses submitted through the process identified in the **Federal Register** (86 FR 7656) dated February 1, 2021. The Secretary did not consider comments that were received in any other manner or were received after the close of the comment period. The written comments were received from the Tribal Self-Governance Title IV Task Force and the following six Tribes: (1) Choctaw Nation of Oklahoma, (2) Central Council Tlingit and Haida Indian Tribes of Alaska, (3) Squaxin Island Tribe, (4) Jamestown S'Klallam Tribe, (5) Muscogee (Creek) Nation, and (6) Sac and Fox Nation.

The Task Force and all Tribal commenters except one indicated the Committee should be exempt from the Federal Advisory Committee Act (FACA) based on the following:

Members are either elected officials, or employees with designated authority from an elected official to act on their behalf, and so the Committee should be exempt from FACA under the intergovernmental exemption in the Unfunded Mandates Reform Act (UMRA).

*Response:* The Unfunded Mandates Reform Act (UMRA) exempts certain committees from compliance with FACA if the committee satisfies two requirements. First, meetings between Federal and Tribal governments must be held exclusively between Federal officials and elected officers of State, local, and Tribal governments (or their representatives acting in their official capacities. Second, the meetings must be solely for the purpose of exchanging views, information or advice relating to the management or implementation of Federal programs established pursuant to public law that explicitly or inherently share intergovernmental

responsibilities or administration. See 2 U.S.C. 154(b). The Self-Governance PROGRESS Act Negotiated Rulemaking Committee meets the first requirement but not the second. The Committee is convened to negotiate and promulgate regulations to carry out relevant provisions of the PROGRESS Act, not simply to exchange views, information, or advice on the management or implementation of federal programs. Accordingly, this Committee cannot be exempted from FACA under UMRA.

*All Tribal commenters and the Task Force* indicated support for using an independent facilitation and six specifically support using the services of the Federal Conciliation and Mediation Service (FMCS).

*Response:* Under 5 U.S.C. 565(c), DOI may nominate either a person from the Federal Government or a person from outside the Federal Government to serve as a facilitator for the negotiations of the Committee, subject to the approval of

the Committee by consensus. DOI will consider the nomination of FMCS as a facilitation team.

*The Task Force and several of the Tribal commenters* indicated: (1) Section IV of the notice was unclear about the nomination of primary and alternative representatives creating confusion if a Tribe should submit a primary and alternate, each region submit a primary and alternate, or each nomination should specify where it is for the primary or alternate representative; (2) the notice indicates Committee members must be able to attend all meetings but then states an alternate who can fulfill the obligations of membership should the primary be unable to attend; (3) selection of Committee members surrounds the use of the terms representation of Tribes with a geographic balance; (4) the deadline was confusing and it seemed contradictory to establish a hard deadline but then state you will accept additional nominations after the deadline passes.

*Response:* (1) A Tribe or Tribal Organization may submit either a primary or alternate representative or both. (2) Primary and alternate candidates will both be expected to attend all meetings. Primary representatives are voting members. Alternate representatives are expected to attend all meetings to remain abreast of discussions and to be prepared to vote in the event the primary is unavailable. (3) Proposed committee membership was based upon elected Tribal leadership or Tribal official, Tribal size, balanced geographical representation (by geographic region, state, or other geographical determination) (4) Section VI. Nominations of this document clarifies that additional nominations may be offered after proposed committee membership has been published.

*The Task Force and two Tribal commenters* indicated: (1) Travel and per diem provisions were hard to decipher and, in some instances, seemed contradictory; (2) the notice is unclear with respect to who is responsible for travel expense; (3) provide travel support to all Tribal representatives without evidence of financial resources.

*Response:* The Negotiated Rulemaking Act section 568(c) states that members of a negotiated rulemaking committee shall be responsible for their own expenses of participation in such committee, except that an agency may, in accordance with section 7(d) of the Federal Advisory Committee Act, pay for a member's reasonable travel and per diem expenses, expenses to obtain

technical assistance, and a reasonable rate of compensation, if:

- (1) Such member certifies a lack of adequate financial resources to participate in the committee; and
- (2) the agency determines that such member's participation in the committee is necessary to assure an adequate representation of the member's interest.

The DOI will follow the statutory requirements within the Negotiated Rulemaking Act as well as the Federal Advisory Committee Act referenced above. The DOI will provide travel and per diem expenses for the Committee as funding allows.

*One Tribal commenter* requested clarification on: (1) Next steps for submitting nominations on first **Federal Register** notice; (2) submitting nominations through a second **Federal Register** notice and the deadline; (3) inaugural meeting of the Committee.

*Response:* (1) Nominations submitted through the process identified in the **Federal Register** (85 FR 7656) dated February 1, 2021, under the "Nominations" section closed on March 3, 2021. (2) Section VI Nominations of this document allows for additional nominations to be considered for this Committee. (3) After considering comments and nominations for Tribal representatives, the DOI will publish a **Federal Register** Notice of Establishment and will indicate the proposed meeting schedule.

#### VI. Nominations

If you are an Indian Tribe or Tribal organization as defined in section 4(I) of the Indian Self-Determination and Education Assistance Act that is currently participating in the Tribal Self-Governance Program or that is not currently participating in, but is interested in participating in Tribal Self-Governance Program, we invite you to comment on the proposed nominations in this document. If there is no adequate representation of those interests that will be significantly affected by a proposed rule, we invite you to nominate other persons for membership on the Committee. The Committee membership should reflect the diversity of Tribal interests, and nominees should only be of representatives and alternates who:

- Are elected officials of Tribal governments (or their designated employees with authority to act on their behalf) acting in their official capacities; and
- Will be able to:
  - Represent one or more of the specified interests with the authority to embody the views of that interest,

communicate with interested constituents, and have a clear means to reach agreement on behalf of the interest(s);

- Coordinate, to the extent possible, with other interests who may not be represented on the Committee;
- Negotiate effectively on behalf of the interest(s) represented;
- Commit to time and effort required to attend and prepare for meetings; and
- Collaborate among diverse parties in a consensus-seeking process.

The Secretary will consider nominations for representatives only if they are nominated through the process identified in this notification of intent and in the **Federal Register** notice of intent at 86 FR 7656. The Secretary will not consider any nominations received in any other manner. The Secretary will not consider nominations for Federal representatives; only the Secretary may nominate Federal employees to the Committee.

Nominations must include the following information about each nominee:

(1) A current letter from the governing body or chairperson of the Tribe representing one of the interest(s) identified supporting the nomination of the individual to serve as a representative for the Tribe on the Committee;

(2) A resume reflecting the nominee's qualifications and experience, to include the nominee's name, Tribal affiliation, job title, major job duties, employer, business address, business telephone and fax numbers (and business email address, if applicable);

(3) The interest(s) to be represented by the nominee (identified in this document) and whether the nominee will represent other interest(s) related to this rulemaking; and

(4) A brief description of how the nominee will represent the views of the identified interest(s), communicate with constituents, and have a clear means to reach agreement on behalf of the interest(s) they are representing; and

(5) A statement on whether the nominee is only representing one interest or whether the expectation is that the nominee represents a specific group of interests.

To be considered, nominations must be received by the close of business on the date listed in the **DATES** section, at the location indicated in the **ADDRESSES** section.

#### VII. Public Disclosure of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that

your entire nomination submission—including your personal identifying information—may be made publicly available at any time. While you can ask us in your submission to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

### VIII. Authority

The Practical Reforms and Other Goals To Reinforce the Effectiveness of Self-Governance and Self-Determination for Indian Tribes Act of 2019 (PROGRESS Act), Public Law 116–180 dated October 21, 2020.

**Bryan Newland,**

*Assistant Secretary—Indian Affairs.*

[FR Doc. 2021–25401 Filed 11–22–21; 8:45 am]

BILLING CODE 4337–15–P

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 54

[REG–117575–21]

RIN 1545–BQ27

#### Prescription Drug and Health Care Spending

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** Elsewhere in this issue of the **Federal Register**, the IRS is issuing temporary regulations that increase transparency by requiring group health plans and health insurance issuers in the group and individual markets to report information about prescription drugs and health care spending to the Department of Health and Human Services (HHS), the Department of Labor (DOL), and the Department of the Treasury (the Departments). The IRS is issuing the temporary regulations at the same time that the Office of Personnel Management (OPM), the Employee Benefits Security Administration of DOL, and the Office of Consumer Information and Insurance Oversight of HHS are issuing substantially similar interim final rules with a request for comments. The text of those temporary regulations also serves as the text of these proposed regulations.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 24, 2022.

**ADDRESSES:** In commenting, please refer to file code REG–117575–21. Comments, including mass comment submissions,

must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9905–IFC, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9905–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

#### FOR FURTHER INFORMATION CONTACT:

Christopher Dellana, (202) 317–5500, Internal Revenue Service, Department of the Treasury, for issues related to Surprise Billing.

#### SUPPLEMENTARY INFORMATION:

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. All comments received are posted before the close of the comment period on the following website as soon as possible after they have been received: <http://regulations.gov>. Follow the search instructions on that website to view public comments.

*Proposed Applicability Date:* These regulations are generally proposed to apply on and after December 27, 2021. As discussed in the preamble to the temporary regulations published elsewhere in this issue of the **Federal Register**, the Departments are temporarily deferring enforcement during the first year of applicability.

#### Background and Regulatory Impact Analysis

The temporary regulations published elsewhere in this issue of the **Federal Register** add §§ 54.9825–1T, 54.9825–2T, 54.9825–3T, 54.9825–4T, 54.9825–5T, and 54.9825–6T to the Miscellaneous Excise Tax Regulations. The proposed and temporary regulations are being published as part of a joint rulemaking with the OPM, DOL, and HHS. The text of those temporary regulations also serves as the text of these proposed regulations. The

preamble to the temporary regulations explains the temporary regulations and provides a regulatory impact analysis.

#### Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Unless an agency determines that a proposal is not likely to have a significant economic impact on a substantial number of small entities, section 603 of the RFA requires the agency to present an initial regulatory flexibility analysis (IRFA) of the proposed rule. The Treasury Department and the IRS have not determined whether the proposed regulations, when finalized, will likely have a significant economic impact on a substantial number of small entities. This determination requires further study. However, because there is a possibility of significant economic impact on a substantial number of small entities, an IRFA is provided in these proposed regulations. The Treasury Department and the IRS invite comments on both the number of entities affected and the economic impact on small entities.

Pursuant to section 7805(f), this notice of proposed rulemaking has been submitted to the Chief Counsel of Advocacy of the Small Business Administration for comment on its impact on small business.

#### 1. Need for and Objectives of the Rule

The proposed regulations will implement a reporting requirement for prescription drug costs and other medical expenses. Specifically, group health plans and health insurance issuers will submit key data, which the Departments will use to report and better understand prescription drug pricing trends and their impact on consumers' premiums and out-of-pocket costs. The reporting requirements apply beginning with the data for the 2020 calendar year. This will allow the Departments to better understand national prescription drug costs and identify major drivers of increases in health care spending, which may aid in examining variation of health care costs across the country.

#### 2. Affected Small Entities

The Small Business Administration estimates in its 2020 Small Business Profile that 99.9 percent of United States