

environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

While this proposed order contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by the OMB under the PRA. The collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910–0231; and the collections of information in part 812 have been approved under OMB control number 0910–0078.

IX. Proposed Effective Date

FDA is proposing that any final order based on this proposal become effective on the date of its publication in the **Federal Register** or at a later date if stated in the final order.

X. Opportunity To Request a Change in Classification

Before requiring the filing of a PMA or notice of completion of a PDP for a device, FDA is required by section 515(b)(2)(D) of the FD&C Act to provide an opportunity for interested persons to request a change in the classification of the device based on new information relevant to the classification. A request for a change in the classification of spinal spheres for use in intervertebral fusion procedures should be provided in response to the proposed rule issued elsewhere in this issue of the **Federal Register** and contain the information required by 21 CFR 860.123, including new information relevant to the classification of the device.

XI. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the

Federal Register, but websites are subject to change over time.

1. *Orthopaedic and Rehabilitation Devices Panel—Classification of Spinal Sphere Devices Meeting, December 12, 2013, available at <https://wayback.archive-it.org/7993/20170114044038/http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel/UCM378083.pdf>.

2. Lindley, E.M., B. Levy, E.L. Burger, et al., “Failure of the Fernstrom Ball in Contemporary Spine Surgery: A Case of History Repeating Itself.” *Current Orthopaedic Practice*, 25(1): 87–91, 2014.

List of Subjects in 21 CFR Part 888

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR part 888 be amended as follows:

PART 888—ORTHOPEDIC DEVICES

■ 1. The authority citation for part 888 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. In § 888.3085, add paragraph (c) to read as follows:

§ 888.3085 Spinal spheres for use in intervertebral fusion procedures.

* * * * *

(c) *Date premarket approval application (PMA) or notice of completion of product development protocol (PDP) is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before [A DATE WILL BE ADDED ON THE LAST DAY OF THE 30TH FULL CALENDAR MONTH AFTER THE FUTURE FINAL REGULATION THAT CLASSIFIES THE DEVICE INTO CLASS III IS EFFECTIVE], for any spinal sphere for use in intervertebral fusion procedures as identified in paragraph (a) of this section that was in commercial distribution before May 28, 1976, or that has, on or before [A DATE WILL BE ADDED ON THE LAST DAY OF THE 30TH FULL CALENDAR MONTH AFTER THE FUTURE FINAL REGULATION THAT CLASSIFIES THE DEVICE INTO CLASS III IS EFFECTIVE], been found to be substantially equivalent to any spinal sphere device for use in intervertebral fusion procedures identified in paragraph (a) of this section, that was in commercial distribution before May 28, 1976. Any other spinal sphere device for use in an intervertebral fusion

procedure identified in paragraph (a) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: December 9, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27139 Filed 12–14–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network

31 CFR Chapter X

[Docket No. FINCEN–2021–0008]

Review of Bank Secrecy Act Regulations and Guidance

AGENCY: Financial Crimes Enforcement Network, Treasury.

ACTION: Request for information and comment.

SUMMARY: The Financial Crimes Enforcement Network (FinCEN) is issuing this request for information (RFI) to solicit comment on ways to streamline, modernize, and update the anti-money laundering and countering the financing of terrorism (AML/CFT) regime of the United States. In particular, FinCEN seeks comment on ways to modernize risk-based AML/CFT regulations and guidance, issued pursuant to the Bank Secrecy Act (BSA), so that they, on a continuing basis, protect U.S. national security in a cost-effective and efficient manner. This RFI also supports FinCEN’s ongoing formal review of BSA regulations and guidance required pursuant to Section 6216 of the Anti-Money Laundering Act of 2020 (the AML Act). Section 6216 requires the Secretary of the Treasury (the Secretary) to solicit public comment and submit a report, in consultation with specified stakeholders, to Congress by January 1, 2022, that contains the findings and determinations that result from the formal review, including administrative and legislative recommendations.

DATES: Written comments on this RFI must be received on or before February 14, 2022.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Refer to Docket Number FINCEN–2021–0008.

• *Mail:* Policy Division, Financial Crimes Enforcement Network, P.O. Box 39, Vienna, VA 22183. Refer to Docket Number FINCEN–2021–0008.

FOR FURTHER INFORMATION CONTACT: The FinCEN Regulatory Support Section at 1–800–767–2825 or electronically at <https://fincen.gov/contact>.

SUPPLEMENTARY INFORMATION:

I. Scope of the RFI

FinCEN seeks comment on ways to streamline, modernize, and update BSA regulations and guidance so that they, on a continuing basis, protect U.S. national security in a cost-effective and efficient manner. FinCEN is particularly interested in new and innovative approaches to BSA compliance that promote a risk-based approach to protecting the financial system from threats to national security posed by various forms of financial crime, including money laundering, the financing of terrorism and proliferation, while also providing for the reporting of information with a high degree of usefulness to government authorities. FinCEN recognizes the evolving illicit finance threat landscape and appreciates the important role that technology, innovation, and the efficient application of resources to BSA reporting play in promoting a risk-based approach to BSA compliance. In this context, the efficient application of resources can refer to the prioritization of resources by financial institutions to provide more useful information to law enforcement or other U.S. Government entities, including reporting highly useful information in a timely manner, or reducing redundancies and information of little use reported to law enforcement or other U.S. Government entities.

The review of BSA regulations and guidance¹ required by Section 6216 of the AML Act will support these efforts by enhancing the protection of U.S. national security and assisting in the development, revision, or update of regulations that are outdated, redundant, or otherwise do not support an effective and risk-based AML/CFT framework.² As described in the BSA,

AML/CFT programs should, among other things, be reasonably designed to assure and monitor compliance with the BSA and be risk-based, including ensuring that financial institutions direct more attention and resources toward higher-risk customers and activities, consistent with the risk profile of the financial institution, rather than toward lower-risk customers and activities.³

According to Section 6216(a), the purposes of the review are to: (i) Ensure the Department of the Treasury (Treasury) provides, on a continuing basis, for appropriate safeguards to protect the financial system from threats, including money laundering and the financing of terrorism and proliferation, to national security posed by various forms of financial crime; (ii) ensure that the regulations and guidance implementing the BSA continue to require certain reports or records that are highly useful in countering financial crime; and (iii) identify regulations and guidance that may be outdated, redundant, or otherwise do not promote a risk-based AML/CFT compliance regime for financial institutions, or that do not conform with the commitments of the United States to meet international standards to combat money laundering, financing of terrorism, serious tax fraud, or other financial crimes. Comments received in response to this RFI will support FinCEN's efforts to conduct the review required by Section 6216 of the AML Act. Following that review, the Secretary—in consultation with specified stakeholders⁴—is required to make appropriate changes to the regulations and guidance to improve, as appropriate, the efficiency of those provisions, and submit a report to Congress that contains all findings and determinations made in carrying out the review, including administrative or legislative recommendations.

chapter 53 of title 31, United States Code. Section 6003(1) of the AML Act.

³ 31 U.S.C. 5318(h)(2)(B)(iv).

⁴ Under Section 6216(a) of the AML Act, the Secretary is required to consult with the Federal functional regulators, the Federal Financial Institutions Examination Council, the Attorney General, Federal law enforcement agencies, the Director of National Intelligence, the Secretary of Homeland Security, and the Commissioner of Internal Revenue. Section 6003(3) of the AML Act defines the term “Federal functional regulator” as having: (A) The meaning given the term in section 509 of the Gramm-Leach-Bliley Act (15 U.S.C. 6809); and (B) includes any Federal regulator that examines a financial institution for compliance with the BSA.

II. Background

A. History of the BSA

Enacted in 1970, the BSA is the principal U.S. law for the prevention of money laundering, terrorist financing and proliferation, and other forms of illicit financial activity. Congress has authorized the Secretary to administer the BSA. The Secretary has delegated to the Director of FinCEN the authority to implement, administer, and enforce compliance with the BSA and associated regulations.⁵ FinCEN is authorized to require financial institutions or nonfinancial trades or businesses to maintain procedures to ensure compliance with the BSA and the regulations promulgated thereunder and to guard against money laundering, the financing of terrorism, and other forms of illicit finance.⁶ Statutory amendments, most recently through the AML Act, have expanded the scope and range of BSA requirements and the complexity of FinCEN's regulations, including the types of information FinCEN can require financial institutions to maintain or report.

The Money Laundering Control Act of 1986 (MLCA)⁷ and the Annunzio-Wylie Anti-Money Laundering Act of 1992 (Annunzio-Wylie) made money laundering a Federal crime, amended the BSA by strengthening sanctions for BSA violations,⁸ and authorized Treasury to require the reporting of suspicious activities.⁹ Annunzio-Wylie also authorized Treasury to issue regulations requiring all financial institutions, as defined in BSA regulations, to maintain “minimum standards” of an AML program.¹⁰ The USA PATRIOT Act also ushered in an expanded role for AML and other financial and economic measures in countering threats to U.S. national security and protecting the U.S. financial system. For example, Title III

⁵ Treasury Order 180–01 (Jan. 14, 2020).

⁶ 31 U.S.C. 5318(a)(2) (as amended by Section 6102(c)(2) of the AML Act).

⁷ Public Law 99–570, 100 Stat. 3207 (Oct. 27, 1986).

⁸ Title XV, Public Law 102–550, 106 Stat. 3672 (Oct. 28, 1992), at sec. 1502 (authorizing proceedings to terminate federal depository institution and credit union charters when convicted of a criminal violation of the BSA), sec. 1503 (authorizing the termination of federal deposit insurance for federally insured, state-chartered depository institutions, and federal share insurance for federally insured, state-chartered credit unions, when convicted of a criminal violation of the BSA), sec. 1504 (authorizing the removal officers or directors of depository institutions, and institution-affiliated parties of federally insured credit unions, when such parties are found to have violated a BSA requirement).

⁹ *Id.* at sec. 1517 (authorizing Treasury to require the reporting of suspicious transactions).

¹⁰ *Id.*

¹ FinCEN's regulations are codified at 31 CFR chapter X. For the purposes of this document, “guidance” should be interpreted broadly and includes, for instance, all administrative rulings, advisories, bulletins, fact sheets, responses to frequently asked questions, and notices issued by FinCEN and posted on FinCEN's website.

² The AML Act is Division F of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, Public Law 116–283 (January 1, 2021). The AML Act defines the BSA as section 21 of the Federal Deposit Insurance Act (12 U.S.C. 1829b), chapter 2 of title 1 of Public Law 91–508 (12 U.S.C. 1951 *et seq.*), and subchapter II of

of the USA PATRIOT Act further amended the BSA by authorizing Treasury to require financial institutions to establish customer identification programs and by directly requiring financial institutions to maintain AML programs that satisfied statutorily mandated requirements.¹¹

Most recently, the AML Act greatly expanded the express purposes of the BSA. In addition to requiring the filing of certain highly useful reports and the maintenance of certain highly useful records, the express purposes of the BSA now include, among other things:

- Preventing the laundering of money and the financing of terrorism through the establishment by financial institutions of reasonably designed risk-based programs to combat money laundering and the financing of terrorism;
- facilitating the tracking of money that has been sourced through criminal activity or is intended to promote criminal or terrorist activity; and
- assessing the money laundering, terrorism finance, tax evasion, and fraud risks to financial institutions, products, or services to—
 - protect the financial system of the United States from criminal abuse; and
 - safeguard the national security of the United States.¹²

B. Regulatory Reform Initiatives Prior to the AML Act

Numerous provisions of the AML Act codify and elaborate upon existing or prior Treasury initiatives on innovation, regulatory reform, and industry engagement, in response to evolving threats. These various efforts include: The BSA Advisory Group; an interagency AML Task Force led by Treasury's Under Secretary for Terrorism and Financial Intelligence;¹³ a Regulatory Reform Working Group for Treasury and the Federal Banking

Agencies (FBAs);¹⁴ FinCEN Exchange;¹⁵ studying the value of BSA data; and, the FinCEN Innovation Hours Initiative.¹⁶ FinCEN has also issued final rules in recent years that have aimed to close AML regulatory gaps that represent vulnerabilities in the U.S. financial system that illicit actors could exploit.¹⁷ In addition, to fulfill its obligations under the Paperwork Reduction Act, FinCEN issued multiple notices soliciting input from the public in an effort to better understand and estimate the burden and cost of various BSA regulations.¹⁸ Many of the comments that FinCEN received are relevant to the formal review required under Section 6216 of the AML Act.

C. Technology and Application of the BSA

New and innovative approaches in the financial sector in recent years have resulted in the development of new business models, products, and services, fueled in part by rapid advances in technology. As innovation has presented new business and other opportunities, illicit finance threats have also evolved and present new challenges for financial institutions to

¹⁴ The FBAs include the Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation, the National Credit Union Administration, and the Office of the Comptroller of the Currency.

¹⁵ See FinCEN, *FinCEN Exchange*, available at <https://www.fincen.gov/resources/financial-crime-enforcement-network-exchange>.

¹⁶ See FinCEN, *FinCEN's Innovation Hours Program*, available at <https://www.fincen.gov/resources/fincens-innovation-hours-program>.

¹⁷ See FinCEN, Final rule—Customer Due Diligence Requirements for Financial Institutions, 81 FR 29397 (May 11, 2016); see also FinCEN, Final rule—Customer Identification Programs, Anti-Money Laundering Programs, and Beneficial Ownership Requirements for Banks Lacking a Federal Functional Regulator, 85 FR 57129 (Sept. 15, 2020).

¹⁸ See, e.g., FinCEN, Agency Information Collection Activities; Proposed Renewal; Comment Request; Renewal Without Change of the Bank Secrecy Act Reports of Transactions in Currency Regulations at 31 CFR 1010.310 Through 1010.314, 31 CFR 1021.311, and 31 CFR 1021.313, and FinCEN Report 112—Currency Transaction Report, 85 FR 29022 (May 14, 2020); FinCEN, Agency Information Collection Activities; Proposed Renewal; Comment Request; Renewal Without Change of the Bank Secrecy Act Reports by Financial Institutions of Suspicious Transactions at 31 CFR 1020.320, 1021.320, 1022.320, 1023.320, 1024.320, 1025.320, 1026.320, and 1029.320, and FinCEN Report 111—Suspicious Activity Report, 85 FR 31598 (May 26, 2020); FinCEN, Agency Information Collection Activities; Proposed Renewal; Comment Request; Renewal Without Change of the Customer Identification Program Regulatory Requirements for Certain Financial Institutions, 85 FR 49425 (Aug. 13, 2020); and FinCEN, Agency Information Collection Activities; Proposed Renewal; Comment Request; Renewal Without Change of the Customer Identification Program Regulatory Requirements for Certain Financial Institutions, 85 FR 49425 (Aug. 13, 2020).

comply with BSA obligations. FinCEN recognizes the need to consider how to adapt the BSA's regulatory requirements to better address illicit finance threats that have changed considerably in scope, nature, and impact since the initial passage of the BSA. FinCEN also recognizes that innovation and technological advancements can enhance the ability of financial institutions to comply with their BSA obligations, making it easier to collect information that may be highly useful in combatting a variety of financial crimes, and for U.S. Government authorities to better analyze the information reported by financial institutions.

III. Requirements Under Section 6216 of the AML Act

A. Safeguards To Protect the Financial System From Threats

Section 6216 of the AML Act directs FinCEN to review BSA regulations and guidance to ensure that Treasury provides, on a continuing basis, for appropriate safeguards to protect the financial system from threats to national security posed by various forms of financial crime, including money laundering and the financing of terrorism and proliferation.¹⁹ To meet this objective, FinCEN is soliciting input regarding financial services and related activity that present risk of exploitation by illicit actors or otherwise present a risk to the U.S. financial system but might not be addressed, in whole or in part, by existing regulations. At the same time, FinCEN seeks comment on whether these risks can be addressed by new or amended approaches toward AML program rule, recordkeeping, and reporting requirements that protect national security and safeguard the U.S. financial system while minimizing regulatory burden. In addition, FinCEN seeks comment identifying BSA regulations or guidance where the present safeguards do not effectively mitigate the risks they are intended to prevent or mitigate. Specifically, FinCEN seeks to understand whether AML program rule, recordkeeping, and reporting requirements are sufficient to prevent or mitigate the serious risks they are intended to address.

FinCEN views this objective as separate from the objective to identify BSA regulations and guidance that do not promote a risk-based approach, which is described in section C below. For this objective, FinCEN is soliciting input from the public regarding: (i) Threats to the financial system and to national security that are not adequately

¹⁹ Section 6216(a)(1)(A) of the AML Act.

¹¹ Public Law 107–56, 115 Stat. 272 (Oct. 26, 2001). FinCEN issued four interim final AML program rules on April 29, 2002 for financial institutions regulated by a Federal functional regulator: Casinos (67 FR 21110), money services businesses (67 FR 21114), mutual funds (67 FR 21117), and operators of credit card systems (67 FR 21121). FinCEN's rule originally cross-referenced the regulations of the Federal functional regulators and provided that satisfaction of the appropriate Federal functional regulator's AML program rule requirements would be deemed to satisfy the requirements of Treasury's rule.

¹² 31 U.S.C. 5311 (as amended by Section 6101(a) of the AML Act).

¹³ See Treasury, *Remarks of Under Secretary David S. Cohen at the American Bankers Association and the American Bar Association Money Laundering Enforcement Conference*, (Nov. 10, 2014), available at <https://www.treasury.gov/press-center/press-releases/Pages/jl2692.aspx>.

addressed by BSA regulations and guidance; and (ii) regulatory safeguards that FinCEN should implement via regulation or guidance to better protect the financial system from such threats.

B. Reports and Records That Are Highly Useful in Countering Financial Crime

Section 6216 also directs FinCEN to evaluate BSA regulations and guidance to ensure that they continue to require certain reports or records that are highly useful in countering financial crimes.²⁰ The purposes of the BSA include requiring reports or records that are highly useful in criminal, tax, regulatory, or intelligence matters, and preventing a variety of financial crime, including money laundering and the financing of terrorism.²¹ FinCEN is authorized to require financial institutions or nonfinancial trades or businesses to maintain procedures to ensure compliance with the BSA and the regulations implementing it, and to guard against money laundering, the financing of terrorism, and other forms of illicit finance.²² The BSA and FinCEN's implementing regulations currently require financial institutions, nonfinancial trades and businesses, and individuals to file a variety of reports, including, for example, suspicious activity reports (SARs), currency transaction reports (CTRs), reports of certain domestic coin and currency transactions (Form 8300s), and reports of foreign bank and financial accounts (FBARs). In addition, under 31 U.S.C. 5326(a), if the Secretary finds that reasonable grounds exist for concluding that additional recordkeeping and reporting are necessary to carry out the purposes of the BSA or to prevent evasions thereof, the Secretary may issue an order requiring any domestic financial institution or nonfinancial trade or business or group of domestic financial institutions or nonfinancial trades or businesses in a geographic area to obtain, record, and report information concerning certain transactions (as the Secretary may describe in such order).

The second objective of Section 6216 essentially poses two questions. First, are the reports or records that are currently required to be filed or maintained highly useful in countering financial crime? Second, are there any reports or records that are *not* currently required to be filed or maintained that, if required, would be highly useful in countering financial crime? This

objective also poses similar questions with respect to the BSA's numerous recordkeeping requirements—namely, whether the current requirements mandate any recordkeeping that is not highly useful in countering financial crime, and whether different or additional recordkeeping would be highly useful in countering financial crime.

C. Identify BSA Regulations and Guidance That May Be Outdated, Redundant, or Do Not Promote a Risk-Based AML/CFT Regime for Financial Institutions

Section 6216 also requires FinCEN to evaluate BSA regulations and guidance that may be outdated, redundant, or otherwise do not promote a risk-based AML and CFT compliance regime for financial institutions.²³

FinCEN considers outdated regulations for the purposes of this RFI to include regulations that: (i) No longer promote the maintenance of risk-based safeguards that adequately address the regulation's original purpose; or (ii) are no longer useful or appropriate. That is, if reports filed consistent with a regulation no longer provides highly useful information to the government, or if a regulation once appropriately addressed a significant risk but no longer does so, that regulation is outdated. Outdated regulations would also include regulations that do not promote a risk-based approach to AML/CFT compliance by failing to take into account innovation or technological advancements in the financial system, or are obsolete in light of subsequent statutory or regulatory changes.

FinCEN considers redundant regulations for the purpose of this RFI to include BSA regulations that: (i) Impose requirements on regulated entities that are identical to, or significantly overlap with, the requirements imposed by other BSA regulations; or (ii) were issued under a different statutory authority, but for which it is not possible to comply with both mandates by taking one set of actions. Regulations imposing such requirements will not be considered redundant to the extent that fully satisfying one requirement under one framework fully satisfies the other requirement as well.

Regulations Failing to Promote a Risk-Based Approach: FinCEN looked at several sources to determine how BSA regulations and guidance might fail to promote a risk-based AML/CFT regime for financial institutions, for the purpose of this RFI, including the 2018

National Money Laundering Risk Assessment (NMLRA),²⁴ FinCEN's AML/CFT National Priorities,²⁵ and guidance from the Financial Action Task Force (FATF),²⁶ the international standard-setting body on combatting money laundering and the financing of terrorism and proliferation. The NMLRA in particular provides definitions of several key concepts that can offer helpful clarification in connection with the Section 6216 review:

Threat: The NMLRA uses this term for predicate crimes associated with money laundering.²⁷ The NMLRA deems the environment in which predicate offenses are committed and criminal proceeds generated as being relevant to understanding why, in some cases, specific crimes are associated with specific money laundering methods.

²⁴ See Treasury, *National Money Laundering Risk Assessment*, (Dec. 20, 2018), at page 6, available at https://home.treasury.gov/system/files/136/2018NMLRA_12-18.pdf; see also Treasury, *National Terrorist Financing Risk Assessment*, (Dec. 20, 2018), available at https://home.treasury.gov/system/files/136/2018ntfra_12182018.pdf; see also Treasury, *National Proliferation Financing Risk Assessment*, (Dec. 20, 2018), available at https://home.treasury.gov/system/files/136/2018npfra_12_18.pdf.

²⁵ FinCEN, *Anti-Money Laundering and Countering the Financing of Terrorism Priorities*, (June 30, 2021), available at [https://www.fincen.gov/sites/default/files/shared/AML_CFT%20Priorities%20\(June%2030%2C%202021\).pdf](https://www.fincen.gov/sites/default/files/shared/AML_CFT%20Priorities%20(June%2030%2C%202021).pdf).

²⁶ The FATF is a member-led taskforce established in 1989 by the Group of 7 (G7). Today it has 39 members, and more than 200 jurisdictions have committed to implementing the FATF standards and are assessed against them by the FATF and/or one of nine FATF-style regional bodies. Through its membership in the G7 and the Group of 20 (G20), the United States has also signed onto numerous G7 and G20 commitments to effectively implement the FATF standards. In 2013, 2019 and 2021, FATF issued guidelines and standards for the assessment of systemic exposures to the risks of money laundering, terrorist financing, and proliferation financing. According to these guidelines, a systemic risk assessment is the result of a process, based on a methodology agreed by those parties involved, that attempts to identify, analyze, and understand the combination of vulnerabilities, threats, and consequences affecting a regulated subject, event, or activity. See FATF, *Guidance on National Money Laundering and Terrorist Financing Risk Assessment*, (Feb. 2013), at page 6, *Introduction and Terminology, Section 1.3—Key concepts and terms relevant to a money laundering risk assessment*, available at https://www.fatf-gafi.org/media/fatf/content/images/national_ml_tf_risk_assessment.pdf; see also FATF, *Guidance on Terrorist Financing Risk Assessment*, (Mar. 2019), at pages 7–9 for terminology relevant to a terrorist financing risk assessment, available at <https://www.fatf-gafi.org/media/fatf/documents/reports/Terrorist-Financing-Risk-Assessment-Guidance.pdf>; see also FATF, *Guidance on Proliferation Risk Assessment and Mitigation*, (June 2021), at pages 9–10 for key terminology, available at <https://www.fatf-gafi.org/media/fatf/documents/reports/Guidance-Proliferation-Financing-Risk-Assessment-Mitigation.pdf>.

²⁷ These predicate crimes are enumerated at 18 U.S.C. 1956(c)(7).

²⁰ Section 6216(a)(1)(B) of the AML Act.

²¹ 31 U.S.C. 5311 (as amended by Section 6101(a) of the AML Act).

²² 31 U.S.C. 5318(a)(2) (as amended by Section 6102(c)(2) of the AML Act).

²³ Section 6216(a)(1)(C)(i) of the AML Act.

Vulnerability: The NMLRA uses this term for circumstances or situations that facilitate or create the opportunity for money laundering. A vulnerability may relate to a specific financial sector or product, or a weakness in regulation, supervision, or enforcement. A vulnerability may also reflect unique circumstances pursuant to which it may be difficult to distinguish legal from illegal activity. The methods that allow for the most amount of money to be laundered most effectively or most quickly present the greatest potential vulnerabilities.

Risk: The NMLRA conceives of risk as a function of threat and vulnerability. Risk represents a synthesis, taking into consideration the effect of mitigating measures including regulation, supervision, and enforcement.

The NMLRA also informed Treasury's 2020 National Strategy for Combating Terrorist and Other Illicit Financing in considering approaches to risk. According to that strategy, a risk-based approach in the context of AML/CFT means allocating resources and implementing measures to prevent or mitigate illicit finance in a way that takes into account identified and well understood risks.²⁸ Further, in 2019 FinCEN and the FBAs issued a Joint Statement on Risk-Focused BSA/AML Supervision noting that risk-based compliance programs enable the allocation of compliance resources commensurate with risk.²⁹ The goal of the risk-based approach is to establish and maintain AML/CFT programs proportionate to the risk present in financial institutions based on customers and activities. It focuses available resources in the areas of highest risk in order to have the greatest impact, while reducing the resources devoted to activities carrying lower risk. For purposes of this RFI, when attempting to identify regulations and guidance that do not promote a risk-based AML/CFT regime for financial institutions, commenters are encouraged

to identify regulations and guidance that discourage or hinder financial institutions from using or allocating resources commensurate with risk.

D. Identify BSA Regulations and Guidance That Do Not Conform With International Standards To Combat Financial Crime

Section 6216 requires FinCEN to identify regulations and guidance that do not conform to commitments of the United States to meet international standards to combat money laundering, financing of terrorism, serious tax fraud, or other financial crimes.³⁰ Preeminent among such standards are the FATF Recommendations that promote effective implementation of legal, regulatory and operational measures for combating money laundering, terrorist financing, and other related threats to the integrity of the international financial system.³¹ FATF monitors countries' progress in implementing the FATF standards through mutual evaluations; reviews money laundering and terrorist financing techniques and counter-measures; and promotes the adoption and implementation of the FATF standards globally.³² Given their international recognition as standards for AML, CFT, and countering the financing of proliferation, the FATF Recommendations will factor into how Treasury approaches meeting this objective under Section 6216.

FATF published its most recent mutual evaluation of the United States in December 2016³³ and, in March 2020, issued a follow-up report.³⁴ The purpose of this third follow-up report was to assess the United States' progress in addressing certain technical compliance deficiencies identified in the 2016 Mutual Evaluation Report, most notably relating to customer due diligence obligations, and to analyze the United States' progress in implementing new requirements relating to FATF

Recommendations that have changed since the end of the 2016 Mutual Evaluation.

E. Make Changes to BSA Regulations and Guidance To Improve Efficiency

Finally, Section 6216 requires FinCEN to make changes, as appropriate, to regulations and guidance to improve the efficiency of those provisions.³⁵ FinCEN is asking the public to identify specific changes to BSA regulations and guidance that would make them more efficient. Efficiency in this context can refer to financial institutions focusing resources on providing information that is more useful to law enforcement, reporting highly useful information in a timely manner, or reducing redundancies and information of little use to law enforcement. As part of this process, FinCEN requests comment on regulations and guidance that do not support timely and cost-effective compliance with BSA obligations that produces highly useful information for law enforcement or U.S. Government entities.

IV. Questions for Comment

A. Safeguards To Protect the Financial System From Threats

1. The objective of Section 6216(a)(1)(A) of the AML Act is to ensure that Treasury provides, on a continuing basis, for appropriate safeguards to protect the financial system from threats to national security posed by various forms of financial crime. Are there any threats, vulnerabilities, or risks that you think Treasury is unaware of, or that you think Treasury is not responding to with sufficient and appropriate safeguards? If so, please identify the threats, along with any suggestions you have for how Treasury might better identify and respond to them, including any safeguards that Treasury should implement.

2. Do AML program requirements for financial institutions sufficiently address the threats, vulnerabilities, and risks faced by the U.S. financial system? If not, what changes do you recommend to ensure that AML program requirements adequately and effectively safeguard U.S. national security?

B. Reports and Records That Are Highly Useful in Countering Financial Crime

3. Are there BSA reporting or recordkeeping requirements that you believe do not provide information that is highly useful in countering financial crimes? If so, what reports or records, and why? Conversely, are there reports

²⁸ See Treasury, *2020 National Strategy for Combating Terrorist and Other Illicit Financing*, at pages 6–7, available at <https://home.treasury.gov/system/files/136/National-Strategy-to-Counter-Illicit-Finance2.pdf>; see also FATF, *FATF Recommendations: International Standards on Combating Money Laundering and the Financing of Terrorism & Proliferation*, (updated Oct. 2021), at page 31, Interpretive Note for FATF Recommendation 1 (describing the risk-based approach), available at <http://www.fatf-gafi.org/media/fatf/documents/recommendations/pdfs/FATFRecommendations2012.pdf>.

²⁹ See FinCEN, *Joint Statement on Risk Focused Bank Secrecy Act Anti Money Laundering Supervision*, (July 22, 2019), available at <https://www.fincen.gov/sites/default/files/2019-10/JointStatementonRisk-FocusedBankSecrecyAct-Anti-MoneyLaunderingSupervisionFINAL1.pdf>.

³⁰ Section 6216(a)(1)(C)(ii) of the AML Act.

³¹ See FATF, *FATF Recommendations—International Standards on Combating Money Laundering and the Financing of Terrorism & Proliferation* (“FATF Recommendations”), (updated Oct. 2021), at page 7, available at <https://www.fatf-gafi.org/media/fatf/documents/recommendations/pdfs/FATFRecommendations2012.pdf>.

³² See FATF, *FATF Recommendations*, at page 8.

³³ See FATF, *Anti-money laundering and counter-terrorist financing measures—United States, Fourth Round Mutual Evaluation Report*, (2016), available at <http://www.fatf-gafi.org/publications/mutualevaluations/documents/mer-united-states-2016.html>.

³⁴ See FATF, *Anti-money laundering and counter-terrorist financing measures—United States, 3rd Enhanced Follow-up Report & Technical Compliance Re-Rating*, (2020), available at <https://www.fatf-gafi.org/media/fatf/documents/reports/fur/Follow-Up-Report-United-States-March-2020.pdf>.

³⁵ Section 6216(a)(2) of the AML Act.

or records not currently required that would be highly useful? If so, what reports and records, and why?

4. Are there specific changes to BSA reporting or recordkeeping requirements that would provide information that is more useful to law enforcement in countering financial crimes or allow financial institutions to better understand what information to report? If so, which reports or records, and what changes do you recommend?

5. How can FinCEN ensure that BSA reporting and recordkeeping requirements are highly useful in countering financial crimes on a continuing basis? For example, should FinCEN conduct certain studies or analyze certain data on a regular basis to ensure BSA reports and records continue to be highly useful in countering financial crimes?

6. Should FinCEN consider certain regular or automatic updates to specific BSA regulations to ensure the reports or records they require continue to be highly useful in countering financial crimes? For example, should FinCEN more regularly update certain BSA reports' fields based on frequency of use, terms included, or other relevant factors and trends identified? What other events might necessitate such updates?

7. Would automatically updating certain BSA reporting or recordkeeping requirements streamline or reduce the potential compliance burden without sacrificing the usefulness of the required BSA reports and records in countering financial crimes? If so, what other requirements might benefit from automatic updates? For example, should automatic updates to dollar thresholds for certain BSA reports and records occur to account for inflation adjustments? What other circumstances might necessitate automatic updates?

8. Should FinCEN consider periodic adjustments, such as customized thresholds, to BSA regulations and guidance to account for changes in risk, such as changes in geographic risk? What circumstances might necessitate customized thresholds and why?

C. Identify BSA Regulations and Guidance That May Be Outdated, Redundant, or Do Not Promote a Risk-Based AML/CFT Regime for Financial Institutions

i. Outdated Regulations

9. Are there BSA regulations or guidance that do not promote risk-based safeguards or that no longer fulfill their original purpose? If so, which regulations or guidance, and what changes do you recommend?

10. Are there BSA regulations or guidance that are obsolete or no longer provide useful information to the government? Alternatively, are there any BSA regulations or guidance that target risks that no longer exists? If so, which regulations or guidance, and what changes do you recommend?

11. Are there any BSA regulations or guidance that are obsolete because of changes in compliance business practices and/or technological innovation in the financial system or elsewhere? If so, how should FinCEN address this?

12. Do FinCEN's regulations and guidance sufficiently allow financial institutions to incorporate innovative and technological approaches to BSA compliance? If not, how can FinCEN facilitate greater use of these tools, while ensuring that appropriate safeguards are in place and highly useful information continues to be reported to government authorities?

ii. Redundant Regulations

13. Are there BSA regulations that impose requirements identical to or significantly overlapping with requirements imposed by other BSA regulations? If so, which BSA regulations, and what amendments do you recommend?

14. Are there BSA regulations that impose requirements that are identical to or significantly overlap with requirements imposed under another regulatory regime? If so, which BSA regulations, and which other regulatory framework?

15. Are there other provisions under the AML Act, or the BSA as amended by the AML Act, that you think will assist in eliminating redundant BSA regulations and guidance? If so, which sections of the AML Act or amended BSA, and why?

iii. Other Regulations That Do Not Promote a Risk-Based Regime

16. Do any BSA regulations or guidance require or encourage resources be allocated inefficiently based on the level of risk that the regulations or guidance are intended to prevent or mitigate? If so, which regulations or guidance, and what changes would you recommend FinCEN make?

17. Aside from any issues mentioned in response to the questions above, are there other BSA regulations or guidance that do not promote a risk-based approach? If so, which regulations or guidance, how do they fail to promote a risk-based regime, and what changes would you recommend FinCEN make? Please distinguish as clearly as possible between issues that result from the

content of a regulation or guidance, and issues that result from compliance supervision, examinations, or audits.

18. How else can FinCEN reaffirm that BSA regulations and guidance are intended to foster a risk-based approach?

19. Are there BSA regulations or guidance for which applying a risk-based approach is challenging? If so, which regulations or guidance, what are the challenges, and how might FinCEN reduce or eliminate those challenges?

20. Are there BSA regulations or guidance that are highly effective at promoting a risk-based approach such that they should be used as a model for other BSA regulations and guidance? If so, which regulations or guidance, and why?

D. Identify BSA Regulations and Guidance That Do Not Conform With International Standards To Combat Financial Crime

21. Do any BSA regulations or guidance fail to conform with U.S. commitments to meet international standards, or do not fully implement international standards, including the FATF Recommendations? If so, which regulations or guidance, and why?

22. Which deficiencies identified in the FATF's 2016 U.S. Mutual Evaluation Report and addressed in the third Follow-Up Report most significantly prevent the United States from fully implementing an effective and risk-based approach? What changes to regulations or guidance would you recommend to address the deficiencies identified?

E. Identify Changes to BSA Regulations and Guidance To Improve Efficiency

23. Are there BSA regulations or guidance that should be amended to improve their efficiency? If so, which regulations or guidance, and what amendments do you recommend?

24. Are there BSA regulations or guidance that are unclear or are overly burdensome in comparison to the risk posed? If so, which regulations or guidance? To what do you attribute the additional burden, and in what way (if any) is the burden excessive compared to the benefits of the regulation? Could the burden be reduced without making the regulations or guidance less effective? If so, how?

25. Aside from any regulations or guidance identified in response to previous questions, are there any BSA regulations or guidance with which you believe compliance provides minimal or no benefit to the government, thus making any compliance burden excessive? If so, which regulations or

guidance, and would you propose to amend or repeal them? If amend, how? And if repeal, why repeal rather than amend?

26. In what ways could BSA regulations or guidance be more efficient in light of innovative approaches and new technologies. For should any BSA regulations or guidance account for technological advancements, such as digital identification, machine learning, and artificial intelligence? If so, how?

V. Conclusion

Conducting the formal review required under Section 6216 of the AML Act will assist FinCEN in modernizing and streamlining BSA regulations and guidance to ensure that they continue to: (i) Support the purposes and goals of the BSA and the AML Act, and (ii) safeguard the U.S. financial system. The formal review will also allow FinCEN to identify and, as appropriate, revise regulations and guidance that do not promote a risk-based AML/CFT regime for financial institutions, are not in conformity with international standards, or are outdated, redundant, or inefficient. In addition, the formal review will assist FinCEN in identifying recommendations for administrative and legislative changes to BSA regulations and guidance. FinCEN seeks input from the public on the questions set forth above, including from regulated parties; state, local, and Tribal governments; law enforcement; regulators; other consumers of BSA data; and any other interested parties. We encourage all interested parties to provide their views.

Himamauli Das,

Acting Director, Financial Crimes Enforcement Network.

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DEPARTMENT OF EDUCATION

34 CFR Chapter II

[Docket ID ED-2021-OESE-0148]

Proposed Definition—Supporting Effective Educator Development Program

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Proposed definition.

SUMMARY: The Department of Education (Department) proposes to establish a definition for the Supporting Effective Educator Development (SEED) program,

Assistance Listing Number 84.423A. We propose to define “national nonprofit entity,” for the purpose of clarifying the SEED program eligibility requirements.

DATES: We must receive your comments on or before January 14, 2022.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

- *Federal eRulemaking Portal:* Go to www.regulations.gov to submit your comments electronically. Information on using Regulations.gov, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under “Help.”

- *Postal Mail, Commercial Delivery, or Hand Delivery:* If you mail or deliver your comments about the proposed definition, address them to Christine Miller, U.S. Department of Education, 400 Maryland Avenue SW, Room 3C152 Washington, DC 20202.

Privacy Note: The Department’s policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at www.regulations.gov. Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: Christine Miller, U.S. Department of Education, 400 Maryland Avenue SW, Room 3C152, Washington, DC 20202. Telephone: (202)260-7350. Email: christine.miller@ed.gov.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll-free, at 1-800-877-8339.

SUPPLEMENTARY INFORMATION:

Invitation to Comment: We invite you to submit comments regarding the proposed definition. To ensure that your comments have maximum effect in developing the final definition, we urge you to identify clearly the specific section of the proposed definition that each comment addresses.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866 and 13563 and their overall requirement of reducing regulatory burden that might result from the proposed

definition. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of our programs.

During and after the comment period, you may inspect all public comments about the proposed definition by accessing Regulations.gov. You may also inspect the comments in person. Please contact the person listed under **FOR FURTHER INFORMATION CONTACT** to make arrangements to inspect the comments in person.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for the proposed definition. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Program Authority: Section 2242 of the ESEA (20 U.S.C. 6672).

Proposed Definition:

Background: Section 2242 of the Elementary and Secondary Education Act of 1965, as amended (ESEA), provides that eligible entities for awards under the SEED program include national nonprofit entities with a demonstrated record of raising student academic achievement, graduation rates, and rates of higher education attendance, matriculation, or completion, or of effectiveness in providing preparation and professional development activities and programs for teachers, principals, or other school leaders. We propose to define “national nonprofit entity,” for purposes of this eligibility requirement, to allow potential applicants to determine their eligibility for a grant under this program more readily, have a clear understanding of the information they must provide to establish eligibility, and allow the Department to make decisions on applicant eligibility more effectively and efficiently. Our experience with administering the fiscal year (FY) 2018 and FY 2020 SEED competitions, including feedback from applicants and funded grantees, demonstrates the need to define the term “national nonprofit entity” and provide more transparency regarding applicant eligibility requirements. The proposed definition incorporates the definition of “nonprofit” under 34 CFR 77.1(c) but also clarifies how an entity would demonstrate that its work is “national” in scope. The proposed definition