Sanford, NC, Raleigh Exec Jetport at Sanford-Lee County, RNAV (GPS) RWY 21, Amdt 1
Sanford, NC, Raleigh Exec Jetport at Sanford-Lee County, Takeoff Minimums and Obstacle DP, Amdt 1
Rugby, ND, Rugby Muni, GPS RWY 12, Orig, CANCELLED
Rugby, ND, Rugby Muni, GPS RWY 30, Orig-B, CANCELLED
Rugby, ND, Rugby Muni, RNAV (GPS) RWY 12, Orig
Rugby, ND, Rugby Muni, RNAV (GPS) RWY 30, Orig
Rugby, ND, Rugby Muni, Takeoff Minimums and Obstacle DP, Orig
Chadron, NE, Chadron Muni, ILS OR LOC RWY 2, Amdt 2
Chadron, NE, Chadron Muni, RNAV (GPS) RWY 2, Orig-A
Chadron, NE, Chadron Muni, RNAV (GPS) RWY 11, Orig
Chadron, NE, Chadron Muni, RNAV (GPS) RWY 20, Amdt 1
Chadron, NE, Chadron Muni, RNAV (GPS) RWY 29, Orig
Chadron, NE, Chadron Muni, Takeoff Minimums and Obstacle DP, Orig
Chadron, NE, Chadron Muni, VOR/DME RWY 2, Amdt 2A, CANCELLED
Chadron, NE, Chadron Muni, VOR/DME RWY 20, Orig-A, CANCELLED
Hartington, NE, Hartington Muni, GPS RWY 13, Orig, CANCELLED
Hartington, NE, Hartington Muni, GPS RWY 31, Orig, CANCELLED
Hartington, NE, Hartington Muni/Bud Becker Fld, RNAV (GPS) RWY 13, Orig
Hartington, NE, Hartington Muni/Bud Becker Fld, RNAV (GPS) RWY 31, Orig
Hartington, NE, Hartington Muni/Bud Becker Fld, Takeoff Minimums and Obstacle DP, Orig
Manville, NJ, Central Jersey Rgnl, RNAV (GPS) RWY 25, Amdt 1A
Morristown, NJ, Morristown Muni, RNAV (GPS) Z RWY 23, Orig-A
Morristown, NJ, Morristown Muni, RNAV (RNP) Y RWY 23, Orig
Albany, NY, Albany Intl, COPTER ILS OR LOC/DME RWY 1, Amdt 1, CANCELLED
Albany, NY, Albany Intl, GPS RWY 10, Orig, CANCELLED
Albany, NY, Albany Intl, GPS RWY 28, Orig-B, CANCELLED
Albany, NY, Albany Intl, ILS OR LOC RWY 1, ILS RWY 1 (SA CAT II), Amdt 11
Albany, NY, Albany Intl, ILS OR LOC RWY 19, Amdt 23
Albany, NY, Albany Intl, RNAV (GPS) RWY 10, Orig
Albany, NY, Albany Intl, RNAV (GPS) RWY 28, Orig
Albany, NY, Albany Intl, RNAV (GPS) Y RWY 1, Amdt 1
Albany, NY, Albany Intl, RNAV (GPS) Y RWY 19, Amdt 1
Albany, NY, Albany Intl, RNAV (RNP) Z RWY 1, Orig
Albany, NY, Albany Intl, RNAV (RNP) Z RWY 19, Orig
Albany, NY, Albany Intl, Takeoff Minimums and Obstacle DP, Amdt 12
Buffalo, NY, Buffalo Airfield, RNAV (GPS) RWY 6, Orig
Buffalo, NY, Buffalo Airfield, RNAV (GPS) RWY 24, Amdt 1
New York, NY, La Guardia, ILS OR LOC RWY 22, ILS RWY 22 (SA CAT I), ILS RWY 22 (SA CAT II), Amdt 20
Eugene, OR, Mahlon Sweet Field, RNAV (GPS) Y RWY 16L, Amdt 2
Eugene, OR, Mahlon Sweet Field, RNAV (GPS) Y RWY 16R, Amdt 1
Eugene, OR, Mahlon Sweet Field, RNAV (GPS) Y RWY 34L, Amdt 2
Eugene, OR, Mahlon Sweet Field, RNAV (GPS) Y RWY 34R, Amdt 2
Eugene, OR, Mahlon Sweet Field, RNAV (RNP) Z RWY 16L, Orig
Eugene, OR, Mahlon Sweet Field, RNAV (RNP) Z RWY 16R, Orig
Eugene, OR, Mahlon Sweet Field, RNAV (RNP) Z RWY 34L, Orig
Eugene, OR, Mahlon Sweet Field, RNAV (RNP) Z RWY 34R, Orig
Redmond, OR, Roberts Field, RNAV (GPS) Y RWY 4, Orig-A
Redmond, OR, Roberts Field, RNAV (GPS) Y RWY 22, Orig-A
Redmond, OR, Roberts Field, RNAV (RNP) Z RWY 4, Orig
Redmond, OR, Roberts Field, RNAV (RNP) Z RWY 22, Orig
Meadville, PA, Port Meadville, RNAV (GPS) RWY 7, Amdt 1
Meadville, PA, Port Meadville, RNAV (GPS) RWY 25, Amdt 1
Philadelphia, PA, Philadelphia Intl, ILS OR LOC RWY 26, Amdt 4
Philadelphia, PA, Philadelphia Intl, ILS PRM RWY 26 (Sim. Close Parallel), Amdt 4
Philadelphia, PA, Philadelphia Intl, RNAV (GPS) RWY 26, Amdt 1
Miller, SD, Miller Muni, GPS RWY 15, Orig, CANCELLED
Miller, SD, Miller Muni, GPS RWY 33, Orig, CANCELLED
Miller, SD, Miller Muni, RNAV (GPS) RWY 15, Orig
Miller, SD, Miller Muni, RNAV (GPS) RWY 33, Orig
Sioux Falls, SD, Joe Foss Field, ILS OR LOC RWY 21, Amdt 10
Sioux Falls, SD, Joe Foss Field, RNAV (GPS) RWY 3, Amdt 1
Sioux Falls, SD, Joe Foss Field, RNAV (GPS) RWY 21, Amdt 1
Alpine, TX, Alpine-Casparis Muni, GPS RWY 19, Orig-A, CANCELLED
Alpine, TX, Alpine-Casparis Muni, RNAV (GPS) RWY 19, Orig
Bonham, TX, Jones Field, RNAV (GPS) RWY 17, Amdt 2
Bonham, TX, Jones Field, RNAV (GPS) RWY 35, Amdt 1
Bonham, TX, Jones Field, Takeoff Minimums and Obstacle DP, Amdt 2
El Paso, TX, El Paso Intl, RNAV (GPS) Y RWY 22, Orig-C
El Paso, TX, El Paso Intl, RNAV (RNP) Z RWY 22, Orig
El Paso, TX, El Paso Intl, Takeoff Minimums and Obstacle DP, Amdt 6
Fort Worth, TX, Fort Worth Alliance, ILS OR LOC RWY 34R, Amdt 6
San Antonio, TX, San Antonio Intl, RNAV (RNP) Z RWY 21, Orig-A
Sulphur Springs, TX, Sulphur Springs Muni, RNAV (GPS) RWY 1, Amdt 1
Sulphur Springs, TX, Sulphur Springs Muni, RNAV (GPS) RWY 19, Orig
Winters, TX, Winters Muni, NDB OR GPS RWY 35, Orig-A, CANCELLED
Winters, TX, Winters Muni, RNAV (GPS) RWY 17, Orig
Winters, TX, Winters Muni, RNAV (GPS) RWY 35, Orig
Winters, TX, Winters Muni, Takeoff Minimums and Obstacle DP, Orig
Richland, WA, Richland, VOR RWY 26, Amdt 7A, CANCELLED
Wenatchee, WA, Pangborn Memorial, RNAV (RNP) RWY 12, Orig-B
Sparta, WI, Sparta/Fort McCoy, RNAV (GPS) RWY 29, Amdt 1
Laramie, WY, Laramie Rgnl, RNAV (GPS) RWY 3, Orig
Laramie, WY, Laramie Rgnl, RNAV (GPS) RWY 21, Orig

[FR Doc. 2011–17984 Filed 7–20–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2007–N–0092] (Formerly Docket No. 2007N–0308)

Cardiovascular Devices; Classification of Electrocardiograph Electrodes

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the electrocardiograph electrode, intended to acquire and transmit the electrical signal at the body surface to a processor that produces an electrocardiogram (ECG) or vectorcardiogram, into class II (special controls). FDA is also exempting this device from the premarket notification requirement.

DATES: This rule is effective August 22, 2011.

FOR FURTHER INFORMATION CONTACT: Sharon Lappalainen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1238, Silver Spring, MD 20993, 301–796–6322.

SUPPLEMENTARY INFORMATION:

I. Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (SMDA) (Pub. L. 101–629), the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115), and the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Pub. L. 107–250), established a comprehensive system for the regulation

of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, defined by the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the FD&C Act, FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), as ''preamendments devices.'' FDA classifies these devices after it takes the following steps: (1) Receives a recommendation from a device classification panel (an FDA advisory committee); (2) publishes the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) publishes a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution before May 28, 1976, generally referred to as postamendments devices, are classified automatically under section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III until FDA does the following: (1) Reclassifies the device into class I or II; (2) issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the FD&C Act; or (3) issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a legally marketed device that has been classified into class I or class II.

The Agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations. FDAMA added a new section 510(m) to the FD&C Act. New section 510(m) provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the FD&C Act, if the Agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device. FDA has determined that premarket notification is not necessary to assure the safety and effectiveness of electrocardiograph electrodes.

Under the 1976 amendments, class II devices were defined as devices for which there was insufficient information to show that general controls themselves would provide reasonable assurance of safety and effectiveness, but for which there was sufficient information to establish performance standards to provide such assurance. SMDA broadened the definition of class II devices to mean those devices for which the general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and any other appropriate actions FDA deems necessary (section 513(a)(1)(B) of the FD&C Act). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control for this device. This action is being taken under the FD&C Act, as amended by the 1976 amendments, SMDA, FDAMA, and MDUFMA.

II. Regulatory History of the Device

In the **Federal Register** of October 4, 2007 (72 FR 56702; Docket No. 2007N–0308), FDA proposed to classify electrocardiograph electrodes, intended to acquire and transmit the electrical signal at the body surface to a processor that produces an electrocardiogram (ECG) or vectorcardiogram, into class II. FDA also proposed to exempt this device from premarket notification requirements. FDA invited interested persons to comment on the proposed regulation by January 2, 2008. FDA received seven comments on the proposed rule.

III. Summary of Final Rule

FDA is amending the classification regulation for electrocardiograph electrodes into class II, by making this device exempt from 510(k) premarket notification requirements and subject to the new special controls described in the special controls guidance document entitled ''Guidance for Industry and Food and Drug Administration Staff: Class II Special Controls Guidance Document: Electrocardiograph Electrodes.''

As described in that special controls guidance document, the special controls include the following:

- Documentation of device description, which includes compliance with 21 CFR 820.181(a) to maintain a device master record;
- Documentation of performance characteristics, which includes documentation on biocompatibility, electrical performance, adhesive performance, shelf life, reuse, electrodes intended for use in specified procedures, sterility, and, with respect to electrode lead wires and patient cables, compliance with 21 CFR part 898; and
- Specific labeling, including indications for use, cautions, precautions, and adverse reactions.

Manufacturers must comply with the special controls as identified in that special controls guidance document, either by meeting the recommendations in the guidance document or by some other means that provides equivalent assurance of safety and effectiveness.

IV. Discussion of Comments

The public comments received in response to the proposed rule addressed issues pertaining to labeling, the scope of the devices subject to the classification rule, and testing as follows:

Regarding labeling, the comments requested the mandatory product labeling of all adhesive coated disposable electrocardiograph electrodes and the establishment of template labeling with which electrocardiograph electrodes should comply. In response, FDA has revised the labeling section of the special controls guidance document; however, FDA has not established template labeling.

Regarding the scope of the devices subject to the notice, the comments requested a products-based definition or listing of examples to flesh out the ''type'' of devices that are consistent with Agency intent, requested a clarification of the type of sensor that is included in the scope of the classification, and requested a clarification if the list of environmental conditions is intended to be an exclusive list. In response, FDA has revised the special controls guidance document to clarify what the scope of this classification rule includes and excludes and to clarify what labeling should be reported regarding conditions of use.

Regarding testing, the comments requested clarification of the shelf life, storage condition testing, and human clinical testing required to establish sensitivity and irritation for all adhesives. In response, FDA has revised the special controls guidance document to clarify testing for shelf life and has clarified the testing for biocompatibility.

FDA is adopting in final form the assessment of the risks to public health stated in the proposed rule published on October 4, 2007, and agrees that the risk of electrical shock should also be taken

into account for purposes of this assessment. The guidance document has been revised accordingly. FDA is issuing this final rule which classifies the generic type of device, electrocardiograph electrode, into class II subject to special controls.

V. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action under the Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because manufacturers are already substantially in compliance with the recommendations in the guidance document and exemption from the premarket notification requirements for the devices following the specific measures recommended in the special control will simplify the entry to market for other manufacturers, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. In addition, this final rule will not impose costs of $100 million or more on either the private sector or state, local, and tribal governments in the aggregate, and therefore a written statement under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

The specific measures recommended largely reflect current practices. With most manufacturers complying with most of the recommendations in the guidance document, any additional burden brought about by the final rule and guidance will likely be small.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires Agencies to ''construe* * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Federal law includes an express preemption provision that preempts certain state requirements ''different from or in addition to'' certain Federal requirements applicable to devices. 21 U.S.C. 360k. See *Medtronic* v. *Lohr,* 518 U.S. 470 (1996); and *Riegel* v. *Medtronic,* 552 U.S. 312 (2008). The special controls established by this final rule create ''requirements'' to address each identified risk to health presented by these specific medical devices under 21 U.S.C. 360k, even though product sponsors may have flexibility in how they meet those requirements Cf. *Papike* v. *Tambrands, Inc.,* 107 F.3d 737, 740–42 (9th Cir. 1997).

VIII. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no new collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520) is not required.

This final rule designates a guidance document as a special control. FDA also concludes that the special control guidance document does not contain new information collection provisions that are subject to review and clearance by OMB under the PRA.

IX. Electronic Access

For access to the docket to read references or the public comments received, go to *http://www.regulations.gov* or go to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A hard copy of any document can be obtained by submitting a Freedom of Information Act request to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

X. References

The following references have been placed on display in the Division of Dockets Management (see section IX of this document) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, or can be obtained in hardcopy by submitting a Freedom of Information Act request to the Division of Freedom of Information (see section IX of this document). (FDA has verified the Web site address, but we are not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register.**)

1. ''Class II Special Controls Guidance Document: Electrocardiograph Electrodes.''
2. ANSI/AAMI/ISO 10993–1, ''Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing.''
3. ISO 10993–5, ''Biological Evaluation of Medical Devices—Part 5: Tests for In Vitro Cytotoxicity.''
4. ISO 10993–10, ''Biological Evaluation of Medical Devices—Part 10: Tests for Irritation and Delayed Type Hypersensitivity.''
5. ANSI/AAMI EC12, ''Disposable ECG Electrodes.''
6. AAMI/ANSI/ISO ST79, ''Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.''
7. ''Updated 520(k) Sterility Review Guidance K90–1.''
8. IEC 601–1.56.3(c), ''Medical Electrical Equipment—Part 1, General Requirements for Safety.''
9. ANSI/AAMI EC53, ''ECG Cables and Leadwires.''
10. FDA Guidance 89–4203, ''Labeling—Regulatory Requirements for Medical Devices,'' available at *http://www.fda.gov/cdrh/dsma/470.pdf.*

List of Subjects in 21 CFR Part 870

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 870 is amended as follows:

PART 870—CARDIOVASCULAR DEVICES

■ 1. The authority citation for 21 CFR part 870 continues to read as follows:

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

■ 2. Revise paragraph (b) in § 870.2360 to read as follows:

§ 870.2360 Electrocardiograph electrode.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9. The special control for this device is the FDA guidance document entitled ''Class II Special Controls Guidance Document: Electrocardiograph Electrodes.'' See § 870.1(e) for availability information of guidance documents.

Dated: July 18, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–18391 Filed 7–20–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network

31 CFR Parts 1010, 1021 and 1022

RIN 1506–AA97

Bank Secrecy Act Regulations; Definitions and Other Regulations Relating to Money Services Businesses

AGENCY: Treasury Department, Financial Crimes Enforcement Network (FinCEN).

ACTION: Final rule.

SUMMARY: The Financial Crimes Enforcement Network (''FinCEN''), a bureau of the Department of the Treasury (''Treasury''), is revising the regulations implementing the Bank Secrecy Act (''BSA'') regarding money services businesses (''MSBs'') to clarify which entities are covered by the definitions.

The changes more clearly delineate the scope of entities regulated as MSBs, so that determining which entities are obligated to comply is more straightforward and predictable. This rulemaking amends the current MSB regulations by: ensuring that certain foreign-located persons engaging in MSB activities within the United States are subject to the BSA rules; updating the MSB definitions to reflect past guidance and rulings, current business operations, evolving technologies, and merging lines of business; and separating the provisions dealing with stored value from those dealing with issuers, sellers, and redeemers of traveler's checks and money orders.

DATES: *Effective Date:* This rule is effective September 19, 2011. *Compliance Date:* The compliance date for the amendments to 31 CFR 1022.380 is January 23, 2012.

FOR FURTHER INFORMATION CONTACT: The FinCEN regulatory helpline at (800) 949–2732 and select Option 1.

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory and Regulatory Background

The BSA, Titles I and II of Public Law 91–508, as amended, codified at 12 U.S.C. 1829b, 12 U.S.C. 1951–1959, and 31 U.S.C. 5311–5314 and 5316–5332, authorizes the Secretary of the Treasury (the ''Secretary'') to issue regulations requiring financial institutions to keep records and file reports that the Secretary determines ''have a high degree of usefulness in criminal, tax, or regulatory investigations or proceedings, or in the conduct of intelligence or counterintelligence matters, including analysis, to protect against international terrorism.'' [1] In addition, the Secretary is authorized to impose anti-money laundering (''AML'') program requirements on financial institutions.[2] The Secretary's authority to administer the BSA has been delegated to the Director of FinCEN.[3] FinCEN has implemented the BSA through regulations (''BSA regulations,'' ''implementing regulations'' or ''BSA rules'') that appear at 31 CFR Chapter X.[4]

The BSA defines the term ''financial institution'' to include, in part: a currency exchange; an issuer, redeemer, or cashier of travelers' checks, checks, money orders, or similar instruments; the United States Postal Service; a person who engages as a business in the transmission of funds; and any business or agency which engages in any activity determined by regulation to be an activity similar to, related to, or a substitute for these activities.[5]

FinCEN has issued regulations under the BSA implementing the recordkeeping, reporting, and other requirements of the BSA with respect to these types of financial institutions. These regulations refer to these types of financial institutions as ''money services businesses'' (''MSBs'').[6] Like other financial institutions under the BSA, MSBs must implement AML programs, make certain reports to FinCEN, and maintain certain records to facilitate financial transparency. MSBs are generally required to: (1) Establish written AML programs that are reasonably designed to prevent the MSB from being used to facilitate money laundering and the financing of terrorist activities; [7] (2) file Currency Transaction Reports (''CTRs'') [8] and Suspicious Activity Reports (''SARs''); [9] and (3) maintain certain records, including those relating to the purchase of certain monetary instruments with currency,[10] transactions by currency dealers or exchangers (to be called ''dealers in foreign exchange'' under this rulemaking),[11] and certain transmittals of funds.[12] Most types of MSBs are required to register with FinCEN [13] and all are subject to examination for BSA compliance by the Internal Revenue Service (''IRS'').[14]

B. Past Public MSB Meetings

In 1997, FinCEN held public meetings to give members of the financial services industry an opportunity to discuss the proposed MSB regulations and any impact they might have on operations.[15]

[1] 31 U.S.C. 5311.

[2] 31 U.S.C. 5318(h).

[3] *See* Treasury Order 180–01 (Sept. 26, 2002).

[4] On October 26, 2010, FinCEN issued a final rule creating a new Chapter X in title 31 of the Code of Federal Regulations for the BSA regulations. *See* 75 FR 65806 (October 26, 2010) (Transfer and Reorganization of Bank Secrecy Act Regulations Final Rule) (referred to herein as the ''Chapter X Final Rule''). The Chapter X Final Rule became effective on March 1, 2011. Because the Notice of Proposed Rulemaking, Definitions and Other Regulations Relating to Money Services Businesses, 74 FR 22129 (May 12, 2009), was issued before the Chapter X Final Rule became effective, it was proposed in the 31 CFR Part 103 format. In this Final Rule, for ease of reference and where appropriate, we have included the former 31 CFR Part 103 citation after the 31 CFR Chapter X regulatory citation.

[5] 31 U.S.C. 5312(a)(2)(J), (K), (R), (V), and (Y).

[6] *See* 31 CFR 1010.100(ff) (formerly 31 CFR 103.11(uu)).

[7] *See* 31 CFR 1022.210 (formerly 31 CFR 103.125).

[8] *See* 31 CFR 1010.311 (formerly 31 CFR 103.22).

[9] *See* 31 CFR 1022.320 (formerly 31 CFR 103.20). Check cashers and transactions solely involving the issuance, sale, or redemption of stored value are not covered by the SAR requirement. *See* 31 CFR 1022.320(a)(1), (5) (formerly 31 CFR 103.20(a)(1), (5). FinCEN recently proposed imposing a SAR requirement with respect to transactions involving stored value. *See* Notice of Proposed Rulemaking, Amendment to the Bank Secrecy Act Regulations—Definitions and Other Regulations Relating to Prepaid Access, 75 FR 36589 (June 28, 2010).

[10] *See* 31 CFR 1010.415 (formerly 31 CFR 103.29).

[11] *See* 31 CFR 1022.410 (formerly 31 CFR 103.37).

[12] *See* 31 CFR 1010.410(e)–(f) (formerly 31 CFR 103.33(f)–(g)).

[13] *See* 31 CFR 1022.380 (formerly 31 CFR 103.41).

[14] *See* 31 CFR 1010.810(b) (formerly 31 CFR 103.56(b)(8)).

[15] These public meetings were held in Vienna, Virginia, on July 22, 1997; New York, New York,

Continued