

(H) An insurance company subject to supervision by a State or foreign insurance authority; and

(v) The aggregate dollar amount of revenues or assets treated by the company as not financially related under this paragraph (e)(2) does not exceed 5 percent of the consolidated annual gross financial revenues of the company or the consolidated total financial assets of the company, respectively, in that year.

(f) *Requests regarding activities that may be financial in nature.* (1) *In general.* A company may request a determination from the Board as to whether a particular activity is financial in nature for purposes of this section.

(2) *Required information.* A request submitted under this paragraph (f) must be in writing and must—

(i) Identify and describe the activity for which the determination is sought, specifically describing what the activity involves and how the activity is conducted;

(ii) Explain in detail why the activity should or should not be considered financial in nature for purposes of this section; and

(iii) Provide information supporting the requested determination and any other information required by the Board concerning the activity.

#### **§ 225.302 Significant nonbank financial companies and significant bank holding companies.**

(a) *In general.* This section defines the terms “significant nonbank financial company” and “significant bank holding company” as such terms are used in—

(1) Section 113 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (“Dodd-Frank Act”) (12 U.S.C. 5323) relating to the designation of nonbank financial companies by the Financial Stability Oversight Council for supervision by the Board; and

(2) Section 165(d)(2) of the Dodd-Frank Act (12 U.S.C. 5365(d)(2)) relating to the credit exposure reports required to be filed by—

(i) A nonbank financial company supervised by the Board; and

(ii) A bank holding company or foreign bank subject to the Bank Holding Company Act (12 U.S.C. 1841 *et seq.*) that has \$50 billion or more in total consolidated assets.

(b) *Significant nonbank financial company.* A “significant nonbank financial company” means—

(1) Any nonbank financial company supervised by the Board; and

(2) Any other nonbank financial company that had \$50 billion or more in total consolidated assets (as

determined in accordance with applicable accounting standards) as of the end of its most recently completed fiscal year.

(c) *Significant bank holding company.*

A “significant bank holding company” means any bank holding company or foreign bank treated as a bank holding company under section 8(a) of the International Banking Act of 1978 (12 U.S.C. 3106(a)) that had \$50 billion or more in total consolidated assets as of the end of the most recently completed calendar year, as reported—

(1) In the case of a bank holding company (other than a foreign banking organization), on the Federal Reserve’s FR Y–9C (Consolidated Financial Statements for Bank Holding Companies); and

(2) In the case of a foreign banking organization that is or is treated as a bank holding company, on the Federal Reserve’s Form FR Y–7Q (Capital and Asset Report for Foreign Banking Organizations).

By order of the Board of Governors of the Federal Reserve System, February 7, 2011.

**Jennifer J. Johnson,**

*Secretary of the Board.*

[FR Doc. 2011–2978 Filed 2–10–11; 8:45 am]

**BILLING CODE 6210–01–P**

## **FEDERAL DEPOSIT INSURANCE CORPORATION**

### **12 CFR Part 330**

**RIN 3064–AD37**

#### **Amendments to Deposit Insurance Regulations: Deposit Insurance Coverage Training; SMDIA Notification**

**AGENCY:** Federal Deposit Insurance Corporation (FDIC).

**ACTION:** Notice of proposed rulemaking with request for comments.

**SUMMARY:** The FDIC is proposing a rule that would promote public confidence in Federal deposit insurance by providing depositors with improved access to accurate information about FDIC insurance coverage of their accounts at insured depository institutions (IDIs). The proposed rule would accomplish this goal in three ways. First, it would require certain IDI personnel to complete FDIC-provided training on the fundamentals of FDIC deposit insurance coverage. These IDI personnel would include any employee with authority to open deposit accounts and/or respond to customer questions about FDIC insurance coverage (hereafter “employees”). Second, the

proposed rule would require IDIs to implement procedures so that employees, when opening a new deposit account, inquire whether the customer has an ownership interest in any other account at the IDI and, if so, whether the customer’s aggregate ownership interest in deposit accounts, including the new account, exceeds the Standard Maximum Deposit Insurance Amount (“SMDIA”). If this is the case, then the IDI employee would be required to provide the customer with a copy of the FDIC’s publication, *Deposit Insurance Summary*. The proposed rule would apply to deposit accounts opened in person at the IDI, by telephone, mail, and via the Internet or other technology. Third, the rule would require IDIs to provide a link to the FDIC’s Electronic Deposit Insurance Estimator (“EDIE”) on any Web site the IDI maintains for use by deposit customers.

**DATES:** Written comments must be received by the FDIC no later than April 12, 2011.

**ADDRESSES:** Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Agency Web site:* <http://www.fdic.gov/regulations/laws/federal/propose.html>. Follow the instructions for submitting comments.

- *E-mail:* [comments@fdic.gov](mailto:comments@fdic.gov).

Include RIN # 3064–AD37 in the subject line of the message.

- *Mail:* Robert E. Feldman, Executive Secretary, *Attention:* Comments, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.

- *Hand Delivery/Courier:* Comments may be hand-delivered to the guard station located at the rear of the FDIC’s 550 17th Street building (accessible from F Street) on business days between 7 a.m. and 5 p.m.

*Instructions:* All submissions must include the agency name and use the title “Part 330—Deposit Insurance Education.” All comments received will be posted generally without change to <http://www.fdic.gov/regulations/laws/federal/propose.html>, including any personal information provided. Paper copies of public comments may be ordered from the Public Information Center by telephone at (877) 275–3342 or (703) 562–2200.

**FOR FURTHER INFORMATION CONTACT:** Martin W. Becker, Senior Consumer Affairs Specialist, Deposit Insurance Section, Division of Supervision and Consumer Protection, (202) 898–6644, [mbecker@fdic.gov](mailto:mbecker@fdic.gov); or Catherine A.

Ribnick, Counsel, Legal Division, (202) 898-6803, [cribnick@fdic.gov](mailto:cribnick@fdic.gov); Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.

#### SUPPLEMENTARY INFORMATION:

### I. Insured Depository Institution Employee Education on Deposit Insurance

FDIC regulations currently do not require employees at IDIs to be trained in the basic principles of FDIC deposit insurance coverage or to assist customers in ascertaining whether their deposits are fully covered by Federal deposit insurance. The FDIC receives tens of thousands of telephone calls, e-mails and correspondence annually from depositors and IDI employees seeking information and advice about FDIC deposit insurance coverage. These inquiries reveal that many depositors do not know whether their deposits are fully insured and that bank employees often are unfamiliar with the scope of deposit insurance coverage. In addition, the FDIC regularly receives complaints from IDI customers, asserting that their banks were unable to answer their deposit insurance questions or, in some cases, may have provided inaccurate deposit insurance guidance. The FDIC is concerned that these situations could cause financial harm to depositors and have the potential to undermine customer confidence in depository institutions and the Federal deposit insurance system.

To address the issues described above, the FDIC is proposing to add a new section to its insurance regulations, which appear at 12 CFR Part 330. This new section would establish three new requirements for IDIs.

First, IDIs would be required to have employees with the authority to open deposit accounts and/or respond to customer questions about FDIC deposit insurance coverage complete a computer-based instructional ("CBI") program provided to IDIs by the FDIC. This program would provide users with an introduction to FDIC deposit insurance coverage, with specific focus on the general principles of insurance coverage and the rules and requirements for the account ownership categories. It would also introduce users to the information resources available from the FDIC, including EDIE, deposit insurance guides and on-demand videos. Further, this self-paced training module would include frequent knowledge checks to help the user evaluate his or her understanding of the information presented.

This self-administered training program would require less than two hours for most employees to complete.

All employees would be required to complete the training once in every 12-month period. Each new employee with the duties previously described would be required to take the training within 30 days of commencing employment. Current employees at the time of the effective date of the final rule would be required to take the training within 60 days of the effective date.

Further, IDIs are encouraged to provide additional training, using a range of media, to help employees understand the FDIC's deposit insurance rules. The FDIC provides multiple, cost-free training resources on the deposit insurance rules to the industry, for use on a voluntary basis, including in-person training sessions, written materials, videos, EDIE and telephone seminars presented by FDIC personnel.

Second, IDIs would be required to institute procedures ensuring that, regardless of the manner in which a customer opens a new account, the employee opening the account must inquire as to the existence of other deposit accounts at the same IDI and whether the aggregated account balance exceeds the SMDIA, currently \$250,000. Thus, for an account opened in person or by telephone, the employee opening the account would ask the customer whether the customer maintains any other accounts at the IDI (including accounts opened at other IDI branch locations) and, if so, whether the combined balances of all the accounts exceed the SMDIA. If the response is in the affirmative, the IDI employee would provide the customer with a copy of the FDIC's *Deposit Insurance Summary* publication. In the case of deposit accounts opened by mail, via the Internet or by means of other technology, these inquiries can be included in the paper or electronic application form, with a link to the *Deposit Insurance Summary* publication supplied. The rule would not require an IDI to provide counsel or advice to the customer regarding how to structure multiple deposit accounts to maximize deposit insurance coverage.

The rule would apply to all types of deposit accounts opened by a customer, with the exception of pass-through accounts as to which the IDI does not, in the normal course of business, keep records of the beneficial owners. The rule would not impose a deposit insurance training requirement on third parties (e.g., deposit brokers or affinity groups) that directly or indirectly promote the deposit of funds in a specified IDI. However, the FDIC makes ample deposit insurance resources publicly available, and the Corporation

urges any entity that encourages or facilitates the placement of deposits in IDIs to provide appropriate information in response to client inquiries regarding FDIC deposit insurance coverage.

Third, the proposed rule would require an IDI to provide a link to EDIE on any Web site it maintains for use by customers. IDIs can link to EDIE, at no cost, in two ways—via Online EDIE or Brandable EDIE. Online EDIE is available directly from the FDIC's Web site at <http://www.fdic.gov/edie>. With Online EDIE, IDIs link to the application, which resides on the FDIC's Web site, and IDI customers are then taken from the IDI's Web site to the FDIC's Web site. Brandable EDIE, which can be accessed free from FDIC Connect, allows an IDI to customize and integrate the EDIE application into the IDI's own Web site, so customers can access EDIE without leaving the IDI's Web site.

### II. Regulatory Burden on Insured Depository Institutions

The FDIC believes the implementation of this rule would not impose a significant regulatory burden on the industry. The proposed rule is circumscribed and modest in its requirements. First, IDI employees with authority to open accounts and/or respond to a customer's deposit insurance question would be required to complete a short training program annually. The training program would be provided to IDIs by the FDIC at no cost. Second, when opening a new account, employees would simply inquire (1) whether the customer has other deposits at the same IDI and (2) whether such deposits, including the new account, exceed the SMDIA. The rule would not require IDI employees to advise customers on how to maximize deposit insurance coverage. The proposed rule would require IDI employees to provide the customer with the FDIC's publication, *Deposit Insurance Summary*. Lastly, the rule would require an IDI to maintain a link to EDIE on its Web site.

The Corporation believes it is reasonable to expect employees at IDIs to have sufficient familiarity with basic rules for Federal deposit insurance coverage so employees can provide accurate information to customers who wish to confirm their deposit insurance coverage. To the extent that compliance with the proposed rule imposes an obligation on the industry, it must be weighed against the benefit to depositors by reinforcing their confidence in Federal deposit insurance and preventing unnecessary financial losses to customers if their IDI should fail.

### III. Request for Comments

The FDIC requests comment on all aspects of the proposed rule, including cost, regulatory burden and benefits to consumers. In particular, the FDIC seeks comments with respect to the following questions:

- Does the proposed rule strike the right balance between meeting depositors' need for accurate deposit insurance information and the potential cost to and regulatory burden on IDIs?

- Is the scope of the proposed rule appropriate? In its present form, the rule would require training for all IDI employees with authority to open accounts and/or respond to customers' inquiries on deposit insurance coverage. Should the training extend to all IDI employees who work in bank retail offices, not just the employees with these specific responsibilities?

- The rule would require IDI employees to inquire whether the customer has an ownership interest in any other deposit accounts at the IDI and, if so, whether the customer's total ownership interest in deposit accounts, including the new account, exceeds the Standard Maximum Deposit Insurance Amount. Should the inquiry only apply to aggregated deposits that exceed the SMDIA of \$250,000 or to aggregated deposits that may approach the SMDIA? And if so, what dollar amount or percentage of the SMDIA should trigger the obligation to provide depositors with the FDIC's *Deposit Insurance Summary* publication?

- In addition to requiring IDIs to make EDIE available on their Web sites, should the FDIC require IDIs to maintain, in their retail office lobbies, a dedicated computer terminal containing the EDIE application, which all customers could use on their own, or with assistance from IDI employees, to generate reports on the customer's deposit insurance coverage?

- In addition to requiring IDIs to provide the FDIC's *Deposit Insurance Summary* publication to depositors whose combined deposits at the IDI exceed the SMDIA, should IDIs be required to make this publication available in their retail office lobbies so all depositors have access to this important information?

- Should the CBI software program include a feature that would allow IDIs to confirm that training has been completed by covered employees?

### IV. Regulatory Analysis and Procedure

#### A. Solicitation of Comments on Use of Plain Language

Section 722 of the Gramm-Leach-Bliley Act, Public Law 106-102, 113

Stat. 1338, 1471 (Nov. 12, 1999), requires the Federal banking agencies to use plain language in all proposed and final rules published after January 1, 2000. We invite your comments on how to make this proposal easier to understand. For example, have we organized the material to suit your needs? If not, how could this material be better organized? Are the requirements in the proposed regulation clearly stated? If not, how could the regulation be more clearly stated? Does the proposed regulation contain language or jargon that is not clear? If so, which language requires clarification? Would a different format (grouping and order of sections, use of headings, paragraphing) make the regulation easier to understand? If so, what changes to the format would make the regulation easier to understand? What else could we do to make the regulation easier to understand?

#### B. Paperwork Reduction Act

Request for Comment on Proposed Information Collection

In accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. Ch. 3501 *et seq.*), the FDIC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The proposed rule requires IDIs to implement procedures so that, whenever a customer opens a new deposit account at an insured depository institution, the employee opening the account shall inquire whether the customer has an ownership interest in any other accounts at the IDI and, if so, whether the customer's aggregate ownership interest in deposit accounts, including the new account, exceeds the Standard Maximum Deposit Insurance Amount. If the customer responds affirmatively, then the IDI employee shall provide the customer with the FDIC's publication, *Deposit Insurance Summary*. Since this is an FDIC-prepared publication, there is no paperwork burden involved. In the case of deposit accounts opened by mail or via the Internet or other technology, the publication can be provided in paper form or through a link to the electronic version.

Commenters may submit comments on aspects of this notice that may affect reporting and disclosure requirements to the addresses listed in the **ADDRESSES** section of this NPR. Paperwork Burden comments should reference "Part 330—

Deposit Insurance Education, OMB Control No. 3064-NEW."

#### C. Regulatory Flexibility Act

The Regulatory Flexibility Act ("RFA") requires a Federal agency publishing a notice of proposed rulemaking to prepare and make available for public comment an initial regulatory flexibility analysis that describes the impact of the proposed rule on small entities. 5 U.S.C. 603(a). Pursuant to regulations issued by the Small Business Administration (13 CFR 121.201), a "small entity" includes a bank holding company, commercial bank or savings association with assets of \$175 million or less (collectively, small banking organizations). The RFA provides that an agency is not required to prepare and publish a regulatory flexibility analysis if the agency certifies that the proposed rule would not have a significant impact on a substantial number of small entities. 5 U.S.C. 605(b). Pursuant to section 605(b) of the RFA, the FDIC certifies that the proposed rule would not have a significant economic impact on a substantial number of small entities.

#### D. The Treasury and General Government Appropriations Act, 1999—Assessment of Federal Regulations and Policies on Families

The FDIC has determined that the proposed rule will not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, enacted as part of the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999 (Pub. L. 105-277, 112 Stat. 268).

#### List of Subjects in 12 CFR Part 330

Bank deposit insurance, Banks, banking, Reporting and recordkeeping requirements, Savings and loan associations, Trusts and trustees.

For the reasons set forth in the preamble, the Board of Directors of the Federal Deposit Insurance Corporation proposes to amend part 330 of Title 12 of the Code of Federal Regulations as follows:

#### **PART 330—DEPOSIT INSURANCE COVERAGE**

1. The authority citation for part 330 continues to read as follows:

**Authority:** 12 U.S.C. 1813(l), 1813(m), 1817(i), 1818(q), 1819(Tenth), 1820(g), 1821(a).

2. Add § 330.17 to read as follows:

**§ 330.17 Deposit insurance training.**

(a) *Purpose.* The purpose of this section is to maintain confidence in Federally insured depository institutions and to protect depositors by requiring insured depository institution employees with authority to open accounts and/or respond to customer inquiries regarding deposit insurance coverage (“employees”), to complete training on basic deposit insurance principles once in any twelve month period. New employees must complete the training within 30 days of commencing employment. Current employees are required to complete the training within 60 days of the effective date of the final rule.

(b) *Applicability.* The requirements in this section shall apply to all insured depository institution employees who have the authority to open accounts and/or respond to customer inquiries regarding deposit insurance coverage.

(c) *Procedure.* (1) *Insured Depository Institution Personnel Education.* (i) *Training.* An insured depository institution must require each employee with the authority to open accounts and/or respond to customer inquiries regarding deposit insurance coverage to complete basic deposit insurance training annually, using an FDIC-provided training module. Each new employee with the authority to open accounts and/or respond to customer inquiries regarding deposit insurance coverage must be required to undergo such training within 30 days of commencing employment.

(ii) *Training Materials.* The FDIC will provide the training module in the form of a self-administered computer-based instructional program.

(2) *Ascertaining Insured Status.* An insured depository institution must implement procedures so that, whenever a customer opens a new deposit account at an insured depository institution, the employee opening the account shall inquire whether the customer has an ownership interest in any other accounts at the IDI and, if so, whether the customer’s aggregate ownership interest in deposit accounts, including the new account, exceeds the Standard Maximum Deposit Insurance Amount. If the customer responds affirmatively, then the IDI employee shall provide the customer with the FDIC’s *Deposit Insurance Summary* publication. In the case of deposit accounts opened by mail or via the Internet or other technology, these inquiries can be included in the paper or electronic application form, with the link to the *Deposit Insurance Summary* publication provided.

(d) *Definitions.* (1) *Account* shall mean a deposit account at a depository institution that is held by or offered to a customer. It includes time, demand, savings, and negotiable order of withdrawal accounts. The term does not include a fiduciary account as to which the insured depository institution does not, in the normal course of business, keep records of beneficial owners of the deposits in the account.

(2) *New Account* shall mean any deposit account at an insured depository institution to which the insured depository institution assigns a unique identifier that serves to distinguish the account from other, existing accounts at the depository institution.

By order of the Board of Directors.

Dated at Washington, DC, this 7th day of February, 2011.

Federal Deposit Insurance Corporation.

**Robert E. Feldman,**

*Executive Secretary.*

[FR Doc. 2011–3085 Filed 2–10–11; 8:45 am]

**BILLING CODE 6714–01–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 310 and 334

[Docket No. FDA–1978–N–0021; Formerly Docket No. 78N–036L]

RIN 0910–AF38

#### Professional Labeling for Laxative Drug Products for Over-the-Counter Human Use; Proposed Amendment to the Tentative Final Monograph

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing a proposed rulemaking to amend the tentative final monograph (1985 TFM) for over-the-counter (OTC) laxative drug products (products that relieve occasional constipation). FDA is proposing that sodium phosphate salts (dibasic sodium phosphate, monobasic sodium phosphate, and the combination of dibasic sodium phosphate/monobasic sodium phosphate salts in a solution dosage form) are not generally recognized as safe (GRAS) for bowel cleansing. This document also would withdraw the professional labeling proposed for sodium phosphate salts in the 1985 TFM. Professional labeling is additional information about an OTC

drug that is directed to healthcare professionals who prescribe, administer, or dispense medications and is not included in OTC drug product labeling for consumers. FDA is issuing this proposed rule after a careful review of new data and information on the serious side effects that have been associated with the customary dose of OTC sodium phosphates solution (approximately 60 grams (g) of sodium phosphates taken in two 45-milliliter (mL) doses 12 hours apart or approximately 50 g of sodium phosphates taken in a 45-mL dose followed by a 30-mL dose 12 hours later) for bowel cleansing prior to colonoscopy. This proposed rule is part of FDA’s ongoing review of OTC drug products.

**DATES:** Submit electronic or written comments by March 14, 2011. See section VI of this document for the effective date of any final rule that may publish based on this proposal.

**ADDRESSES:** You may submit comments, identified by Docket No. FDA–1978–N–0021 (formerly Docket No. 78–N–036L) and RIN number 0910–AF38, by any of the following methods:

#### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

#### Written Submissions

Submit written submissions in the following ways:

- *FAX:* 301–827–6870.
- *Mail/Hand delivery/Courier (For paper, disk, or CD-ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

*Instructions:* All submissions received must include the agency name, docket number (Docket No. FDA–1978–N–0021) (formerly Docket No. 78N–036L) and Regulatory Information Number (RIN) (RIN 0910–AF38) for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov> including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket, to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts