Medical Necessity Disclosure Under MHPAEA

MHPAEA section 512(b) specifically amends the Public Health Service (PHS) Act to require plan administrators or health insurance issuers to provide, upon request, the criteria for medical necessity determinations made with respect to MH/SUD benefits to current or potential participants, beneficiaries, or contracting providers. The Interim Final Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (75 FR 5410, February 2, 2010) and the Final Rules under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 set forth rules for providing criteria for medical necessity determinations. CMS oversees non-Federal governmental plans and health insurance issuers.

Claims Denial Disclosure Under MHPAEA

MHPAEA section 512(b) specifically amends the PHS Act to require plan administrators or health insurance issuers to supply, upon request, the reason for any denial or reimbursement of payment for MH/SUD services to the participant or beneficiary involved in the case. The Interim Final Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (75 FR 5410, February 2, 2010) and the Final Rules under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 implement 45 CFR 146.136(d)(2), which sets forth rules for providing reasons for claims denial. CMS oversees non-Federal governmental plans and health insurance issuers, and the regulation provides a safe harbor such that non-Federal governmental plans (and issuers offering coverage in connection with such plans) are deemed to comply with requirements of paragraph (d)(2) of 45 CFR 146.136 if they provide the reason for claims denial in a form and manner consistent with ERISA requirements found in 29 CFR 2560.503–1. Section 146.136(d)(3) of the final rule clarifies that PHS Act section 2719 governing internal claims and appeals and external review as implemented by 45 CFR 147.136, covers MHPAEA claims denials and requires that, when a non-quantitative treatment limitation (NQTL) is the basis for a claims denial, that a non-grandfathered plan or issuer must provide the processes, strategies, evidentiary standard, and other factors used in developing and applying the NQTL with respect to med/surg benefits and MH/SUD benefits.

Disclosure Request Form

Group health plan participants, beneficiaries, covered individuals in the individual market, or persons acting on their behalf, may use this optional model form to request information from plans regarding NQTLs that may affect patients' MH/SUD benefits or that may have resulted in their coverage being denied. *Form Number:* CMS–10307; *Frequency:* On Occasion; *Affected Public:* State, Local, or Tribal Governments, Private Sector, Individuals; *Number of Respondents:* 267,538; *Number of Responses:* 1,081,929; *Total Annual Hours:* 43,327. (For policy questions regarding this collection contact Usree Bandyopadhyay at 410–786–6650).

Dated: June 28, 2017.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2017–13973 Filed 6–30–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–2232]

Product Identifier Requirements Under the Drug Supply Chain Security Act—Compliance Policy; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Product Identifier Requirements Under the Drug Supply Chain Security Act—Compliance Policy.'' This draft guidance describes FDA's intention with regard to enforcement of requirements related to product identifiers under the Drug Supply Chain Security Act (DSCSA). Specifically, this guidance addresses manufacturers' product identifier and verification requirements, which begin November 27, 2017. This guidance also addresses certain requirements for repackagers, wholesale distributors, and dispensers to only engage in transactions involving products with product identifiers and to verify the product identifier when investigating suspect product, in addition to repackager and wholesale distributor requirements related to saleable returned products.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 1, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

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

Written/Paper Submissions

Submit written/paper submissions as follows:

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

Instructions: All submissions received must include the Docket No. FDA–2017–D–2232 for ''Product Identifier Requirements Under the Drug Supply Chain Security Act—Compliance Policy; Draft Guidance for Industry; Availability.'' Received comments, those filed in a timely manner (see **DATES**), will be placed in the docket and, except for those submitted as

''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

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

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

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Connie Jung, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *drugtrackandtrace@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The DSCSA (Title II of Pub. L. 113–54) was signed into law on November 27, 2013. Section 202 of the DSCSA added section 582 to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360eee–1). This section established product tracing, product identifier, and verification requirements for manufacturers, repackagers, wholesale distributors, and dispensers to facilitate the tracing of products through the pharmaceutical distribution supply chain. Failure to comply with the requirements of section 582 is also a prohibited act under section 301(t) of the FD&C Act (21 U.S.C. 331(t)).

Beginning November 27, 2017, manufacturers are required, under section 582(b)(2)(A) of the FD&C Act, to ''affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction into commerce.'' Also beginning on November 27, 2017, section 582(b)(4)(A)(i)(II) of the FD&C Act requires manufacturers to verify the product at the package level, including the standardized numerical identifier, which is part of the product identifier, when they determine that the product in their possession or control is suspect or they receive a verification request from FDA. Section 582(b)(4)(C) of the FD&C Act requires a manufacturer, upon receiving a request from an authorized trading partner that believes a product in its possession or control was manufactured by the manufacturer, to verify whether the product identifier on a product corresponds with the product identifier affixed or imprinted by the manufacturer. Section 582(b)(4)(E) of the FD&C Act requires manufacturers to verify the product identifier of a package or a sealed homogenous case of a saleable returned product before the manufacturer further distributes such product.

In addition, under section 582(e)(2)(A)(iii) of the FD&C Act, beginning on November 27, 2018, repackagers may engage in transactions involving a product only if such product is encoded with a product identifier, unless the product is grandfathered under section 582(a)(5) of the FD&C Act. This same requirement applies to wholesale distributors beginning on November 27, 2019, under section 582(c)(2) of the FD&C Act, and to dispensers beginning on November 27, 2020, under section 582(d)(2) of the FD&C Act. Additionally, under section 582(c)(4)(A)(i)(II), (d)(4)(A)(ii)(II), and (e)(4)(A)(i)(II) of the FD&C Act, wholesale distributors, dispensers, and repackagers are required to verify the product at the package level, including the standardized numerical identifier, which is part of the product identifier, to investigate a suspect product. For a saleable returned product, the wholesale distributor or repackager must verify the product identifier, including the standardized numerical identifier, of each package or sealed homogenous case of such product before it further distributes such product, under section 582(c)(4)(D) and (e)(4)(E) of the FD&C Act, respectively.

As described in the draft guidance, FDA has received comments and feedback from manufacturers and other trading partners expressing concern with industry-wide readiness for implementation of the product identifier requirements for manufacturers and describing challenges they face. Given the concerns expressed, FDA recognizes that some manufacturers may need additional time beyond November 27, 2017, to ensure that products are properly labeled with a product identifier. To minimize possible disruptions in the distribution of prescription drugs in the United States, FDA has adopted the compliance policy described in the guidance.

Under this compliance policy, FDA does not intend to take action against manufacturers who do not affix or imprint a product identifier to their packages and homogenous cases of product that are intended to be introduced in a transaction into commerce between November 27, 2017, and November 26, 2018. For such product that does not contain a product identifier and was first introduced in a transaction into commerce by the manufacturer between November 27, 2017, and November 26, 2018, FDA also does not intend to take action against manufacturers who do not use the product identifier to verify a product at the package level when investigating suspect product, upon receiving a verification request from FDA, after receiving a request from an authorized trading partner, or for a saleable returned product.

This guidance also explains that, for a product that does not have a product identifier and that was first introduced

in a transaction into commerce by the manufacturer between November 27, 2017, and November 26, 2018, FDA does not intend to take action against: (1) Repackagers who accept ownership of such product in a transaction; (2) wholesale distributors who engage in transactions involving such product; and (3) dispensers who engage in transactions involving such product, or repackagers, wholesale distributors, and dispensers who do not verify the product at the package level, using the product identifier, when investigating suspect product or for a saleable returned product as applicable. In addition, the guidance explains that FDA does not intend to take action against a manufacturer, repackager, or wholesale distributor who engages in certain prohibited acts involving products that are misbranded based on lack of product identifier alone, where the package and/or homogeneous case of product that lacks a product identifier was introduced in a transaction into commerce by a manufacturer between November 27, 2017, and November 26, 2018. The guidance document explains the scope of the compliance policy in further detail. FDA invites comment on the compliance policy, including comments on how manufacturers can indicate the date they initially introduced the product in a transaction into commerce and how downstream trading partners can determine that product was initially introduced by manufacturers in a transaction into commerce during that time period.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Product Identifier Requirements Under the Drug Supply Chain Security Act—Compliance Policy.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This is not a significant regulatory action subject to Executive Order 12866.

II. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov.*

Dated: June 28, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–13979 Filed 6–30–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0360]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration Safety Communication Readership Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 2, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0341. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

FDA Safety Communication Readership Survey

OMB Control Number 0910–0341—Extension

Section 705(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 375(b)) gives FDA authority to disseminate information concerning suspected or imminent danger to public health by any regulated product. Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) also authorizes FDA to conduct research relating to health information.

FDA's Center for Devices and Radiological Health (CDRH) carries out FDA's regulatory responsibilities regarding medical devices and radiological products. CDRH must be able to effectively communicate risk to health care practitioners, patients, caregivers, and consumers when there is a real or suspected threat to the public's health. CDRH uses safety communications to transmit information concerning these risks to user communities. Safety communications are released and available to organizations such as hospitals, nursing homes, hospices, home health care agencies, manufacturers, retail pharmacies, and other health care providers, as well as patients, caregivers, consumers, and patient advocacy groups. Through a process for identifying and addressing postmarket safety issues related to regulated products, CDRH determines when to release safety communications.

FDA seeks to evaluate the clarity, timeliness, and impact of safety communications by surveying a sample of recipients and obtain their voluntary responses to determine the impact of safety communications on the knowledge of the recipients. Understanding how the target audiences view these publications will aid in determining what, if any, changes should be considered in their content, format, and method of dissemination. The collection of this data is an important step in determining how well CDRH is communicating risk. The results from this survey will emphasize the quality of the safety communications and customer satisfaction. This will enable us to better serve the public by improving the effectiveness of safety communications.

In the **Federal Register** of March 15, 2017 (82 FR 13814), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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