

Dated: July 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0743]

Medical Device Reporting for Manufacturers; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “Medical Device Reporting for Manufacturers.” This draft guidance describes and explains the current FDA regulation that addresses reporting and recordkeeping requirements applicable to manufacturers of medical devices for certain device-related adverse events. This draft guidance is intended to update FDA’s policy and to further clarify FDA’s interpretations of the regulation requirements and, when final, will supersede the previous manufacturer guidances issued in 1988 and 1997. This draft guidance also provides answers to frequently asked questions and includes a section on common reporting errors. This draft guidance is not final nor is it in effect at this time.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 7, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled “Medical Device Reporting for Manufacturers” to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. Please use the document number 1828 to identify the guidance

you are requesting. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Barbara Myklebust, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2312, Silver Spring, MD 20993-0002, 301-796-6005.

SUPPLEMENTARY INFORMATION:

I. Background

The first Medical Device Reporting (MDR) regulation became effective December 13, 1984, with mandatory device-related adverse event reporting obligations for manufacturers and importers. FDA published “Medical Device Reporting Questions and Answers” as part of its Compliance Guidance Series in February 1988. Subsequent changes to the reporting requirements, including mandatory reporting by domestic distributors and device user facilities, resulted from amendments to the Federal Food Drug and Cosmetic Act (the FD&C Act) in 1990 and 1992.

The MDR regulation was revised significantly after the 1990 and 1992 amendments to the FD&C Act. The amended MDR regulation was published with significant revisions on December 11, 1995, and effective on July 31, 1996. FDA published a guidance document “Medical Device Reporting for Manufacturers” in March 1997 to clarify the changes to reporting requirements under the new regulation. The FD&C Act was further modified by amendments in 1997, 2002, and 2007, requiring further changes to the regulation. A plain language version of the MDR regulation was published on February 28, 2005, effective (in part) on July 13, 2005.

This draft guidance describes and explains the current FDA regulation that addresses reporting and recordkeeping requirements applicable to manufacturers of medical devices for certain device-related adverse events. This draft guidance is intended to update FDA’s policy and to further clarify FDA’s interpretations of the regulation requirements and, when final, will supersede the previous

manufacturer guidances issued in 1988 and 1997. The draft guidance also provides answers to frequently asked questions and includes a section on common reporting errors.

II. Significance of Guidance

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 Agency’s current thinking on medical device reporting for manufacturers. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive “Medical Device Reporting for Manufacturers,” you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1828 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collection of information in 21 CFR part 803 subparts A to E have been approved under OMB 0910-0437 (expires August 31, 2015), and the collection of information in 21 CFR 803.11 and 803.20 have been approved under OMB control number 0910-0291 (expires June 30, 2015).

V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management. It is necessary to send only one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be

seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: July 1, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Discretionary Grant Program

AGENCY: Health Resources and Services Administration (HRSA), Health and Human Services (HHS).

ACTION: Notice of Single-Source Replacement Award to the Michigan Public Health Institute.

SUMMARY: HRSA will be transferring the Michigan Family-to-Family Health Information Center (F2F HIC) grant (H84MC09365) from the Family Center for Children and Youth with Special Health Care Needs (FCCYSHCN) in Detroit, Michigan, to the Michigan Public Health Institute (MPHI) in Okemos, Michigan, to ensure the continued provision of health resources, financing, related services, and parent-to-parent support for families with children and youth with special health care needs (CYSHCN) in the state of Michigan.

SUPPLEMENTARY INFORMATION: *Former Grantee of Record:* Family Center for Children and Youth with Special Health Care Needs.

Original Grant Period: June 1, 2008, to May 31, 2013.

Replacement Awardee: The Michigan Public Health Institute.

Amount of Replacement Award: Up to \$95,700 for the remainder of the project period.

Period of Replacement Award: May 1, 2013, to May 31, 2013.

Authority: Section 501(c)(1)(A) of the Social Security Act, as amended.

CFDA Number: 93.504.

Justification: The former grantee, FCCYSHCN, has relinquished the F2F HIC grant due to internal oversight decisions. The former grantee has requested that HRSA transfer the F2F HIC funds to a Michigan-based family services agency in order to implement and carry out grant activities originally proposed under the FCCYSHCN grant application.

The MPHI was chosen as the best qualified grantee for this replacement award due to its capacity to provide an array of services to the target population and its record of compliance and sound fiscal management with other HHS grants. The MPHI has demonstrated its ability to successfully implement the goals and objectives of the F2F HIC project.

It is critical that the MPHI continue helping families of CYSHCN gain access to information they need to make informed health care decisions, be full partners in decision-making, and access needed resources/referrals and financing for those services in the state of Michigan. It is also imperative that the center continues to train and support health care providers and other professionals in public and private agencies who serve Michigan's CYSHCN, helping them better understand the needs of children, youth, and their families.

This replacement award will ensure that an F2F HIC will be accessible to families and professionals to continue providing essential information and referral and support services to families with CYSHCN throughout Michigan in a manner which avoids any disruption of services.

FOR FURTHER INFORMATION CONTACT: LaQuanta Smalley, Integrated Services Branch, Division of Services for Children with Special Health Needs, Maternal and Child Health Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 13-61, Rockville, MD 20857; 301.443.2370; lsmalley@hrsa.gov.

Dated: July 2, 2013.

Mary K. Wakefield,
Administrator.

[FR Doc. 2013-16424 Filed 7-8-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Single-Case Deviation from Competition Requirements: Transfer of Grantee Request for the Detroit Healthy Start Program, Detroit, MI

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of Single-Case Deviation from Competition Requirements: Transfer of Grantee Request for the Detroit Healthy Start Program, Detroit, MI, Grant Number H49MC00147.

SUMMARY: HRSA will be issuing a grantee transfer without competition for the Detroit Michigan Healthy Start program to the Institute for Population Health (IPH). The IPH will assume responsibility for the Healthy Start program and receive year 5 funding in the amount of \$1,575,000, from Grant Number H49MC00147, during the budget period of 6/1/2013-5/31/2014 to support the objectives of the Eliminating Disparities in Perinatal Health Healthy Start Program.

The Eliminating Disparities in Perinatal Health Healthy Start Program (H49), CFDA No. 93.926, is authorized by the Public Health Service Act, Title III, Part D, Section 330H (42 USC 254c-8).

The purpose of the Eliminating Disparities in Perinatal Health Healthy Start Program is to address significant disparities in perinatal health. Differences in perinatal health indicators may occur by virtue of education, income, disability, or living in rural/isolated areas. To address disparities and the factors contributing to them, project services have been designed to cover the pregnancy and interconceptional phases for women and infants residing in the proposed project area. In order to promote longer interconceptional periods and prevent relapses of risk behaviors, the women and infants are to be followed through the infant's second year of life and/or two years following delivery.

SUPPLEMENTARY INFORMATION: Intended Recipients of the Award: The Institute for Population Health will assume responsibilities associated with the grant and all associated funding will be transferred to the Institute for Population Health.

Amount of the Non-Competitive

Award: \$1,575,000

CFDA Number: 93.926

Current Project Period: 06/01/2009-05/31/2014

Period of Grantee Transfer Funding: 6/1/2013-5/31/2014

Authority: Public Health Service Act, Title III, Part D, Section 330H (42 U.S.C. 254c-8).

Justification: HRSA is transferring responsibility of the Detroit Healthy Start Program to the Institute for Population Health for the purpose of continuing Healthy Start services, including prenatal and interconception care, to men, women, infants, and children residing in Wayne County. The current grantee agency, the Detroit Department of Health and Wellness Promotion (DHWP) is phasing out its provision of direct public health services and will no longer have the ability to manage the Healthy Start