Estimated Total Annual Burden Hours: 3,600

Additional Information:

ACF is requesting that OMB grant a 180 day approval for this information collection under procedures for emergency processing by September 30, 2013. A copy of this information collection, with applicable supporting documentation, may be obtained by calling the Administration for Children and Families, Reports Clearance Officer, Robert Sargis at (202) 690–7275.

Comments and questions about the information collection described above should be directed to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ACF, Office of Management and Budget, Paperwork Reduction Project, 725 17th Street NW., Washington, DC 20503; FAX: (202) 395–7285; email: *oira_submission@omb.eop.gov.*

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2013–23188 Filed 9–23–13; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0636]

Global Unique Device Identification Database; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Global Unique Device Identification Database (GUDID).'' FDA is issuing this draft guidance to communicate our current thinking of how the GUDID will operate. The guidance includes both information about how device labelers (in most instances, the device manufacturer) will interface with the GUDID, as well as information on the database elements that must be submitted to the GUDID and their definitions. We intend to publish a final guidance after the close of the comment period and our implementation of the GUDID.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 25, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Global Unique Device Identification Database (GUDID)'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002. Send a fax request to 301–847–8149 to receive a hard copy. Alternatively, you may submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Evaluation and Research, 1401 Rockville Pike, suite 200N, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your request. 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: Jay Crowley, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3216, Silver Spring, MD 20993–0002, email: *udi@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

Section 226 of the Food and Drug Administration Amendments Act of 2007, 121 Stat. 854, and Section 614 of the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012, 126 Stat. 1061, amended the Federal Food, Drug, and Cosmetic Act to add section 519(f) (21 U.S.C. 360i(f)), which directs FDA to issue regulations establishing a unique device identification system for medical devices along with implementation timeframes for certain medical devices. The unique device identification (UDI) system proposed rule was published on July 10, 2012 (77 FR 40736), followed by an amendment modifying the implementation timeframe for certain devices, which was published on November 19, 2012 (77 FR 69393).

In developing the proposed rule, FDA solicited and considered input from a variety of stakeholders (e.g., manufacturers, global regulatory bodies, the clinical community, patient advocates) to ensure that as many perspectives as possible were incorporated. The GUDID is a critical component of the UDI System. While the UDI assigned to each device is a globally unique, yet unintelligent code, the GUDID will house a uniform set of required attribute information, including the device identifier (DI) component of the UDI, for the devices reported to the GUDID. Being unique for each device, the DI component of the UDI can be effectively used by stakeholders to access the other GUDID attribute information for that device.

Labelers will be responsible for submitting information to the GUDID as part of their UDI requirements. This draft guidance document describes how labelers would obtain access to the GUDID, how to submit DI records to the GUDID, and how all stakeholders can search and retrieve device information. This draft guidance is being issued to provide general information about the GUDID.

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 the GUDID. 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 CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or at *http://www.regulations.gov.* To receive ''Global Unique Device Identification Database (GUDID),'' 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 1831 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to proposed collections of information described in FDA's July 10, 2012, proposed rule on the UDI system (77 FR 40736), which this draft guidance is intended to interpret. The proposed collections of information in the proposed rule are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). As required by the PRA, FDA has published an analysis of the information collection provisions of the proposed rule (77 FR 40736 at 40762) and has submitted them for OMB approval (OMB control number 0910–0720).

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 (see **ADDRESSES**). It is only necessary to send 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: September 18, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–23058 Filed 9–20–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

State System Development Initiative (SSDI) Grant Program; Single-Case Deviation From Competition Requirements

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

ACTION: Notice of Single-Case Deviation from Competition Requirements for the Maternal and Child Health (MCH) Bureau's States System Development Initiative (SSDI) Grant.

SUMMARY: HRSA will be issuing a non-competitive program expansion supplement for one State SSDI Grant. Approximately $82,332 in supplemental funding will be made available in the form of a grant to the Department of Health Care Services, Sacramento, California, Grant Number H18MC24474, during the budget period of December 1, 2012, through November 30, 2013.

The SSDI Grant program, CFDA No. 93.110, is authorized by Title V, Social Security Act, Section 501(a)(2); as amended (42 U.S.C. 701(a)(2)).

The SSDI Grant program was developed to complement the Title V MCH Services Block Grant program by assisting state MCH and Children with Special Health Care Needs (CSHCN) programs in the building of state data capacity and infrastructure that support comprehensive, community-based systems of care for all children and their families. SSDI grants to states are intended to not only advance and strengthen data capacity by directing grant resources towards Title V MCH Block Grant program's Health Systems Capacity Indicator (HSCI) #09A (i.e., the ability of states to assure that the MCH programs and Title V agency have access to policy and program relevant information and data), but also to move states forward in developing improved capacity for reporting standardized and quality data that is timely.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: Department of Health Care Services, Sacramento, California.

Amount of the Non-Competitive Award: $82,332.

CFDA Number: 93.110.

Current Project Period: 05/01/2012–11/30/2014.

Period of Supplemental Funding: 12/01/2012–11/30/2013.

Authority: Title V, Social Security Act, Section 501(a)(2); as amended (42 U.S.C. 701).

Justification: Consistent with its legislative purpose to improve the health of all mothers and children, a key objective of the Title V MCH Block Grant program is to reduce maternal mortality. Due to small numbers for many states, maternal mortality cannot be universally tracked whereas severe, life-threatening maternal morbidity is at least 100 times as common and may be tracked annually for all states. Although a severe maternal morbidity index has been developed using administrative hospital discharge data, a validation in comparison to medical records is needed to determine whether its accuracy is sufficient for use as a national performance measure reported at the state level.

The California Title V MCH program has been a leader in assessing maternal mortality and conducting maternal mortality reviews. In particular, the California Maternal Quality Care Collaborative (CMQCC) is the oldest and largest maternity care collaborative in the country with a longstanding track record of analyzing maternal health data and developing metrics to improve clinical practice and prevent maternal death and injury. The promising work that the California Title V program is doing stands to benefit not only the state but all state MCH programs in promoting a better understanding of the causes of maternal mortality/morbidity and in offering potential solutions. Based on their prior work, established data networks, and sheer size of their birth cohort, the State of California is uniquely qualified to evaluate and make recommendations for a state-level severe maternal morbidity measure.

FOR FURTHER INFORMATION CONTACT: Scott Snyder, MPH, Division of State and Community Health, Maternal and Child Health Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 18–31, Rockville, Maryland 20857; *ssnyder@hrsa.gov.*

Grantee/organization name	Grant No.	State	FY 2013 authorized funding level	FY 2013 estimated supplemental funding
Department of Health Care Services	H18MC24474	CA	$100,000	$82,332