

- DHR is located in Hidalgo County, which has a percentage increase in population that is at least 150 percent of the percentage increase in Texas' population during the most recent 5-year period for which data was available as of the date that DHR submitted its request;

- DHR has an annual percentage of total inpatient admissions under Medicaid that is equal to or greater than the average percentage with respect to such admissions for all hospitals located in Hidalgo County during the most recent 12-month period for which data are available as of the date that DHR submitted its request;

- DHR certified and provided satisfactory documentation that it does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries;

- DHR is located in Texas, which has an average bed capacity that is less than the national average bed capacity during the most recent fiscal year for which HCRIS, as of the date that the hospital submitted its request, contained data from a sufficient number of hospitals to determine Texas' average bed capacity and the national average bed capacity; and

- DHR has an average bed occupancy rate that is greater than the average bed occupancy rate in Texas during the most recent fiscal year for which HCRIS, as of the date that DHR submitted its request, contained data from a sufficient number of hospitals to determine its average bed occupancy rate and Texas' average bed occupancy rate.

In determining that DHR satisfied the Medicaid inpatient admissions, bed capacity and bed occupancy criteria, we deemed the HCRIS and Texas State Medicaid Agency data used by DHR to satisfy the standards set forth in the regulations published on November 10, 2014, for those criteria.

Our approval grants DHR's request to add a total of 551 operating rooms, procedure rooms, and beds for which DHR is licensed. Pursuant to § 411.362(c)(6), the expansion may occur only in facilities on the hospital's main campus and may not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed to exceed 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds. DHR certified that its baseline number of operating rooms, procedure rooms, and beds for which it was licensed as of March 23, 2010, was 551. Accordingly, we find that granting the additional 551 operating rooms, procedure rooms, and beds will not exceed the limitation on a permitted expansion.

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: September 4, 2015.

Andrew M. Slavitt,
Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Goal-Oriented Adult Learning in Self-Sufficiency Study

OMB No.: New Collection

Description: The Administration for Children and Families (ACF) is proposing a data collection activity as part of the Goal-Oriented Adult Learning in Self-Sufficiency (GOALS) study. The purpose of the GOALS project is to address the nexus between the growing knowledge base in the psychological sciences and long-standing approaches to self-sufficiency programs targeted to adults and young adults. The project will explore the programmatic implications of existing research on psychological processes associated with goal-directed behaviors, including socio-emotional regulation and cognitive skills, executive functioning, and related areas. The project will synthesize current research on these topics; address how insights gained from research can be used to promote economic advancement among low-income populations, identify promising strategies, or strengthen underlying skills in these areas; and inform measurement of changes and developments in skill acquisition.

The proposed information collection activity consists of exploratory calls with program directors and administrators, semi-structured interviews with key program staff and community partner organization staff, and focus group discussions with program participants. ACF seeks to gain an in-depth, systematic understanding of program administration and implementation, service delivery and operation, outputs and outcomes, and identify promising practices and other areas for further study.

Respondents: Key program directors and administrators, program staff and community partner organization staff, and program participants at selected program sites.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Exploratory telephone call semi-structured interview—program directors and administrators	24	12	1	1	12
Site visit semi-structured interview—program staff and community partner organization staff	180	90	1	1.25	113
Site visit group discussion—program participants	84	42	1	1.25	53

Estimated Total Annual Burden Hours: 178.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for

Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should

be identified by the title of the information collection. Email address: OPREinfocollection@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the

collection of information between 30 and 60 days after publication of this document in the **Federal Register**.

Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

ACF Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-3287]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device User Fee Small Business Qualification and Certification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on Form FDA 3602 and Form FDA 3602A, which will allow domestic and foreign applicants to certify that they qualify as a small business and pay certain medical device user fees at reduced rates.

DATES: Submit either electronic or written comments on the collection of information by November 16, 2015.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All

comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Device User Fee Small Business Qualification and Certification—OMB Control Number 0910-0508—Extension

Section 101 of the Medical Device User Fee and Modernization Act (MDUFMA) (Pub. L. 107-250) amends the Federal Food, Drug, and Cosmetic Act, to provide for user fees for certain medical device applications. FDA published a **Federal Register** notice on August 3, 2015 (80 FR 46033), announcing fees for fiscal year (FY) 2016. To avoid harming small

businesses, MDUFMA provides for reduced or waived fees for applicants who qualify as a small business. This means there are two levels of fees; a standard fee and a reduced or waived small business fee. You can qualify for a small business fee discount under MDUFMA if you reported gross receipts or sales of no more than \$100 million on your Federal income tax return for the most recent tax year. If you have any affiliates, partners, or parent firms, you must add their gross receipts or sales to yours, and the total must be no more than \$100 million. If your gross receipts or sales are no more than \$30 million, including all of your affiliates, partners, and parent firms, you will also qualify for a waiver of the fee for your first (ever) premarket application (product development protocol, biologics licensing application, or premarket report). An applicant must pay the full standard fee unless it provides evidence demonstrating to FDA that it meets the small business criteria (Form FDA 3602, "FY 2016 MDUFMA Small Business Qualification Certification—For a Business Headquartered in the United States"). The evidence required by MDUFMA is a copy of the most recent Federal income tax return of the applicant, and any affiliate, partner, or parent firm. FDA will review these materials and decide whether an applicant is a small business within the meaning of MDUFMA.

The 2007 Amendments provide an alternative way for a foreign business to qualify as a small business eligible to pay a significantly lower fee when a medical device user fee must be paid (Form FDA 3602A, "FY 2016 MDUFMA Foreign Small Business Qualification Certification—For a Business Headquartered Outside the United States"). Before passage of the 2007 Amendments, the only way a business could qualify as a small business was to submit a Federal (U.S.) income tax return showing its gross receipts or sales that did not exceed a statutory threshold, currently, \$100 million. If a business could not provide a Federal income tax return, it did not qualify as a small business and had to pay the standard (full) fee. Because many foreign businesses have not, and cannot, file a Federal (U.S.) income tax return, this requirement has effectively prevented those businesses from qualifying for the small business fee rates. Thus, foreign governments, including the European Union, have objected. In lieu of a Federal income tax return, the 2007 Amendments will allow a foreign business to qualify as a small business by submitting a