

subject to reallocation. The 1994 reauthorization of the LIHEAP statute, the Human Service Amendments of 1994 (Pub. L. 103–252), requires that the Carryover and Reallocation Report for one fiscal year be submitted to HHS via the On-Line Data Collection (OLDC) system by the grantee before the allotment for the next fiscal year may be awarded.

The Administration for Children and Families is requesting no changes in the electronic collection of data with the Carryover and Reallocation Report, and the Simplified Instructions for Timely Obligations of LIHEAP Funds and Reporting Funds for Carryover and Reallocation. The form clarifies the information being requested and ensures the submission of all the

required information. The form facilitates our response to numerous queries each year concerning the amounts of obligated funds. Use of the form is voluntary. Grantees have the option to use another format.

*Respondents:* State Governments, Tribal Governments, Insular Areas, the District of Columbia, and the Commonwealth of Puerto Rico.

#### ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Carryover and Reallocation Report .....	216	1	3	648

#### *Estimated Total Annual Burden Hours: 648*

*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: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@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](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*Reports Clearance Officer.*

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**BILLING CODE 4184–01–P**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Administration on Community Living**

##### **Proposed Information Collection Activity; Comment Request; State Developmental Disabilities Council—Annual Program Performance Report (PPR)**

**AGENCY:** Administration for Community Living, Administration on Intellectual and Developmental Disabilities, HHS.

#### **ACTION:** Notice.

**SUMMARY:** A Plan developed by the State Council on Developmental Disabilities is required by federal statute. Each State Council on Developmental Disabilities must develop the plan, provide for public comments in the State, provide for approval by the State's Governor, and finally submit the plan on a five-year basis. On an annual basis, the Council must submit a Program Performance Report (PPR) to described the extent to which annual progress is being achieved on the 5 year state plan goals. The PPR will be used by (1) the Council as a planning document to track progress made in meeting state plan goals; (2) the citizenry of the State as a mechanism for monitoring progress and activities on the plans of the Council; (3) the Department as a stewardship tool, for ensuring compliance with the Developmental Disabilities Assistance and Bill of Rights Act, as one basis for monitoring and providing technical assistance (e.g., during site visits), and as a support for management decision making.

**DATES:** Submit written comments on the collection of information by August 10, 2015.

**ADDRESSES:** Submit written comments on the collection of information by email to: [allison.cruz@acl.hhs.gov](mailto:allison.cruz@acl.hhs.gov).

#### **FOR FURTHER INFORMATION CONTACT:**

Allison Cruz, Administration on Community Living, Administration on Intellectual and Developmental Disabilities, Office of Program Support, One Massachusetts Avenue NW., Room 4306, Washington, DC 20201, 202–357–3439.

**SUPPLEMENTARY INFORMATION:** In compliance with the requirements of section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration on Community Living is

soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to: Allison Cruz, Administration on Community Living, Administration on Intellectual and Developmental Disabilities, Office of Program Support, One Massachusetts Avenue NW., Room 4306, Washington, DC 20201.

The Department specifically requests comments on: (a) Whether the proposed Collection of information is necessary for the proper performance of the function of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden information to be collected; and (e) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection technique comments and or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

#### **Respondents**

56 State Developmental Disabilities Councils.

## ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Developmental Disabilities Program Performance Report (PPR) .....	56	1	138	7,728
Estimated Total Annual Burden Hours: .....	.....	.....	.....	7,728

Dated: June 3, 2015.

**Kathy Greenlee,**  
Administrator and Assistant Secretary for Aging.

[FR Doc. 2015-14051 Filed 6-9-15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-D-1884]

#### Duchenne Muscular Dystrophy and Related Dystrophinopathies: Developing Drugs for Treatment; Draft Guidance for Industry; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Duchenne Muscular Dystrophy and Related Dystrophinopathies: Developing Drugs for Treatment.” The purpose of this draft guidance is to assist sponsors in the clinical development of drugs for the treatment of X-linked Duchenne muscular dystrophy (DMD) and related dystrophinopathies.

**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 August 10, 2015.

**ADDRESSES:** 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. 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.

Submit electronic comments on the draft guidance to [http://](http://www.regulations.gov)

[www.regulations.gov](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.

#### FOR FURTHER INFORMATION CONTACT:

Colleen Locicero, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4242, Silver Spring, MD 20993-0002, 301-796-1114.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Duchenne Muscular Dystrophy and Related Dystrophinopathies: Developing Drugs for Treatment.”

DMD and other dystrophinopathies result from genetic mutations in the dystrophin gene that decrease levels of dystrophin and/or cause dysfunction of the dystrophin protein, leading to muscle degeneration, including cardiac and respiratory muscles, and greatly decreased life expectancy. There remains a high level unmet medical need for effective drug treatments for DMD and other dystrophinopathies. This draft guidance addresses FDA’s current thinking regarding the clinical development program and clinical trial designs for drugs to support an indication for the treatment of dystrophinopathies. Development of this draft guidance was greatly facilitated by the efforts of Parent Project Muscular Dystrophy to coordinate a consortium of stakeholders including patients, parents and caregivers, clinicians, academic experts, and industry representatives in producing a proposed draft guidance with extensive background information about DMD. That stakeholder proposal was submitted to FDA and made available for comment through a **Federal Register** notice seeking public comment. The comments received were also considered in writing this draft 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 current thinking of FDA

on developing drugs for the treatment of DMD. 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.

## II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that 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 collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910-0014 and 0910-0001, respectively.

## III. 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>.

## IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: June 4, 2015.

**Leslie Kux,**

Associate Commissioner for Policy.

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