

long-term housing outcomes of youth after exiting the program. In addition to collecting information on housing outcomes, the study will also consider the living, employment, education, and family situation of the youth before and

after their time in the TLP. This information will be used to better understand the most effective practices in improving long-term outcomes of youth in an effort to guide program improvements.

Respondents: (1) Youth ages 16–21 participating in Transitional Living Programs and (2) the Executive Director and Program Manager representing TLP grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Grantee Survey	70	1	1	70
Youth Baseline Survey	760	1	0.50	380
Youth Exit Survey	760	1	0.50	380
Youth 6-Month Follow Up	760	1	0.50	380
Youth 12-Month Follow Up	760	1	0.50	380
Service Log	760	1	0.25	190

Estimated Total Annual Burden Hours: 1,780.

Additional Information:

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 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. E-mail address: 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, Fax: 202–395–7245, Attn: Desk Officer for the Administration for Children and Families.

Dated: April 28, 2009.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E9–10020 Filed 4–30–09; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0181]

Draft Guidance for Industry on Label Comprehension Studies for Nonprescription Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Label Comprehension Studies for Nonprescription Drug Products.” The draft guidance provides recommendations on the design of label comprehension studies, which can be used to assess the extent to which consumers understand the information conveyed by proposed nonprescription drug product labeling and then apply that information when making hypothetical drug product use decisions.

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 written or electronic comments on the draft guidance by July 30, 2009.

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, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on

the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Laura Shay, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5466, Silver Spring, MD 20993–0002, 301–796–0994.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Label Comprehension Studies for Nonprescription Drug Products.” This draft guidance is intended for individuals or organizations involved in the development of label comprehension studies for nonprescription drug products. This draft guidance discusses general concepts to be considered in the design and conduct of a label comprehension study. This draft guidance also incorporates advice obtained from the September 25, 2006, meeting of the Nonprescription Drug Advisory Committee that considered issues related to the analysis and interpretation of consumer behavior studies conducted to support marketing of nonprescription drug products.

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 label comprehension studies for nonprescription drug products. 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 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 to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.regulations.gov>.

Dated: April 22, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–10005 Filed 4–30–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2303–N]

DEPARTMENT OF LABOR

Employee Benefits Security Administration

Establishment of the Children's Health Insurance Program Working Group and Request for Nominations for Members

AGENCIES: Centers for Medicare & Medicaid Services (CMS), HHS; Employee Benefits Security Administration (EBSA), DOL

ACTION: Notice.

SUMMARY: This notice announces the establishment of the Children's Health Insurance Program Working Group and discusses the group's purpose and charter. It also solicits nominations for members.

DATES: Nominations for membership will be considered if they are received by June 1, 2009.

ADDRESSES: Send nominations and written requests for copies of the Charter of the Children's Health Insurance Program Working Group to—Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Mail stop: S2–06–28, Attention: Stacey Green.

Web page: You may also review the charter online at: http://www.cms.hhs.gov/FACA/06_CHIPWorkingGroup.asp.

FOR FURTHER INFORMATION CONTACT: Stacey Green, Centers for Medicare & Medicaid Services, HHS at Stacey.Green@cms.hhs.gov or (410) 786–6102; or Amy Turner, Employee Benefits Security Administration, DOL at (202) 693–8335. Press inquiries are handled through the CMS Press Office at (202) 690–6145.

SUPPLEMENTARY INFORMATION:

I. Background

Section 311(b)(1)(C) of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) (Pub. L. 111–3) (Feb. 4, 2009), directs the Secretary of Health and Human Services and the Secretary of Labor to jointly establish a Medicaid, CHIP, and Employer-Sponsored Coverage Coordination Working Group (“the CHIP Working Group”). The CHIP Working Group, as chartered, under the legal authority of section 311(b)(1)(C) of CHIPRA (Pub. L. 111–3), is also governed by the provisions of the Federal Advisory Committee Act (FACA), 5 U.S.C. App.

II. Charter, General Responsibilities, and Composition of the Children's Health Insurance Program Working Group

A. Charter Information and General Responsibilities

On April 3, 2009 the Secretary of Health and Human Services and the Secretary of Labor signed the charter establishing the CHIP Working Group. This group will meet up to 3 times over the life of the Group and will terminate 17 months from the charter filing date. You may obtain a copy of the charter for the CHIP Working Group by mailing a

written request to the address specified in the **ADDRESSES** section of this notice. The purpose of the Working Group shall be to:

- Develop a model coverage coordination disclosure form for plan administrators of group health plans to complete for purposes of permitting a State to determine the availability and cost-effectiveness of coverage available under group health plans to employees who have family members who are eligible for premium assistance offered under a State plan under titles XIX or XXI of the Social Security Act (the Act) and to allow for coordination of coverage for enrollees of such plans. The form shall provide the following information in addition to other information as the Working Group determines appropriate: (1) A determination of whether the employee is eligible for coverage under the group health plan, (2) the name and contact information of the plan administrator of the group health plan, (3) the benefits offered under the plan, (4) the premiums and cost-sharing required under the plan, and (5) any other information relevant to the coverage under the plan.

- Identify the impediments to the effective coordination of coverage available to families that include employees of employers that maintain group health plans and members who are eligible for medical assistance under title XIX of the Act or child health assistance or other health benefits coverage under title XXI of the Act.

- Not later than August 5, 2010, submit to the Secretary of Labor and the Secretary of Health and Human Services the model disclosure form as stated above along with a report containing recommendations for appropriate measures for addressing the impediments (as stated above) to the effective coordination of coverage between group health plans and the State plans under titles XIX and XXI of the Act.

B. Composition of the CHIP Working Group

The Working Group shall consist of not more than 30 members, jointly appointed by the Secretary of Health and Human Services and the Secretary of Labor, including the chair(s), one of whom shall be appointed by the Secretary of Health and Human Services and one of whom shall be appointed by the Secretary of Labor. Members will serve without compensation but will receive reimbursement for travel costs.

The Working Group shall be composed of representatives of: The Department of Labor; the Department of