

to an advance written agreement; however, for the meetings, CMS reimburses travel, meals, lodging, and related expenses in accordance with standard Government travel regulations. CMS has a special interest in ensuring, while taking into account the nominee pool, that the Panel is diverse in all respects of the following: Geography; rural or urban practice; race, ethnicity, sex, and disability; medical or technical specialty; and type of hospital, hospital health system, or other Medicare provider subject to the OPPTS.

Based upon either self-nominations or nominations submitted by providers or interested organizations, the Secretary, or her designee, appoints new members to the Panel from among those candidates determined to have the required expertise. New appointments are made in a manner that ensures a balanced membership under the FACA guidelines.

## II. Criteria for Nominees

The Panel must be fairly balanced in its membership in terms of the points of view represented and the functions to be performed. Each Panel member must be employed full-time by a hospital, hospital system, or other Medicare provider subject to payment under the OPPTS. All members must have technical expertise to enable them to participate fully in the Panel's work. Such expertise encompasses hospital payment systems; hospital medical care delivery systems; provider billing systems; APC groups; Current Procedural Terminology codes; and alpha-numeric Health Care Common Procedure Coding System codes; and the use of, and payment for, drugs, medical devices, and other services in the outpatient setting, as well as other forms of relevant expertise. For supervision deliberations, the Panel shall have members that represent the interests of Critical Access Hospitals

(CAHs), who advise CMS only regarding the level of supervision for hospital outpatient services.

It is not necessary for a nominee to possess expertise in all of the areas listed, but each must have a minimum of 5 years experience and currently have full-time employment in his or her area of expertise. Generally, members of the Panel serve overlapping terms up to 4 years, based on the needs of the Panel and contingent upon the rechartering of the Panel. A member may serve after the expiration of his or her term until a successor has been sworn in.

Any interested person or organization may nominate one or more qualified individuals. Self-nominations will also be accepted. Each nomination must include the following:

- Letter of Nomination stating the reasons why the nominee should be considered.
- Curriculum vitae or resume of the nominee that includes an email address where the nominee can be contacted.
- Written and signed statement from the nominee that the nominee is willing to serve on the Panel under the conditions described in this notice and further specified in the Charter.
- The hospital or hospital system name and address, or CAH name and address, as well as all Medicare hospital and or Medicare CAH billing numbers of the facility where the nominee is employed.

## III. Copies of the Charter

To obtain a copy of the Panel's Charter, we refer readers to our Web site at the following: <http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html>.

## 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.

Dated: September 15, 2014.

**Marilyn Tavenner,**  
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:* Annual Statistical Report on Children in Foster Homes and Children in Families Receiving Payment in Excess of the Poverty Income Level from a State Program Funded Under Part A of Title IV of the Social Security Act.

OMB No.: 0970-0004.

#### Description

The Department of Health and Human Services is required to collect these data under section 1124 of Title I of the Elementary and Secondary Education Act, as amended by Public Law 103-382. The data are used by the U.S. Department of Education for allocation of funds for programs to aid disadvantaged elementary and secondary students. Respondents include various components of State Human Service agencies.

#### Respondents

The 52 respondents include the 50 States, the District of Columbia, and Puerto Rico.

### ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Annual Statistical Report on Children in Foster Homes and Children Receiving Payments in Excess of the Poverty Level From a State Program Funded Under Part A of Title IV of the Social Security Act .....	52	1	264.35	13,746.20

*Estimated Total Annual Burden Hours:* 13,746.20

#### 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, Fax: 202-395-7285, 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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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-N-1359]

#### Development and Regulation of Abuse-Deterrent Formulations of Opioid Medications; Public Meeting

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

**ACTION:** Notice of public meeting; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting to discuss the development, assessment, and regulation of abuse-deterrent formulations of opioid medications. The meeting will focus on scientific and technical issues related to the development and in vitro assessment of these products, as well as FDA's approach towards assessing the benefits and risks of all opioid medications, including those with abuse-deterrent properties.

FDA is seeking input on these issues from all stakeholders, including patients, health care providers, the pharmaceutical industry, patient advocates, academics, researchers, and other governmental entities.

**DATES:** The public meeting will be held on October 30, 2014, from 8:30 a.m. to 5 p.m. and October 31, 2014, from 8:30 a.m. to 3 p.m. The public meeting may be extended or may end early depending on the level of public participation. Individuals who wish to present at the meeting must register by October 14, 2014. Individuals who wish to attend the meeting but do not wish to make a presentation should register by October 24, 2014. See section III under the **SUPPLEMENTARY INFORMATION** section for information on how to register to speak at the meeting. Submit

either electronic or written comments by January 9, 2015.

**ADDRESSES:** The public meeting will be held at the Sheraton Silver Spring Hotel, 8777 Georgia Ave., Silver Spring, MD 20910, 301-589-0800, FAX: 301-587-4791.

Submit electronic comments 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 all comments with the docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Mary C. Gross, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 301-796-3519, FAX: 301-796-9899, email: [mary.gross@fda.hhs.gov](mailto:mary.gross@fda.hhs.gov); or Brutrinia D. Cain, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-4633, email: [Brutrinia.cain@fda.hhs.gov](mailto:Brutrinia.cain@fda.hhs.gov); or Georgiann Ienzi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-3515, FAX: 301-847-8737, email: [Georgiann.Ienzi@fda.hhs.gov](mailto:Georgiann.Ienzi@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Introduction

Opioid analgesics are important medications that are widely prescribed for the treatment of pain, and certain opioids are also used in drug treatment programs. When used properly, opioid drugs provide significant benefits for patients. However, they also carry a risk of misuse, abuse, addiction, overdose, and death. According to an analysis from the Centers for Disease Control and Prevention (CDC), in 2010, opioid analgesics were involved in 16,651 overdose deaths, which represented a 313 percent increase over the past decade (Ref. 1). The Substance Abuse and Mental Health Services Administration (SAMHSA) reports that for each overdose death, there were an additional 11 treatment admissions (Ref. 2), 33 emergency department visits (Ref. 3), and 880 non-medical users of these drugs (Ref. 4).

The development of and transition to use of opioids with meaningful abuse-deterrent properties is one important component of a multipronged approach to addressing abuse of opioid medications. FDA looks forward to a future in which most or all opioid

medications are available in formulations that are less susceptible to abuse than the formulations that are on the market today.

To achieve this goal, FDA is taking steps to incentivize and support the development of opioid medications with progressively better abuse-deterrent properties. These steps include working with individual sponsors on promising abuse-deterrent technologies, developing appropriate testing methodologies for both innovator and generic products, and publishing guidance on the development and labeling of abuse-deterrent opioids.

FDA understands that the iterative innovation in abuse-deterrent technologies we envision could have implications for generic opioid medications. It is important that generic options remain available to ensure widespread access to effective analgesics for patients who need them.

The transition to abuse-deterrent formulations of opioid medications presents a number of complex scientific and regulatory challenges. The purpose of this public meeting is to share and solicit comments on the Agency's ongoing work to identify and address these challenges.

##### II. Background

Opioid analgesics (e.g., hydrocodone, oxycodone, morphine, and fentanyl) play a vital role in treating both chronic and acute pain. The Institute of Medicine reports that millions of Americans are living with chronic pain, including those suffering from back pain, neuropathic pain, and pain associated with cancer, with an annual economic cost of approximately \$600 billion in health care expenses and lost productivity (Ref. 5). Millions more suffer from acute pain following common medical procedures performed every day across the country, such as dental and orthopedic procedures. While FDA is working to support the efficient development of safer, non-opioid alternatives for treating pain, opioids are currently an indispensable component of the pain treatment armamentarium, and will remain so for some time to come.

Unfortunately, the abuse and misuse of opioid medications has become a public health crisis. Opioid-involved drug overdose death rates in the United States have increased four-fold from 1999 to 2008 (Ref. 6). Emergency department visits, substance abuse treatment admissions, and economic costs associated with opioid abuse have also increased dramatically over the same period (Ref. 7). This rise in adverse events has largely paralleled the