

pharmacists) of the PDMPs in the states where these projects are taking place.

This evaluation is consistent with CDC's strategic goals of improving surveillance, informing policy, and improving clinical practice. CDC believes that the most effective interventions in combating the prescription drug overdose epidemic include those designed to identify and address high-risk patients at a stage when their risky behaviors can be most effectively addressed. Strong yet accessible PDMPs that promote comprehensive of PDMP data, proactive patient interventions are a critical component of this high-risk focused strategy. By enabling providers to identify high-risk patients at the point of care, via improved access to and use of PDMPs and improved comprehensiveness of PDMP data, providers can intervene with patients and address their high-risk behaviors, including providing or redirecting patients to substance abuse treatment as necessary. Through this evaluation, CDC will better understand the impact of PDMP integration and interoperability in the funded states.

The total annual estimated burden hours for the planned qualitative information collection are 235 hours. Total burden time includes the time to

conduct interviews with key project staff/stakeholders and clinical end users, and the time spent by recruiters at the PEHRIIE implementation sites to identify potential clinical end user interviewees.

It will take 79 hours of interviewee time to complete all of the key project staff/stakeholder interviews necessary for the planned evaluation of the PEHRIIE program. Interviews will be conducted with 91 key project staff members/stakeholders across the nine PEHRIIE-funded states (range: 6–16 interviews per state) as well as 14 key project staff/stakeholders representing five companies working with multiples states involved in the PEHRIIE program, for a total of 105 key project staff/stakeholders interviewees. Based on pilot testing with three individuals, each key project staff/stakeholder interview will take approximately 45 minutes to complete. Therefore, 105 key project staff/stakeholder interviews at 45 minutes each will require 79 hours of interviewee time.

It will take 117 hours of interviewee time to complete all of the clinical end user interviews necessary for the planned evaluation of the PEHRIIE program. Each interviewee will be interviewed once. End user interviews

will be conducted at 39 implementation sites distributed across all nine PEHRIIE states (range: 3–8 sites per state). Interviews will be conducted with three clinical end users per implementation site for a total of 117 clinical end user interviews. Based on pilot testing with three individuals, each clinical end user interview will take one hour to complete. Therefore, 117 clinical end users at 1 hour each will require 117 hours of interviewee time.

It will take 39 hours of recruiter time to identify potential clinical end user interviewees, to collect the contact information from these clinical end users, and to disseminate this collected information to the CDC evaluation time. The CDC will work with one recruiter per implementation site to complete these tasks. Based on the time required to complete similar tasks during the planning of the clinical end user pilot interviews, each recruiter is expected to spend approximately one hour on these tasks. Therefore, 39 recruiters spending one hour each on this information collection will require 39 hours of recruiter time.

There are no costs to respondents other than their time.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)	Total burden (in hrs)
Key Project Staff/Stakeholders .....	Key Project Staff/Stakeholders Interview Guide.	105	1	45/60	79
Clinical End Users .....	Clinical End Users Interview Guide	117	1	1	117
Clinical End User Recruiters .....	N/A .....	39	1	1	39
<b>Total .....</b>					<b>235</b>

**Leroy A. Richardson,**  
 Chief, Information Collection Review Office,  
 Office of Scientific Integrity, Office of the  
 Associate Director for Science, Office of the  
 Director, Centers for Disease Control and  
 Prevention.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request**

**Proposed Projects**

*Title:* Income Withholding Order/ Notice for Support (IWO).

OMB No.: 0970-0154.

*Description:* Statutory requirements under subsections 466(a)(1), (a)(8) and 466(b)(6) of the Social Security Act require the use of the Income Withholding for Support (IWO) form in all child support cases. The form must be used by child support agencies, courts, tribes, private attorneys and other entities when ordering or sending notices to withhold. 42 U.S.C 666(a)(1) and (8); 42 U.S.C 666(b)(6).

The Income Withholding for Support (IWO) form previously approved by the Office of Management and Budget has been modified to address items identified by states and employers/ income withholders. The title of the form is changed to Income Withholding Order/Notice for Support (IWO) to correspond to the first line of the form.

The blank box for court use is removed and text shifted to make better use of available space. Language is inserted to explain that provisions of the Consumer Credit Protection Act (CCPA) apply only to employees and not to independent contractors. A header with case-identifying information is added on Page Two and a Social Security Number on Page Three to place case-identifying information on each page and allow future automated improvements for employers and states. Clarifications are added to the Instructions emphasizing that each IWO should represent the information for only one case, as defined in the Code of Federal Regulations.

*Respondents:* Not applicable.

## ANNUAL BURDEN ESTIMATES

Reporting requirement	Number of respondents	Number of responses per respondent	Annual number of responses	Average burden hours per response	Total burden hours
Employers .....	1,283,965	7.44	9,552,699.60	2 minutes .....	318,423
Non-IV-D CPs .....	2,436,312	1.00	2,436,312.00	5 minutes .....	203,026
e IWO Employers .....	4,763	131.75	627,525.25	3 seconds .....	523
Total .....	3,721,508	.....	12,052,319	.....	521,449

*Estimated Total Annual Burden Hours: 521,449*

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families 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 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. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) whether the proposed collection of information is necessary for the proper performance of the functions 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; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Robert Sargis,**

*Reports Clearance Officer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2013-N-0815]

**Narcolepsy Public Meeting on Patient-Focused Drug Development**

**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 and an opportunity for public comment on Patient-Focused Drug Development for narcolepsy. Patient-Focused Drug Development is part of FDA's performance commitments in the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to allow FDA to obtain patients' perspectives on the impact of narcolepsy on daily life as well as the available therapies for narcolepsy.

**DATES:** The public meeting will be held on September 24, 2013, from 1 p.m. to 5 p.m. Registration to attend the meeting must be received by September 13, 2013. See the **SUPPLEMENTARY**

**INFORMATION** section for information on how to register for the meeting. Submit electronic or written comments by November 25, 2013.

**ADDRESSES:** The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, Section A of the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants is through Building 1, where routine security check procedures will be performed. For more information on parking and security procedures, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

Submit electronic comments to [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. All comments should be identified with the docket number found in brackets in the heading of this document.

FDA will post the agenda approximately 5 days before the meeting at: <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm359018.htm>.

**FOR FURTHER INFORMATION CONTACT:** Pujita Vaidya, Center for Drug

Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1170, Silver Spring, MD 20993, 301-796-0684, FAX: 301-847-8443, email: [Pujita.Vaidya@fda.hhs.gov](mailto:Pujita.Vaidya@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background on Patient-Focused Drug Development**

FDA has selected narcolepsy to be the focus of a meeting under Patient-Focused Drug Development, an initiative that involves obtaining a better understanding of patients' perspectives on the severity of the disease and the available therapies for the condition. Patient-Focused Drug Development is being conducted to fulfill FDA's performance commitments made as part of the authorization of PDUFA under Title I of the Food and Drug Safety and Innovation Act (FDASIA) (Pub. L. 112-144). The full set of performance commitments is available on the FDA Web site at <http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf>.

FDA has committed to obtain the patient perspective in 20 disease areas during the course of PDUFA V. For each disease area, the Agency will conduct a public meeting to discuss the disease and its impact on patients' daily lives, the types of treatment benefit that matter most to patients, and patients' perspectives on the adequacy of the available therapies. These meetings will include participation of FDA review divisions, the relevant patient community, and other interested stakeholders.

On April 11, 2013, FDA published a notice in the **Federal Register** (78 FR 22613) announcing the disease areas for meetings in fiscal years (FY) 2013-2015, the first 3 years of the 5-year PDUFA V timeframe. To develop the list of disease areas, the Agency used several criteria that were outlined in the April 11 notice. The Agency gathered public comment on these criteria and potential disease areas through a notice for public comment published in the **Federal Register** on September 24, 2012 (77 FR 55849), and through a public meeting