

guidance on statistically appropriate uses of the data. Participation in the ACBS is voluntary and there are no costs to respondents other than their time. The burden table reflects the landline and cell phone data collection

methods used in 2013 and later years. Additionally, the burden table accounts for reporting burden incurred by the states for the monthly or quarterly data submission to CDC. The burden hour estimates represent the 2013 data

collection which is the most recent data released.

The total estimated annualized burden hours for all respondents are 6,029 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
BRFSS Adults	ACBS Landline Screener—Adult	21,424	1	1/60
	ACBS Cell Phone Screener—Adult	8,976	1	1/60
BRFSS Parents or Guardians of Children	ACBS Landline Screener—Child	4,245	1	1/60
	ACBS Cell Phone Screener—Child	2,238	1	1/60
ACBS Adults	ACBS Adult Consent and Survey—2013	19,954	1	10/60
ACBS Parents or Guardians of Children	ACBS Child Consent and Survey—2013	3,887	1	10/60
State BRFSS Coordinators	ACBS Data Submission Layout	40	12	3

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

Title: Accomplishments of the Domestic Violence Hotline, Online Connections and Text (ADVHOCaT) Study.

OMB No.: 0970–0468.

Description: The National Domestic Violence Hotline (The Hotline) and

loveisrespect (LIR), which are supported by the Division of Family Violence Prevention and Services within the Family and Youth Services Bureau (FYSB) of the Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), serve as partners in the intervention, prevention, and resource assistance efforts of the network of domestic violence and dating violence service providers.

In order to describe the activities and accomplishments of The Hotline and LIR and develop potential new or revised performance measures, the ACF/HHS Office of Planning, Research and Evaluation (OPRE) and FYSB are proposing a data collection activity as part of the Accomplishments of the Domestic Violence Hotline, Online Connections and Text (ADVHOCaT) Study.

As part of ongoing program activities and monitoring for The Hotline and LIR,

ACF proposes to collect information via voluntary phone, chat, and web-based surveys of individuals who contact The Hotline and LIR. Participants will complete a baseline survey at the end of their contact with The Hotline and LIR, and a follow-up survey approximately two weeks later. The survey will include questions about reasons for contacting The Hotline/LIR, whether needs were met, satisfaction with services received, and helpfulness of information provided. This data collection builds on a previous data collection that was focused on understanding the preferred mode of contact by those who contact The Hotline and LIR. This new information will inform future efforts to monitor and improve the performance of domestic violence hotlines and provide hotline services.

Respondents: Individuals aged 18 and older who contact The Hotline and LIR via phone or chat.

ANNUAL BURDEN ESTIMATES—2 YEAR REQUEST

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
The Hotline/LIR Baseline Survey	2200	1100	1	0.056	62
The Hotline/LIR Follow Up Survey	2200	1100	1	0.1	110

Estimated Total Annual Burden Hours: 172.

In compliance with the requirements of Section 3506(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, 330 C Street SW., Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: OPREinfocollection@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.

Mary Jones,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-3466]

Immediately in Effect Guidance Document: Conditions for Sale for Air-Conduction Hearing Aids; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled “Immediately in Effect Guidance Document: Conditions for Sale for Air-Conduction Hearing Aids.” FDA is issuing this guidance to communicate to consumers, hearing aid dispensers, hearing aid manufacturers, and hearing health professionals that FDA does not intend to enforce certain conditions for sale of hearing aid devices that are required per FDA regulation. Specifically, FDA does not intend to enforce the medical evaluation or recordkeeping requirements prior to the dispensing of certain hearing aid devices to individuals 18 years of age and older.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are

solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2016-D-3466 for “Immediately in Effect Guidance Document: Conditions for Sale for Air-Conduction Hearing Aids.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both

copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled “Immediately in Effect Guidance Document: Conditions for Sale for Air-Conduction Hearing Aids” to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Srinivas Nandkumar, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2436, Silver Spring, MD 20993-0002, 301-796-6480.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing this guidance to communicate to consumers, hearing aid dispensers, hearing aid manufacturers, and hearing health professionals that FDA does not intend to enforce certain conditions for sale of hearing aid devices that are required per FDA regulation. Specifically, FDA does not intend to enforce the medical evaluation (§ 801.421(a) (21 CFR 801.421(a)) or recordkeeping (§ 801.421(d))