

ANNUAL BURDEN ESTIMATES

	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hour per response	Annual burden hours
Guide for Recruitment with PHA and PCWA Administrators	20	7	1	1.00	7
Guide to Develop an Evaluation Plan for PCWA FUP Management	10	4	1	1.00	4
Guide to Develop an Evaluation Plan for PHA FUP Management	10	4	1	1.00	4
Guide for Implementation Study for PCWA Management ..	10	4	1	1.00	4
Guide for Implementation Study for PHA Management	10	4	1	1.00	4
Guide for Implementation Study for Referral Provider Administrators	4	2	1	1.00	2
Guide for Implementation Study with PCWA FUP Management (First)	10	4	1	1.00	4
Guide for Implementation Study for PHA FUP Management	10	4	1	1.00	4
Guide for Implementation Study Focus Groups with Frontline Workers	320	107	1	1.50	161
Guide for Implementation Study Focus Groups with PHA Frontline Workers	30	10	1	1.50	15
Guide for Implementation Study for PCWA FUP Management (Follow Up)	10	4	1	1.00	4
Guide for Implementation Study for Service Provider Management	8	3	1	1.00	3
Referral Form	200	67	6	0.17	68
Randomization Tool	10	4	106	0.02	8
Housing Assistance Questionnaire	200	67	3	0.09	18
Ongoing Services Questionnaire	200	67	3	0.09	18
Dashboard	20	7	27	0.17	32
Administrative Data List	30	10	2	5.00	100

Estimated Total Annual Burden Hours: 460.

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 St 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,
ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Study of We Grow Together: The Q-CCIIT Professional Development System.

OMB No.: New Collection
Description: The Administration for Children and Families (ACF) at the U.S. Department of Health and Human Services (HHS) seeks approval to conduct a field test of We Grow Together, a system of professional development supports including web-based resources and exercises to be used by caregivers/teachers, with the help of professional development providers, to

improve the quality of infant and toddler care. The study team has developed We Grow Together: The Q-CCIIT Professional Development System based on the research literature to support caregiver-child interactions in care settings serving infants and toddlers. This field test is designed to (1) examine changes associated with use of the We Grow Together system and (2) examine implementation and participant experiences with the We Grow Together system. As a secondary goal, ACF will also further evaluate the properties of the Q-CCIIT observational measure. Ultimately, findings from the field test will provide information about the experiences of professional development providers (PD providers) and caregivers with the We Grow Together system so that ACF can improve the system to make the resources as accessible as possible for infant-toddler caregivers.

Prior to using the We Grow Together system, PD providers will complete a web-based training survey and all participants will complete a web-based background survey. Periodically during the field test, website users will be asked at log-on to respond to a series of web-based questions. After system implementation, participants will complete a web-based feedback survey.

The study team will also collect classroom rosters from caregivers before and after the field test.

Respondents: Early care and education (ECE) setting representatives (e.g., directors or owners), caregivers (in

center-based and family child care settings), and professional development providers (e.g., coaches).

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Instrument	Total/annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
ECE setting eligibility screener	745	1	.25	186
Caregiver background survey	300	1	.75	225
PD provider background survey	175	1	.50	88
Caregiver We Grow Together website user data pop-up questions	300	6	.17	306
PD provider We Grow Together website user pop-up questions	175	5	.10	88
Caregiver feedback survey	300	1	1.0	300
PD provider feedback survey	175	1	.75	131
Classroom roster	300	2	.08	48
PD provider training survey	175	1	.17	30

Estimated Total Annual Burden Hours: 1,402.

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,
ACF/OPRE Certifying Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA-2017-D-6759]

Establishing Effectiveness for Drugs Intended To Treat Male Hypogonadotropic Hypogonadism Attributed to Non-Structural Disorders; Draft Guidance for Industry; 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 a draft guidance for industry entitled "Establishing Effectiveness for Drugs Intended to Treat Male Hypogonadotropic Hypogonadism Attributed to Non-Structural Disorders." This draft guidance provides key design considerations, including recommendations for patient enrollment criteria and efficacy endpoints, for clinical trials to establish effectiveness for drugs intended to treat male hypogonadotropic hypogonadism associated with obesity and other conditions that do not cause intrinsic damage to the hypothalamus or pituitary gland. This draft guidance is consistent with recommendations FDA received at the December 2014 advisory committee meeting on the appropriate indicated population for testosterone replacement therapy, and the December 2016 advisory committee meeting on hypogonadotropic hypogonadism.

DATES: Submit either electronic or written comments on the draft guidance by March 5, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and