

approximately 360,000 stays from the IDR data and approximately 380,000 stays from the MedPAR data. Further complicating a current analysis relative to the analysis performed at that time, when we examine the FY 2011 IDR data available to us now (claims processed through October 2015) compared to when the original – 0.2 percent estimate was developed (claims processed through June 2013), we get approximately 340,000 stays instead of the originally estimated 360,000 stays, which we suspect is at least partly driven by subsequent claim denials for these cases that have occurred since the data was examined for the original – 0.2 percent estimate. Because the historical MedPAR data for a given fiscal year is not generally refreshed after it is created, unlike the IDR which is refreshed, there is no analogous number to the 340,000 for the FY 2011 MedPAR.

In determining the 380,000 number from the FY 2011 MedPAR, the following inpatient claim selection criteria and data trims were applied to the data. We selected FY 2011 MedPAR claims based on a FY 2011 date of discharge where the National Claims History (NCH) claim type code was equal to “60” (inpatient hospital), the third position of the provider number group was equal to “0” (short-term hospital), the first 2 positions of the provider number were not equal to “21” (excludes Maryland hospitals), the destination discharge code was not equal to “30” (excludes still a patient), the special unit code was blank (excludes, for example, PPS exempt units), the GHO paid code was not equal to “1” (a group health organization has not paid the provider), the total charge amount was greater than 0, and the IME amount was not equal to the DRG price amount (indicating it was not a managed care claim).

As described in section II.D of this notice, we have also been performing an analysis of the claims experience since the implementation of the 2-midnight policy. This analysis has used data from the publicly available MedPAR file and the IDR.

We seek comment on the appropriate inpatient data source to use for the – 0.2 percent estimate and any data trims and claims selection criteria that we should apply to the data.

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Administration for Children and Families**

#### **Proposed Information Collection Activity; Comment Request**

*Title:* Building Bridges and Bonds (B3) Study: Data Collection.

*OMB No.:* New Collection.

*Description:* The Administration for Children and Families (ACF), Office of Planning, Research and Evaluation (OPRE) proposes to collect information as part of the Building Bridges and Bonds (B3) study. B3 will inform policymakers, program operators, and stakeholders about effective ways for fatherhood programs to support fathers in their parenting and employment. In particular, partnering with programs that serve low-income fathers to promote responsible fatherhood, the B3 study will examine the effectiveness of strategies used to (1) engage fathers in program activities, (2) develop and support parenting and co-parenting skills, and (3) advance the employment of disadvantaged fathers. B3 will test innovative, evidence-informed approaches that will be added to the core components of fatherhood programs and will reflect the most recent developments in behavioral science, adult skill-building, child development, and other relevant disciplines. The study will include up to six sites and specific interventions will vary by site.

B3 includes an impact evaluation and a process study. The impact evaluation will involve randomly assigning individuals to a treatment or comparison condition and comparing key outcomes. In addition, the study will collect information on employment, criminal justice and child support outcomes from administrative records. These data will be used to estimate the effects of the parenting or employment intervention on a range of outcomes including employment; earnings; child support; father/child contact, shared activities, and relationship quality; father's commitment to his child, parenting skills, and parenting efficacy; co-parenting relationship quality; and criminal justice outcomes.

The process study will describe and document each newly established intervention and how it operated to provide insight into the treatment differentials and the context for interpreting findings of the impact study. The process study will also highlight lessons to the field including what it takes to engage participants, the challenges sites face when implementing the parenting or employment intervention, and the participants' perspectives on whether

the program components offered met their needs.

Data collection instruments for the B3 study include the following: (1) Screening for program eligibility to help ensure that only eligible fathers enroll in the study.

(2) nFORM management information system (MIS) to record study and participation information. Note: Only B3-specific burden is included with this request. All Responsible Fatherhood Grantees (funded by the ACF Office of Family Assistance) are required to use nFORM. nFORM is being developed by the Fatherhood and Marriage Local Evaluation and Cross-site (FaMLE Cross-site) Project and burden for these sites are captured under OMB #0970-0460. (3) Applicant characteristics and program operations data for one non-grantee site. We expect most of the B3 sites will be federally funded Responsible Fatherhood grantees, but it is possible that one site will not and therefore, this request includes burden for one site to use nFORM. (4) Baseline and follow-up surveys for the impact study. There will be two versions of each survey, specific to the intervention tested. (5) Baseline and follow-up questionnaires, interviews, focus groups, and surveys to inform the process study; these will also be specific to the intervention tested.

The sites that are part of the B3 study will use a slightly modified version of nFORM that includes B–3 specific information, such as: (1) B3-specific enrollment data (2) B3-specific information about focal child and co-parent in sites testing a parenting intervention, and (3) B3 tracking of child and co-parent attendance in services with the father for program group members in sites testing a parenting intervention.

**RESPONDENTS:** Fathers seeking services from one of the six Responsible Fatherhood Programs in the B3 study and staff members working at the B3 sites.

## ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
<b>Instruments for Recruitment and Screening</b>					
Screening questions for parenting intervention (applicant burden) .....	4,000	1,333	1	0.03	44
Screening questions for parenting intervention (staff burden) .....	48	16	83	0.03	44
Screening questions for employment intervention (applicant burden) .....	2,000	667	1	0.17	111
Screening questions for employment intervention (staff burden) .....	24	8	83	0.17	111
Consent/Assent Materials for Fathers (applicant burden) ...	2,500	833	1	0.17	139
Consent/Assent Materials for Fathers (staff burden) .....	72	24	35	0.17	139
Consent Materials for Parents of Fathers under 18 (applicant burden) .....	833	278	1	0.17	46
Consent Materials for Parents of Fathers under 18 (staff burden) .....	72	24	12	0.17	46
Recruitment script for parenting intervention (applicant burden) .....	1,500	500	1	0.08	42
Recruitment script for parenting intervention (staff burden) .....	48	16	31	0.08	42
Recruitment script for employment intervention (applicant burden) .....	1,000	333	1	0.08	28
Recruitment script for employment intervention (staff burden) .....	24	8	42	0.08	28
<b>Instruments for Impact Study</b>					
B3-specific enrollment data collected in the nFORM MIS from all sample members (applicant burden) .....	2,500	833	1	0.12	97
B3-specific enrollment data collected in the nFORM MIS from all sample members (staff burden) .....	72	24	35	0.12	97
B3-specific information collected about focal child and co-parent in the nFORM MIS from program group members in sites testing parenting intervention (applicant burden) .....	750	250	1	0.17	42
B3-specific information collected about focal child and co-parent in the nFORM MIS from program group members in sites testing parenting intervention (staff burden) .....	48	16	16	0.17	42
B3 tracking of child and co-parent attendance in services with the father for program group members in sites testing parenting intervention (staff burden) .....	48	16	156	0.01	21
Additional nFORM burden for non-Grantee site (applicant burden) .....	600	200	1	0.25	50
Additional nFORM burden for non-Grantee site (staff burden) .....	12	4	2,625	0.03	363
Baseline survey for sites testing parenting intervention .....	1,500	500	1	0.67	333
Baseline survey for sites testing employment intervention .....	1,000	333	1	0.67	222
6 month follow-up survey for sites testing parenting intervention .....	1,200	400	1	0.67	267
6 month follow-up survey for sites testing employment intervention .....	800	267	1	0.67	178
<b>Instruments for Process Study</b>					
In-program participant questionnaire for program and control group members in sites testing parenting intervention .....	1,500	500	1	0.5	250
In-program participant questionnaire for program and control group members in sites testing employment intervention .....	1,000	333	1	0.5	167
Staff baseline questionnaire for sites testing parenting intervention .....	208	69	1	0.5	35
Staff baseline questionnaire for sites testing employment intervention .....	104	35	1	0.5	17
Staff and management semi-structured interviews for sites testing parenting intervention .....	160	53	2	1.5	160
Staff and management semi-structured interviews for sites testing employment intervention .....	80	27	2	1.5	80
Staff follow-up questionnaire for sites testing parenting intervention .....	160	53	1	1.0	53

## ANNUAL BURDEN ESTIMATES—Continued

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Staff follow-up questionnaire for sites testing employment intervention .....	80	27	1	1.0	27
Participant focus groups .....	96	32	1	1.5	48
Mother focus groups in sites testing parenting intervention .....	80	27	1	1.0	27
Mobile device process survey .....	2,000	667	5	0.08	278
Mobile device employment survey .....	400	133	5	0.08	56
Mobile device parenting and co-parenting survey .....	600	200	5	0.08	83
Post-workshop questionnaires for sites testing parenting intervention .....	750	250	5	0.05	63

*Estimated Total Annual Burden Hours: 3,876.*

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](mailto: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.

**Robert Sargis,**

*ACF Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0155]

#### Veterinary Feed Directive Common Format Questions and Answers; 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 #233 entitled "Veterinary Feed Directive Common Format Questions and Answers." On June 3, 2015, FDA published a final rule that revised the Agency's veterinary feed directive (VFD) regulations. During the rulemaking process, FDA received a few comments requesting that we require a uniform VFD form. Although we declined this request because we think that requiring a specific VFD form would be too prescriptive, we acknowledge that a common VFD format would help clients, veterinarians, and distributors (including feed mills) quickly identify relevant information on the VFD and are issuing this draft guidance to recommend a common VFD format.

**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 either electronic or written comments on the draft guidance by February 1, 2016.

**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-2010-N-0155 for "Veterinary Feed Directive Common Format Questions and Answers." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at