

CityMatCH, and participating communities. This request is for 3-years.

The original Fetal-Infant Mortality Review (FIMR) methodology was an approach designed to lead to community-level improvements in infant health outcomes. The methodology consists of four steps: Data gathering, case review, community action, and changes in community systems.

The FHPM has adapted the steps of FIMR in order to evaluate and address the causes of perinatal HIV transmission. This is the first program to approach perinatal HIV prevention using a community-based systems investigation and improvement strategy.

During FHPM's first step of the methodology, cases of perinatal HIV will be identified based on a pre-established case definition, and will be prioritized for community review.

Data for selected cases will be collected from a variety of sources, including medical, public health, and case management records, and then de-identified. A maternal interview will only be conducted if consent is provided by the woman. Data collection can proceed using hospital records if there is no consent for an interview. Data collected during interviews with consenting women will be de-identified. There will be no cost to participants

beyond their time, and women can decline to be interviewed.

The maternal interview is the only portion of the project which interacts with individual patients. As is the case for all data collected by FHPM, the intent for the data is for local use to understand and improve local systems. Face-to-face interviews will average 1.5 hours in duration and will not need to be repeated, unless a woman has a second pregnancy and is selected for case review under the priority assessment, and consents to participate a second time. Each of the 10 FHPM sites will conduct 30 maternal interviews annually. The number of elements in the interview is presently being reduced. When the FIMR-HIV Data System (FHDS) is implemented (see below), each of these 10 sites will be asked to send its data to the FHDS.

After the data collection phase, a multidisciplinary case review team (CRT) will conduct a regularly scheduled case review session. The recommendations and findings of the CRT will then be passed on to a Community Action Team (CAT), a diverse, broad-based group of community leaders and representatives capable of defining and initiating changes in the local systems.

Since 2009, partner organizations have been funded to operate FHPM in

10 sites. Sites have been collecting and evaluating data on mother-to-child transmissions in their communities since 2010. Currently de-identified FHPM data is stored electronically at participating sites. This data has been collected by local health agencies for local public health action and programming. NCHHSTP also plans to launch the FIMR-HIV Data System (FHDS) in 2011, which would provide a centralized, Web-based data system that could be accessed and utilized by all participating sites and partner organizations. This Information Collection Request is being submitted since the FHDS since FHDS will be managed by CDC, thus centralizing the data and allowing aggregated analysis.

NCHHSTP is considering ways to eliminate perinatal HIV transmission in the U.S., and has incorporated FHPM into a framework to do so.

Data collected by FHPM will primarily serve to inform and improve local health systems in order to prevent future perinatal HIV transmissions. This data will provide a clearer picture of the systems-level strengths and weaknesses in participating communities. There will be no cost to participants other than their time.

Estimated Annualized Burden Hours

Form name	Respondents	Number of respondents	Number of responses per respondent	Average burden response (in hours)	Total burden (in hours)
Face-to-Face Maternal Interview Form.	Sites participating in FHPM	10	30	1.5	450

Dated: December 30, 2010.

Carol E. Walker,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number NIOSH-189]

Request for Information on 2,3-Pentanedione and Other Alpha-Diketones Used As Diacetyl Substitutes

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC),

Department of Health and Human Services (HHS).

ACTION: Notice of public comment period.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) intends to evaluate the scientific data on 2,3-pentanedione (CAS #600-14-6, also known as pentane-2,3-dione; acetyl propionyl) and other alpha-diketones and develop appropriate communication documents, such as a Current Intelligence Bulletin, Criteria Document and/or other informational products, and potentially establish a Recommended Exposure Limit (REL) for diacetyl substitutes. NIOSH is requesting information on the following: (1) Published and unpublished reports and findings from *in vitro* and *in vivo* toxicity studies with 2,3-pentanedione,

and other alpha diketones, (2) information on possible health effects observed in workers exposed to 2,3-pentanedione, and other alpha-diketones, (3) information on workplaces and products in which 2,3-pentanedione and other alpha-diketones can be found, (4) description of work tasks and scenarios with a potential for exposure to 2,3-pentanedione and other alpha-diketones, (5) workplace exposure data, and (6) information on control measures (e.g., engineering controls, work practices, personal protective equipment) that are being used in workplaces where potential exposures to 2,3-pentanedione and other alpha diketones occur.

Public Comment Period: Comments must be received by February 9, 2011.

ADDRESSES: You may submit comments, identified by docket number NIOSH-189 by any of the following methods:

• *Mail*: NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, OH 45226.

- *Facsimile*: (513) 533-8285.
- *E-mail*: nioshdocket@cdc.gov.

All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, Room 111, 4676 Columbia Parkway, Cincinnati, Ohio 45226. A complete electronic docket containing all comments submitted will be available on the NIOSH Web page at <http://www.cdc.gov/niosh/docket>, and comments will be available in writing by request. NIOSH includes all comments received without change in the docket, including any personal information provided.

FOR FURTHER INFORMATION CONTACT:

Lauralynn Taylor McKernan, NIOSH, Robert A Taft Laboratories, MS-C32, 4676 Columbia Parkway, Cincinnati, OH 45226, telephone: (513) 533-8542.

SUPPLEMENTARY INFORMATION: 2,3-

pentanedione is an alpha-diketone that has received attention as a substitute for diacetyl. 2,3-pentanedione is structurally very similar to diacetyl since 2,3-pentanedione is a 5-carbon alpha-diketone and diacetyl is a 4-carbon alpha-diketone. Published reports on the toxicity of 2,3-pentanedione are currently only in abstract form but suggest that in rats 2,3-pentanedione causes airway epithelial damage similar to that produced by diacetyl (Hubbs *et al.* 2010b; Morgan *et al.* 2010). Preliminary data also suggest that, under certain conditions, both diacetyl and 2,3-pentanedione can cause changes in the central nervous system (Hubbs *et al.* 2010a). Additional alpha-diketones of interest include, but are not limited to, those used in food manufacturing such as 2,3-hexanedione and 2,3-heptanedione (Kreiss *et al.* 2010).

NIOSH seeks to obtain materials, including published and unpublished reports and research findings, to evaluate the possible health risks of occupational exposure to 2,3-pentanedione and other alpha-diketones used as diacetyl substitutes. Examples of requested information include, but are not limited to, the following:

- (1) Identification of industries or occupations in which exposures to 2,3-pentanedione, and other alpha-diketones used as diacetyl substitutes may occur;
- (2) Trends in the production and use of 2,3-pentanedione, and other alpha-diketones;
- (3) Description of work tasks and scenarios with a potential for exposure

to 2,3-pentanedione, and other alpha-diketones used as diacetyl substitutes;

(4) Workplace exposure measurement data in various types of industries and jobs where 2,3-pentanedione, and other alpha-diketones are used;

(5) Case reports or other health information demonstrating potential health effects in workers exposed to 2,3-pentanedione, and other alpha-diketones;

(6) Research findings from *in vitro* and *in vivo* toxicity studies;

(7) Information on control measures (e.g., engineering controls, work practices, personal protective equipment) being taken to minimize worker exposure to 2,3-pentanedione, and other alpha-diketones used as diacetyl substitutes;

(8) Educational materials for worker safety and training on the safe handling of 2,3-pentanedione and other alpha-diketones; and

(9) Data pertaining to the feasibility of establishing a REL for 2,3-pentanedione, and other alpha-diketones.

References

- Hubbs, A. F., Cumpston, A., Goldsmith, W. T., Battelli, L. A., Kashon, M. L., Jackson, M. C., Frazer, D. G., Fedan, J. S., Goravanahally, M. P., and Sriram, K. (2010a). Acute central neurotoxicity of inhaled alpha-diketone butter flavoring compounds in the rat brain. *Vet Path* 47(6), 57S.
- Hubbs, A. F., Moseley, A. E., Goldsmith, W. T., Jackson, M. C., Kashon, M. L., Battelli, L. A., Schwegler-Berry, D., Goravanahally, M. P., Frazer, D., Fedan, J. S., Kreiss, K., and Castranova, V. (2010b). Airway epithelial toxicity of the flavoring agent, 2,3-pentanedione. *The Toxicologist: Supplement to Toxicological Sciences* 114(1), 319.
- Kreiss, K., Day, G. A., Cummings, K. J., and Kullman, G. (2010). Diacetyl substitutes in bakery product manufacture *Am J Respir Crit Care Med* 181(1), A4650.
- Morgan, D. L., Kirby, P. J., Price, H. C., Bosquet, R. W., Taylor, G. J., Gage, N., and Flake, G. P. (2010). Inhalation toxicity of acetyl propionyl in rats and mice. *The Toxicologist: Supplement to Toxicological Sciences* 114(1), 316.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10142 and CMS-R-262]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* CY 2012 Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); *Use:* Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), and implementing regulations at 42 CFR, Medicare Advantage organizations (MAO) and Prescription Drug Plans are required to submit an actuarial pricing "bid" for each plan offered to Medicare beneficiaries for approval by CMS.

MAOs and PDPs use the Bid Pricing Tool (BPT) software to develop their actuarial pricing bid. The information provided in the BPT is the basis for the plan's enrollee premiums and CMS payments for each contract year. The tool collects data such as medical expense development (from claims data and/or manual rating), administrative expenses, profit levels, and projected plan enrollment information. By statute, completed BPTs are due to CMS by the first Monday of June each year. CMS reviews and analyzes the information provided on the Bid Pricing Tool.