

FOR FURTHER INFORMATION CONTACT:

Carole C. Webb, Center for Devices and Radiological Health (HFZ-520), 1350 Piccard Dr., Rockville, MD 20850, 301-594-3948, or internet "CCW@cdrh.fda.gov".

SUPPLEMENTARY INFORMATION:

Pulmonary artery catheters (PAC's), also known as right heart catheters, provide data on blood pressure, blood flow, and oxygen levels that many doctors consider crucial to the care of critically ill hospital patients. A study reported in the September 18, 1996, *Journal of the American Medical Association* (JAMA), however, suggests use of these catheters may increase risks of morbidity and mortality (the JAMA article).

PAC's have been used in the practice of critical care medicine since 1970. The initial marketing of these devices preceded FDA's authority to regulate medical devices which began in 1976. The JAMA article by Connors et al. examined the survival of patients monitored with and without this device in an intensive care setting. The Connors et al. study does not provide evidence that the catheter itself is unsafe; however, it does raise questions about the benefit to patients of the device as it is currently being used. Concerns about the benefits and risks of using PAC's are not new. As early as 1987, other scientists found a greater risk of morbidity and mortality in use of PAC's, but those early studies, as in the Connors et al. study, were not randomized. Although the Connors et al. study showed a relationship between use of PAC's and a higher risk of death, it did not show that use of the catheter caused those additional deaths. The additional risk might be related to how information gained from the catheter is used or the result of medical therapy a patient receives. It is possible the results may not apply when the catheter is used for diseases or in situations other than those studied by Connors et al. The device provides important clinical information relied upon in determining a course of treatment. However, FDA and the National Institutes of Health (NIH) believe rigorous scientific evaluations of the device may be needed in evaluating the context of appropriate clinical care.

The Pulmonary Artery Catheter and Clinical Outcomes Workshop will be cosponsored by FDA and NIH. The goals of the workshop are to summarize the following:

- (1) Clinical indications, benefits, and major risks of PAC use;
- (2) Current standards for clinical practice in PAC use;

(3) The need and specific clinical issues for PAC use in specific patient populations;

(4) To identify suggestions or opportunities for future research, regulatory action, or clinical practice guidelines.

The workshop will commence with introductions, overviews of goals, discussion of contemporary clinical knowledge of PAC use, and catheter technology issues. Two concurrent sessions will be convened in the morning and afternoon. Each session will cover two major disease and trauma topics in separate breakout groups. The first pair of breakout groups will focus on PAC use in respiratory disease and trauma/perioperative/postoperative management. The second pair of breakout groups will include sepsis/multiorgan dysfunction syndrome and cardiovascular disease. The objective of these sessions will be to debate critical clinical issues specific to these areas. Attendees may observe any available session and may participate in open discussions. Following these sessions, cochairs will guide their teams to identify pragmatic and prioritized research considerations. On August 26, 1997, each group will present their report to the entire workshop. Open discussions and concluding remarks will follow. Cochairs will only remain after the formal part of the workshop to discuss areas of disagreement and to write the first draft of the final document. It is expected the final document will be delivered to Federal agencies within 2 weeks.

Dated: August 13, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97-21835 Filed 8-13-97; 2:56 pm]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4263-N-04]

Office of the Assistant Secretary for Fair Housing and Equal Opportunity; Proposed Information Collection for Public Comment

AGENCY: Office of the Assistant Secretary for Fair Housing and Equal Opportunity; HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork

Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due: October 17, 1997.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Josie D. Harrison, Reports Liaison Officer, Fair Housing and Equal Opportunity, Department of Housing and Urban Development, 451-7th Street, SW, Room 5124, Washington, DC 20410-5000.

FOR FURTHER INFORMATION CONTACT: Susan Scanlan (202) 708-2740 (this is not a toll-free number) for copies of the proposed forms and other available documents.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

The Notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to:

- (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information;
- (3) Enhance the quality, utility, and clarity of the information to be collected; and
- (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Survey Questionnaires.

OMB Control Number: 2529-0045.

Description of the need for the information and proposed use: HUD will use this information to assess the adequacy of its customer service and review comments and suggestions made by its customers to better enhance its customer service as required by Executive Order 12862.

Agency form numbers: None.

Members of affected public: Complainants, Respondents of complaints, Public Housing Authorities (PHAs), Private Property Managers and Representatives for Complainants,

members of the mortgage lending industry who have signed voluntary agreements with HUD.

Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: This survey will be completed on a voluntary basis. The number of actual respondents can not be exactly calculated as there are various programs being surveyed each with their own unique set of customers. The attached sample survey instruments have been pretested. The amount of time required to complete the questionnaires is estimated at not more than 15 minutes for the complainants, and not more than 30 minutes for all other recipients.

Status of the proposed information collection: This is an amended survey instrument that is being completed to assess the customer service given by the Office of Fair Housing and Equal Opportunity.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: August 8, 1997.

Laurence D. Pearl,

Acting Deputy Assistant Secretary for Program Operations and Standards.

[FR Doc. 97-21768 Filed 8-15-97; 8:45 am]

BILLING CODE 4210-28-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4263-N-05]

Office of the Assistant Secretary for Housing, Federal Housing Commissioner; Proposed Information Collection for Public Comment

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposals.

DATES: Comments due: October 17, 1997.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Oliver Walker, Housing, Department of Housing & Urban Development, 451-7th

Street, SW, Room 9116, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT:

Michael Diggs, telephone number (202) 708-3944 (this is not a toll-free number) for copies of the proposed forms and other available documents.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

The Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Owner/Tenant Certification for Multifamily Housing Programs.

OMB Control Number: 2502-0204.

Description of the need for the information and proposed use: Housing Programs, subsidies, rental assistance, eligibility criteria. Information is needed to determine tenant eligibility and to compute tenant annual rents for those occupying HUD subsidized housing units.

Agency form numbers: HUD 50059, 50059D, 50059F, 50059G.

Members of affected public: Businesses or other for-profit, Non-profit institutions, individuals or households, federal agencies or employees, small business or organizations.

Status of the proposed information collection: Extension without change.

Authority: Section 236 of the Paperwork Reduction Act of 1995, 44 U.S.C., Chapter 35, as amended.

Dated: August 8, 1997.

Karen A. Miller,

Deputy Assistant Secretary for Multifamily Housing.

[FR Doc. 97-21769 Filed 8-15-97; 8:45 am]

BILLING CODE 4210-27-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4211-N-02]

NOFA for Lead-Based Paint Hazard Control in Privately-Owned Housing, Fiscal Year 1997; Notice of Extension of Application Deadline Date Due to United Parcel Service (UPS) Labor Strike

AGENCY: Office of the Secretary—Office of Lead Hazard Control, HUD.

ACTION: Notice of funding availability for FY 1997; extension of application deadline date.

SUMMARY: On June 3, 1997 (62 FR 30380), HUD published a notice announcing the availability of approximately \$50 million for two categories of lead hazard control activities in privately-owned housing. The June 3, 1997 notice of funding availability (NOFA) provided that applications had to be received by HUD no later than 3:00 p.m. (Eastern Time) on August 5, 1997. Due to the United Parcel Service (UPS) labor strike, HUD is retroactively extending the application deadline date to 5:00 p.m. (Eastern Time), August 5, 1997. HUD will also accept late applications which are either postmarked on or contain a receipt of delivery to a private express mail carrier by midnight (Eastern Time) on August 5, 1997. HUD is extending the application due date in order to prevent the unfair rejection of NOFA applications which, although completed on a timely basis, could not be delivered to HUD by the original deadline date due to the UPS strike.

FOR FURTHER INFORMATION CONTACT: For Category A applicants: Ellis G. Goldman, Director, Program Management Division, Office of Lead Hazard Control, Room B-133, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 755-1785, extension 112 (this is not a toll-free number). For Category B applicants: Melissa F. Shapiro, telephone (202) 755-1785, extension 153 (this is not a toll-free number). For hearing- and speech-impaired persons, the telephone number may be accessed via TTY (text telephone) by calling the toll-free Federal Information Relay Service at 1-800-877-8339.

SUPPLEMENTARY INFORMATION:

On June 3, 1997 (62 FR 30380), HUD published a notice announcing the competition for two categories of grant funding: Category A for approximately \$46 million for a grant program for State and local governments to undertake lead-based paint hazard control in