

firearm injury, (2) examine the factors that influence patient recovery, and (3) document the use of post-acute services and barriers to receiving those services.

The following data will be collected: (1) Patients will be interviewed in person prior to discharge and by phone at three months and nine months after

discharge, and (2) the medical record will also be abstracted.

Respondents	No. of respondents	No. of responses/respondent	Avg. burden/response (in hrs.)
Patients with firearms injuries	320	3	0.60

The total annual burden is 576. Send comments to Allison Eydt, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: November 29, 1995.
 Wilma G. Johnson,
Acting Associate Director for Policy Planning And Evaluation, Centers for Disease Control and Prevention (CDC).
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[INFO-95-07]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639-3453.

Comments are invited 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) ways to enhance 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 for other forms of information technology. Send comments to Wilma Johnson, CDC Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Projects

1. Resources and Services Database of the CDC National AIDS Clearinghouse (NAC)—(0920-0255)—Extension—This is a request to extend this project for three years. NAC will mail the Resource Organization Questionnaire along with a cover letter once an organization is identified as providing AIDS-related services. Each organization will also receive a stamped, self-addressed envelope for the return of the questionnaire. If there is no response a follow-up letter will be sent along with another questionnaire and return envelope. A telephone call will be made to those organizations who respond but whose responses need clarification. Approximately one third of the entire Resources and Services Database is verified each year. As part of this process, 40 percent of these organizations will receive a copy of their current database entry by mail, including a cover letter, a list of

instructions, and a stamped, self-addressed envelope. The remaining 60 percent will receive a telephone call to review their record.

The Centers for Disease Control and Prevention (CDC) National AIDS Clearinghouse (NAC), is a critical member of the network of government agencies, community organizations, businesses, health professionals, educators, and human services providers that educate the American public about Acquired immunodeficiency syndrome (AIDS) and provide services for persons infected with human immunodeficiency virus (HIV). NAC's Resources and Services Database contains records of approximately 18,000 organizations and is the most comprehensive listing of AIDS resources and services available throughout the country.

NAC's reference staff rely on the Resources and Services Database to respond to more than 100,000 requests for information or referral each year. The Database is also the main information source for the CDC National AIDS Hotline which refers approximately 1.8 million callers from the general public each year to appropriate organizations for information, services, and treatment.

In its continuing efforts to maintain an up-to-date, comprehensive database, NAC is seeking renewal of approval of the survey instrument and proposed methods. The total cost to respondents is estimated at \$94,466.00.

Respondents	No. of respondents	No. of responses/respondent	Avg. burden/response (in hrs.)	Total burden (in hrs.)
Questionnaire	2,400	1	0.33	800
Clarification follow-up	360	1	0.17	60
Verification	10,636	1	0.33	3545
Verif. follow-up	993	1	0.17	166
Total				3771

2. Evaluation of a Training Curriculum for Hemophilia Nurses Who Teach Home Infusion and Infection

Control—New—The Hematologic Disorders Branch at CDC has plans to develop, pilot, and evaluate training

curricula for hemophilia health care providers to improve their knowledge and skills in teaching home infusion of

Factors VII and IX (coagulating agents which reduce the bleeding resulting from a deficiency of natural clotting agents in the blood of people with hemophilia) and infection control related to the infusion. CDC has initiated the development of a self-learning manual for nurses with responsibility of teaching hemophilia patients and their families about home infusion and infection control (HI/IC). The goals of the manual are (1) to facilitate nurses' understanding of

content that should be covered when teaching HI/IC techniques, and (2) to assist nurses in determining how they can best teach HI/IC to patients and their families. The purpose of the proposed data collection is to assess the efficacy of the manual in achieving those goals.

An experimental design will be employed in this study in which 100 randomly sampled nurses will be assigned to either an experimental condition (n=50) or to a control group

(n=50). Nurses in the experimental condition will be asked to use the manual, while those in the control condition will continue their current practices and engage in any naturally-occurring learning experiences related to HI/IC. Baseline and follow-up surveys administered to both groups will yield data that will be used to determine the difference in knowledge, attitudes, and skills that can be attributed to use of the self-learning guide.

Respondents	No. of re-spond-ents	No. of re-sponses/respond-ent	Avg. bur-den/re-sponse (in hrs.)	Total burden (in hrs.)
Nurses in experimental condition	50	2	0.50	50
Nurses in control condition	50	2	0.50	50
Total				100

3. Complications Associated with Home Infusion Therapy: The Nature and Frequency of Blood Contacts Among Health Care Workers—NEW—

Occupational blood contact and the potential for transmission of bloodborne pathogens is a serious concern for health care workers (HCWs) who provide care to patients. There are no data on the frequency of occupational percutaneous injuries and mucocutaneous blood contact among HCWs who provide home infusion therapy.

The Hospital Infections Program, National Center for Infectious Diseases, will conduct prospective, active surveillance of HCWs who provide home infusion therapy. The objectives of the surveillance project are to (1) estimate the procedure-specific

frequency of and assess risk factors for percutaneous, mucous membrane, or cutaneous blood contacts sustained by HCWS during the delivery of home infusion therapy and the performance of related procedures, such as phlebotomy and blood culture collection; (2) describe and evaluate the effectiveness of infection control precautions and safety devices to prevent blood contacts; and (3) evaluate the impact of HCWs' knowledge of universal precautions on the use of protective equipment, safety devices, and the frequency of blood contacts.

The population under surveillance will be nurses and phlebotomists from three home health care agencies. Before beginning data collection, HCWs will complete a background questionnaire to provide basic demographic information

as well as information about previous blood contacts. HCWs will then complete an exposure questionnaire after each home visit for a two-four week data collection period. This questionnaire will include information about the reason for the visit, the types of procedures performed, the length of the visit, the number and types of blood contacts sustained, and the use of infection control precautions and any safety devices. At the end of their individual data collection period, each HCW will complete an infection control questionnaire to assess knowledge and attitudes related to blood contacts and the use of universal precautions. The total cost to respondents is estimated at \$24,633.

Respondents (HCWs)	No. of re-spond-ents	No. of re-sponses/respond-ent	Avg. bur-den/re-sponse (in hrs.)	Total burden
Background questionnaire	1337	1	.083	111
Exposure questionnaire	1337	41	.0167	915
Infection control questionnaire	1337	1	.083	111
Total				1137

4. Surveillance and Epidemiology Study Core Questionnaire and Supplement Modules—(0923-0010)—Revision—ATSDR is revising and renewing the project which follows populations exposed to specific hazardous substances over a period of

time to determine if they are experiencing elevated occurrence of diseases. In addition to demographic information, additional core information is collected on behavioral characteristics and health conditions. The supplemental modules are also included

in the request that may be used, depending on the organ system targeted or the type of respondent (renal, liver, occupational, respiratory, etc). The total cost to respondents is estimated at \$53,153.64.

Respondents	No. of Re-spondents	No. of re-sponses/respondent	Avg. burden/re-sponses (in hrs.)	Total burden (in hrs.)
Households	2667	7	.369	4908

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 Wilma G. Johnson,
*Acting Associate Director for Policy Planning
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Food and Drug Administration

[Docket No. 95N-0358]

Revised FDA Form 2830 Blood Establishment Registration and Product Listing (8/95); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the revised FDA Form 2830 Blood Establishment Registration and Product Listing (8/95). This form replaces the previous edition of FDA Form 2830 (7/93). FDA Form 2830 is used for blood establishment registration and product listing, in accordance with the agency's regulations. FDA has made minor changes to the blood establishment registration and product listing which are intended to update the form, simplify processing, provide for efficient and effective use of the data base, and decrease expenditure of resources for both FDA and industry.

DATES: FDA will continue to accept submissions using the previous FDA Form 2830 (7/93) until June 5, 1996.

FOR FURTHER INFORMATION CONTACT: Valerie A. Windsor, Center for Biologics Evaluation and Research (HFM-630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-3074.

ADDRESSES: Submit written requests for single copies of the revised FDA Form 2830 Blood Establishment Registration and Product Listing (8/95) to the Congressional and Consumer Affairs Branch (HFM-12), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, or call FDA's automated information system at 800-835-4709. Send two self-addressed adhesive labels to assist that office in processing your requests. The revised FDA Form 2830 Blood Establishment

Registration and Product Listing (8/95) may also be obtained by calling the CBER FAX Information System (FAX—ON—DEMAND) at 301-594-1939 from a touch tone phone. Submit written comments on the revised FDA Form 2830 Blood Establishment Registration and Product Listing (8/95) to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Requests and comments should be identified with the docket number found in brackets in the heading of this document. The revised FDA Form 2830 Blood Establishment Registration and Product Listing (8/95) and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION: FDA is making available revised FDA Form 2830 Blood Establishment Registration and Product Listing (8/95), used in accordance with part 607 (21 CFR part 607), by owners or operators of establishments that engage in the manufacturing of blood products. Minor revisions have been made to the format of the form and the information solicited which include, but are not limited to, the following: (1) Revised FDA Form 2830 was reformatted into a single copy form, which replaces the previous four-copy form; (2) item 15, products, was revised by: (a) Adding Red Blood Cells Rejuvenated Frozen and Red Blood Cells Rejuvenated Deglycerolized and (b) adding a column to identify irradiated blood products; (3) item 13, type establishment, was revised by adding product testing laboratory, with the subheadings: Independent and associated with community or hospital blood bank; and (4) instructions for completing blood registration FDA Form 2830, were revised and included on a separate page.

In addition, the revised form continues to solicit the following information: (1) Registration number; (2) legal name and location; (3) reporting official; (4) type of ownership; (5) type establishment; (6) listing of products collected, processed, prepared, tested, and stored for distribution; and (7)

human immunodeficiency virus (HIV) and hepatitis B surface antigen (HBsAg) proficiency test program name.

In accordance with § 607.20, owners or operators of all establishments that engage in the manufacture of blood products are required to register and to submit a list of every blood product in commercial distribution, whether or not the output of such blood product establishment or any particular blood product so listed enters interstate commerce.

Owners or operators of establishments that engage in the manufacturing of blood products that are currently registered with FDA need not request the revised form. In accordance with § 607.22, FDA Form 2830 will be distributed by FDA before November 15 of each year to establishments whose product registration for that year was validated, pursuant to § 607.35. In addition, these establishments are required to update their blood product listing information every June and December. New owners or operators of establishments that engage in the manufacturing of blood products may request the revised form as instructed under the ADDRESSES caption (see above).

Owners or operators of establishments that engage in the manufacturing of blood products that are preparing to submit applications for blood establishment registration and product listing should now utilize the revised FDA Form 2830 (8/95). FDA will continue to accept submissions using the previous FDA Form 2830 (7/93) until June 5, 1996.

Under the Paperwork Reduction Act of 1995 (Pub. L. 104-13), all forms requesting a collection of information on identical items from 10 or more public respondents must be approved by the Office of Management and Budget (OMB) and must display a valid OMB control number and expiration date. OMB approval for FDA Form 2830 was obtained on February 9, 1993, and given OMB approval number 0910-0052; expiration date February 28, 1996, however, the expiration date has been extended by OMB to May 31, 1996. Since these minor revisions to FDA Form 2830 did not increase burden to the public, OMB approval was not required.