



## Safety Net Hospitals for Pharmaceutical Access

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### Principles to Help Hospitals Comply with 340B Prohibition Against Diversion

- I. With respect to outpatient drugs administered by a physician or otherwise used incident to a physician's services, the drugs must be administered in a hospital facility that is reimbursable on the 340B hospital's Medicare cost report.
- II. With respect to covered drugs dispensed by an outpatient pharmacy for self-administration by patients, the individual receiving such drugs is an eligible 340B patient only if (1) the hospital maintains a record of health care services for that individual, (2) the individual receives care from a professional who is employed by, under contract with, or has other arrangements with the hospital, such that the hospital remains responsible for the care, and (3) the outpatient pharmacy is reimbursable on the hospital's cost report. Requirement (3) does not apply to contract pharmacy arrangements.
- III. With respect to a prescription for a self-administered drug written by a non-hospital physician in connection with treatment rendered outside the hospital, the prescription may be filled with a 340B drug only if the treatment is proximate in type and time to services provided by the hospital to the patient at issue. A non-hospital prescription is proximate in type and time to hospital-based services if the prescription or refill is presented within one year of the hospital encounter and the hospital encounter is part of the continuum of care that gives rise to the prescription. A continuum of care exists if the hospital makes a referral to the outside provider for follow-up care or if there is an established pattern of the hospital and non-hospital provider working together to serve a common patient population.
- IV. Although an individual does not have to receive all of his or her services from a hospital in order to qualify as a patient of the facility, he or she must receive more than just pharmacy services from the hospital.

*Sources: Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55,156 (October 24, 1996)(attached); Letter from Thomas G. Morford, Deputy Administrator, Health Resources and Services Administration, to William von Oehsen, General Counsel, Safety Net Hospitals for Pharmaceutical Access (formerly Public Hospital Pharmacy Coalition), clarifying the government's 340B patient definition (January 26, 2001)(attached).*

**For more information, please contact SNHPA President and General Counsel, Bill von Oehsen at [william.vonoehsen@snhpa.org](mailto:william.vonoehsen@snhpa.org) or (202) 872-6765.**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Health Resources and  
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William H. von Oehsen, III, Esquire  
Powell, Goldstein, Frazer & Murphy, LLP  
1001 Pennsylvania Avenue, N.W., Suite 600  
Washington, D.C., 20004

Dear Mr. von Oehsen:

Thank you for your letter of November 22, 2000, in which you recapitulated the Public Hospital Pharmacy Coalition's position in its ongoing dialogue with HRSA regarding the 340B definition of a disproportionate share hospital *patient*. Since 1998, the Coalition has engaged HRSA in a reevaluation of the two guidelines which, when read together, have constituted our definition of a covered entity hospital *patient*: 61 Fed. Reg. 55157, October 24, 1996 (defining the term *patient*) and 59 Fed. Reg. 47884, September 19, 1994 (340B criteria for off-site hospital clinics). After our meeting last Fall, and as a result of your advocacy, HRSA is thoroughly aware of, and sympathetic to, the challenges Coalition hospitals continue to confront while treating patients pursuant to the 340B guidelines.

You have urged that this interpretive definition—with its reliance on the Medicare Cost Report—is not responsive to recent market changes that reorganized the provision of nonprofit hospital services under the umbrella of larger health care systems. Despite our effort to accommodate this trend, it is apparent from our discussions that many integrated Coalition hospitals are providing health care services through facilities that do not report their treatment on the covered entity hospital's Medicare Cost Report. The Coalition's acknowledgment of its responsibility under §340B(a)(5)(B) to prevent the unlawful diversion of drugs is nonetheless well received. Our mission to develop the accessibility of the 340B program carries with it the responsibility to implement the related statutory directive to prevent drug diversion.

We expressed to your client, both during our recent and previous meetings, that HRSA remains committed to its policy of ensuring that the 340B Drug Pricing Program is accessible to all of its intended beneficiaries. Mr. Mitchell and the Office of Pharmacy Affairs lead the program in a perennial planning process to increase covered entity access through reasonable and equitable guidelines. Although our October 24, 1996, *Federal Register* notice defining eligible patients received favorable comment from the Coalition, Mr. Mitchell's September 15, 1998, letter (hereinafter "the 1998 letter") has led you to seek further clarification. On reexamination, we agree with the Coalition, that a point referenced in Mr. Mitchell's 1998 letter should be clarified. In order to demonstrate how we have reached this issue, I would like to proceed as you have and present our discussion in its broader policy context.

### *The Medicare Cost Report Test*

Although section 340B(a)(4)(L) lists some of the criteria for covered entity (CE) DSH eligibility, the definition does not include criteria to determine which off-site outpatient facilities are integral parts of the eligible hospital and thus eligible for the program. The movement of nonprofit hospitals in recent years to reorganize and offer a variety of services other than traditional hospital services through separate divisions, lines of business, or off-site facilities made it imperative that we develop a clear test to determine which of these sites could be considered an actual part of the hospital and thus eligible for the Program. In concert with the Health Care Financing Administration (HCFA), we developed an eligibility test utilizing the Medicare Cost Report standard (i.e., the outpatient facility is considered an integral part of the hospital and therefore eligible for 340B drug discounts if it is a reimbursable hospital-based facility on the hospital's Medicare cost report). For example, if a hospital with one Medicare provider number meets the disproportionate share criteria, other 340B requirements, and program guidelines, and this hospital has associated outpatient facilities whose costs are listed on the Medicare cost report, these services would be eligible for the program. Free-standing clinics that submit their own cost reports, not under the single hospital Medicare provider number, would not be eligible.

Since 1994, this standard has met with little criticism for several reasons.<sup>1/</sup> First, Congress, in section 340B(a)(4)(L), referred to section 1886 of the Social Security Act (SSA) for part of the definition of a *CE hospital*; therefore, it was reasonable to utilize existing Medicare rules to determine eligibility for certain hospital sites. The proposed Medicare cost report test was developed by Medicare officials and is used, in part, to determine whether a facility is an integral part of a hospital. The criteria of the test include common licensure; operation under hospital ownership and control; same level of accountability as other hospital departments; integrated clinical services; and financial integration. If activities of an off-site facility are not reported on the hospital Medicare cost report, it is properly viewed as an independent, free-standing facility.

Second, the relative administrative burden of the proposed Medicare Cost Report test (i.e., obtaining HCFA verification) has been minimal. Hospitals seeking Medicare reimbursement are required to submit annual cost reports including all hospital units (e.g., off-site clinics); therefore,

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<sup>1/</sup> In response to a *Federal Register* notice soliciting comments on the proposed Medicare Cost Report standard, the Public Hospital Coalition provided a letter commenting that the standard was fair and reasonable. However, the Coalition proposed to expand the standard to include nontraditional outpatient clinics (e.g., facilities that serve prison inmates, HMOs, home infusion, and home health patients). Our response was to defer to HCFA guidelines and permit any outpatient clinic of a covered entity DSH to participate in the Program as long as the clinic was included on the Medicare Cost Report. See 59 Fed. Reg. 47885.

the information necessary to determine facility eligibility is available and needs no further analysis. Third, the test incorporates criteria (i.e., the Medicare cost report) that form an independent and objective basis upon which to determine eligibility. This has provided fair and relatively simple administration.

### *The Definition of a "Covered Entity Patient"*

The Program eligibility requirements for *covered entities* are set forth in section 340B(a)(4) & (5). Hospitals become eligible through §340B(a)(4)(L), which includes facilities with a greater than 11.75% disproportionate share adjustment percentage, with certain State or local government connections, and having no participation in a group purchasing organization as provided by section 340B. However, due to a cross-reference to the SSA, this section excludes psychiatric, rehabilitation, pediatric and long term care facilities and also excludes facilities not located in the 50 States or the District of Columbia. §1886(d)(1)(B) of the SSA. A hospital's eligibility to participate in the Program includes not only the requirements in section 340B(a)(4)(L), but also 340B(a)(5). Section 340B(a)(5) enumerates the following Program requirements for covered entities: Covered entities must not (1) resell or otherwise transfer §340B drugs to individuals who are not its patients or (2) generate a Medicaid rebate on 340B discounted drug. A covered entity must, in addition, submit to agency and manufacturer audits enforcing prohibitions (1) and (2). An entity that is found to have engaged in the proscribed activity will no longer meet the definition of a *covered entity*.

Central to program integrity is the prohibition on the unauthorized transfer of 340B drugs, what is termed "drug diversion." Section 340B(a)(5)(B) reads as follows:

(B) PROHIBITING RESALE OF DRUGS.—With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

The duty to implement section 340B(a)(5)(B) confers upon the agency the authority to pursue comprehensive oversight of potential drug diversion. Under section 340(a)(5)(D), if the agency makes a finding that a covered entity (CE) has violated 340B(a)(5) provisions, the covered entity will be liable to the manufacturers for an amount equal to the total discount received.

A CE hospital is thus precluded from transferring drugs to persons who are not the actual patients of the covered entity—as defined by HRSA. Given the number and diversity of covered entities, the definition of a *patient* was drafted to assist covered entities in the task of identifying those individuals who could be considered the actual patients of the covered entity. The term *patient* was defined in a *Federal Register* notice, published on October 24, 1996. 61 Fed. Reg. 55157. This definition consists of several criteria, all of which must be satisfied before an eligible outpatient clinic or service of a CE hospital may dispense a covered drug to an individual:

1. The covered entity has established a relationship with the individual, such that the covered entity

- maintains records of the individual's health care; and
2. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and
  3. The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.

An individual will not be considered a "patient" of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

### *Program Clarification*

You urged in your letter of November 22, 2000, that we divorce the two *Federal Register* notices by applying the DSH definition's reliance on the Medicare cost report only to defining which entity may purchase section 340B drugs, while allowing the dispensing of such drugs to patients who are seen at outpatient clinics affiliated with, but not on the same cost report as, the DSH hospital. However, at our meeting, you clarified that you did not propose to do so in any across-the-board fashion. You have recognized the issue of drug diversion as guiding our policy-making in this area and have admitted that patients at the non-cost report clinic would not all be viewed as patients of the CE DSH. At the same time, we agreed to consider whether there are situations in which patients seen at the non-cost report clinic could nonetheless be viewed as appropriate patients of the DSH. It is in concluding that this last question may be answered affirmatively that we recognize the need to clarify the letter of September 15, 1998.

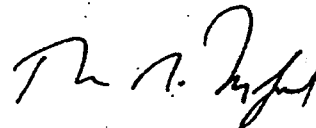
In our view, an appropriate interpretation of the *Federal Register* patient definition places emphasis on the nature of an individual's medical relationship, or medical contact, with the eligible CE hospital. The primacy of the patient's medical relationship is apparent in the *Federal Register* definition, which focuses on the affiliation of the provider with the CE and the maintenance of records by the CE. The September, 15, 1998, letter assumed that the dispensing pharmacy was located in the same clinic which provides the physicians' services not included in the hospital's Medicare cost report. If the dispensing pharmacy is included on the Medicare cost report but the physicians' services are not, there are circumstances where it would be permissible for the pharmacy to dispense drugs purchased at the 340B discount. HRSA would not object to program participation where a patient initiates his or her care at an eligible CE hospital and pursues additional care through its non-cost report clinics, so long as the continuing non-cost report care bears a proximate relationship to the care that was initially cost reported at the CE hospital and the patient fills his or her prescription at the CE's Medicare cost report pharmacy.

A patient's subsequent, non-cost report care should bear a proximate relationship to the initial CE hospital care with respect to both type and time of care. Assuming all the *Federal Register patient* criteria are met, a CE hospital pharmacy on the hospital's Medicare cost report may dispense 340B drugs, for example, to a diabetic who seeks CE hospital emergency room care for a diabetes crisis, and then receives a prescription as a result of follow-up diabetes care from a non-cost report clinic. If the same individual returned to the clinic 2 years later with an unrelated complaint, for example, HRSA would view the medical relationship as sufficiently attenuated to not classify the individual as a 340B *patient*.

Let me add a word of clarification, based on our discussions. You have indicated that the DSHs you represent are capable of implementing such a clarified policy. You have stated that they have sufficiently sophisticated accounting systems as to distinguish between the diabetic patient described above and other patients of the same physician, seen at the same non-cost report clinic, who do not have a relationship with the DSH that would justify providing them section 340B drugs. Further, we trust that these accounting systems can distinguish between the type of care for which there is an adequate nexus between the initial care that is recognized on a cost report-based facility and other care for which such nexus does not exist.

We certainly hope that this clarification of policy regarding CE hospital patient eligibility will assist you in advising the Coalition on appropriate procedures for complying with 340B Drug Discount Program guidelines.

Sincerely,



Thomas G. Morford  
Deputy Administrator

cc: Dave Benor  
James Corrigan  
Jimmy Mitchell

emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 C.F.R., Part 1320. Medicare must comply with all provisions of the group health plans including a plan of "timely filing requirements." The Agency cannot reasonably comply with the normal clearance procedures because public harm is likely to result if normal clearance procedures are followed. Any additional delay in this approval will result in a loss of \$904 million to the trust fund.

HCFA is requesting that OMB provide a two-day review and a 90-day approval. During this 90-day period HCFA will publish a separate Federal Register notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. Then HCFA will submit the requirements for OMB review and an extension of this emergency approval.

**Type of Information Collection Request:** Reinstatement, with change, of a previously approved collection for which approval has expired; **Title of Information Collection:** Internal Revenue Service/Social Security Administration/Health Care Financing Administration Data Match 42 CFR 411; **Form No.:** HCFA-R-137; **Use:** Employers who are identified through a match of IRS, SSA, and Medicare records will be contacted concerning group health plan coverage of identified individuals to ensure compliance with Medicare Secondary Payer provisions found at 42 U.S.C. 1395y(b). **Frequency:** Semi-annually; **Affected Public:** Individuals or Households, Business or other for profit, Not for profit institutions, Farms, Federal Government and State, Local or Tribal Government; **Number of Respondents:** 596,241; **Total Annual Responses:** 596,241; **Total Annual Hours Requested:** 2,325,449.

To request copies of the proposed paperwork collections referenced above, call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections should be sent within 2 working days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: October 17, 1996.

Edwin J. Glatzel,  
*Director, Management Analysis and Planning Staff, Office of Financial and Human Resources, Health Care Financing Administration.*

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BILLING CODE 4120-03-P

#### Health Resources and Services Administration

[0905-ZA92]

#### Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final Notice.

**SUMMARY:** Section 602 of Public Law 102-585, the "Veterans Health Care Act of 1992," enacted section 340B of the Public Health Service Act ("PHS Act"), "Limitation on Prices of Drugs Purchased by Covered Entities." Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula.

The purpose of this notice is to inform interested parties of final guidelines regarding a definition of covered entity "patient."

**FOR FURTHER INFORMATION CONTACT:** Annette Byrne, R.Ph., Attn: Drug Pricing Program, Bureau of Primary Health Care, 4350 East-West Highway, 10th Floor, Bethesda, MD 20814, Phone (301) 594-4353.

**EFFECTIVE DATE:** October 24, 1996.

#### SUPPLEMENTARY INFORMATION:

##### (A) Background

Proposed guidelines were announced in the Federal Register at 60 FR 39762 on August 3, 1995. A period of 30 days was established to allow interested parties to submit comments. The Department received 15 letters including comments concerning legal authority for developing the proposed guidelines and a need for a more specific definition. Comments were received on issues not within the scope of the definition of covered entity "patient" and were not addressed.

The following section presents a summary of all major comments relevant to the definition of "patient" and a response to each comment. The guidelines are adopted as proposed.

#### (B) Comments and Responses

**Comment:** The Federal Register notice was not promulgated in accordance with the Administrative Procedure Act (APA) and contains procedural irregularities. The Department has issued eight Federal Register notices containing drug pricing program guidelines and has not proposed a single regulation pursuant to APA requirements. Because of this, the program guidelines are invalid.

**Response:** During the early months following enactment, it became clear that there were many gaps in the legislation and some form of program structure was necessary to move the program forward. There were approximately 11,500 eligible entities, 500 participating manufacturers, numerous wholesalers and many Federal programs affected by this legislation and all seeking guidance. It was incumbent upon the Department, acting through the Health and Resources and Services Administration, Bureau of Primary Health Care, Office of Drug Pricing (ODP), to implement this difficult congressional mandate in an expeditious manner.

Interpretive rules and statements of policy were developed to provide necessary program guidance. The Department has published these guidelines in the Federal Register, used a Federal review process (including review by the Office of Management and Budget) and provided a public comment period to obtain both Federal as well as public input into guideline development. The Department considered all comments in developing these final guidelines.

The guidelines explain how the Department intends to administer the 340B program, further explain the statutory language by clarifying the meaning given by the Department to particular words or phrases, and do not exceed the purpose of 340B or conflict with any of its provisions. We believe that these guidelines create no new law and create no new rights or duties; therefore, they are not subject to the Administrative Procedure Act's requirement of notice and comment. Nevertheless, the Department chose to solicit and respond to public comment.

**Comment:** The Federal Register notice has not complied with the 60 day comment period required by the Social Security Act, 42 U.S.C. 1395hh(b).

**Response:** Section 340B is part of the Public Health Service Act, and its implementation is not subject to the provisions of the Social Security Act.

**Comment:** The definition of a "patient" is ambiguous and difficult to

administer from a drug diversion standpoint.

*Response:* The definition of a "patient" was developed in order to identify those individuals eligible to receive 340B drugs from covered entities. Because of the large number of covered entities and the wide diversity of eligible groups (e.g., hemophilia, HIV, black lung, migrant health, and family planning services), it was essential that we work closely with each Federal program office to develop a definition flexible enough to describe accurately each covered entity's patient while at the same time not excluding eligible patients. In addition, not only comments received in response to this notice but also comments from prior Federal Register notices (59 FR 25111, May 13, 1994, and 59 FR 47886, September 19, 1994) were incorporated into the definition. By using such input, we are confident that the definition will assist covered entities and manufacturers in determining which individuals are eligible to receive 340B drugs.

*Comment:* Covered entities should be required to restrict purchases to drug products that are directly related to the provision of services for which Federal funding has been provided.

*Response:* We do not consider a limitation on which drug products a covered entity may purchase to be a reasonable component of the definition of covered entity "patient." To the extent that purchasing certain drugs would contravene a Federal or State law or certain PHS grant principles (and this information is brought to the Department's attention), the Department reserves the right to take such action as it deems appropriate.

*Comment:* The definition of a "patient" establishes a requirement that a State must register eligible individuals who may then receive services for which funding has been provided under Title II of the Ryan White Act of 1990.

*Response:* The proposed patient definition does not impose a new requirement that States register individuals as eligible for benefits under the Ryan White Act. Instead, the definition reflects the States' current practice of recording and verifying patient eligibility through a registration mechanism. An individual listed in a State Ryan White Title II drug assistance program will, for purposes of the patient definition, be considered a patient of the entity.

*Comment:* The definition would permit a patient to obtain one medical treatment from a covered entity at any time in his or her lifetime and then continue (forever) to purchase drugs

through prescription refills by using such services as mail order. The proposed patient definition should require that a covered entity patient be currently receiving care, and an additional section should be added to address the frequency of medical care.

*Response:* All covered entities must establish a relationship with their patients such that the entity will maintain records of the individuals' health care. The entity will document in the record the care provided and, when appropriate, the prescriptions written. It would be inappropriate for the Department to proceed further and dictate to health care providers guidelines regarding the appropriateness of certain prescriptions. We understand that States typically regulate the refilling of prescriptions.

*Comment:* Employees of covered entities should be either specifically precluded or included as eligible patients to receive discounted drug products.

*Response:* Any employee of a covered entity who meets the criteria of the definition of covered entity "patient" would be eligible to access 340B pricing.

*Comment:* Private patients of a physician who is under a contract to provide services to a covered entity should be considered patients of the entity.

*Response:* Entity health record documentation (section one of the patient definition) and responsibility for care provided (section two of the patient definition) must remain with the covered entity. A physician, under contract with a covered entity, may see an individual and provide care for a medical indication. However, if care is provided outside of the contractual arrangement with the covered entity, the individual would not be considered a patient of the entity.

*Comment:* The pharmacy of a covered entity should be required to have access to the records of the individual's health care maintained by the entity.

*Response:* This type of requirement deals with the professional practice of pharmacy and not with the issue of identification and clarification of who is or is not a patient.

*Comment:* The phrase in section one of the patient definition is not clear as to if "records of the individual's health care" is equivalent to the term "medical record(s)."

*Response:* The phrase "records of the individual's health care" was specifically used to avoid the term "medical record," as the latter term may have different meanings in various locations. In addition, some covered

entities may not, at the present time, use health records that comply with certain legal definitions of the term "medical record." The wording permits the use of health care documentation presently contained in a "medical record," if such is the current health record system maintained by an entity.

*Comment:* The requirement in section one of the patient definition that "the covered entity maintain records of the individual's health care" could establish a requirement that such health records be centralized at one location.

*Response:* The requirement that covered entities maintain the records of an individual's health care does not establish a requirement that such health records be centralized in one location.

*Comment:* The exclusion of individuals who receive no health care services from the covered entity other than the dispensing of a drug for subsequent self-administration or administration at home may exclude otherwise legitimate patients from receiving "refills" of prescribed medications previously authorized by the covered entity's health care provider.

*Response:* A "refill" of a medication previously prescribed by an authorized entity health care provider, as part of the health care services provided by the covered entity, would meet the requirements of the patient definition. The "refill" would be a continuation of responsibility for the health care services provided by the covered entity. The covered entity would document the initial prescription for treatment in the record of health care, and the "refill" would be part of the range of health care services provided.

#### (C) Definition of a Patient

An individual is a "patient" of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) only if:

1. the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and

2. the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and

3. the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status

has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.

An individual will not be considered a "patient" of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

An individual registered in a State operated or funded AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the PHS Act will be considered a "patient" of the covered entity for purposes of this definition if so registered as eligible by the State program.

Dated: October 21, 1996.

Ciro V. Sumaya,  
Administrator, Health Resources and Services Administration.

[FR Doc. 96-27344 Filed 10-23-96; 8:45 am]

BILLING CODE 4160-15-P

**National Institutes of Health**

**National Heart, Lung, and Blood Institute; Proposed Collection; Comment Request—National Donor Research and Education Study-II**

**SUMMARY:** 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 National Heart, Lung and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of

Management and Budget (OMB) for review and approval.

**PROPOSED COLLECTION:** *Title:* National Donor Research and Education Study-II. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* This study is the second stage anonymous mail survey to be sent to a random sample of blood donors at five blood centers participating in the Retrovirus Epidemiology Donor Study (REDS). In addition to monitoring the safety of the U.S. blood supply, study results will facilitate the development, evaluation and refinement of educational, recruitment and qualification strategies for U.S. blood donors. The proposed new study will update and extend the unique findings obtained in the first blood donor survey so as to minimize the likelihood that donors with risk factors for transfusion-transmitted diseases will participate in the blood donor pool. There is a strong likelihood that, like the first survey effort, the resulting findings will be directly applied to blood banking operational practice. Specific objectives of this survey are to: (1) Evaluate donor understanding and acceptance, and the safety impact of newly-changed laboratory and donor screening procedures that have been implemented since the previous donor survey study (e.g. removal of the confidential unit exclusion "CUE" process at two REDS sites; additional questions about Creutzfeldt-Jacob and parasitic diseases; addition of HIV p24 antigen testing; increased use of donation incentives); (2) Pilot test new donor screening procedures that are anticipated to occur within the next 12-24 months in order to estimate their efficacy, safety impact and donor acceptance (e.g. improved CUE procedures, implementation of

computer-assisted donor screening); (3) Provide "pre-" (baseline) and "post-" (evaluation) measures for new donor qualification procedures expected to occur operationally at blood centers within the time period of study including: deferral for intranasal cocaine use in the past year; modification of the time period for sexual risk deferrals from "since 1977" to within the past 12 (or 24) months; clarification of wording regarding sexual contact with "at-risk" individuals; and addition of questions about donating primarily for the purpose of receiving the tests results for the AIDS virus; (4) Assess changes in the prevalence and characteristics of donors who report donating for therapeutic reasons (e.g., those with iron storage disease), and donors who report donating primarily to receive test results for the AIDS virus as a result of the March 1996 implementation of HIV p24 antigen testing; (5) Determine the extent to which active donors with reactive tests for anti-HBc and syphilis have increased levels of behavioral risks that should have resulted in deferral; (6) Measure the extent to which seropositivity for current syphilis screening tests predicts a recent history of diagnosed syphilis; (7) Measure blood donor knowledge of infectious disease risks and the behavioral factors that should defer them from donating, to identify weaknesses in the current donor educational process; and (8) Assess the attitudes of donors regarding establishment of stored frozen repositories from their donations, use of these samples for future research testing designed to improve transfusion safety, and the adequacy of different levels of informed consent. *Frequency of Response:* One-time data collection. *Affected Public:* Individuals.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per responses	Estimated total annual burden hours requested
Blood donors .....	38,500	1	.3333	12,832

The annualized cost to respondents is estimated at: \$128,320 (based on \$10 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

**REQUEST FOR COMMENTS:** Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the

agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of

appropriate automated, electronic, mechanical or other technical collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. George J. Nemo, Group Leader, Transfusion Medicine, Scientific Research Group, Division of Blood Diseases and Resources, NHLBI,