

Tab 1-10

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,