deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of the meeting(s) shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (a)(2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: October 18, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–27278 Filed 10–23–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[Document Identifier: HCFA–1500]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summaries 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 functions; (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:* Reinstatement, with change, of previously approved collection for which approval has expired; *Title of Information Collection:* Medicare/Medicaid Health Insurance Common Claim Form and Instructions, and Supporting Regulations 42 CFR 424.32 (Basic Requirements for all Claims) and 42 CFR 414.40 (Coding and Ancillary Policies); *Form No.:* HCFA–1500; *Use:* This form and instructions are standardized for use in the Medicare/Medicaid programs to apply for reimbursement for covered services. HCFA does not require exclusive use of this form for Medicaid. 42 CFR 424.32 and 42 CFR 414.40 are regulations underlying the use of the form HCFA–1500 and the information captured on the form HCFA–1500, including the use of diagnostic and procedural coding systems. HCFA solicits comments on any and all aspects of the HCFA–1500, and the use of diagnostic and procedural coding systems: HCFA currently uses the most current version of the ICD–9–CM and CPT/HCPCS; *Frequency:* On occasion; *Affected Public:* Business or other for profit, not for profit institutions, State, local or tribal government; *Number of Respondents:* 976,239; *Total Annual Responses:* 644,802,413; *Total Annual Hours:* 46,797,008.

To obtain copies of the supporting statement and any related forms and instructions for the proposed paperwork collection referenced above, E-mail your request, including your address and phone number, to JBurke1@hcfa.gov, or call the Reports Clearance Office on (410) 786–1325. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Analysis and Planning Staff, Attention: John Burke, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: October 15, 1996.

Edwin J. Glatzel,

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

[FR Doc. 96–27292 Filed 10–23–96; 8:45 am]

BILLING CODE 4120–03–P

[HCFA–R–137]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services (DHHS), has submitted to the Office of Management and Budget (OMB) the following request for Emergency review. We are requesting an

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.

[FR Doc. 96–27262 Filed 10–23–96; 8:45 am]

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 of 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