European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the: European Commission; European Medicines Evaluation Agency; European Federation of Animal Health; Committee on Veterinary Medicinal Products; U.S. FDA; U.S. Department of Agriculture; Animal Health Institute; Japanese Veterinary Pharmaceutical Association; Japanese Association of Veterinary Biologics; and Japanese Ministry of Agriculture, Forestry, and Fisheries.

Two observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/New Zealand and one representative from the industry in Australia/New Zealand. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confederation Mondiale de L'Industrie de la Sante Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

The VICH Steering Committee held a meeting on November 16 through 19, 1999, and agreed that the three draft guidances entitled ''Effectiveness of Anthelmintics: Specific Recommendations for Equine'' (VICH GL15), ''Effectiveness of Anthelmintics: Specific Recommendations for Porcine'' (VICH GL16), and ''Effectiveness of Anthelmintics: Specific Recommendations for Canine'' (VICH GL19) should be made available for public comment.

The three draft guidances: VICH GL15, VICH GL16, and VICH GL19, should be read in conjunction with the ''Efficacy of Anthelmintics: General Recommendations (EAGR)'' announced in the **Federal Register** of July 16, 1999 (64 FR 38445). The draft guidances for equine, porcine, and canine are part of the EAGR, and the aim of these three draft guidances is to: (1) Be more specific for certain issues not discussed in the general guidance, (2) highlight differences with the EAGR on effectiveness data recommendations, and (3) give explanations for disparities with the EAGR. Comments about the draft guidances will be considered by the FDA and the VICH Anthelmintic Working Group. Ultimately, FDA intends to adopt the VICH Steering Committee's final guidances and publish them as future guidances.

These draft guidances, developed under the VICH process, have been revised to conform to FDA's good guidance practices (65 FR 56468, September 19, 2000). For example, the documents have been designated ''guidance'' rather than ''guideline.'' Because guidance documents are not binding, unless specifically supported by statute or regulation, mandatory words such as ''must,'' ''shall,'' and ''will'' in the original VICH documents have been substituted with ''should.'' Similarly, words such as ''requirement'' or ''acceptable'' have been replaced by ''recommendation'' or ''recommended'' as appropriate to the context.

These draft guidances represent current FDA thinking on effectiveness recommendations for certain veterinary anthelmintic medicinal products. These draft guidances do not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternate method may be used as long as it satisfies the requirements of applicable statutes and regulations.

II. Comments

These draft guidances are being distributed for comment purposes only, and they are not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the draft guidance documents by December 18, 2000. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidances and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 6, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–26897 Filed 10–18–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–250 through HCFA–254]

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

AGENCY: Health Care Financing Administration, DHHS.

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 summary 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.

We are, however, requesting an emergency review of the information collections referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR, Part 1320. A disruption in this collection activity may cause public harm. This is due to the potential and unnecessary loss to the Medicare Trust Fund as the result of the non-identification of health insurance coverage that is primary to Medicare. Collection of this information allows HCFA to identify those Medicare beneficiaries who have other group health insurance that would pay before Medicare, resulting in savings to the Medicare Trust Fund. The annual savings from the Medicare Secondary Payer (MSP) program are more than $3 billion per year.

Emergency Clearance

HCFA is requesting OMB review and approval of this collection by November 24, 2000, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by November 23, 2000. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Request: Revision of a currently approved collection; *Title of Information Collection:* Medicare Secondary Payer Information Collection

and Supporting Regulations in 42 CFR 411.25, 489.2, and 489.20; *Form Number:* HCFA–250 through HCFA–254 (OMB approval #: 0938–0214); *Use:* Medicare Secondary Payer (MSP) refers to those situations where Medicare does not have primary responsibility for paying the medical expenses of a Medicare beneficiary. Medicare intermediaries and carriers must collect information to perform various tasks to detect MSP cases, develop and disseminate tools to enable them to better perform their tasks, and monitor their performance in achievement of their assigned MSP functions. These information collection requirements describe the MSP requirements and consist of the following:

1. Initial enrollment questionnaire
2. MSP claims investigation, which consists of first claim development, trauma code development, self-reporting MSP liability development, notice to responsible third party development (411.25 notice), secondary claims development, and ''08'' development (involving claims where information cannot be obtained from the beneficiary)
3. Provider MSP development, which requires the provider to request information from the beneficiary or representative during admission and other encounters; *Frequency:* On occasion; *Affected Public:* Individuals or households, Business or other for-profit, and Not-for-profit institutions; *Number of Respondents:* 14,204,000; *Total Annual Responses:* 116,394,528; *Total Annual Hours Requested:* 3,305,814.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326.

Public Meeting

HCFA will be holding a public meeting to permit interested parties an opportunity to give their views on how the content and use of the MSP collection requirements may need to be revised. Representatives of the hospital industry, health care consumer advocacy groups, and provider groups who wish to participate in the public meeting are asked to notify the Agency in advance of their interest in attending. At this meeting, the Health Care Financing Administration will solicit comments on the topics listed in the first paragraph of this notice and as referenced in the supporting statement, which may be obtained as described above.

The public meeting will be held on Friday, November 3, 2000, from 1:00–4:00 p.m., in the Multipurpose Room (Capacity: 100 persons) of the Health Care Financing Administration, 7500 Security Boulevard, Baltimore, Maryland 21244. Interested parties should provide notification of their planned attendance to Tom Bouchat or Joan Fowler, either via telephone (410) 786–4621 or (410) 786–0922, fax (410) 786–9963, or e-mail: Tbouchat@hcfa.gov or Jfowler@hcfa.gov by no later than 3 p.m., Monday, October 30, 2000.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection requirements must be mailed and/or faxed to the designees referenced below by November 23, 2000:

Health Care Financing Administration, Office of Information Services, Division of HCFA Enterprise Standards, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850, Fax Number: (410) 786–0262, Attn: Julie Brown HCFA–250 through HCFA–254 and,

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Fax Number: (202) 395–6974 or (202) 395–5167, Attn: Wendy Taylor, HCFA Desk Officer.

Dated: October 17, 2000.

John P. Burke, III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

[FR Doc. 00–27028 Filed 10–17–00; 3:06 pm]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–8007–N]

RIN 0938–AK27

Medicare Program; Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for 2001

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year 2001 under Medicare's hospital insurance program (Medicare Part A). The Medicare statute specifies the formulae used to determine these amounts.

The inpatient hospital deductible will be $792. The daily coinsurance amounts will be: (a) $198 for the 61st through 90th day of hospitalization in a benefit period; (b) $396 for lifetime reserve days; and (c) $99 for the 21st through 100th day of extended care services in a skilled nursing facility in a benefit period.

EFFECTIVE DATE: This notice is effective on January 1, 2001.

FOR FURTHER INFORMATION CONTACT: Clare McFarland, (410) 786–6390. For case-mix analysis only: Gregory J. Savord, (410) 786–1521.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1813 of the Social Security Act (the Act) provides for an inpatient hospital deductible to be subtracted from the amount payable by Medicare for inpatient hospital services furnished to a beneficiary. It also provides for certain coinsurance amounts to be subtracted from the amounts payable by Medicare for inpatient hospital and extended care services. Section 1813(b)(2) of the Act requires us to determine and publish, between September 1 and September 15 of each year, the amount of the inpatient hospital deductible and the hospital and extended care services coinsurance amounts applicable for services furnished in the following calendar year.

II. Computing the Inpatient Hospital Deductible for 2001

Section 1813(b) of the Act prescribes the method for computing the amount of the inpatient hospital deductible. The inpatient hospital deductible is an amount equal to the inpatient hospital deductible for the preceding calendar year, changed by our best estimate of the payment-weighted average of the applicable percentage increases (as defined in section 1886(b)(3)(B) of the Act) used for updating the payment rates to hospitals for discharges in the fiscal year that begins on October 1 of the same preceding calendar year, and adjusted to reflect real case mix. The adjustment to reflect real case mix is determined on the basis of the most recent case mix data available. The amount determined under this formula is rounded to the nearest multiple of $4