

interim policy, sponsors of such approved drugs may have delayed submission of their requests for designation. Further, FDA is delaying the effective date because of the changes in the orphan drug provisions of the act resulting from the Orphan Drug Amendments of 1985 that were enacted and made effective on August 15, 1985. Before enactment of those amendments, only drugs for which a U.S. letter of patent could not be issued were eligible for marketing exclusivity of orphan drugs. Effective on August 15, 1985, both patented and unpatented drugs are eligible for the resulting 7 years of marketing exclusivity provided to the first designated orphan drug approved for the rare disease or condition. FDA's 90-day delayed effective date will allow sponsors who may not know about the eligibility for marketing exclusivity of their patented approved drugs to request designation and obtain the 7-year marketing exclusivity intended by Congress when it enacted the Orphan Drug Amendments of 1985.

Accordingly, FDA is delaying the effective date of its termination of its interim policy. After May 6, 1986, FDA no longer will accept for review and processing a sponsor's request that a drug approved for an orphan indication be designated as an orphan drug for the same indication. Requests for orphan drug designation will continue to be accepted for drugs previously approved for other uses.

Comments and recommendations received by FDA regarding this notice will be considered by the agency during preparation of its proposed rule implementing the orphan drug provisions of the act. FDA intends to incorporate its continuing policy regarding eligibility of products for orphan designation in that proposed rule that will be subject to notice and comment rulemaking.

Interested person may, on or before March 24, 1986, submit to the Dockets Management Branch (address above) written comments regarding the interim policy change. 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. Received comments are available for public inspection in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 2, 1986.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 86-2408 Filed 2-4-86; 8:45 am]

BILLING CODE 4199-01-20

## DEPARTMENT OF THE INTERIOR

### Minerals Management Service

#### 30 CFR Parts 202, 203, 206, and 212

#### Product Valuation for Royalty Purposes

**AGENCY:** Minerals Management Service (MMS), Interior.

**ACTION:** Advance notice of proposed rulemaking.

**SUMMARY:** The Minerals Management Service (MMS) hereby gives notice that it is making available for public comment drafts of proposed methods of valuing, for royalty purposes, coal, oil, and gas and associated products from Federal and Indian leases. MMS is making these drafts available to obtain initial public comment on specific proposed methods before it formally issues proposed regulations.

**DATES:** Comments must be received on or before April 7, 1986. A public meeting will be held on March 18 and 19, 1986, at 8:30 a.m. to 4:00 p.m.

**ADDRESSES:** Comments should be mailed to Minerals Management Service, Royalty Management Program, Office of External Affairs, Denver Federal Center, Building 85, P.O. Box 25165, Mail Stop 660, Denver, Colorado 80225, Attention: Vernon B. Ingraham. Copies of the draft regulations may be obtained from the above address. The public meeting will be held at the Denver Federal Center, Building 25, Room 1254, Lakewood, Colorado 80225.

**FOR FURTHER INFORMATION CONTACT:** Vernon B. Ingraham, telephone: (303) 231-3360, (FTS) 326-3360.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Regulations governing the valuation for royalty purposes of coal, oil, and gas and associated products from Federal and Indian leases are codified in various sections of Title 30 and 43 of the Code of Federal Regulations. In addition, other regulatory and related provisions are included in various Notices to Lessees and orders.

For the past several months, MMS has been reviewing the existing regulatory scheme for royalty valuation and developing proposals for new methods for valuation which would simplify, clarify, and consolidate the existing provisions. In furtherance of the effort to develop comprehensive and workable product value regulations, the Secretary of the Interior recently Royalty Management Advisory Committee comprised of 31 representatives from industry, the states and Indian Tribes,

which will have as one of its first tasks to advise the Secretary on the new product value regulations. The Advisory Committee held its first meeting in Lakewood, Colorado on January 9 and 10, 1986.

##### II. Draft Regulations

As a result of its extensive review and consideration of royalty valuation issues, MMS has developed draft regulations for product valuation. There are five separate draft regulations: coal, oil, gas and associated products, gas processing allowances, and transportation allowances. Each draft is in the form of a notice of proposed rulemaking, including proposed regulatory language and a preamble.

Because the issues related to product valuation are so complex, and because MMS expects extensive public comment, it has decided to make drafts of the proposed regulations available for public review and comment before issuing formal Notices of Proposed Rulemaking. The existing draft regulations reflect MMS current proposals for addressing product valuation but we expect that changes will be made as a result of comments before proposed rules are issued.

Commenters are specifically requested to provide alternative suggestions to those specified in the draft rules. In addition, a public meeting will be held for the purpose of receiving comments at the time and location stated in the DATES and ADDRESSES sections. All written comments, plus comments received at the public meeting, will be made available to the Royalty Management Advisory Committee for its consideration in providing advice to the Secretary of the Interior on product valuation.

Although each of the five drafts is in the form of a proposed rule, MMS is not considering them as proposed rules at this time and the proposed rules will be published in the Federal Register for public comment before final rules are issued.

##### III. Availability of Draft Regulations

At this time, only four of the five draft regulatory packages are being made available for comment: coal, oil, gas processing allowances and transportation allowances. The draft rule for gas and associated products will be available in a few weeks and MMS will send copies to those requesting them at that time. Interested persons may obtain a copy of the draft regulations upon request from the MMS at the address above in ADDRESSES.

The format of the public meeting will be the same as that specified in the preamble sections of the draft regulations.

Dated: January 30, 1986.

William D. Bettenberg,

Director, Minerals Management Service.

[FR Doc. 86-2526 Filed 2-4-86; 8:45 am]

BILLING CODE 4310-38R

## DEPARTMENT OF THE TREASURY

### Fiscal Service

#### 31 CFR Part 210

#### Federal Payments Made Through Financial Institutions by the Automated Clearing House Method

[Editorial Note: The following document was originally published at page 2899 in the issue of Wednesday, January 22, 1986. The document is being republished in its entirety because of typesetting errors.]

**AGENCY:** Financial Management Service, Fiscal Service, Treasury.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This amendment revises 31 CFR Part 210, which defines the responsibilities and liabilities of the Federal Government, Federal Reserve Banks, financial institutions, and recipients participating in the Automated Clearing House (ACH) payment system. There are three reasons for the proposed revision. First, changes regarding enrollment are necessary in order to allow Treasury to devise, test, and implement creative and innovative means of enrollment while improving the Direct Deposit/Electronic Funds Transfer (DD/EFT) system's flexibility. Second, the problem of fraud in the Direct Deposit Program needs to be addressed. Finally, it was felt that overall clarity and arrangement of the regulations could be improved. The proposed revision will address these needs.

**DATE:** Comments on this proposed rule must be received by February 21, 1986.

**ADDRESS:** Comments may be mailed to the ACH Programs Branch, Financial Management Service, U.S. Department of Treasury, Room 226, Treasury Annex No. 1, Washington, DC 20226.

**FOR FURTHER INFORMATION CONTACT:** Christine Ricci, (202) 535-6328 or Maurice Galloway, (202) 535-6323.

**SUPPLEMENTARY INFORMATION:** Part 210 of Title 31 of the Code of Federal Regulations sets forth the rights and liabilities of the Government, Federal Reserve Banks, financial institutions and recipients where a recipient of

Federal recurring payments authorizes Direct Deposit of recurring payments made by means other than by check. The regulations in this Part were promulgated in 1975, with amendments in 1976, 1984, and 1985. Since that time, it has become apparent that the regulations need clarification and improvement in a number of respects. Notably, this notice proposes to expand the coverage of the regulations to include changes designed to meet increased utilization of the Automated Clearing House (ACH) method for Federal payments.

Changes have been proposed to the current regulations to make them more clear and understandable, as well as to make them more flexible so as to allow for future innovations in technology and payment methods. Thus, the phrase in the title of Part 210 referring to payment "by means other than by check" has been changed to payments "by the Automated Clearing House method." While the ACH method is presently used only for recurring payments, the word "recurring" has been eliminated in order to allow for the use of this method in the future for non-recurring payments, as well. Present §§ 210.1-210.8 plus § 210.13, which are applicable to both benefit and nonbenefit payments, have been grouped together as Subpart A. They have also been rearranged and renumbered. Minor changes have been made to present §§ 210.9-210.12, which relate only to benefit payments, and they have been renumbered and labeled Subpart B.

There are a number of new definitions found in these proposed regulations. "Automated Clearing House" refers to a computerized clearing system that effects the paperless exchange of funds. "Benefit payment" is a payment of money for any Federal Government entitlement program or annuity, either one-time or recurring. "Enrollment" means any method approved and prescribed by Treasury's Financial Management Service for authorizing or conveying instructions for the use of the ACH payment method. This term replaces "Standard Authorization Form" in the present regulations. New definitions are also provided for "Federal Reserve Bank," and "financial institution." Definitions of "Government" and "recurring payment" have been eliminated.

The present term "credit payment" is replaced in these proposed rules by two terms: "payment" and "payment instruction." The phrase "credit payment" is not only unclear, but is used in two different senses in the present regulations. The Service believes that this creates needless

confusion in interpreting the present regulations. Accordingly, the term "credit payment" is replaced through these proposed rules by either "payment" or "payment instruction," as the context dictates. "Payment" is used in its most commonly accepted sense to mean the transfer of a sum of money, while "payment instruction" means an order for the payment of money, including the information necessary to make the indicated payment.

The section on recipients reflects proposed changes which are designed to improve the system's flexibility as well as simplify the enrollment process for recipients of Federal payments.

Present § 210.5 on program agencies has been eliminated as unnecessary, while a new section 210.3 has been added to state the policy for making payments by the ACH method. The authority citation has also been updated.

A new section 210.10 on fraud has been added. Paragraph (a) references the liabilities which are imposed by the False Claims Act, 31 U.S.C. 3729 *et. seq.*, for the submission of false claims or falsified documents in support of such claims, and also references applicable criminal statutes and common law remedies. This section is intended to apply to falsified enrollments, as well as to such activities as the initiation of an improper ACH payment by an employee of the Federal Government, or the diversion of a properly authorized payment by employees of the Federal Government, Federal Reserve Banks, or financial institutions to their own bank account or the account of another. Present § 210.9(g) has been added to this section and designated paragraph (b).

Numerous small, non-substantive changes in wording have been made throughout these proposed regulations in order to achieve greater clarity and precision.

The changes and new procedures will be published as amendments to the Financial Management Service's Green Book on Direct Deposit.

This proposed revision is not a major rule as defined by Executive Order 12291. Accordingly, a regulatory impact analysis is not required. It is hereby certified pursuant to the Regulatory Flexibility Act that the proposed revision will not have a significant economic impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required.

#### List of Subjects in 31 CFR Part 210

Banks, banking, Electronic funds transfer, Federal Reserve System.