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[FR Doc. E6-9950 Filed 6-22-06; 8:45 am]

BILLING CODE 6560-50-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services****42 CFR Part 423****[CMS-0018-IFC]****RIN 0938-A042****Medicare Program; Identification of Backward Compatible Version of Adopted Standard for E-Prescribing and the Medicare Prescription Drug Program (Version 8.1)****AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Interim final rule with comment period.

**SUMMARY:** This interim final rule with comment period identifies the Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8.1 (hereafter referred to as "Version 8.1 of the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard") as a backward compatible update of the adopted Version 5.0. This interim final rule with comment period also permits the voluntary use of Version 8.1 of the NCPDP SCRIPT Standard for conducting certain e-prescribing transactions for the electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

**DATES:** *Effective date:* These regulations are effective on June 23, 2006. The incorporation by reference of the publication listed in these regulations is approved by the Director of the Federal Register as of June 23, 2006.

*Comment date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 22, 2006.

**ADDRESSES:** In commenting, please refer to file code CMS-0018-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.cms.hhs.gov/eRulemaking>. Click on the link "Submit electronic comments on CMS regulations with an

open comment period." (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-0018-IFC, P.O. Box 8015, Baltimore, MD 21244-8015.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-0018-IFC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members. Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244-1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Gladys Wheeler, (410) 786-0273. [Gladys.Wheeler@cms.hhs.gov](mailto:Gladys.Wheeler@cms.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

*Submitting Comments:* We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS-0018-IFC and the specific "issue identifier" that

precedes the section on which you choose to comment.

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.cms.hhs.gov/eRulemaking>. Click on the link "Electronic Comments on CMS Regulations" on that Web site to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

**I. Background**

[If you choose to comment on issues in this section, please include the caption "BACKGROUND" at the beginning of your comments.]

**A. Statutory Basis**

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) amended title XVIII of the Social Security Act (the Act) to establish the Voluntary Prescription Drug Benefit Program. Included in the provisions at section 1860D-4(e) of the Act is the requirement that any prescriptions for covered program (Part D) drugs prescribed for Part D eligible individuals that are transmitted electronically, comply with final standards adopted by the Secretary under an electronic prescription drug program.

The Medicare Prescription Drug Benefit Program final rule, published January 28, 2005 (70 FR 4194), established cost control and quality improvement requirements for prescription drug benefit plans. Among those requirements, prescription drug plan (PDP) sponsors and Medicare Advantage (MA) organizations offering Medicare Advantage-Prescription Drug (MA-PD) plans must have the capacity to support e-prescribing programs in accordance with the final e-prescribing standards established by the Secretary.

The requirement that PDP sponsors and MA organizations offering MA-PD

plans have the capacity to support e-prescribing programs in accordance with final standards established by the Secretary does not require that prescriptions be written or transmitted electronically by physicians or pharmacies. However, physicians, pharmacies, and others in the health care industry that are not required to use the standards at the time they are adopted are encouraged to do so. The MMA directs the Secretary to promulgate regulations, in consultation with the Attorney General, which provide for an anti-kickback statute safe harbor and a Federal physician self-referral prohibition exception for e-prescribing of covered Part D drugs.

For a more detailed discussion of the proposed physician self-referral prohibition exceptions and the proposed anti-kickback statute safe harbors, please refer to our proposed rules, "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements" (October 11, 2005, 70 FR 59182); and "Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Certain Electronic Prescribing Arrangements Under the Anti-Kickback Statute" (October 11, 2005, 70 FR 59015).

Section 1860D-4(e) of the Act contains the provisions for e-prescribing programs. The statute specifies when initial standards are to be developed, adopted, recognized or modified (not later than September 1, 2005), and when final standards must be promulgated (not later than April 1, 2008) and then become effective (not later than 1 year after the date of promulgation of the final standards).

The provisions at section 1860D-4(e) of the Act require that electronic transmissions of prescription and certain other information for covered Part D drugs prescribed for Part D eligible individuals, be transmitted in accordance with final standards and that the following requirements be met:

- An electronic prescription drug program will provide for the electronic transmittal by the prescribing health care professional and the dispensing pharmacy and pharmacist of the prescription and information on eligibility and benefits (including the drugs included in the applicable formulary, any tiered formulary structure, and any requirements for prior authorization) and of the following information with respect to the prescribing and dispensing of a covered Part D drug:

- + Information on the drug being prescribed or dispensed and other drugs listed on the medication history, including information on drug-to-drug interactions, warnings or cautions, and, when indicated, dosage adjustments.

- + Information on the availability of lower cost and therapeutically appropriate alternatives (if any) for the drug prescribed.

- Effective on and after a date that the Secretary specifies and after the establishment of appropriate standards, the program will provide for the electronic transmittal of information that relates to the medical history concerning the individual and related to a covered Part D drug being prescribed or dispensed, upon request of the professional or pharmacist involved.

- Information will only be disclosed if the disclosure of this information is permitted under the Federal regulations (concerning the privacy of individually identifiable health information) established under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

- To the extent feasible, the information exchanged will be on an interactive, real-time basis.

The statute also requires the National Committee on Vital and Health Statistics (NCVHS) to develop recommendations for standards, in consultation with a specific group of constituencies. The Secretary will take into consideration NCVHS's recommendation, if any, when developing, adopting, recognizing, or modifying initial uniform standards.

The statute requires pilot testing of the initial standards before publishing the final standards in order to facilitate efficient implementation of the requirements. However, it also permits an exception to the pilot testing requirement for standards where there already is adequate industry experience with these standards, as determined by the Secretary after consultation with affected standard-setting organizations and industry users. Under this exception, standards can be proposed and adopted as standards through rulemaking without pilot testing, and would then become final standards.

#### *B. Provisions of the Final Rule*

In the final rule, Medicare Program; E-Prescribing and the Prescription Drug Program," (November 7, 2005, 70 FR 67567), and codified at 42 CFR 423.160(b), we adopted Version 5.0 of the NCPDP SCRIPT standard for the communication of a prescription or prescription-related information between prescribers and dispensers, for the following:

- Get message transaction.
- Status response transaction.
- Error response transaction.
- New prescription transaction.
- Prescription change request transaction.
- Prescription change response transaction.
- Refill prescription request transaction.
- Refill prescription response transaction.
- Verification transaction.
- Password change transaction.
- Cancel prescription request transaction.
- Cancel prescription response transaction.

In the preamble of the November 7, 2005 final rule, we discussed version updating and maintenance of implementation specifications for the adopted standards (70 FR 67579). We stated that when updating a standard, we would look at a variety of factors to consider how an update should occur, including the significance of the corrections or revisions and whether the newer version is backward compatible with the previously adopted version.

As explained in the preamble of the November 7, 2005 final rule, many commenters supported this proposed method of permitting voluntary implementation of later versions of adopted standards that are backward compatible. They also expressed concern that the version updating and maintenance process should not be hindered by extensive rulemaking, particularly when voluntary adoption of newer versions of standards would be precluded. These commenters explained that progress and innovation would be stifled if the voluntary adoption of backward compatible versions were to be prohibited. We agreed with the majority of commenters and intend to identify backward compatible version updates of adopted standards, which the industry may voluntarily implement.

As discussed in section II. below, "backward compatible" means that the newer version of a data transmission standard would retain, at a minimum, the full functionality of the version(s) previously adopted in regulation, and would permit the successful completion of the applicable transaction(s) with entities that continue to use the older version(s).

After a review of Version 8.1 of the NCPDP SCRIPT Standard, and taking into account input from the NCVHS and industry stakeholders, we have determined that Version 8.1 of the NCPDP SCRIPT Standard maintains full functionality of version 5.0, and would permit the successful completion of the

applicable transaction with entities that continue to use 5.0. Therefore, Version 8.1 of the NCPDP SCRIPT Standard is backward compatible with Version 5.0 and we will permit its use to carry out the transactions described above. Furthermore, as explained in section III of this notice (“Waiver of Proposed Rulemaking”), we have found good cause to waive notice and comment rulemaking.

In the November 7, 2005 final rule, we adopted specific versions of the foundation standards. We noted in the preamble of that rule that we anticipate, as appropriate, updating these foundation standards and other adopted standards through the incorporation by reference update process. When updating a standard, we stated that we would look at a variety of factors to consider how the update should occur. If the update or new version of the standard would impose new requirements on the public, we noted that we would initiate notice and comment rulemaking. If, on the other hand, changes to an updated version were not substantive and imposed no new requirements on the public, we stated that the Secretary would consider waiving notice and comment under an Administrative Procedure Act exception to the requirement for notice and comment rulemaking. This, we noted, would mean that compliance with either version for a covered transaction would be viewed as compliance with the transaction standard. However, we intend to permit use of an alternative version of a standard and must make a conforming change to the Code of Federal Regulations which reflects this alternative. Therefore, we are making this change in this interim final rule with comment period. If we anticipate mandating adoption of a new version of a standard or a new standard in the future, we will, through notice and comment rulemaking, provide ample opportunity for public comment.

Based upon numerous testimonies presented to the NCVHS during their 2005 hearings regarding e-prescribing, comments from the NCPDP, and CMS consultation with industry stakeholders that currently are conducting e-prescribing transactions, we concluded that Version 8.1 of the NCPDP SCRIPT Standard retains the full functionality of Version 5.0 and would permit the successful completion of the applicable transactions with entities that continue to use version 5.0, without imposing any new regulatory burdens or costs on participating entities.

## II. Provisions of the Interim Final Rule

[If you choose to comment on issues in this section, please include the caption “PROVISIONS” at the beginning of your comments.]

Use of either Version 5.0 or Version 8.1 of the NCPDP SCRIPT Standard for the covered transactions listed below will be permitted under 42 CFR 423.160(b), effective June 23, 2006. Version 8.1 of the NCPDP SCRIPT Standard is an update to Version 5.0, and we have determined that it is backward compatible with the adopted NCPDP SCRIPT Standard Version 5.0. (Although Version 8.1 of the NCPDP SCRIPT Standard has additional e-prescribing functionalities, we are not adopting any of these additional functionalities at this time.) Use of Version 8.1 of the NCPDP SCRIPT Standard for the communication of a prescription or prescription-related information between prescribers and dispensers, for the following functions, constitutes compliance with the adopted e-prescribing standard:

- Get message transaction.
- Status response transaction.
- Error response transaction.
- New prescription transaction.
- Prescription change request transaction.
- Prescription change response transaction.
- Refill prescription request transaction.
- Refill prescription response transaction.
- Verification transaction.
- Password change transaction.
- Cancel prescription request transaction.
- Cancel prescription response transaction.

According to the November 7, 2005 final rule (70 FR 67580), entities that voluntarily adopt later versions of standards that are backward compatible must still accommodate the earlier adopted version without modification. Since both versions of the standard would be compliant, trading partners who wish to conduct standard e-prescribing transactions may voluntarily adopt Version 8.1 of the NCPDP SCRIPT Standard, but must continue to accept the earlier Version 5.0 transactions without alteration until Version 5.0 is officially retired. In this interim final rule with comment period, we will revise § 423.160(b)(1) and (c) to reflect the voluntary use of Version 8.1 of the NCPDP SCRIPT Standard. We seek comment on permitting the voluntary use of the backward compatible Version 8.1 of the NCPDP SCRIPT Standard as satisfying the requirements of the

adopted standard Version 5.0. We also seek comment on whether and when to retire Version 5.0.

## III. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

## IV. Waiver of Proposed Rulemaking and Delay in Effective Date

The adoption of a standard ordinarily requires notice and comment rulemaking and a 30 day delay in effective date. A notice of proposed rulemaking is published in the **Federal Register** to invite public comment on the proposed rule and generally includes a reference to the legal authority under which the rule is proposed, the provisions of the proposed rule and a description of the subjects and issues addressed by the proposed rule. Notice and comment rulemaking procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of a finding and its reasons in the final notice or rule that is issued.

In this case, we find that notice and comment are unnecessary because this interim final rule with comment period imposes no additional or different legal requirements upon entities participating in the e-prescribing program, but merely provides an additional method by which they may carry out the transactions described in regulations.

Moreover, we ordinarily provide a 30-day delay in the effective date of the provisions of a rule in accordance with the Administrative Procedure Act (APA) (5 U.S.C. 553(d), which requires a 30-day delayed effective date, and the Congressional Review Act (5 U.S.C. 801(a)(3), which requires a 30-day delayed effective date for non-major rules. However, we can waive the delay in effective date if the Secretary finds, for good cause, that such delay is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons in the rule issued. (5 U.S.C. 553(d)(3); 5 U.S.C. 808(2)).

As noted above, this interim final rule with comment period imposes no new requirements on the public. It merely serves to permit the voluntary use of the

backward compatible Version 8.1 of the NCPDP SCRIPT Standard in lieu of Version 5.0, recognizing that the use of Version 8.1 constitutes compliance with the adopted standard for the specified e-prescribing transactions. Entities that elect to use Version 8.1 must support and continue to accept NCPDP SCRIPT Standard Version 5.0 transactions.

For all these reasons, we believe that a notice and comment period and 30-day delay in the effective date would be unnecessary and contrary to the public interest. We therefore find good cause for waiving the notice and comment period 30-day delay in the effective date for the voluntary use of the backward compatible Version 8.1 of the NCPDP SCRIPT Standard in lieu of Version 5.0.

## V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

## VI. Regulatory Impact Statement

[If you choose to comment on issues in this section, please include the caption "IMPACT" at the beginning of your comments.]

We have examined the impact of this interim final rule with comment period as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This interim final rule with comment period does not reach the economic threshold and, thus, is not considered a major rule. Therefore, an RIA has, not been prepared.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most

hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 million to \$29 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined that this interim final rule with comment period imposes no new requirements on small entities because use of Version 8.1 of the NCPDP SCRIPT Standard is voluntary and it will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 for final rules of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this interim final rule with comment period imposes no new requirements on small rural hospitals because use of Version 8.1 of the NCPDP SCRIPT Standard is voluntary and it will not have a significant economic impact on a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$120 million. This notice will have no consequential effect on State, local, or tribal governments or on the private sector because we have determined that this interim final rule with comment period imposes no new requirements on State, local, or tribal governments or on the private sector because the use of Version 8.1 of the NCPDP SCRIPT Standard is voluntary and it will not have a significant economic impact on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this interim final rule with

comment period does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this interim final rule with comment period was reviewed by the Office of Management and Budget.

## List of Subjects in 42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations, (HMO), Health professions, Incorporation by Reference, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 423 as follows:

## PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 1. The authority citation for part 423 continues to read as follows:

**Authority:** Secs 1102, 1860D-1 through 1860D-42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w-101 through 1395w-152, and 1395hh).

■ 2. Section 423.160 is amended by revising paragraphs (b)(1) and (c) to read as follows:

### § 423.160 Standards for electronic prescribing.

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(b) *Standards.* (1) *Prescription.* The National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide, Version 5, Release 0, May 12, 2004, or Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1, October 2005, to provide for the communication of a prescription or prescription-related information between prescribers and dispensers, for the following:

- (i) Get message transaction.
- (ii) Status response transaction.
- (iii) Error response transaction.
- (iv) New prescription transaction.
- (v) Prescription change request transaction.
- (vi) Prescription change response transaction.
- (vii) Refill prescription request transaction.
- (viii) Refill prescription response transaction.
- (ix) Verification transaction.
- (x) Password change transaction.
- (xi) Cancel prescription request transaction.
- (xii) Cancel prescription response transaction.

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(c) *Incorporation by reference.* The Director of the Federal Register approves, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, the incorporation by reference of the National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide, Version 5, Release 0, May 12, 2004, excluding the Prescription Fill Status Notification Transaction (and its three business cases; Prescription Fill Status Notification Transaction—Filled, Prescription Fill Status Notification Transaction—Not Filled, and Prescription Fill Status Notification Transaction—Partial Fill), Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1, October 2005, excluding the Prescription Fill Status Notification Transaction (and its three business cases; Prescription Fill Status Notification Transaction—Filled, Prescription Fill Status Notification Transaction—Not Filled, and Prescription Fill Status Notification Transaction—Partial Fill); the Accredited Standards Committee X12N 270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1, and the National Council for Prescription Drug Programs Telecommunication Standard Specification, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, for the NCPDP Data Record in the Detail Data Record. You may inspect copies of these materials at the headquarters of the Centers for Medicare & Medicaid Services (CMS), 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday from 8:30 a.m. to 4 p.m. or at the National Archives and Records Administration (NARA). For information on the availability of this material at CMS, call 410-786-0273. For information on the availability of this material at NARA, call 202-741-6030, or go to [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html). You may obtain a copy of the National Council for Prescription Drug Programs SCRIPT Standard, Version 5, Release 0, May 12, 2004 or the Prescriber/Pharmacist

Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1, October 2005, from the National Council for Prescription Drug Programs, Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260-7518; Telephone (480) 477-1000; and fax (480) 767-1042 or <http://www.ncdp.org>. You may obtain a copy of the Accredited Standards Committee X12N 270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, 004010X092A1, October 2002, from the Washington Publishing Company, 301 West North Bend Way, Suite 107, P.O. Box 15388, North Bend, WA 98045; Telephone (425) 831-4999; and fax (425) 831-3233 or <http://www.wpc-ed.com/>. You may obtain a copy of the National Council for Prescription Drug Programs Telecommunication Standard Specification, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, for the NCPDP Data Record in the Detail Data Record, from the National Council for Prescription Drug Programs, Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260-7518; Telephone (480) 477-1000; and FAX (480) 767-1042 or <http://www.ncdp.org>.

**Authority:** Section 1860D-4(e) of the Social Security Act (42 U.S.C. 1395w-104(e)) (Catalog of Federal Domestic Assistance Program No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: March 30, 2006.

**Mark B. McClellan,**

*Administrator, Centers for Medicare & Medicaid Services.*

Approved: May 22, 2006.

**Michael O. Leavitt,**

*Secretary.*

[FR Doc. E6-9521 Filed 6-22-06; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Parts 222 and 223

[Docket No. 060405097-6161-02; I.D. 033006E]

RIN 0648-AU10

#### Sea Turtle Conservation; Modification to Fishing Activities

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Final rule.

**SUMMARY:** NMFS is requiring that any offshore pound net leader in the Virginia waters of the mainstem Chesapeake Bay, south of 37°19.0' N. lat. and west of 76°13.0' W. long., and all waters south of 37°13.0' N. lat. to the Chesapeake Bay Bridge Tunnel at the mouth of the Chesapeake Bay, and the James and York Rivers downstream of the first bridge in each tributary, during the period of May 6 through July 15, meet the definition of a modified pound net leader. Without this final rule, existing regulations would continue to prohibit all offshore pound net leaders in that area during that time frame. An offshore pound net leader refers to a leader with the inland end set greater than 10 horizontal feet (3 m) from the mean low water line. While restrictions promulgated in 2004 on pound net leaders in the Virginia waters of the Chesapeake Bay outside the aforementioned area remain in effect, this final rule creates an exception to those restrictions by allowing the use of modified pound net leaders in this area. This action, taken under the Endangered Species Act of 1973 (ESA), responds to new information generated by gear research. It is intended to conserve sea turtles listed as threatened under the ESA and to help enforce the provisions of the ESA, including the provisions against takes of endangered species, while enabling fishermen to use leaders, an important component of pound net gear, during the regulated period.

**DATES:** Effective June 23, 2006.

**FOR FURTHER INFORMATION CONTACT:** Pasquale Scida (ph. 978-281-9208, fax 978-281-9394), or Therese Conant (ph. 301-713-2322, fax 301-427-2522).

#### SUPPLEMENTARY INFORMATION:

##### Background

NMFS issued a final rule on May 5, 2004 (69 FR 24997), which prohibited the use of offshore pound net leaders in