3. Section 52.241 is revised to read as follows:

§52.241 Inspection and maintenance program.

(a) [Reserved]

(b) Approval. On June 5, 2009, the California Air Resources Board submitted a revision to the California Motor Vehicle Inspection and Maintenance Program (2009 I/M Revision) to satisfy the requirements for basic and enhanced motor vehicle inspection and maintenance (I/M) in applicable ozone nonattainment areas. On October 28, 2009, the California Air Resources Board amended the 2009 I/M Revision to include revised enhanced performance program evaluations for six nonattainment areas. Approved elements of the 2009 I/M Revision, as amended on October 28, 2009, include a discussion of each of the required design elements of the I/M program; description of the current geographic coverage of the program; I/M-related statutes and regulations; enhanced I/M performance standard evaluations for the urbanized areas within six California ozone nonattainment areas (South Coast Air Basin, San Joaquin Valley, Sacramento Metro, Coachella Valley, Ventura County, and Western Mojave Desert); basic I/M performance standard evaluation for the urbanized area within the San Francisco Bay Area ozone nonattainment area; and emission analyzer specifications and test procedures, including BAR–97 specifications. The 2009 I/M Revision, as amended on October 28, 2009, meets the requirements of sections 182(a)(2)(B) and 182(c)(3) of the Clean Air Act, as amended in 1990, and 40 CFR part 51, subpart S and is approved as a revision to the California State Implementation Plan.

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 423

[CMS–0023–IFC]

RIN 0938–AP49


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 National Council for the Prescription Drug Programs (NCPDP) Prescriber/Pharmacist Interface SCRIPT standard, Implementation Guide, Version 10, Release 6 (Version 10.6), hereafter referred to as “NCPDP SCRIPT 10.6,” as a backward compatible update of the adopted NCPDP SCRIPT 8.1. This interim final rule with comment period therefore permits the voluntary use of NCPDP SCRIPT 10.6 for conducting certain e-prescribing transactions for the Medicare Part D electronic prescription drug program.

DATES: Effective date: These regulations are effective on July 1, 2010. The incorporation by reference of the publication listed in these regulations is approved by the Director of the Federal Register as of July 1, 2010.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. Eastern Daylight Time (e.d.t.) on August 30, 2010.

ADDRESSES: In commenting, please refer to file code CMS–0023–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to http://www.regulations.gov. Follow the instructions for “Submitting a Comment”.

2. By regular mail. You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–0023–IFC, P.O. Box 8013, Baltimore, MD 21244–1850.

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 to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–0023–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–8013.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:


(b) For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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.

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

Submission of comments on paperwork requirements. You may submit comments on the document’s paperwork requirements by following the instructions at the end of the
There is no requirement that prescribers or dispensers implement e-prescribing. However, prescribers and dispensers who electronically transmit prescription and certain other prescription-related information for Medicare Part D covered drugs prescribed for Medicare Part D eligible individuals, directly or through an intermediary, are required to comply with any applicable final standards that are in effect.

Section 1860D–4(e)(4)(A) of the Act required the Secretary to conduct a pilot project to test these six initial standards that were recognized under section 1860D–4(e)(4)(A) of the Act. Based on the results of that pilot testing, the Secretary could then adopt these standards as final standards in accordance with section 1860D–4(e)(4)(D) of the Act. Section 1860D–4(e)(4)(C)(ii) of the Act created an exception to the requirement for pilot testing of initial standards where, after consultation with the National Committee on Vital and Health Statistics (NCVHS), the Secretary determined that there already was adequate industry experience with the standards. Standards could be recognized by the Secretary and adopted through notice and comment rulemaking as final standards without pilot testing.

We exercised this option in the “Medicare Program: E-Prescribing and Prescription Drug Program” final rule, published on November 7, 2005 (70 FR 67568). In that final rule we adopted three “foundation standards” that met the criteria for adoption without pilot testing. Those foundation standards included a standard for communicating prescription or prescription related information between the prescriber and dispensers for the transactions listed at §423.160(b)(2). That standard was entitled “the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard, Implementation Guide, Version 5, Release 0 (Version 5.0),” hereinafter referred to as “NCPDP SCRIPT 5.0.”

The November 7, 2005 final rule (70 FR 67579) also established a means of addressing the desire for a streamlined standards updating and maintenance process that could keep pace with changing business needs. That process provided for when a standard could be updated with a newer “backward-compatible” version of the adopted standard, and identified whether and when the update/maintenance would necessitate notice and comment rulemaking. In instances in which the user of the later version can accommodate users of the earlier version of the adopted standard without modification, notice and comment rulemaking could be waived, and use of either the new or old version of the adopted standard would be considered compliant upon the effective date of the newer version’s incorporation by reference in the Federal Register. This “Backward Compatible” version updating process allows for the standards’ updating/maintenance to correct technical errors, eliminate technical inconsistencies, and add optional functions that provide optional enhancements to the specified e-prescribing transaction standard.

Subsequent industry input indicated that the adopted e-prescribing standard (NCPDP SCRIPT 5.0) should be updated to permit the use of either NCPDP SCRIPT 5.0 or a later version of the standard, NCPDP SCRIPT standard, Implementation Guide, Version 8. Release 1 (Version 8.1), October 2005, hereinafter referred to as NCPDP SCRIPT 8.1.

Using the streamlined process established in the November 7, 2005 final rule (70 FR 67568), we published an interim final rule with comment period on June 23, 2006, updating the adopted NCPDP SCRIPT standard, thereby permitting either NCPDP SCRIPT 5.0 or 8.1 to be used. (For more information on the content, the report to Congress can be viewed at http://www.cms.hhs.gov/EPrescribing/Downloads/E-RxReporttoCongress.pdf.) Sections 1860D–4(e)(1) and 1860D–4(e)(4)(D) of the Act provided that successfully pilot tested initial standards were to be adopted through notice and comment rulemaking no later than April 1, 2008, and made effective no later than 1 year after the date of that final rule.
Based on the pilot results in the report to Congress, we issued a notice of proposed rulemaking on November 16, 2007 (72 FR 64900) and solicited comments from stakeholders and other interested parties on industry experience with certain standards. In that proposed rule (72 FR 64906 through 64907), we also solicited comments regarding the impact of adopting NCPDP SCRIPT 8.1 and retiring NCPDP SCRIPT 5.0.

In the April 7, 2008 Federal Register (73 FR 18918), we published a final rule that responded to comments, adopted several new Part D e-prescribing standards, finalized the identification of the NCPDP SCRIPT 8.1 as a backward compatible update of the NCPDP SCRIPT 5.0, and, effective April 1, 2009, retired NCPDP SCRIPT 5.0 and adopted NCPDP SCRIPT 8.1 as the official Part D e-prescribing standard for communicating prescription or prescription related information between the prescriber and dispensers for the transactions listed at §423.160(b)(2).

II. Provisions of the Interim Final Rule
A. Voluntary Use of NCPDP Script 10.6

On February 26, 2009, NCVHS heard testimony from industry representatives who requested the adoption of the current balloted NCPDP SCRIPT 10.6 as an alternate for e-prescribing under Medicare Part D. NCVHS also heard testimony from industry stating that NCPDP SCRIPT 10.6 was backward compatible to the current adopted e-prescribing standard NCPDP SCRIPT 8.1. Industry also noted that they are ready to move to the new balloted NCPDP version of the SCRIPT standard. Based upon stakeholder testimony presented to the NCVHS during their 2008 hearings regarding e-prescribing, the NCVHS recommendations that derived from their 2008 hearings, testimony from the NCPDP detailing NCPDP SCRIPT 10.6's backward compatibility to NCPDP SCRIPT 8.1, and information received by CMS from industry stakeholders who currently conduct e-prescribing transactions, we conclude that the recognition of NCPDP SCRIPT 10.6 as a backward compatible version of the adopted standard (NCPDP SCRIPT 8.1) is desirable, that NCPDP SCRIPT 10.6 retains the full functionality of NCPDP SCRIPT 8.1 and would permit the successful completion of the applicable e-prescribing transactions with entities that continue to use NCPDP SCRIPT 8.1, and that use of the streamlined process to recognize NCPDP SCRIPT 10.6 as a backward compatible version of the adopted standard (NCPDP SCRIPT 8.1) would be appropriate. We anticipate proposing the adoption of NCPDP SCRIPT 10.6 as an adopted standard at a later date in a future notice of proposed rulemaking. At that time we would propose to adopt NCPDP SCRIPT 10.6 and retire the current adopted standard.

We have also reviewed NCPDP SCRIPT 10.6, and the July 1, 2009 NCVHS letter to the Secretary recommending, based on input from industry stakeholders, the adoption of NCPDP SCRIPT 10.6 in Medicare Part D e-prescribing (http://www.ncvhs.hhs.gov). We have determined that NCPDP SCRIPT 10.6 maintains full functionality of NCPDP SCRIPT 8.1, and would permit the successful completion of the applicable transactions with entities that continue to use NCPDP SCRIPT 8.1 for Part D e-prescribing transactions.

NCPDP SCRIPT 10.6 also has a number of new functionalities that, if users elect to use them, will mesh with their use of the recently adopted NCPDP Prescriber/Pharmacist Interface SCRIPT standard, Version 8, Release 1 and its equivalent NCPDP Prescriber/Pharmacist Interface SCRIPT Implementation Guide, Version 8, Release 1 (hereinafter referred to as the medication history standard), which was adopted in the April 7, 2008 e-prescribing final rule (73 FR 18918). These new functions would allow users to provide prescriber order numbers, drug NDC source information, pharmacy prescription fill numbers and date of sale information that could then be used in a medication history response. These added functionalities would therefore be expected to facilitate better record matching, the identification and elimination of duplicate records, and the provision of richer information to the prescriber between willing trading partners.

We are revising §423.160(b)(2)(ii) to specify that providers and dispensers may use NCPDP SCRIPT 10.6 or 8.1 in electronic transactions that convey prescription or prescription related information for the following transactions:

- 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.
- Fill status notification transaction.

We are also revising §423.160(b)(4) to specify that entities may use either NCPDP SCRIPT 10.6 or 8.1 for the communication of Medicare Part D medication history among sponsors, prescribers, and dispensers.

In addition, we are adding a new §423.160(c)(1)(v) to specify the incorporation by reference of NCPDP SCRIPT 10.6.

In accordance with the streamlined process established in the November 7, 2005 final rule (70 FR 67580), entities that voluntarily adopt later versions of standards that are backward compatible to the adopted standard 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 NCPDP SCRIPT 10.6, but must continue to accept transactions using the earlier NCPDP SCRIPT 8.1 standard without alteration, and they must be able to generate transactions that can be processed or read by those using the NCPDP SCRIPT 8.1 standard until NCPDP SCRIPT 8.1 is officially retired.

We seek comment on recognizing NCPDP SCRIPT 10.6 as a backward compatible version of the adopted NCPDP SCRIPT 8.1 standard. We also seek comment on the voluntary use of the backward compatible NCPDP SCRIPT 10.6. Furthermore, we seek comment on whether and when to retire NCPDP SCRIPT 8.1.

B. NCPDP SCRIPT 10.6 and the Long-Term Care Setting Exemption

During the NCVHS testimony, industry also stated that the changes that were present in NCPDP SCRIPT 10.6 created an environment where long-term care (LTC) facilities could carry out e-prescribing under Medicare Part D. They asked the NCVHS to seek comment on whether and when to retire NCPDP SCRIPT 8.1.

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for a patient to a non-prescribing provider (such as a nursing facility) that in turn forwards the prescription to a dispenser (“three-way prescribing communications” between facility, physician, and pharmacy), we provided an exemption from the requirement to use the adopted NCPDP SCRIPT standard in transmitting such prescriptions or prescription-related information. We also noted the results of the calendar year (CY) 2006 e-prescribing pilot relative to the use of NCPDP SCRIPT 8.1 in the LTC setting, namely that workarounds were still needed to accommodate the unique workflow needs in LTC setting.

As a result of the 2006 pilot findings and other industry and stakeholder input, NCPDP added other segments to subsequently developed versions of its NCPDP SCRIPT standard to enhance its use in e-prescribing in the LTC setting. Many of these enhancements first appeared in NCPDP SCRIPT 10.2 and appear in the subsequent higher versions of the transaction standard. We believe these shortcomings that were identified in NCPDP SCRIPT 8.1 for use in LTC settings in the 2006 CMS e-prescribing pilot are now fully addressed in NCPDP SCRIPT 10.6.

On July 1, 2009, the NCVHS sent a letter to the Secretary of HHS. It recommended the recognition of NCPDP SCRIPT 10.6 as a backward compatible version of the adopted standard (NCPDP SCRIPT 8.1) through the “streamlined process.” It also recommended elimination of the LTC exemption for use of the NCPDP SCRIPT standard. The LTC setting issues are addressed in NCPDP SCRIPT 10.2 and subsequent versions. It would not be appropriate to lift the LTC exemption prior to retiring any NCPDP SCRIPT versions prior to NCPDP SCRIPT 10.2. As the retirement of NCPDP SCRIPT 8.1 and the elimination of the LTC exemption will be substantive changes to the Part D e-prescribing regulations, we will need to use notice and comment rulemaking to effectuate these changes. We anticipate proposing these changes at a later date in a noticed rulemaking.

More information on the testimony given to, and the recommendations given by NCVHS, can be found at the NCVHS Web site http://www.ncvhshhs.gov.

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 rule that is issued.

In this case, we find that notice and comment rulemaking is unnecessary because this interim final rule with comment period imposes no additional or different legal requirements upon entities participating in the Part D e-prescribing program. It merely provides an additional method by which entities may carry out transactions using the standards adopted 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(n)(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 previously, 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 NCPDP SCRIPT Standard, NCPDP SCRIPT 10.6, in lieu of the adopted NCPDP SCRIPT 8.1 standard. The use of NCPDP SCRIPT 10.6 constitutes compliance with the adopted standard for the specified e-prescribing transactions. Entities that elect to use NCPDP SCRIPT 10.6 must support and continue to accept NCPDP SCRIPT Standard Version 8.1 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 NCPDP SCRIPT Standard NCPDP SCRIPT 10.6 in lieu of NCPDP SCRIPT 8.1.

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

We have examined the impact of this interim final rule with comment period as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (as amended by Executive Orders 13285 and 13422) 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 $7.0 million to $34.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis

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for the RFA because we have determined, and the Secretary certifies, that this interim final rule with comment period imposes no new requirements on small entities because use of NCPDP SCRIPT 10.6 is voluntary, and as such, 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 Act. 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 for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this interim final rule with comment period imposes no new requirements on small rural hospitals, because use of NCPDP SCRIPT 10.6 is voluntary and as such, 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. In 2010, that threshold level is currently approximately $135 million. This rule 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 use NCPDP SCRIPT 10.6 is voluntary and as such, 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, preempt 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 Executive Order 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 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:


2. Section 423.160 is amended by—

A. Revising the introductory text of paragraph (b)(2)(ii).

B. Revising paragraph (b)(4).

C. Adding a new paragraph (c)(1)(v).

The revisions and addition read as follows:


* * * * *

(b) * * *

(2) * * *

(ii) The National Council for Prescription Drug Programs SCRIPT standard, Implementation Guide Version 10.6, approved November 12, 2008 (incorporated by reference in paragraph (c)(1)(v) of this section), or the National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1 (Version 8.1), October 2005 (incorporated by reference in paragraph (c)(1)(i) of this section), to provide for the communication of a prescription or prescription-related information between prescribers and dispensers, for the following:

* * * * *

(4) Medication history. The National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide Version 8, Release 1 (Version 8.1), October 2005 (incorporated by reference in paragraph (c)(1)(v) of this section) or the National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide Version 10.6, approved November 12, 2008 (incorporated by reference in paragraph (c)(1)(v) of this section) to provide for the communication of Medicare Part D medication history information among Medicare Part D sponsors, prescribers, and dispensers.

(c) * * *

(1) * * *


* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: March 4, 2010.

Charlene Frizzera,
Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: May 26, 2010.

Kathleen Sebelius,
Secretary.

[FR Doc. 2010–15505 Filed 6–28–10; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 090428799–9802–01]

RIN 0648–BA00

Magnuson-Stevens Act Provisions; Fisheries Off West Coast States; Pacific Coast Groundfish Fishery; 2010 Harvest Specifications for Yelloweye Rockfish and In-Season Adjustments to Fishery Management Measures

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

ACTION: Final rule; in-season adjustments to biennial groundfish management measures; request for comments.

SUMMARY: This final rule revises the 2010 harvest guidelines for yelloweye rockfish and makes in-season adjustments to trawl fishery management measures for several groundfish species taken in the U.S. exclusive economic zone (EEZ) off the coasts of Washington, Oregon, and California. These actions, which are authorized by the Pacific Coast Groundfish Fishery Management Plan (FMP), are intended to prevent exceeding the 2010 OYs for yelloweye rockfish.