SUMMARY: In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), notice is hereby given of the following meeting of the Negotiated Rulemaking Committee on Designation of Medically Underserved Populations and Health Professional Shortage Areas.

DATES: Meetings will be held on June 22, 2011, 9:30 a.m. to 6 p.m.; June 23, 2011, 9 a.m. to 6 p.m.; and June 24, 2011, 9 a.m. to 3 p.m.

ADDRESSES: Meetings will be held at the Legacy Hotel and Meeting Centre, 1775 Rockville Pike, Rockville, Maryland 20852, (301) 881–2300.

FOR FURTHER INFORMATION CONTACT: For more information, please contact Nicole Patterson, Office of Shortage Designation, Bureau of Health Professions, Health Resources and Services Administration, Room 9A–18, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–9027, E-mail: *npatterson@hrsa.gov* or visit *http://www.hrsa.gov/advisorycommittees/shortage/.*

SUPPLEMENTARY INFORMATION:

Status: The meeting will be open to the public.

Purpose: The purpose of the Negotiated Rulemaking Committee on Designation of Medically Underserved Populations and Health Professional Shortage Areas is to establish a criteria and a comprehensive methodology for Designation of Medically Underserved Populations and Primary Care Health Professional Shortage Areas, using a Negotiated Rulemaking (NR) process. It is hoped that use of the NR process will yield a consensus among technical experts and stakeholders on a new rule for designation of medically underserved populations and primary care health professions shortage areas, which would be published as an Interim Final Rule in accordance with Section 5602 of the Affordable Care Act, Public Law 111–148.

Agenda: The meeting will be held on Wednesday, June 22; Thursday, June 23; and Friday, June 24. It will include a discussion of various components of a possible methodology for identifying areas of shortage and underservice, based on the recommendations of the Committee in the previous meeting. Members of the public will have the opportunity to provide comments during the meeting on Friday afternoon.

Requests from the public to make oral comments or to provide written comments to the Committee should be sent to Nicole Patterson at the contact address above at least 10 days prior to the first day of the meeting, Wednesday, June 22. The meetings will be open to the public as indicated above, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed above at least 10 days prior to the meeting.

Dated: May 24, 2011.

Wendy Ponton,

Director, Office of Management.

[FR Doc. 2011–13480 Filed 5–31–11; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–3248–P]

RIN 0938–AR00

Medicare Program; Proposed Changes to the Electronic Prescribing (eRx) Incentive Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would modify the 2011 electronic prescribing (eRx) quality measure (that is, the eRx quality measure used for certain reporting periods in calendar year (CY) 2011), provide additional significant hardship exemption categories for eligible professionals and group practices to request an exemption during 2011 for the 2012 eRx payment adjustment due to a significant hardship, and extend the deadline for submitting requests for consideration for the two significant hardship exemption categories for the 2012 eRx payment adjustment that were finalized in the CY 2011 Medicare Physician Fee Schedule (PFS) final rule with comment period.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on July 25, 2011.

ADDRESSES: In commenting, please refer to file code CMS–3248–P. 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 "Submit a comment" instructions.

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–3248–P, P.O. Box 8013, Baltimore, MD 21244–8013.

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–3248–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey 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.)

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, call telephone number (410) 786–1066 in advance to schedule your arrival with one of our staff members.

Comments erroneously 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: Christine Estella, (410) 786–0485.

SUPPLEMENTARY INFORMATION: *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.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be 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

Section 132 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), Public Law 110–275, authorized the Secretary to establish a program to encourage the adoption and use of eRx technology. Implemented in 2009, the program offers a combination of financial incentives and payment adjustments to eligible professionals, which are defined under section 1848(k)(3)(B) of the Social Security Act (the Act). We understand that the term "eligible professional" is used in multiple CMS programs. However, for the purpose of this proposed rule, the eligible professionals to whom we refer are only those professionals eligible to participate in the eRx Incentive Program unless we specify otherwise. For more information on which professionals are eligible to participate in the eRx Incentive Program, we refer readers to the Eligible Professionals page of the eRx Incentive Program section of the CMS Web site at: *http://www.cms.gov/ERxIncentive/05_Eligible%20Professionals.asp#TopOfPage.* Under section 1848(m)(2)(C) of the Act, an eligible professional (or group practice participating in the eRx group practice reporting option (GPRO)) who is a successful electronic prescriber during 2011 can qualify for an incentive payment equal to 1.0 percent of its total estimated Medicare Part B Physician Fee Schedule (PFS) allowed charges for covered professional services furnished during the 2011 reporting period.

In accordance with section 1848(a)(5)(A) of the Act, a PFS payment adjustment will begin in 2012 for those eligible professionals and group practices who are not successful electronic prescribers and will increase each year through 2014. Specifically, under 42 CFR 414.92(c)(2), for covered professional services furnished by an eligible professional during 2012, 2013, and 2014, if an eligible professional (or in the case of a group practice, the group practice) is not a successful electronic prescriber (as specified by CMS for purposes of the payment adjustment) for an applicable reporting period (as specified by CMS), then the PFS amount for such services furnished by such professional (or group practice) during the year shall be equal to the applicable percent (99 percent for 2012, 98.5 percent for 2013, and 98 percent for 2014) of the PFS amount that would otherwise apply. For each year of the program thus far, we have established program requirements for the eRx Incentive Program in the annual Medicare PFS rulemaking, including the applicable reporting period(s) for the year and how an eligible professional can become a successful electronic prescriber for the year. For example, we finalized the program requirements for qualifying for 2009 and 2010 eRx incentive payments in the CY 2009 and 2010 PFS final rules with comment period (73 FR 69847 through 69852 and 74 FR 61849 through 61861), respectively. In the November 29, 2010 **Federal Register** (75 FR 73551 through 73556), we published the CY 2011 PFS final rule with comment period, which set forth the requirements for qualifying for a CY 2011 incentive payment, as well as the requirements for the 2012 and 2013 eRx payment adjustments.

Since publication of the CY 2011 PFS final rule with comment period, we have received a number of inquiries from stakeholders regarding the eRx Incentive Program. Many stakeholders voiced concerns about differences between the requirements under the eRx Incentive Program and the Medicare Electronic Health Record (EHR) Incentive Program, which also requires, among other things, eligible professionals to satisfy an eRx objective and measure to be considered a meaningful user of certified EHR technology ("eligible professional" is defined at 42 CFR 495.100 for purposes of the Medicare EHR Incentive Program). (For more information regarding the EHR Incentive Program see the published **Federal Register** on July 28, 2010; 75 FR 44314 through 44588.) While Medicare eligible professionals and group practices cannot earn an incentive under both the eRx Incentive Program and the EHR Incentive Program for the same year, eligible professionals will be subject to an eRx payment adjustment if they do not meet the requirements under the eRx Incentive Program, regardless of whether the eligible professional participates in and earns an incentive under the Medicare EHR Incentive Program.

Stakeholders claim that the requirements under both programs are administratively confusing, cumbersome, and unnecessarily duplicative. On February 17, 2011, the Government Accountability Office (GAO) also published a report which indicated that CMS should address the inconsistencies between the eRx Incentive Program and the EHR Incentive Program (GAO–11–159, "Electronic Prescribing: CMS Should Address Inconsistencies in Its Two Incentive Programs That Encourage the Use of Health Information Technology," available at *http://www.gao.gov/products/GAO–11–159*).

As a result of the above concerns and in accordance with Executive Order 13563, which directs government agencies to identify and reduce redundant, inconsistent, or overlapping regulatory requirements and, among other things, identify and consider regulatory approaches that reduce burden and maintain flexibility of choice when possible, we are proposing to make changes to the eRx Incentive Program. As described further in section II.A. of the proposed rule, we are specifically proposing to modify the 2011 eRx quality measure (that is, the eRx quality measure used for certain reporting periods in CY 2011) and to create additional significant hardship exemption categories for the 2012 eRx payment adjustment.

II. Provisions of the Proposed Regulations

A. Modification of the CY 2011 Electronic Prescribing Quality Measure

In the CY 2011 PFS final rule with comment period (75 FR 73553 through 76566), we finalized an eRx quality measure that would be used during the reporting periods in 2011 used to determine whether an eligible professional is a successful electronic prescriber under the eRx Incentive Program for the 2011 eRx incentive, as well as for the 2012 and 2013 eRx payment adjustments. The measure that we adopted for reporting in 2011 (which is the same measure that was adopted for the 2010 eRx Incentive Program) is described as a measure that documents whether an eligible professional or group practice has adopted a "qualified" eRx system.

A qualified eRx system is a system that is capable of performing the following four specific functionalities:

- Generate a complete active medication list incorporating electronic

data received from applicable pharmacies and pharmacy benefit managers (PBMs), if available.

• Allow eligible professionals to select medications, print prescriptions, electronically transmit prescriptions, and conduct alerts (that is, written or acoustic signals to warn the prescriber of possible undesirable or unsafe situations including potentially inappropriate doses or routes of administration of a drug, drug-drug interactions, allergy concerns, or warnings and cautions) and this functionality must be enabled,

• Provide information related to lower cost therapeutically appropriate alternatives (if any) (that is, the ability of an eRx system to receive tiered formulary information, if available, would again suffice for this requirement for 2011 and until this function is more widely available in the marketplace)

• Provide information on formulary or tiered formulary medications, patient eligibility, and authorization requirements received electronically from the patient's drug plan (if available).

In addition, to be a qualified eRx system under the eRx Incentive Program, electronic systems must convey the information above using the standards currently in effect for the Part D eRx program, including certain National Council for Prescription Drug Programs' (NCPDP) standards. (To view the current eRx quality measure specifications, we refer readers to the "2011 eRx Measure Specifications, Release Notes, and Claims-Based Reporting Principles" download found on the E-Prescribing Measure page of the eRx Incentive Program section of the CMS Web site at: *http://www.cms.gov/ERxIncentive/06_E-Prescribing_Measure.asp#TopOfPage*.)

The technological requirements for eRx in the EHR Incentive Program are similar to the technological requirements for the eRx Incentive Program. Under the EHR Incentive Program, eligible professionals are required to adopt certified EHR technology, which must include the capability to perform certain eRx functions that are similar to those required for the eRx Incentive Program. Certified EHR technology must be tested and certified by a certification body authorized by the National Coordinator for Health Information Technology (at the present time, these bodies are Office of the National Coordinator for Health Information Technology (ONC)-Authorized Testing and Certification Bodies (ONC–ATCBs)). This means that eligible professionals participating in the EHR Incentive Program can rely on a third party certification body to ensure that the vendor's EHR technology includes certain technical capabilities. EHR technology is certified as a "Complete EHR" or an "EHR module," as those terms are defined at 45 CFR 170.102. A Complete EHR is EHR technology that has been developed to meet, at a minimum, all applicable certification criteria adopted by the Secretary. An EHR Module is any service, component, or combination thereof that can meet the requirements of at least one certification criterion adopted by the Secretary.

In contrast, the eRx Incentive Program does not require certification of the system used for eRx. Thus, eligible professionals or group practices are generally required to rely on information that they obtain from the vendors of the systems and demonstration of the functionalities of the system, to determine if the system meets the required standard. We believe that the eRx capabilities of certified EHR technology are sufficiently similar in nature (and in fact, would more than likely be capable of performing all of the required functionalities) and would be appropriate for purposes of the eRx Incentive Program. Among other requirements, certified EHR technology must be able to electronically generate and transmit prescriptions and prescription-related information in accordance with certain standards, some of which have been adopted for purposes of electronic prescribing under Part D. Similar to the required functionalities of a qualified eRx system, certified EHR technology also must be able to check for drug-drug interactions and check whether drugs are in a formulary or a preferred drug list, although the certification criteria do not specify any standards for the performance of those functions. We believe that it is acceptable that not all of the Part D eRx standards are required for certified EHR technology in light of our desire to better align the requirements of the eRx and the Medicare EHR Incentive Program and potentially reduce unnecessary investment in multiple technologies for purposes of meeting the requirements for each program. Furthermore, to the extent that an eligible professional uses certified EHR technology to electronically prescribe under Part D, he or she would still be required to comply with the Part D standards to do so.

In addition, we believe it is important to provide more certainty to eligible professionals (including those in group practices) that may be participating in both the EHR Incentive Program and the eRx Incentive Program with regard to purchasing systems for use under these programs, and to encourage adoption of certified EHR technology. Accordingly, we are proposing changes to the eRx measure reported in 2011 for purposes of reporting for the 2011 eRx incentive and the 2013 eRx payment adjustment (the "2011 eRx quality measure") in accordance with section 1848(k)(2)(C) of the Act. This section of the Act requires the eRx measure to be endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act (currently, that entity is the National Quality Forum (NQF)) except for in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the NQF. While the electronic prescribing measure, as originally implemented in the 2009 eRx Incentive Program is an NQF-endorsed measure, subsequent modifications made to the measure for implementation purposes (for example, to reduce eligible professionals' reporting burden and to increase applicability of the measure to a broader range of eligible professionals) have not yet been reviewed by the NQF. In light of this, we are not aware of any other NQF-endorsed measure related to electronic prescribing by eligible professionals that would be appropriate for use in the eRx Incentive Program. Therefore, we believe that the use of this eRx measure falls within the exception under section 1848(k)(2)(C)(ii) of the Act.

Specifically, we are proposing to revise the description statement for the 2011 eRx measure that we adopted for reporting in 2011 for purposes of the 2011 eRx incentive and the 2013 eRx payment adjustment. Currently, the description statement indicates that the measure documents whether an eligible professional or group practice has adopted a "qualified" eRx system that performs the four functionalities discussed above. We propose to revise this description statement to indicate that the measure documents whether an eligible professional or group practice has adopted a "qualified" eRx system that performs the four functionalities previously discussed *or* is certified EHR technology as defined at 42 CFR 495.4 and 45 CFR 170.102. We believe that this proposed change merely expands on the definition of a "qualified" eRx system without altering the original intent of the measure, which was to evaluate the extent to which eligible professionals generate and transmit prescriptions and prescription-related information electronically. Both eRx systems that perform the four

functionalities previously discussed and certified EHR technology are able to generate and transmit prescriptions and prescription-related information electronically. An eligible professional or group practice that has already purchased an eRx system that meets the definition of a "qualified" eRx system would be able to continue using that system (that is, even with the proposed changes to the measure, systems that meet the four functionalities would continue to constitute "qualified" eRx systems). In accordance with section 1848(m)(3)(B)(v) of the Act, which requires the Secretary, to the extent practicable, to ensure that eligible professionals utilize electronic prescribing systems in compliance with standards established for such systems pursuant to the Part D eRx Program under section 1860D–4(e) of the Act, we also propose that for purposes of the 2011 eRx measure certified EHR technology must comply with the Part D standards for the electronic transmission of prescriptions at 42 CFR 423.160(b)(2)(ii). This proposed requirement is consistent with the ONC certification requirements at 45 CFR 170.304(b) and 170.205(b)(1) and (2). With this proposed change to the 2011 eRx measure, eligible professionals (including those in group practices) that are participating in the eRx Incentive Program would have the option of adopting either a qualified eRx system that performs the four functionalities previously discussed or certified EHR technology as defined at 42 CFR 495.4 and 45 CFR 170.102. Thus, under this proposal, certified EHR technology would be recognized as a qualified system under the revised eRx quality measure regardless of whether the certified EHR technology has all four of the functionalities previously described. Because the proposed change to the 2011 eRx measure, if finalized, would not be effective until the effective date of a subsequent final rule, this change would only be effective for the remainder of the reporting periods in CY 2011 for the 2011 eRx incentive and the 2013 eRx payment adjustment. The proposed change to the 2011 eRx quality measure, if finalized, would not apply retrospectively to any part of the CY 2011 reporting periods for the 2011 eRx incentive or the 2013 eRx payment adjustments that occurred prior to the effective date of a subsequent final rule. The proposed change to the eRx measure does not change any of the regulations for the eRx Incentive Program payment adjustment, which are codified at 42 CFR 414.92(c)(2). In addition, because this proposed change would not be finalized prior to the end of the 2012 eRx payment adjustment reporting period (that is, June 30, 2011), such a change would not apply for purposes of reporting the eRx measure for the 2012 eRx payment adjustment. However, as we noted previously, we believe that most certified EHR technology meet the requirements for "qualified" eRx systems under the current 2011 eRx quality measure. Therefore, for purposes of reporting the current eRx quality measure during 2011 (including reporting for purposes of the 2012 eRx payment adjustment), nothing precludes eligible professionals (or a group practice) that already have certified EHR technology that meet the four functionalities from using the certified EHR technology for purposes of the eRx Incentive Program (that is, the technology would constitute a "qualified" system under the current 2011 eRx quality measure because such system meets the four specified functionalities). For future program years, we anticipate using the revised eRx quality measure, which we would adopt through future notice and comment rulemaking. We invite public comment on the proposed modification to the 2011 eRx quality measure.

B. Significant Hardship Exemption Categories for the 2012 Payment Adjustment

1. Overview of the 2012 Payment Adjustment

As required by section 1848(a)(5) of the Act, and in accordance with our regulations at 42 CFR 414.92(c)(2), eligible professionals or group practices who are not successful electronic prescribers (as specified by CMS for purposes of the payment adjustment) are subject to the eRx payment adjustment in 2012. In the CY 2011 PFS final rule with comment period (75 FR 73560 through 73565), we finalized the program requirements for the 2012 eRx payment adjustment. Specifically, the 2012 eRx payment adjustment does not apply to the following: (1) An eligible professional who is not a physician (includes doctors of medicine, doctors of osteopathy, and podiatrists), nurse practitioner, or physician assistant as of June 30, 2011; (2) an eligible professional who does not have at least 100 cases (that is, claims for patient services) containing an encounter code that falls within the denominator of the eRx measure for dates of service between January 1, 2011 and June 30, 2011; or (3) an eligible professional who is a successful electronic prescriber for the January 1, 2011 through June 30, 2011 reporting period (that is, reports the eRx measure 10 times via claims between January 1, 2011 and June 30, 2011).

We also finalized the requirement that the 2012 eRx payment adjustment does not apply to an individual eligible professional or group practice if less than 10 percent of an eligible professional's or group practice's estimated total allowed charges for the January 1, 2011 through June 30, 2011 reporting period are comprised of services that appear in the denominator of the 2011 eRx measure. Information and other details about the eRx Incentive Program, including the requirements for group practices participating in the eRx GPRO in 2011 with regard to the 2012 eRx payment adjustment can be found on the eRx Incentive Program section of the CMS Web site at: *http://www.cms.gov/erxincentive*.

2. Current Significant Hardship Exemptions for the 2012 eRx Payment Adjustment

In addition to the requirements for the 2012 eRx payment adjustment, 42 CFR 414.92(c)(2)(ii) provides that we may, on a case-by-case basis, exempt an eligible professional (or group practice) from the application of the payment adjustment, if we determine, subject to annual renewal, that compliance with the requirement for being a successful electronic prescriber would result in a significant hardship. In the CY 2011 PFS final rule with comment period (75 FR 73564 through 75 FR 73565), we finalized two circumstances under which an eligible professional or group practice can request consideration for a significant hardship exemption for the 2012 eRx payment adjustment—

- The eligible professional or group practice practices in a rural area with limited high speed Internet access; or
- The eligible professional or group practice practices in an area with limited available pharmacies for eRx.

In order for eligible professionals and group practices to identify these categories for purposes of requesting a hardship exemption, we created a G-code for each of the above situations. Thus, to request consideration for a significant hardship exemption for the 2012 eRx payment adjustment, individual eligible professionals must report the appropriate G-code at least once on claims for services rendered between January 1, 2011 and June 30, 2011. Group practices that wished to participate in the 2011 eRx GPRO and be considered for exemption under one of the significant hardship categories were required to request a hardship exemption at the time they self-

nominated to participate in the 2011 eRx GPRO earlier this year.

3. Proposed Additional Significant Hardship Exemption Categories for the 2012 eRx Payment Adjustment

Since publication of the CY 2011 PFS final rule with comment period, we have received numerous requests to expand the categories under the significant hardship exemption for the 2012 eRx payment adjustment. Some stakeholders have recommended specific circumstances of significant hardship for our consideration (for example, eligible professionals who have prescribing privileges but do not prescribe under their NPI, eligible professionals who prescribe a high volume of narcotics, and eligible professionals who electronically prescribe but typically do not do so for any of the services included in the eRx measure's denominator), while others strongly suggested we consider increasing the number of specific hardship exemption categories. We believe that many of the circumstances raised by stakeholders may pose a significant hardship and limit eligible professionals and group practices in their ability to meet the requirements for being successful electronic prescribers either because of the nature of their practice or because of the limitations of the eRx measure itself, and as a result, such professionals might be unfairly penalized. Therefore, we are proposing to revise the significant hardship regulation at 42 CFR 414.92(c)(2)(ii) to add paragraphs that—(1) codify the two hardship exemption categories for the 2012 eRx payment adjustment that we finalized in the CY 2011 PFS final rule; and (2) codify the additional significant hardship categories for the 2012 eRx payment adjustment that we are proposing in this proposed rule. We also are proposing to allow some additional time for submitting significant hardship exemption requests to CMS.

Specifically, we are proposing the following additional significant hardship exemption categories for the 2012 eRx payment adjustment with regard to the reporting period of January 1, 2011 through June 30, 2011:

a. Eligible Professionals Who Register To Participate in the Medicare or Medicaid EHR Incentive Programs and Adopt Certified EHR Technology

We are proposing this exemption category at proposed 42 CFR 414.92(c)(2)(ii)(C) because eligible professionals (including those in group practices) that intended to participate in the EHR Incentive Program may have delayed adopting eRx technology for purposes of the eRx Incentive Program until the list of certified EHR technology became available so that the same technology could be used to satisfy both programs' requirements. The ONC final rule establishing a temporary certification program for health information technology (75 FR 36158) was not published in the **Federal Register** until June 24, 2010. The certification and listing of EHR technologies (certified Complete EHRs and certified EHR Modules) on the ONC Certified HIT Products List (CHPL) did not begin until September 2010. Until then, eligible professionals and group practices had no way of knowing which EHR technologies would be certified. At the same time, we did not propose to use the first half of 2011 as the reporting period for the 2012 eRx payment adjustment until the CY 2011 PFS proposed rule went on public display at the Office of the Federal Register on June 25, 2010. As such, we believe it may be a significant hardship for eligible professionals in this situation to have both adopted certified EHR technology and fully integrated the technology into their practice's clinical workflows and processes so that they would be able to successfully report the eRx measure prior to June 30, 2011, especially given that an eligible professional under the Medicare EHR Incentive Program has until October 1, 2011, to begin a 90-day EHR reporting period for the 2011 payment year. Similarly, this extended time period provides Medicare eligible professionals under the eRx Incentive Program but who are eligible for incentives under the Medicaid EHR Incentive Program with a majority of 2011 to adopt, implement, or upgrade to certified EHR technology. We believe this hardship exemption category is necessary and appropriate in order to fully support and encourage eligible professionals to actively take steps to become meaningful users of certified EHR technology. Also, in the absence of this significant hardship exemption category, eligible professionals may potentially have to adopt two systems (for example, a standalone eRx system for purposes of participation in the eRx Incentive Program, followed by certified EHR technology), which could potentially be financially burdensome. To be considered for a significant hardship exemption under this category, we are proposing that the eligible professional, at a minimum, must: (1) Have registered for either the Medicare or Medicaid EHR Incentive Program (for instructions on how to register for one of the EHR Incentive Programs, we refer readers to the Registration and Attestation page of the EHR Incentive Programs section of the CMS Web site at *http://www.cms.gov/EHRIncentivePrograms/20_RegistrationandAttestation.asp#TopOfPage*); and (2) provide identifying information as to the certified EHR technology (as defined at 45 CFR 170.102) that has been adopted for use no later than October 1, 2011, for a hardship exemption to be submitted, which then would be reviewed on a case-by-case basis. We propose that for purposes of this proposed significant hardship exemption category, the identifying information would consist of the certification number that is assigned to the EHR technology for purposes of ONC's CHPL. In addition, we are considering requiring eligible professionals to provide a serial number for their specific product but have concerns about whether such information would be readily accessible by eligible professionals. We invite comments on the feasibility of requiring eligible professionals to provide a serial number in addition to the certification number for the certified EHR technology, or other information identifying and verifying the specific product. In requesting a significant hardship exemption under this proposed category, an eligible professional would be attesting that he or she either has purchased the specified certified EHR technology (as identified by the certification number and/or serial number) or has the specified certified EHR technology available for immediate use and that the professional intends to use that technology to qualify for a Medicare or Medicaid EHR incentive for payment year 2011.

b. Inability To Electronically Prescribe Due to Local, State, or Federal Law or Regulation

We are proposing at 42 CFR 414.92(c)(2)(ii)(D) that, to the extent that local, State, or Federal law or regulation limits or prevents an eligible professional or group practice that otherwise has general prescribing authority from electronically prescribing (for example, eligible professionals who prescribe a large volume of narcotics, which may not be electronically prescribed in some states, or eligible professionals who practice in a State that prohibits or limits the transmission of electronic prescriptions via a third party network such as Surescripts), the eligible professional or group practice would be able to request consideration for an exemption from application of the 2012 eRx payment adjustment, which would be reviewed on a case-by-case

basis. We believe eligible professionals in this situation face a significant hardship with regard to the requirements for being successful electronic prescribers because while they may meet the 10-percent threshold for applicability of the payment adjustment, they may not have sufficient opportunities to meet the requirements for being a successful electronic prescriber because Federal, State, or local law or regulation may limit the number of opportunities that an eligible professional or group practice has to electronically prescribe (that is, having at least 100 denominator-eligible visits prior to June 30, 2011, but being unable to electronically prescribe for at least 10 of these denominator-eligible visits due to Federal, State, or local law or regulation).

c. Limited Prescribing Activity

We are proposing at 42 CFR 414.92(c)(2)(ii)(E) that an eligible professional who has prescribing privileges but does not prescribe or very infrequently prescribes in his or her practice (for example, a nurse practitioner who may not write prescriptions under his or her own NPI, a physician who decides to let his Drug Enforcement Administration registration expire during the reporting period without renewing it, or an eligible professional who prescribed fewer than 10 prescriptions between January 1, 2011 and June 30, 2011 regardless of whether the prescriptions were electronically prescribed or not), yet still meets the 10-percent threshold for applicability of the payment adjustment, would be able to request consideration for a significant hardship exemption from application of the 2012 eRx payment adjustment, which would be reviewed on a case-by-case basis. We believe that it is a significant hardship for eligible professionals who have prescribing privileges, but infrequently prescribe, to become successful electronic prescribers because the nature of their practice may limit the number of opportunities an eligible professional or group practice to prescribe, much less electronically prescribe.

d. Insufficient Opportunities To Report the Electronic Prescribing Measure Due to Limitations of the Measure's Denominator

To the extent an eligible professional or group practice has an eRx system, electronically prescribes, and has denominator-eligible visits, but does not normally write prescriptions associated with any of the types of visits included in the eRx measure's denominator (for example, certain types of physicians such as surgeons), we are proposing at 42 CFR 414.92(c)(2)(ii)(F) that the eligible professional or group practice would be able to request consideration for a significant hardship exemption from application of the 2012 eRx payment adjustment, which would be reviewed on a case-by-case basis. Similar to the proposed hardship category for lack of prescribing activity, we believe it would be a significant hardship for eligible professionals who do not have a sufficient opportunity to report the eRx measure because of the limitations of the eRx measure's denominator to meet the criteria for being a successful electronic prescriber. While such eligible professionals may meet the 10-percent threshold for applicability of the payment adjustment and have at least 100 denominator-eligible visits prior to June 30, 2011, they may not be able to report their eRx activity at least 10 times because the bulk of their prescribing activity occurs in other circumstances that are not accounted for by the measure's denominator.

We invite public comments on the additional hardship exemption categories proposed in this proposed rule. In addition, we also invite input on other categories of significant hardship that were not specifically proposed so that we may consider them for purposes of the 2013 or 2014 eRx payment adjustment.

To request a hardship exemption for any of the categories proposed and previously described, we are proposing that an eligible professional or group practice participating in the 2011 eRx GPRO provide to us by the date specified below, the following:

- Identifying information such as the TIN, NPI, name, mailing address, and e-mail address of all affected eligible professionals.
- The significant hardship exemption category(ies) above that apply.
- A justification statement describing how compliance with the requirement for being a successful electronic prescriber for the 2012 eRx payment adjustment during the reporting period would result in a significant hardship to the eligible professional or group practice.
- An attestation of the accuracy of the information provided.

The justification statement should be specific to the category under which the eligible professional or group practice is submitting its request and must explain how the exemption applies to the professional or group practice. For example, if the eligible professional is requesting a significant hardship exemption due to Federal, State, or local law or regulation, he or she must cite the applicable law and how the law restricts the eligible professional's ability to electronically prescribe. Similarly, if the eligible professional is requesting a significant hardship due to lack of prescribing activity, the eligible professional must provide the number of prescriptions generated during the 2012 eRx payment adjustment reporting period. We would review the information submitted by each eligible professional and group practice on a case-by-case basis. In addition, we are proposing that an eligible professional or group practice must, upon request, provide additional supporting documentation if there is insufficient information (such as, but not limited to, a TIN or NPI that we cannot match to the Medicare claims, a certification number for the certified EHR technology that does not appear on the list of certified EHR technology, or an incomplete justification for the significant hardship exemption request) to justify the request or make the determination of whether a significant hardship exists.

We also are proposing that eligible professionals or group practices would be able to submit significant hardship exemption requests using a Web-based tool or interface. However, our ability to receive the significant hardship requests in this manner would be dependent on the development of such a Web site being completed prior to the publication of the final rule. In the event that such a Web site is not available, an eligible professional or group practice would be required to send us an application for a hardship exemption with such information by mail. We are not proposing to allow an eligible professional or group practice to submit significant hardship exemption requests via e-mail or fax because additional security precautions would need to be put into place. In some cases, a TIN may consist of an eligible professional's social security number, which is considered to be personally identifiable information.

We are proposing that the eligible professional or group practice must submit the hardship request by no later than October 1, 2011, which, if submitted by mail, means postmarked no later than October 1, 2011. We also propose to extend the deadline for submitting requests for consideration for the two significant hardship exemption categories (that is, eligible professional or group practice practices in rural areas with limited high speed Internet access and eligible professional or group

practice practices in an area with limited available pharmacies for eRx) for the 2012 eRx payment adjustment that were finalized in the CY 2011 PFS final rule (75 FR 73564 through 73565) to October 1, 2011. Since this rule is not expected to be finalized prior to the current deadline of June 30, 2011, for submitting the G-codes that were created for these two significant hardship exemption categories via claims (or, for group practices, at the time group practices self-nominate), we propose that the Web-based tool or interface, if available, would be used to submit all significant hardship exemption requests (including those for the current significant hardship exemption categories). Eligible professionals who wish to request a significant hardship exemption for one of the current significant hardship exemption categories via claims-based submission of a G-code would still have to do so prior to the current deadline of June 30, 2011. If the Web-based tool is not developed prior to the publication of the final rule, then we would default to mail submission of all significant hardship exemption requests (including those for the current hardship exemption categories).

We are proposing October 1, 2011, because we seek to complete our review of the requests in time to instruct the carriers/MACs as to those eligible professionals or group practices that are not subject to the 2012 eRx payment adjustments based on the proposed additional significant hardship exemption categories. We would like to be able to process all such requests before we begin making the claims processing systems changes later this year to adjust eligible professionals' or group practices' payments starting on January 1, 2012. However, we anticipate that, in some cases, we may not be able to complete our review of the requests before the claims processing systems updates are made to begin reducing eligible professionals' and group practices' PFS amounts in 2012. In such cases, if we ultimately approve the eligible professional's or group practice's request for a significant hardship exemption, we would need to reprocess all claims for services furnished up to that point in 2012 that were paid at the reduced PFS amount. We also believe that this date allows sufficient time for eligible professionals (including those in group practices) that intend to use certified EHR technology and to qualify for the 2011 EHR Incentive Program in 2011 to have adopted the technology.

While we considered providing eligible professionals and group practices with additional time to submit requests for a significant hardship exemption under the proposed additional categories, we believe that doing so might result in the need to reprocess claims for 2012 services for eligible professionals. We invite public comment on the proposed process for submitting these requests for significant hardship exemptions to us (including comments on the type of information we are proposing eligible professionals and group practices must submit, the proposed options for how the information could be submitted, and the proposed timeframes for submission). We also invite comment on our proposal to extend the timeframe for submitting hardship exemption requests for the two categories we finalized in the CY 2011 PFS final rule and the proposed process for submitting these requests under the extended timeframe.

To the extent the final rule is not effective by October 1, 2011, then we propose that the eligible professional or group practice must submit the hardship request by no later than 5 business days after the effective date of the final rule. Eligible professionals and group practices may begin submitting significant hardship exemption requests at any time after the final rule is made available for public inspection by the Office of the Federal Register. In the event that the final rule is not made available for public inspection by the Office of the Federal Register by October 1, 2011, we seek comment on whether 5 business days after the effective date of the final rule would be an adequate amount of time for eligible professionals and group practices to submit a significant hardship exemption request.

We also are proposing that once we have completed our review of the eligible professional's or group practice's request and made a decision, we will notify the eligible professional or group practice of our decision and all such decisions would be final. Eligible professionals and group practices would not have the opportunity to request reconsiderations of their requests for significant hardship exemption.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Related to Proposed Changes to the 2011 Electronic Prescribing Measure

We do not believe there is any burden associated with the proposed changes to the 2011 eRx measure as the changes solely clarify whether we consider certified EHR technology to meet the technological requirements of the eRx measure and do not change the reporting requirements for purposes of reporting the eRx quality measure for the 2011 eRx incentive and 2013 eRx payment adjustment.

B. ICRs Regarding Proposed Additional Significant Hardship Exemption Categories for the 2012 eRx Payment Adjustment

We believe that any burden associated with submitting the hardship exemption requests for the additional categories we are proposing would be minimal and would be limited to the time and effort associated with gathering the requested information and submitting the information to CMS in the specified form and manner. Whether the application can be submitted online or through other means, we do not anticipate it taking more than a 2 hours per eligible professional to review the hardship exemption codes available, determine which code(s) applies to their particular situation, gather the information needed for the justification, and then complete and submit the information to CMS.

To provide an estimate of the burden associated with submitting a hardship exemption request, we need to determine the approximate number of physicians and eligible professionals that could be subject to the eRx payment adjustment in 2012 as well as the number of eligible professionals that could submit a hardship exemption request. Based on Medicare Part B claims data, it is estimated that approximately 209,000 eligible professionals could potentially be

subject to the 2012 payment adjustment unless they become a successful electronic prescriber (that is, report the electronic prescribing measure at least 10 times during the 6-month reporting period) or request a significant hardship exemption. Thus, the maximum total number of eligible professionals that could potentially need to request a significant hardship exemption is believed to be approximately 209,000. However based on participation numbers from previous eRx Incentive Program years, we predict that the number of eligible professionals impacted will in fact be lower. In 2009, 92,132 eligible professionals participated in the eRx program and preliminary data for 2010 indicates that 100,444 professionals have participated in the eRx Incentive Program. Based on this data, we have determined that it is more accurate to estimate that approximately 109,000 eligible professionals could potentially submit a significant hardship exemption request as over 100,000 eligible professionals are already participating in the program. While we do not have a precise estimate of how many of the eligible professionals that are not able to be successful electronic prescribers will request a significant hardship, we do know that since the proposed hardship exemption categories will not apply to all eligible professionals since they represent specific circumstances. Therefore, for purposes of this burden estimate, we will assume that, at a minimum, approximately 10 percent of the 109,000 eligible professionals that could potentially request a significant hardship exemption will do so. This brings our minimum estimated number of eligible professionals impacted to approximately 10,900. Based on our estimate that the time needed to collect and report the information requested will be 2 hours, we believe that the total burden associated with requesting a significant hardship exemption will range from approximately 21,800 hours (10,900 eligible professionals × 2 hours per eligible professional) to 418,000 hours (209,000 eligible professionals × 2 hours per eligible professional). Based on an average group practice labor cost of $58 per hour, we predict the annual burden cost to be between approximately $1,264,400 ($58 per hour × 21,800 hours) and $24,244,000 ($58 per hour × 418,000 hours). We welcome comments on the above estimates.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, *Attention:* CMS Desk Officer, CMS–3248–P. *Fax:* (202) 395–7245; or *E-mail: OIRA_submission@omb.eop.gov.*

IV. 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.

V. Regulatory Impact Statement

This proposed rule includes changes to the eRx Incentive Program. The first proposed change involves modifying the eRx quality measure used for certain reporting periods in CY 2011 to address uncertainties related to the technological requirements of the Medicare eRx Incentive Program. The eRx measure would be revised to indicate whether an eligible professional has adopted a qualified electronic prescribing system or certified EHR technology as defined at 45 CFR 170.102. The second proposed change involves proposing additions to the significant hardship exemption categories for the 2012 eRx payment adjustment. The proposed additional exemption categories for the 2012 e Rx payment adjustment include—(1) Eligible professionals who register to participate in the Medicare or Medicaid EHR Incentive Program and Adopt Certified EHR Technology; (2) the inability to electronically prescribe due to local, State, or Federal law; (3) limited prescribing activity; and (4) insufficient opportunities to report the electronic prescribing measure due to limitations of the measure's denominator. Finally, this rule proposes an extension of the deadline for the 2012 eRx payment adjustment, thereby allowing eligible professionals and group practices to submit the existing two significant hardship codes established in the 2011 PFS final rule with comment period. These hardship exemption categories are: (1) The eligible professional practices in a rural area without sufficient high speed Internet access; and (2) the eligible professional practices in an area without sufficient available pharmacies for electronic prescribing.

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January18, 2011), 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 Orders 12866 and 13563 direct 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). We estimate that the impact of the proposed changes would be $30 million for fiscal year (FY) 2012, net of premium offset based on the FY 2012 President's budget baseline and $20 million for FY 2013. Therefore, this proposed rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities if a rule has a significant economic impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Individuals and States are not included in the definition of a small entity. A majority of the physicians and other eligible professionals affected by this proposed rule are small entities either by being nonprofit organizations or by meeting the Small Business Administration size thresholds for a small healthcare business (having revenues of less than $7.0 million to $34.5 million in any 1 year). While we do not have precise estimates, we believe this proposed rule would affect a substantial number of small entities (that is, several thousand or more). We welcome detailed information on the number of physicians and other professionals who would be affected by these proposals (that is, the number of physicians and other professionals who currently believe they are not able to meet the requirements for the 2012 eRx payment adjustment on the grounds that it would pose a significant hardship and for whom one or more of the proposed

significant hardship exemption categories could apply).

We interpret the requirement for preparation of an Initial Regulatory Flexibility Analysis as applying to proposed rules that impose significant economic burden. The Office of the Chief Council for Advocacy within the Small Business Administration believes that the requirement applies whether the economic impact is positive or negative. Regardless, we normally prepare a voluntary analysis when proposed rules would have a significant positive impact. In this case, the proposed change to the eRx measure under the eRx Incentive Program for purpose of reporting for the 2011 eRx incentive and the 2013 eRx payment adjustment and the proposed additional significant hardship exemption categories, if applicable, for purposes of the 2012 eRx payment adjustment would reduce burden for eligible professionals. The proposed modification to the eRx measure would eliminate any uncertainty as to whether eligible professionals who are participating in both the eRx Incentive Program and the EHR Incentive Program can use the certified EHR technology that they adopted for the EHR Incentive Program to electronically prescribe under the eRx Incentive Program. Therefore, there would no longer be any ambiguity as to whether eligible professionals can use the same technology for both programs and less time and effort spent by eligible professionals to determine whether the certified EHR technology they have adopted for purposes of the EHR Incentive Program could be used to meet the eRx quality measure under the eRx Incentive Program. It is difficult to estimate the precise economic impacts of these changes on the affected entities.

We believe that the proposed additional significant hardship exemption categories for the 2012 eRx payment adjustment would reduce the number of eligible professionals that would otherwise be subject to a 1.0 percent adjustment in the PFS amount for covered professional services furnished in 2012. Also, the proposed changes would continue to encourage adoption of electronic prescribing in the interest of improving the medication prescription process while acknowledging circumstances that may prevent physicians and other professionals from successfully participating in the eRx Incentive Program. Based on 2010 Medicare Part B claims data, we believe approximately 209,000 eligible professionals would need to either be a successful electronic prescriber or request a hardship exemption to avoid the 2012 payment adjustment. However, we are unable to provide a precise estimate as to the number of eligible professionals, out of the total 209,000, that would potentially request a significant hardship exemption for one of the proposed hardship exemption categories. While we are aware, from public comments received in response to the 2011 PFS proposed and final rules with comment period, correspondence, inquiries received by our help desk, and comments made by eligible professionals on our national provider calls, open door forums, and a February 9, 2011 Town Hall Meeting, that there are eligible professionals who have expressed their inability to meet the successful electronic prescriber requirements for the 2012 eRx payment adjustment for one or more of the circumstances addressed by the proposed additional significant hardship exemption categories, we are not able to quantify in detail how many eligible professionals these proposed additional significant hardship exemptions could apply to since each eligible professional's individual circumstances are unique. We believe that any cost associated with requesting the significant hardship exemptions would be minimal since it would be limited to the time and effort associated with submitting a significant hardship exemption from the 2012 eRx payment adjustment either via the proposed Web tool or by mail. We believe that any cost associated with requesting a significant hardship exemption would, if applicable to the eligible professional, be offset by the eligible professional avoiding the payment adjustment in 2012.

Overall, we estimate that the impact of the proposed changes would be $30 million for FY 2012, net of premium offset based on the FY 2012 President's budget baseline and $20 million for FY 2013. We also welcome comments and information on the likely magnitudes of savings, and the likely numbers of affected physicians and other professionals who would achieve savings of various sizes, under the specific alternatives we propose. We note that each of the regulatory relief options discussed previously in this preamble constitutes a distinct alternative that we have considered. We welcome comments on whether there are any additional alternatives that are both reasonable and achievable under the time constraints imposed by the existing rule.

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 603 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 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 proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals. The eRx Incentive Program does not apply to 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 2011, that threshold is approximately $136 million. This rule would have no consequential effect 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 regulation 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 regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping.

For the reasons set forth in the preamble of this proposed rule, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR part 414 as set forth below:

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

1. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

Subpart B—Physicians and Other Practitioners

2. Section 414.92 is amended by revising paragraph (c)(2)(ii) to read as follows:

§ 414.92 Electronic Prescribing Incentive Program.

* * * * *

(c) * * *

(2) * * *

(ii) *Significant hardship exception.* CMS may, on a case-by-case basis, exempt an eligible professional (or in the case of a group practice under paragraph (e) of this section, a group practice) from the application of the payment adjustment under paragraph (c)(2) of this section if, CMS determines, subject to annual renewal, that compliance with the requirement for being a successful electronic prescriber would result in a significant hardship. Eligible professionals (or, in the case of a group practice under paragraph (e) of this section, a group practice) may request consideration for a significant hardship exemption from the 2012 eRx payment adjustment if one of the following circumstances apply:

(A) The practice is located in a rural area without high speed Internet access.

(B) The practice is located in an area without sufficient available pharmacies for electronic prescribing.

(C) Registration to participate in the Medicare or Medicaid EHR Incentive Program and adoption of certified EHR technology.

(D) Inability to electronically prescribe due to local, State or Federal law or regulation.

(E) Limited prescribing activity.

(F) Insufficient opportunities to report the electronic prescribing measure due to limitation's of the measure's denominator.

* * * * *

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

Dated: April 28, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: May 4, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2011–13463 Filed 5–26–11; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 223 and 224

[Docket No. 100903415–1286–02]

RIN 0648–XW96

Endangered and Threatened Wildlife and Plants; Endangered Species Act Listing Determination for Atlantic Bluefin Tuna

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

ACTION: Notice of a listing determination and availability of a status review document.

SUMMARY: After we, NMFS, received a petition to list Atlantic bluefin tuna (*Thunnus thynnus*) as threatened or endangered under the Endangered Species Act (ESA), we established a status review team (SRT) to conduct a review of the status of Atlantic bluefin tuna. We have reviewed the SRT's status review report (SRR) and other available scientific and commercial information and have determined that listing Atlantic bluefin tuna as threatened or endangered under the ESA is not warranted at this time. We also announce the availability of the SRR.

DATES: This finding is made as of May 27, 2011.

ADDRESSES: The Atlantic bluefin tuna status review report and list of references are available by submitting a request to the Assistant Regional Administrator, Protected Resources Division, Northeast Region, NMFS, 55 Great Republic Way, Gloucester, MA 01930. The status review report and other reference materials regarding this determination can also be obtained via the Internet at: *http://www.nero.noaa.gov/prot_res/CandidateSpeciesProgram/cs.htm.*

FOR FURTHER INFORMATION CONTACT: Kim Damon-Randall, NMFS Northeast Regional Office, (978) 282–8485; or Marta Nammack, NMFS, Office of Protected Resources (301) 713–1401.

SUPPLEMENTARY INFORMATION:

Background

On May 24, 2010, the National Marine Fisheries Service (NMFS) received a petition from the Center for Biological Diversity (CBD) (hereafter referred to as the Petitioner), requesting that we list the entire species of Atlantic bluefin tuna (*Thunnus thynnus*) or in the alternative, an Atlantic bluefin tuna distinct population segment (DPS) consisting of one or more subpopulations in United States waters, as endangered or threatened under the ESA, and designate critical habitat for the species. The petition contains information on the species, including the taxonomy; historical and current distribution; physical and biological characteristics of its habitat and ecosystem relationships; population status and trends; and factors contributing to the species' decline. The Petitioners also included information regarding possible DPSs of Atlantic bluefin tuna. The petition addresses the five factors identified in section 4(a)(1) of the ESA as they pertain to Atlantic bluefin tuna: (A) Current or threatened habitat destruction or modification or curtailment of habitat or range; (B) overutilization for commercial purposes; (C) disease or predation; (D) inadequacy of existing regulatory mechanisms; and (E) other natural or man-made factors affecting the species' continued existence.

On September 21, 2010, we determined that the petition presented substantial information indicating that the petitioned action may be warranted and published a positive 90-day finding in the **Federal Register** (FR) (75 FR 57431). Following our positive 90-day finding, we convened an Atlantic bluefin tuna status review team (SRT) to review the status of the species.

In order to conduct a comprehensive review, we asked the SRT to assess the species' status and degree of threat to the species with regard to the factors provided in Section 4(a)(1) of the ESA without making a recommendation regarding listing. The SRT was provided a copy of the petition and all information submitted in response to the data request in the FR notice announcing the 90-day finding. In order to provide the SRT with all available information, we invited several Atlantic bluefin tuna experts to present information on the life history, genetics, and habitat used by Atlantic bluefin tuna to the SRT.

We also hosted five listening sessions with Atlantic bluefin tuna fishermen. These sessions were held in Maine, Massachusetts, New Jersey, North Carolina, and Mississippi. Those with information relevant to the discussion topics for the sessions were also encouraged to submit information via mail or electronic mail. The SRT reviewed all this information during its consideration and analysis of potential threats to the species. The SRR is a summary of the information assembled by the SRT and incorporates the best scientific and commercial data available