

must clearly identify the information that is claimed confidential by marking the specific information on each page with a label such as “confidential business information,” “proprietary,” or “trade secret.”

(e) *No claim of confidentiality.* If no claim of confidentiality is indicated on Form U submitted to EPA under this part; if Form U lacks the certification required by § 711.15(b)(1); if confidentiality claim substantiation required under paragraphs (b), (c), and (d) of this section is not submitted with Form U; or if the identity of a chemical substance listed on the non-confidential portion of the Master Inventory File is claimed as confidential, EPA may make the information available to the public without further notice to the submitter.

§ 711.35 Electronic filing.

(a) You must use e-CDRweb to complete and submit Form U (EPA Form 7740–8). Submissions may only be made as set forth in this section.

(b) Submissions must be sent electronically to EPA via CDX.

(c) Access e-CDRweb and instructions, as follows:

(1) *By Web site.* Go to the EPA Inventory Update Reporting Internet homepage at <http://www.epa.gov/iur> and follow the appropriate links.

(2) *By phone or e-mail.* Contact the EPA TSCA Hotline at (202) 554–1404 or TSCA-Hotline@epa.gov for a CD–ROM containing the instructions.

[FR Doc. C1–2011–19922 Filed 9–2–11; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–3248–F]

RIN 0938–AR00

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

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

ACTION: Final rule.

SUMMARY: This final rule modifies the electronic prescribing (eRx) quality measure used for certain reporting periods in calendar year (CY) 2011; provides 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 extends 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 final rule with comment period.

DATES: *Effective Date:* These regulations are effective on October 6, 2011.

Deadline for Submission of Hardship Exemption Requests for the 2012 eRx Payment Adjustment: Hardship exemption requests for the 2012 eRx payment must be received by November 1, 2011.

FOR FURTHER INFORMATION CONTACT: Christine Estella, (410) 786–0485.

SUPPLEMENTARY INFORMATION:

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 final 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) 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 the Secretary’s estimate of Medicare Part B Physician Fee Schedule (PFS) allowed charges for covered professional services furnished by the eligible professional (or group practice) 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.

Following the 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 electronic prescribing 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 final rule published in the **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 concerns noted previously and in accordance with Executive Order 13563 (entitled "Improving Regulation and Regulatory Review" and released January 18, 2011), 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 subsequently proposed to make changes to the eRx Incentive Program in a proposed rule that appeared in the June 1, 2011 **Federal Register** (76 FR 31547) entitled "Medicare Program; Proposed Changes to the Electronic Prescribing (eRx) Incentive Program" (hereinafter referred to as the June 2011 proposed rule). As described further in sections II.A and II.B of this final rule, in that proposed rule we specifically proposed 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. Summary of the Proposed Rule and Analysis of and Responses to Public Comments

In this section of the final rule, we summarize our proposals, public comments, and our responses. We received over 404 public comments on the proposed rule. Approximately 39 comments were from groups representing eligible professionals, such as academic institutions, government agencies, and professional societies. The remaining comments were from

individual physicians and private citizens.

We received numerous comments that were not related to our proposal to modify the 2011 eRx quality measure or the proposals for additional significant hardship exemption categories for the 2012 eRx payment adjustment. While we appreciate the commenters' feedback, these comments are outside the scope of the issues addressed in this final rule. This final rule addresses our proposals to modify the 2011 eRx quality measure and establish additional significant hardship exemption categories related to the 2012 eRx payment adjustment. We will take these comments into consideration for future eRx Incentive Program years.

A. Modification of the CY 2011 Electronic Prescribing Quality Measure

In the CY 2011 PFS final rule with comment period entitled "Medicare Program; Payment Policies Under the Physicians Fee Schedule and Other Revisions to Part B for CY 2011" (75 FR 73553 through 76566), we finalized an eRx quality measure that would be used during the reporting periods in 2011 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" electronic prescribing system.

A qualified electronic prescribing 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 electronic prescribing 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 being a qualified electronic prescribing 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 electronic prescribing 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 electronic prescribing 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 the 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 electronic prescribing 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 electronic prescribing 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, in the proposed rule (76 FR 31549), we proposed changes to the eRx quality 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. This 2011 eRx measure, as it is written prior to the changes to the eRx measure we are finalizing in this final rule, is currently NQF-endorsed.

In the June 2011 proposed rule (76 FR 31549), we proposed 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" electronic prescribing system that performs the four functionalities previously discussed. We proposed to revise this description statement to indicate that the measure documents whether an eligible professional or group practice has adopted a "qualified" electronic prescribing 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.

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, in the June 2011 proposed rule (76 FR 31549), we also proposed that, for purposes of the 2011 eRx measure, Certified EHR Technology is required to comply with at least one of the Part D standards for the electronic transmission of prescriptions at 42 CFR 423.160(b)(2)(ii) (that is, NCPDP SCRIPT Version 8.1 and NCPDP SCRIPT Version 10.6). This requirement is consistent with the ONC certification requirements at 45 CFR 170.304(b) and 170.205(b)(1) and (2). We received no comments regarding our proposal to require that Certified EHR Technology comply with the Part D standards for the electronic transmission of prescriptions at 42 CFR 423.160(b)(2)(ii). Therefore, for the reasons we stated previously, we are finalizing this requirement.

Below we discuss comments regarding our proposal to change the description statement and what constitutes a "qualified" electronic prescribing system under the 2011 eRx quality measure.

Comment: Several commenters supported our proposal to modify the 2011 eRx measure to allow for use of Certified EHR Technology, and did not offer any other suggestions to modify the 2011 eRx measure.

Response: We appreciate the commenter's supportive comments and are finalizing this proposal.

Comment: One commenter asked us to reinstate G-codes G8445 and G8446, which were G-codes used in the eRx Incentive Program under previous program years that indicate actions other than the generation of an electronic prescription.

Response: Our intention for 2011 is to focus on the reporting of actual electronic prescribing events. G-code G8445 indicates that, although an eligible professional has an electronic prescribing system, no prescriptions were generated during the denominator-eligible encounter. G-code G8446 indicates that, although an eligible professional has access to an electronic prescribing system, a prescription was not generated electronically during the encounter because, due to State or Federal law or regulation, such as a prescription could not be generated electronically. These two G-codes do not indicate the use of an electronic prescribing system to generate a prescription. Since it is our desire to concentrate solely on the reporting of actual prescribing events, we are not allowing for the use of G8445 or G8446 for reporting for the 2011 eRx incentive and the 2013 eRx payment adjustment.

Comment: Some commenters expressed concern over not being able to report the eRx measure in instances where, although an electronic prescription was generated, eligible professionals could not appropriately report the eRx measure because these encounters did not fall within the eRx measure's denominator. Therefore, to account for this limitation, these commenters asked us to include codes not currently included in the eRx measure's denominator, such as CPT 77427, which is a code tied to radiation therapy; CPT 99024, which is a code related to postoperative visits; and G0438, which is one of the two newly introduced annual wellness visit codes.

Response: We appreciate the commenters' suggestions to modify the eRx measure's denominator to include these CPT and G codes. However, it is not operationally feasible to modify the analytics for the eRx measure used for the 2011 eRx incentive and 2013 eRx payment adjustment in this manner. Whereas our proposal to modify the measure for allowing use of Certified EHR Technology expands the types of

electronic prescribing systems recognized as “qualified” for purposes of reporting, the addition of denominator codes to the eRx measure for the 2011 eRx incentive and 2013 eRx payment adjustment would change the analytics of the eRx measure. We believe, however, the commenters’ concern about not being able to report the eRx measure due to electronically prescribing during encounters not included in the measure’s denominator is addressed by one of the additional significant hardship exemption categories we are finalizing in section II.B of this final rule. Specifically, for the reasons we state in section II.B.3.d of this final rule, we are finalizing a significant hardship exemption category due to insufficient opportunities to report the electronic prescribing measure due to limitations of the measure’s denominator.

Comment: Some commenters stated that, although they support our proposal to modify the eRx measure to allow for use of Certified EHR Technology, our proposal does not go far enough to align the eRx Incentive Program with the Medicare EHR Incentive Program, as the Certified EHR Technology must still meet the four functionalities of a “qualified” electronic prescribing system.

Response: We appreciate the commenters’ feedback. We are working to address differences, where appropriate, between the eRx Incentive Program and Medicare EHR Incentive Program. However, we did not propose to require that Certified EHR Technology to still meet the four functionalities identified in the measure to be a “qualified” electronic system. As we stated in the proposed rule (76 FR 31550), “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.” In addition, as we noted, we believe that Certified EHR Technology will be capable of performing all of the required functionalities for purposes of reporting the 2011 eRx quality measure.

After considering the comments received and for the reasons we articulated previously, we are finalizing our proposal to modify the description of the 2011 eRx measure to indicate that the measure documents whether an eligible professional or group practice has adopted a “qualified” electronic prescribing system that performs the four functionalities previously described or is Certified EHR Technology as defined at 42 CFR 495.4 and 45 CFR 170.102. We believe that

this change merely expands on the definition of a “qualified” electronic prescribing 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.

However, as stated previously, 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, Certified EHR Technology must comply with the Part D standards for the electronic transmission of prescriptions at 42 CFR 423.160(b)(2)(ii).

As stated previously, section 1848(k)(2)(C) 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 eRx measure is currently an NQF-endorsed measure, this modification to change the 2011 eRx measure description has 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.

With this change to the 2011 eRx measure description that we are finalizing in this final rule, eligible professionals (including those in group practices) that are participating in the eRx Incentive Program have the option of adopting either a qualified electronic prescribing system that performs the four functionalities previously discussed or Certified EHR Technology as defined at 42 CFR 495.4 and 45 CFR 170.102 regardless of whether the Certified EHR Technology has all four of the functionalities previously described.

Because the change to the 2011 eRx measure we are finalizing will not be effective until the effective date of this final rule, this change will 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 change to the 2011 eRx quality measure does 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 this final rule. The 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 was not finalized prior to the end of the 2012 eRx payment adjustment reporting period ended on June 30, 2011, the change to the eRx quality measures that we are finalizing in this final rule does not apply for purposes of reporting the eRx measure for the 2012 eRx payment adjustment. We note that this change to the eRx measure is consistent with our proposal under the CY 2012 PFS proposed rule entitled “Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2012” (76 FR 42890) to change the eRx measure for the 2012 through 2014 program years, which are the remaining years of the eRx Incentive Program.

B. Significant Hardship Exemption Categories for the 2012 eRx Payment Adjustment

1. Overview of the 2012 eRx Payment Adjustment

As required by section 1848(a)(5) of the Act, and in accordance with our regulations at § 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. Established Significant Hardship Exemption Categories 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 electronic prescribing.

In order for eligible professionals and group practices to identify these categories for purposes of requesting a significant 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 reported 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. Additional Significant Hardship Exemption Categories for the 2012 eRx Payment Adjustment

Following the publication of the CY 2011 PFS final rule with comment period, we received numerous requests to expand the categories under the significant hardship exemption for the 2012 eRx payment adjustment. Some stakeholders 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 posed a significant hardship and limited 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, in the proposed rule (76 FR 31551), we proposed 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. We also proposed to allow some additional time for submitting significant hardship exemption requests to CMS.

Specifically, we proposed 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:

- Eligible professionals who register to participate in the Medicare or Medicaid EHR Incentive Programs and adopt Certified EHR Technology.
- Inability to electronically prescribe due to local, State, or Federal law or regulation.
- Limited prescribing activity.
- Insufficient opportunities to report the eRx measure due to limitations of the measure's denominator.

Comment: One commenter suggested that we make changes to the regulation

text at § 414.92 to reflect our finalized changes.

Response: We agree and have revised the significant hardship regulation at 42 CFR 414.92(c)(2)(ii) to reflect the changes we are finalizing in this final rule.

Comment: One commenter was worried that if these additional significant hardship exemption categories to the 2012 eRx payment adjustment were finalized, he would not be able to earn a 2011 eRx incentive.

Response: Incentives earned under the eRx Incentive Program are governed by section 1848(m)(2)(C) of the Act, whereas payment adjustments earned under the eRx Incentive Program are governed by section 1848(a)(5)(A) of the Act. The Secretary's authority to establish significant hardship exemption categories for those circumstances where compliance with the requirement for being a successful electronic prescriber would result in a significant hardship only apply to the provisions related to eRx payment adjustments. Separate criteria for being a successful electronic prescriber were established for the 2011 eRx incentive in the CY 2011 PFS final rule with comment period (75 FR 73553).

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

In the June 2011 proposed rule (76 FR 31551), we proposed this exemption category at 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 electronic prescribing technology for purposes of the eRx Incentive Program until the list of Certified EHR Technologies 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 certified 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 considered Certified EHR Technology. 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 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 who are eligible for incentives under the Medicaid EHR Incentive Program with the majority of CY 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 electronic prescribing system for purposes of participation in the eRx Incentive Program, and Certified EHR Technology for purposes of participating in the Medicare and Medicaid EHR Incentive Programs), which could potentially be financially burdensome.

Comment: Several commenters supported our proposal to add a significant hardship exemption category for the 2012 eRx payment adjustment for eligible professionals who register to participate in the Medicare or Medicaid EHR Incentive Programs and adopt Certified EHR Technology without offering any other suggestions regarding this proposed significant hardship exemption category. Several commenters also stated that they would request an exemption under this significant hardship exemption category, should the category be finalized.

Response: We appreciate the commenters' supportive comments and are finalizing this significant hardship exemption category for the 2012 eRx payment adjustment.

Comment: Although commenters supported this significant hardship exemption category, several commenters recommended that we extend this significant hardship exemption category to eligible professionals other than those who have registered for the Medicare or Medicaid EHR Incentive Programs and adopted Certified EHR Technology,

such as those eligible professionals who: (1) Intend to adopt EHR technology in either CY 2011 or 2012; (2) attest in CY 2012; or (3) achieve meaningful use in CY 2012.

Response: We appreciate the commenters' feedback. However, we proposed this significant hardship exemption category for the 2012 eRx payment adjustment for those eligible professionals who have taken proactive steps, such as having an electronic prescribing system available for immediate use, towards participating in the Medicare or Medicaid EHR Incentive Programs, under which there is a component on reporting electronic prescribing activities. With respect to eligible professionals who intend to adopt EHR technology in CY 2011 or have not yet taken the steps required in order to apply for this significant hardship exemption, we believe that mere intent to adopt Certified EHR Technology or attest at a later date does not sufficiently demonstrate that an eligible professional will adopt Certified EHR Technology to participate in the Medicare or Medicaid EHR Incentive Programs. Unlike those eligible professionals who have already registered for the Medicare or Medicaid EHR Incentive Programs and have Certified EHR Technology available for immediate use, we would have to monitor and provide oversight over those eligible professionals who have not yet taken these steps to participate in the Medicare or Medicaid EHR Incentive Programs. To prevent these monitoring and oversight issues, we believe that all requirements to qualify for an exemption under this significant hardship exemption category must be met by October 1, 2011 and prior to the time the eligible professional requests an exemption.

Comment: While commenters supported our proposal to allow eligible professionals participating in the Medicaid EHR Incentive Program to request a significant hardship exemption from the 2012 eRx payment adjustment, some commenters stated that we should use the "adopt, implement, and upgrade" mechanism for receiving an incentive payment under the Medicaid EHR Incentive Program to determine whether an eligible professional should be exempt from the 2012 eRx payment adjustment.

Response: We recognize that eligible professionals who participate in the Medicaid EHR Incentive Program may qualify for an incentive payment if they adopt, implement, upgrade, or demonstrate meaningful use of Certified EHR Technology in their first year of participation. Eligible professionals who

attempt to qualify for an incentive payment under the Medicaid EHR Incentive Program by adopting, implementing, or upgrading Certified EHR Technology may request an exemption under this significant hardship exemption category provided that the eligible professional meets the requirements for this significant hardship exemption finalized in this final rule.

Comment: One commenter asked that we clarify the term "adopted" as it applies to this significant hardship exemption category.

Response: This significant hardship exemption category is intended for those eligible professionals who have registered to participate in the Medicare or Medicaid EHR Incentive Programs and adopted Certified EHR Technology. That is, in order to potentially qualify for an exemption under this significant hardship exemption category, an eligible professional or group practice must have Certified EHR Technology available for immediate use for purposes of participating in the Medicare or Medicaid EHR Incentive Programs.

Comment: Some commenters asked whether eligible professionals practicing in states that have not yet fully implemented their Medicaid EHR Incentive Program, and therefore do not have the ability to register for participation in the Medicaid EHR Incentive Program, could apply for an exemption under this significant hardship exemption category.

Response: We appreciate the commenters' feedback. We realize that not all states have fully implemented their Medicaid EHR Incentive Programs. Rather, the implementation of these Medicaid EHR Incentive Programs is pending. This, however, does not affect an eligible professional's ability to register to participate in his/her state's Medicaid EHR Incentive Program. Therefore, eligible professionals practicing in states where their respective Medicaid EHR Incentive Program have not yet been implemented are not precluded from requesting or qualifying for an exemption under this significant hardship exemption category. We note that eligible professionals must still meet the finalized requirements we are finalizing as described below, with regard to this significant hardship exemption category.

Comment: One commenter stated that eligible professionals participating under Medicare Advantage (MA) also be allowed to submit a significant hardship request under this exemption category.

Response: We appreciate the commenters' feedback. To the extent

that professionals that participate under MA are eligible to participate in the eRx Incentive Program for purposes of the 2012 eRx payment adjustment, these eligible professionals may qualify for an exemption under this significant hardship exemption category.

Comment: One commenter asked that practices working with Regional Extension Centers to achieve meaningful use under the Medicare or Medicaid EHR Incentive Programs be able to apply for this exemption.

Response: We appreciate the commenter's feedback. As long as the eligible professionals within the practice meet the requirements described for this significant hardship exemption category for the 2012 eRx payment adjustment, the eligible professionals within the practice may apply for this significant hardship exemption category.

Comment: Several commenters opposed our proposed requirement to provide a serial number of the product the eligible professional has adopted in order to be eligible to request a significant hardship exemption under this category. Some of these commenters stated that a serial number, in some instances, not available for his or her Certified EHR Technology.

Response: We solicited comments on whether eligible professionals should provide a serial number for their specific product. Based on the comments received and our belief that providing the "CMS EHR Certification ID" for the Certified EHR Technology which can be generated through the Certified HIT Products List (CHPL) Web site maintained by the Office of the National Coordinator for Health Information Technology (ONC) is sufficient evidence that an eligible professional possesses Certified EHR Technology available for immediate use, we will not require that eligible professionals provide his or her product's serial number when requesting an exemption under this significant hardship exemption category.

Comment: Several commenters suggested that an eligible professional be provided with flexibility in providing proof that an eligible professional has adopted Certified EHR Technology for purposes of participating in the Medicare or Medicaid EHR Incentive Programs. Some commenters suggested that eligible professionals have the option of either providing a certification or serial number. One commenter stated it was unnecessary for eligible professionals to provide such proof because CMS already has access to information on those eligible

professionals participating in the EHR Incentive Program.

Response: To qualify for an exemption under this significant hardship exemption category, an eligible professional must have Certified EHR Technology available for immediate use. In order to efficiently review and process requests for exemptions under this significant hardship exemption category, it is necessary to apply uniform requirements for qualifying for an exemption under this significant hardship exemption category. Therefore, rather than allow eligible professionals to submit either a certification number or serial number as proof that these eligible professionals have adopted Certified EHR Technology, we are requiring that every eligible professional submit the certification number associated with his or her Certified EHR Technology in order to qualify for consideration for an exemption under this significant hardship exemption category. We are requiring an eligible professional provide us with the CMS EHR Certification ID, not a serial number, because, as commenters stated, a serial number is, in some instances, not available for his or her Certified EHR Technology. With respect to the comment stating CMS already has this information, we note that providing a certification number for his or her Certified EHR Technology is not required at the time an eligible professional registers for participation under the Medicare or Medicaid EHR Incentive Programs. Rather, an eligible professional is not required to provide a certification number for his or her Certified EHR Technology by the time of attestation.

Comment: Some commenters stated that we should not perform a case-by-case review of exemption under this significant hardship exemption category. Rather, eligible professionals participating in the Medicare or Medicaid EHR Incentive Programs should be automatically exempt from the 2012 eRx payment adjustment.

Response: We appreciate the commenters' feedback. However, we are required by section 1848(a)(5)(b) of the Act to review requests for significant hardship exemption on a case-by-case basis.

After considering the comments received and for the reasons previously discussed, we are finalizing this significant hardship exemption category for the 2012 eRx payment adjustment for eligible professionals or group practices who register to participate in the Medicare or Medicaid EHR Incentive Programs and adopt Certified

EHR Technology. To be considered for a significant hardship exemption under this category, an eligible professional 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 42 CFR 495.4 and 45 CFR 170.102) that has been adopted for use no later than October 1, 2011.

Please note that, in order to qualify for an exemption to the 2012 eRx payment adjustment under this significant hardship exemption category, it is not necessary that an eligible professional receive an incentive payment under the Medicare or Medicaid EHR Incentive Program.

A request for a significant hardship exemption category under this category will then be reviewed on a case-by-case basis. For purposes of this significant hardship exemption category, the identifying information consists of the "CMS EHR Certification ID" for the Certified EHR Technology which can be generated through the CHPL Web site maintained by ONC. In requesting a significant hardship exemption category under this category, an eligible professional is attesting that he or she either has purchased the specified Certified EHR Technology (as identified by the CMS ID) or has the specified Certified EHR Technology (as identified by the CMS ID) available for immediate use and that the eligible professional intends to use that Certified EHR Technology to qualify for a Medicare or Medicaid EHR incentive for payment year 2011 "CMS EHR Certification ID" for the Certified EHR Technology which can be generated through the CHPL Web site maintained by ONC.

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

In the June 2011 proposed rule (76 FR 31551), we proposed 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, 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).

Comment: Several commenters supported our proposal to add a significant hardship exemption category for the 2012 eRx payment adjustment for eligible professionals who are unable to electronically prescribe due to local, State, or Federal law or regulation without offering any other suggestions regarding this significant hardship exemption category. Several commenters also indicated that they would request an exemption under this significant hardship exemption category, should the category be finalized.

Response: We appreciate the commenters' supportive comments and are finalizing this category.

Comment: Some commenters suggested that we encourage eligible professionals who cannot electronically prescribe narcotics because their electronic prescribing system is not yet compliant with Federal or State law to apply for an exemption under this significant hardship exemption category.

Response: This significant hardship exemption category is indeed intended for these eligible professionals who mainly prescribe narcotics but, due to limitations in local, State, or Federal law or regulation, cannot submit these prescriptions electronically.

After considering the comments received and for the reasons discussed, we are finalizing the significant hardship exemption category for the 2012 eRx payment adjustment for eligible professionals or group practices whose prescribing authority is limited 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). Please note that this significant hardship exemption category is not limited to those eligible professionals that practice in states that do not allow narcotic prescriptions to be transmitted electronically. Eligible professionals or group practices may request consideration for an exemption under this significant hardship category from application of the 2012 eRx payment adjustment, which will be reviewed on a case-by-case basis.

c. Limited Prescribing Activity

In the June 2011 proposed rule (76 FR 31552), we proposed 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, 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 of an eligible professional or group practice to prescribe, much less electronically prescribe.

Comment: Several commenters supported our proposal to add a significant hardship exemption category for the 2012 eRx payment adjustment for eligible professionals who have limited prescribing activity without offering any other suggestions regarding this significant hardship exemption category. Several commenters also stated that they would request an exemption under this significant hardship exemption category, should the category be finalized.

Response: We appreciate the commenters' supportive comments. We are finalizing the significant hardship exemption category for eligible professionals who have limited prescribing activity.

Comment: One commenter suggested that we establish a G-code for this significant hardship exemption category, similar to the G-codes we've established for the two significant hardship exemption categories finalized

in 2011 PFS final rule described in section II.B.2 of this final rule.

Response: We appreciate the commenters' feedback. Unfortunately, it is not technically feasible for us to create a G-code for this significant hardship prior to the deadline we are finalizing in section II.B.5 of this final rule for submitting significant hardship exemption requests for the 2012 eRx payment adjustment.

After considering the comments received and for the reasons previously discussed, we are finalizing this significant hardship exemption category for the 2012 eRx payment adjustment for eligible professionals or group practices who have prescribing privileges but do not prescribe or very infrequently prescribe in 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 meet the 10-percent threshold for applicability of the payment adjustment. Exemption requests under this significant hardship exemption category will be reviewed on a case-by-case basis.

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

To the extent an eligible professional or group practice has an electronic prescribing 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), in the proposed rule (76 FR 31552), we proposed 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 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.

Comment: Several commenters supported our proposal to add a significant hardship exemption category for the 2012 eRx payment adjustment for eligible professionals who have insufficient opportunities to report the electronic prescribing measure due to limitations of the measure's denominator without offering any other suggestions regarding this proposed significant hardship exemption category. Several commenters also stated that they would request an exemption under this significant hardship exemption category, should the category be finalized.

Response: We appreciate the commenters' supportive comments and are finalizing this category.

Comment: One commenter stated that eligible professionals who provide electronic prescriptions on a day different than the beneficiary's visit, such as the situation where an eligible professional provides a prescription during a postoperative visit, should be able to apply for a significant hardship exemption category.

Response: We agree. This significant hardship exemption category is intended for instances such as these, where an eligible professional electronically prescribes but, because the measure's denominator only accounts for certain patient encounters, cannot report the electronic prescribing instance.

After considering the comments received, we are finalizing the significant hardship exemption category for the 2012 eRx payment adjustment for eligible professionals or group practices that have an electronic prescribing system, electronically prescribes, and has denominator-eligible visits, but do 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). Requests for an exemption under this significant hardship exemption category will be reviewed on a case-by-case basis.

e. Significant Hardship Exemption Categories Not Proposed in the Proposed Rule

Comment: While our proposal for additional significant hardship

exemption categories was appreciated, several commenters suggested we, in general, add more hardship exemption categories for the 2012 eRx payment adjustment, or offered specific additional hardship circumstances for our consideration.

Response: We appreciate the commenters' feedback. However, as discussed below, we are not finalizing any of the additional significant hardship exemption categories commenters suggested because such suggested significant hardship exemption categories were not proposed in the proposed rule, do not constitute a significant hardship under section 1848(a)(5) of the Act, or involve circumstances that may be covered by the limitations to the 2012 eRx payment adjustment established in the CY 2011 PFS final rule (75 FR 73562), the significant hardship exemption categories previously established in the CY 2011 PFS final rule, or the significant hardship exemption categories we are finalizing in this final rule.

Comment: Several commenters stated that surgeons, neuro-ophthalmologists, orthopedic doctors, and radio-oncologists could not meet the criteria for being a successful electronic prescriber for the 2012 eRx payment adjustment because these specialties mainly prescribe narcotics. Several commenters also stated that optometrists, eligible professionals who prescribe narcotics, eligible professionals who prescribe durable equipment, and other physicians whose specialties do not necessitate providing prescriptions on a regular basis should be exempt from the 2012 eRx payment adjustment.

Response: We appreciate the commenters' feedback. However, we believe that these suggested additional categories may already be addressed under the significant hardship exemption categories we are finalizing in this final rule.

For those eligible professionals who mainly prescribe narcotics, durable equipment, or only provide prescriptions on a limited basis, we believe that that these circumstances may be addressed by the additional significant hardship exemption categories we are finalizing, such as the significant hardship exemption categories discussed in sections II.B.3.b, II.B.3.c, and II.B.3.d of this final rule. For example, the significant hardship exemption category for eligible professionals or group practices whose prescribing authority is limited to the extent that local, State, or Federal law or regulation described in section

II.B.3.b. of this final rule is intended to provide for possible exemptions for those eligible professionals or group practices who cannot meet the criteria for being a successful prescriber for the 2012 eRx payment adjustment because they mainly prescribe narcotics. This significant hardship exemption category may apply, for example, to eligible professionals such as surgeons who mainly prescribe narcotics in a State that does not permit or limits the transmission of a narcotic prescription through electronic means.

The significant hardship exemption category for eligible professionals and group practices with limited prescribing activity described in section II.B.3.c of this final rule is intended to provide for possible exemption of eligible professionals who rarely prescribe yet still meet the 10-percent threshold for applicability of the payment adjustment and have at least 100 denominator eligible visits prior to June 30, 2011. This significant hardship exemption category may, for example, apply to those specialties where prescriptions are not given on a regular basis.

Furthermore, the significant hardship exemption category for eligible professionals or group practices who do not normally write prescriptions associated with any of the types of visits included in the eRx quality measure's denominator described in section II.B.3.d of this final rule is intended to exempt those eligible professionals such as surgeons or radio-oncologists who usually provide prescriptions outside denominator-eligible encounters.

Comment: Several commenters stated that chiropractors should be exempt from the 2012 eRx payment adjustment.

Response: With respect to chiropractors, as we mentioned previously in section II.B.1. of this final rule, we note that we finalized limitations to the 2012 eRx payment adjustment in the CY 2011 PFS final rule (75 FR 73562). Because chiropractors are not within the category of eligible professionals to which the 2012 eRx payment adjustment applies, chiropractors are not subject to the 2012 eRx payment adjustment.

Comment: Some commenters stated that eligible professionals who only see Medicare patients on an occasional basis, part-time providers, eligible professionals who dispense medications from their offices, eligible professionals who only perform home visits for patients, eligible professionals who practice on military bases, and eligible professionals who work in nursing homes or long-term care facilities should be exempt from the 2012 eRx

payment adjustment because these eligible professionals either only have limited opportunities to prescribe medications or cannot electronically prescribe on-site.

Response: With respect to these eligible professionals with a limited practice, such as part-time providers, we believe that, given the limitations finalized in the CY 2011 PFS final rule (75 FR 73562) that are described in section II.B.1 of this final rule, these groups potentially may not be subject to the 2012 eRx payment adjustment. Specifically, an eligible professional will not be subject to the 2012 eRx payment adjustment if the eligible professional 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. For those eligible professionals who practice off-site, such as eligible professionals who perform home visits, we note that, although an eligible professional may not have a readily available electronic prescribing system during instances such as a home visit, we believe that these eligible professionals still have the ability to dispense an electronic prescription. Therefore, we do not believe that these instances constitute significant hardships in the manner that these significant hardship exemption categories we are finalizing do.

Comment: Several commenters stated that physicians who are over 60, eligible for Social Security benefits, or nearing retirement may find it difficult to justify the cost of implementing electronic prescribing systems.

Response: With respect to eligible professionals who are over 60, eligible for social security benefits, or nearing retirement, these scenarios were raised by commenters during the comment period and addressed in the CY 2011 PFS rule. As we stated in the CY 2011 PFS final rule (75 FR 73564), we believe these instances do not constitute significant hardships in the manner that these significant hardship exemption categories we are finalizing do. We believe that encouraging the use of electronic prescribing outweighs the cost of purchasing an electronic prescribing system, because we believe use of these systems will readily provide patient prescription history leading to better management of patient prescriptions and greater patient safety and care.

Comment: Some commenters also suggested that a significant hardship category be created for eligible professionals who did not meet the

criteria for being a successful electronic prescriber for the 2012 eRx payment adjustment due to circumstances beyond one's control, such as natural disasters (for example, major floods), being on maternity leave, or having patients who do not consent to the use of electronic prescribing.

Response: With respect to eligible professionals who did not meet the criteria for being a successful electronic prescriber for the 2012 eRx payment adjustment due to circumstances beyond one's control, such as being on maternity leave or having patients who do not consent to the use of electronic prescribing, we understand that unforeseen circumstances may arise that prevent an eligible professional from reporting the eRx measure. However, we believe that these circumstances may be addressed by the limitations to the 2012 eRx payment adjustment we have finalized.

With respect to those eligible professionals who have experienced natural disasters during a substantial portion of the 2012 eRx payment adjustment reporting period (that is, January 1, 2011 through June 30, 2011), such as the case of major flooding in the Midwest, we believe that these eligible professionals may apply for an exemption under the significant hardship exemption categories we have previously finalized (that is, the significant hardship exemption categories we finalized in the CY 2011 PFS final rule). For example, as described in section II.B.2 of this final rule, in the CY 2011 PFS final rule, we established a significant hardship exemption for those eligible professionals who practice in an area with limited available pharmacies for electronic prescribing. If a natural disaster such as a major flood leaves electronic prescribing systems, both in physician offices and pharmacies, offline, then an eligible professional may potentially qualify for a significant hardship exemption under this significant hardship exemption category. In addition, if, for instance, an eligible professional's practice is severely stunted due to a devastating natural disaster, an eligible professional could request consideration for an exemption under the limited prescribing activity significant hardship exemption category.

Comment: Several commenters have also requested that a significant hardship exemption category to the 2012 eRx payment adjustment be established for those eligible professionals who attempted but did not meet the criteria for being a successful electronic prescriber for the 2012 eRx

payment adjustment due to problems encountered using the electronic prescribing system or reporting the eRx quality measure via claims. For example, some commenters stated they reported G-code G8443 (which was the eRx measure's numerator under the 2009 eRx Incentive Program) instead of G-code G8553, which is the 2011 eRx measure's numerator. Several commenters stated that, although they reported G-code G8553 on claims, the G-codes were stripped because the eligible professionals were submitting claims with a zero dollar amount. Some commenters have also encountered vendor issues with respect to reporting the eRx measure.

Response: We appreciate the commenters' feedback. In general, we understand that problems may occur that prevent the successful reporting of the eRx measure. However, we do not believe that these errors constitute a significant hardship under section 1848(a)(5)(B) of the Act. Rather, these are reporting errors that may have prevented an eligible professional from successfully reporting the eRx measure.

In addition, with respect to those eligible professionals who mistakenly reported G-code G8443, which was one of codes in the eRx measure's numerator in 2009, instead of G8553, which has been the only code in the eRx measure's numerator since 2010, we note that the public was given ample notice via rulemaking, which included an opportunity to comment on the eRx measure's proposed numerator G-code. Educational materials and other outreach opportunities such as national provider calls and special open door forums also provided instruction to report G8553 for all reporting periods occurring in 2011.

With respect to those instances where the G-codes were stripped because the eligible professionals were submitting claims with a zero dollar amount, we note that eligible professionals were provided with guidance as to how to successfully report the eRx measure. Specifically, we provided a guidance document titled "Claims-Based Reporting Principles for Electronic Prescribing (eRx) Incentive Program," which provided instructions on how to properly report the eRx measure via claims. This document, which is available at https://www.cms.gov/ERxIncentive/06_E-Prescribing_Measure.asp#TopOfPage, states that, if a system does not allow a \$0.00 line-item charge, a nominal amount can be substituted."

With respect to experiencing vendor issues, we understand that these eligible professionals have made a good faith

effort to successfully report the eRx measure for the 2012 eRx payment adjustment. However, we do not believe that these errors constitute a significant hardship.

Comment: Some commenters also stated that small business practices should be exempt from the 2012 eRx payment adjustment, since the purchase of an electronic prescribing system puts a significant financial burden on these small practices.

Response: We understand that there are significant costs associated with purchasing an electronic prescribing system. However, we do not believe that this constitutes a significant hardship under section 1848(a)(5)(8) of the Act. We believe that encouraging the use of electronic prescribing outweighs the cost of purchasing an electronic prescribing system, because we believe use of these systems will readily provide patient prescription history, leading to better management of patient prescriptions and greater patient safety and care.

As stated earlier, after considering the comments received and for the reasons we discussed previously, we are finalizing the all of the following additional significant hardship exemption categories for the 2012 eRx payment adjustment:

- Eligible professionals who register to participate in the Medicare or Medicaid EHR Incentive Programs and Adopt Certified EHR Technology.
- Inability to electronically prescribe due to local, State, or Federal law or regulation.
- Limited prescribing activity.
- Insufficient opportunities to report the eRx measure due to limitations of the measure's denominator.

Therefore, we are finalizing our proposal to modify 42 CFR 414.92 to specify these significant hardship exemption categories to the 2012 eRx payment adjustment as well as making a minor edit to 42 CFR 414.92.

4. Process for Requesting Significant Hardship Exemption Categories for the 2012 eRx Payment Adjustment

In the June 2011 proposed rule (76 FR 31552), we proposed a process different from that finalized in the CY 2011 PFS final rule for requesting the significant hardships for the 2012 eRx payment adjustment described above.

Specifically, to request a significant hardship exemption for any of the categories proposed and previously described for the 2012 eRx payment adjustment, we proposed that an eligible professional or group practice provide to us, via a Web-based tool or interface (or by mail, if it is not technically

feasible for use to develop such a Web site) 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. 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.
- An attestation of the accuracy of the information provided.

In addition, we proposed 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 whether a significant hardship exists.

We did not propose, nor are we allowing, 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.

Comment: While several commenters supported our proposal to use a Web-based tool to process requests for significant hardship exemptions, some commenters stated that we should allow an eligible professional or group practice's administration and staff to

complete a significant hardship exemption request on his/her behalf.

Response: We appreciate the commenter's feedback. However, we believe it is necessary that the eligible professional complete the request for an exemption to the 2012 eRx payment adjustment for the finalized significant hardship exemption category(ies). The eligible professional must personally attest with respect to the accuracy of the statements provided in the request for an exemption. We believe that requiring an eligible professional, rather than his or her staff, to apply for an exemption will not result in a significant burden to the eligible professional as the eligible professional need only request an exemption once.

However, for group practices, according to the CY 2011 PFS final rule, a single individual is designated as the single contact person for that group practice. Because, this individual has previously been chosen to act on behalf of the group for issues relating to the eRx Incentive Program, the contact person for the respective group practice must submit the request for an exemption for the respective group practice under these finalized significant hardship exemption categories. In submitting the request for an exemption under these finalized significant hardship exemption categories, this contact person is attesting to the accuracy of the information provided on behalf of the group practice.

Comment: One commenter suggested that we develop a tool that allows for the submission of supporting documentation, should additional information need to be submitted in order to thoroughly review a request for an exemption.

Response: While we agree that such a tool would be useful, at this time, it is not technically feasible for us to develop an upload function on the Web-based tool in time to receive supporting documentation. Despite our inability to provide an upload tool for submitting additional documentation, we note that all required information for a request for an exemption may be provided on the Web-based tool. In the event that we specifically requests additional documentation in order to thoroughly review an exemption request though, the eligible professional will send this documentation to us via mail.

Comment: One commenter suggested that CMS develop the submission tool in such a way as to prevent an eligible professional from submitting incomplete information. Another commenter suggested that we develop the Web-based tool to be user friendly.

Response: It is our intention that the Web-based tool be easily navigable. This includes indicating which fields are required for the eligible professional to complete in order to submit a complete request for a significant hardship exemption. We also intend to provide additional guidance for eligible professionals to learn how to navigate through the Web-based tool for purposes of submitting a significant hardship exemption request and to minimize the potential for errors.

Comment: Some commenters stated that we should encourage eligible professionals to submit more than one significant hardship exemption, should more than one apply.

Response: While an eligible professional need only request a significant hardship exemption to the 2012 eRx payment adjustment under one category, we are allowing eligible professionals to request a significant hardship exemption under more than one exemption category, should more than one category apply. While an eligible professional will only be required to select one applicable significant hardship exemption category when entering their request in the Web-based tool, they can include the other categories that apply in their justification statement should more than one category apply.

Comment: One commenter stated that we should encourage eligible professionals who have already reported the eRx measure during the applicable 2012 eRx payment adjustment payment reporting period to apply for a significant hardship exemption, should one apply.

Response: We did not propose to limit the pool of eligible professionals who can apply for an exemption request under the finalized significant hardship exemption categories. If an eligible professional believes that he or she qualifies for an exemption under one or more of the significant hardship exemption categories for the 2012 eRx payment adjustment, he or she may submit a request for an exemption regardless of whether he or she attempted to report the eRx measure for purposes of the 2012 eRx payment adjustment. As noted previously, all requests for a significant hardship exemption from the 2012 eRx payment adjustment will be reviewed on a case-by-case basis.

Comment: One commenter stated that CMS should provide a resource to address questions eligible professionals may have about submitting significant hardship exemption requests.

Response: We appreciate the commenter's feedback. We note that

questions regarding use of the Web-based tool may be directed to the Quality Net Help Desk. The Quality Net Help Desk may be contacted via telephone at 1-866-288-8912 or via e-mail at Qnetsupport@sdps.org. Further information on the QualityNet Help Desk is available at https://www.cms.gov/ERxIncentive/11_HelpDeskSupport.asp#TopOfPage.

Comment: Some commenters stated that CMS should, prior to allowing for submission of significant hardship requests, notify each eligible professional of the following: (1) Whether an eligible professional falls under a limitation to the 2012 eRx payment adjustment that was finalized in the 2011 PFS Final Rule and described in section II.B.1 of this final rule and (2) whether an eligible professional has met the criteria for being a successful electronic prescriber for the 2012 eRx payment adjustment.

Response: We appreciate the commenter's feedback. However, it is not technically feasible for us to provide notification to each eligible professional as to whether the 2012 eRx payment adjustment applies or whether an eligible professional has met the criteria for being a successful electronic prescriber for the 2012 eRx payment adjustment prior to the deadline for submitting a significant hardship request. Claims for dates of service within the 2012 eRx payment adjustment reporting period (that is, January 1, 2011 through June 30, 2011) are still being processed and analyzed.

Furthermore, we note that the burden of requesting an exemption to the 2012 eRx payment adjustment under the finalized significant hardship exemption categories lies with the eligible professional or group practice.

Comment: Some commenters stressed the importance of providing sufficient education and outreach so that eligible professionals are aware of the finalized proposals relating to the addition of significant hardship exemption categories, as well as the process for submitting significant hardship requests for the 2012 eRx payment adjustment. Some commenters suggested that we work with physician organizations to inform eligible professionals of these changes.

Response: We agree and intend to provide education and outreach opportunities to inform eligible professionals of the changes to the program we are finalizing in this final rule. We also plan to work with organizations outside of CMS to ensure that the provider community is aware of these changes.

Comment: One commenter suggested that CMS work to avoid the reprocessing of claims.

Response: We appreciate the commenter's feedback. We will work to avoid the reprocessing of claims. We intend to complete our review of the request for exemptions under the significant hardship exemption categories finalized in this final rule and the CY 2011 PFS final rule in time to instruct the carrier/MACs as to those eligible professionals or group practices we determine are exempted from the 2012 eRx payment adjustment. 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, particularly in instances where eligible professionals submit significant hardship exemption requests closer towards the November 1, 2011 deadline, 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 or group practice's request for a significant hardship exemption after January 1, 2012, we would need to reprocess all claims for services furnished up to that point in 2012 that were paid at the reduced PFS amount, which we anticipate may take several months. In order to avoid the reprocessing of claims, we encourage eligible professionals who wish to submit a significant hardship exemption request to do so as soon as possible, rather than waiting until the November 1, 2011 deadline to submit such a request.

Comment: One commenter stated that submitting significant hardship exemption requests via mail would be too burdensome.

Response: We appreciate the commenter's feedback. Based on the comments received, we believe the Web-based tool is the most effective way to receive and process significant hardship exemption requests. We are only allowing individual eligible professionals to submit a significant hardship exemption request via the Web-based tool.

Comment: One commenter sought clarification and instructions as to how to request an exemption under the significant hardship exemption categories via the Web-based tool and asked how we will provide a case-by-case review of these requests.

Response: We appreciate the commenter's feedback. Instructions on how to access the Web-based tool and request an exemption will be available on the eRx Incentive Program Web site at <http://www.cms.gov/ERxIncentive/>. With respect to how we will review all exemption requests, given the requirement that we do so on a case-by-case basis, we expect that each review will be tailored to the specific case presented.

After considering all the comments received and for the reasons stated previously, we are finalizing the following process to request a significant hardship exemption from the 2012 eRx payment adjustment under any of the categories (including multiple categories, if applicable) that we are finalizing in this final rule:

- Identifying information which include 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 (as was previously described).
- An attestation of the accuracy of the information provided.

Individual eligible professionals must submit significant hardship exemption requests using a Web-based tool only. Information on how to access the Web-based tool as well as detailed instructions for applying for a significant hardship exemption will be available on the eRx Incentive Program Web site at <http://www.cms.gov/erx incentive/>.

Although in the June 2011 proposed rule (76 FR 31552), we proposed to allow group practices participating in the eRx Incentive Program as an eRx GPRO to also submit an exemption request via the Web-based tool, for technical reasons, we cannot allow group practices to submit significant hardship exemption requests using this Web-based tool. In the proposed rule, we also stated that, if not technically feasible to use a Web-based tool, an eligible professional or group practice may submit an exemption request via mail. As such, group practices who wish to submit an exemption request under one or more of the finalized 2012 eRx payment adjustment significant hardship exemption categories must submit this request via a mailed letter containing all of the information specified in the bullet points previously

listed. More information on how group practices may request a significant hardship via mail, such as the mailing address for submitting this request, will be available on the eRx Incentive Program Web site at <http://www.cms.gov/erx incentive/>.

Comment: Some commenters asked us to establish a process whereby an eligible professional or group practice may appeal a denial of a request for an exemption from the 2012 eRx payment adjustment under the finalized significant hardship exemption categories.

Response: We appreciate the commenters' feedback. We will perform a case-by-case review of each request for an exemption to the 2012 eRx payment adjustment. We believe that this review of a request will be sufficient to determine whether an eligible professional or group practice should be granted the exemption. Therefore, we are not providing a means for reconsideration of our determination to approve or deny exemption requests. We note that, although there is no reconsideration of our determination regarding an exemption, eligible professionals and group practices may contact the QualityNet Help Desk should they have additional questions regarding our determination.

5. Deadline for Submission of Significant Hardship Exemption Requests for the 2012 eRx Payment Adjustment

We proposed 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 (76 FR 31553). We also proposed to extend the deadline for submitting requests for consideration for the two significant hardship exemption category 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 electronic prescribing) 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.

We also considered providing eligible professionals and group practices with additional time to submit requests for a significant hardship exemption under the proposed additional categories but stated that we believed that doing so might result in the need to reprocess claims for 2012 services for eligible professionals. We also proposed a submission deadline for significant

hardship exemption requests no later than 5 business days after the effective date of the final rule to the extent the final rule was not effective by October 1, 2011, and sought comments whether such time would be adequate.

Comment: Some commenters stated that CMS will be overwhelmed by requests for significant hardship exemption categories, even with the creation and use of a Web-based tool, and, as a result, will not be able to timely review all significant hardship exemption requests.

Response: Since this is the first payment adjustment implemented under the eRx Incentive Program, we cannot determine how many requests we will receive. However, we will make every effort to review and process requests for significant hardship exemption categories in a manner as to avoid the reprocessing of claims.

Comment: Several commenters supported our proposal to extend the deadline for submitting significant hardship exemption requests for purposes of the 2012 eRx payment adjustment to October 1, 2011. Several commenters stated that a deadline of 5 business days after the effective date provides insufficient time for eligible professionals to be informed of and learn how to request a significant hardship exemption. Therefore, these commenters suggested other deadlines that they believe would allow for sufficient time for eligible professionals to be informed of and request an exemption. Some commenters suggested that eligible professionals and group practices be given at least 30 or 60 days after the effective date of the rule to submit significant hardship requests. Some commenters asked that the deadline for submitting a significant hardship exemption be extended to December 31, 2011. One commenter asked that the deadline for submitting requests for significant hardship exemption categories be extended to 180 days following publication of this final rule.

Response: We appreciate the commenters' feedback. We understand the commenters' concerns and believe it is important to provide eligible professionals with sufficient time to be informed of our finalized changes to the eRx Incentive Program for CY 2011. In order to ensure that eligible professionals are fully informed about these significant hardship exemption categories to the 2012 eRx payment adjustment, we are finalizing a deadline of November 1, 2011 for eligible professionals to submit a significant hardship request under the finalized significant hardship exemption

categories for the 2012 eRx payment adjustment.

Although we still believe the October 1, 2011 deadline would provide sufficient time for eligible professionals to be informed of and request an exemption, we are finalizing an extended deadline of November 1, 2011 to provide eligible professionals with more time to submit requests for a significant hardship exemption. Eligible professionals and group practices do not need to wait until the effective date of this final rule to submit a request for an exemption from the 2012 eRx payment adjustment. Rather, eligible professionals and group practices may begin submitting exemption requests immediately following the display of this final rule. As such, we believe that eligible professionals will have ample time to submit an exemption request.

Comment: Some commenters asked to align the deadline for submitting significant hardship exemption requests under the eRx Incentive Program with the deadline for achieving meaningful use under the Medicare or Medicaid EHR Incentive Programs.

Response: We appreciate the commenters' feedback. However, it is not technically feasible for us to extend the deadline for submitting significant hardship exemption category requests past November 1, 2011 in order to align it with the deadline for achieving meaningful use under the Medicare or Medicaid EHR Incentive Programs which for payment year 2011 does not occur until 2012. In order to avoid retroactive payments and claims reprocessing, we must allow for sufficient time to analyze the request and make the necessary system changes prior to January 1, 2012.

After considering the comments received and for the reasons we explained previously, we are finalizing a deadline of November 1, 2011, for the submission of significant hardship exemption requests for purposes of the 2012 eRx payment adjustment. Therefore, an individual eligible professional must submit his or her request for a request for a significant hardship exemption via the Web-based tool by November 1, 2011. Please note that eligible professionals who wish to request a significant hardship exemption for one of the two significant hardship exemption categories that were previously finalized in the CY 2011 PFS final rule (75 FR 73564 through 73565) will not be able to do so via claims-based submission of a G-code, as the June 30, 2011 deadline for requesting the two established significant hardship categories in this manner has passed. Group practices must submit a request

for a significant hardship exemption via letter that must be postmarked no later than November 1, 2011.

We are implementing a deadline of November 1, 2011, and not later, 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 adjustment. 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 will need to reprocess all claims for services furnished up to that point in 2012 that were paid at the reduced PFS amount.

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 will be final.

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

A. ICRs Related to Changes to the 2011 eRx 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 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 proposed would be minimal and would be limited to the time and effort associated with gathering the requested information described in section II.B.4 of this final rule and submitting the information to CMS in the specified form and manner. Whether the application can be submitted online or mail, we do not anticipate it taking more than a 2 hours per eligible professional or group practice to review the significant hardship exemption, determine which category(ies) 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 eRx payment adjustment unless they become a successful electronic prescriber (that is, report the eRx measure at least 10 times during the 6-month reporting period) or receive 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 209,000 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 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 209,000 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 \times 2 hours per eligible professional) to 418,000 hours (209,000 eligible professionals \times 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 \times 21,800 hours) and \$24,244,000 (\$58 per hour \times 418,000 hours).

Comment: Some commenters suggested that CMS' estimates regarding how many eligible professionals will apply for a significant hardship exemption for the 2012 eRx payment adjustment is too low.

Response: We appreciate the commenters' feedback. While our minimum estimate are based on our participation numbers from the 2009 eRx Incentive Program, which is the latest complete participation information available for the eRx Incentive Program at this time, we note that the maximum estimate was based on an analysis of 2010 claims data to determine how many MDs, DOs, podiatrists, nurse practitioners, and physician assistants have at least 100 denominator eligible visits and meet the 10% threshold in a 6-month period. Thus, the maximum estimate assumes that every eligible professional who needs to report the eRx measure or be

subject to the payment adjustment will apply for a significant hardship exemption. Unfortunately, because we never implemented a payment adjustment under the eRx Incentive Program before, we cannot precisely estimate how many eligible professionals will apply for a significant hardship exemption.

IV. Regulatory Impact Statement

This final rule includes changes to the eRx Incentive Program. The first change we are finalizing 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 is being revised to indicate whether an eligible professional has adopted a qualified electronic prescribing system, which is a system that meets the four functionalities discussed above, or Certified EHR Technology as defined at 42 CFR 495.4 and 45 CFR 170.102. The second change we are finalizing is the adoption of additional significant hardship exemption categories for the 2012 eRx payment adjustment. The additional significant hardship exemption categories we are finalizing for the 2012 eRx 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 eRx measure due to limitations of the measure's denominator. Finally, this final rule provides an extension of the deadline for submitting requests for exemptions from the 2012 eRx payment adjustment under the additional significant hardship exemption categories, as well as the two significant hardship codes established in the CY 2011 PFS final rule with comment period: (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 (January 18, 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 changes will 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 final 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 final 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 final rule will affect a substantial number of small entities (that is, several thousand or more).

We interpret the requirement for preparation of an Initial Regulatory Flexibility Analysis as applying to final 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 final rules will have a significant positive impact. In this case, the 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 additional significant hardship exemption categories, if applicable, for purposes of the 2012 eRx payment adjustment will

reduce burden for eligible professionals. The modification to the eRx measure eliminates 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 is no 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 additional significant hardship exemption categories for the 2012 eRx payment adjustment we are finalizing in this final rule will reduce the number of eligible professionals that will otherwise be subject to a 1.0 percent adjustment in the PFS amount for covered professional services furnished in 2012. Also, the changes we are finalizing will 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 will need to either be a successful electronic prescriber or request a hardship exemption to avoid the 2012 eRx 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 will potentially request a significant hardship exemption for one of the hardship exemption categories. While we are aware, from public comments received in response to the CY 2011 PFS proposed rule and final rule 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 additional significant hardship

exemption categories, we are not able to quantify in detail how many eligible professionals these additional significant hardship exemption categories could apply to since each eligible professional's individual circumstances are unique. We believe that any cost associated with requesting a significant hardship exemption under these categories will be minimal since it will be limited to the time and effort associated with submitting an exemption request based on a finalized significant hardship exemption category from the 2012 eRx payment adjustment either via the Web tool or by mail. We believe that any cost associated with requesting a significant hardship exemption will, 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 changes we are finalizing will 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.

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 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 final rule will 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 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 for 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, the Centers for Medicare & Medicaid Services amends 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)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

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 eRx measure due to limitations 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: August 25, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: August 26, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2011-22629 Filed 8-31-11; 11:15 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 154

[CMS-9999-F]

RIN 0938-AR26

Rate Increase Disclosure and Review: Definitions of “Individual Market” and “Small Group Market”

AGENCY: Center for Consumer Information and Insurance Oversight, Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule amends a May 23, 2011, final rule entitled “Rate Increase Disclosure and Review”. The final rule provided that, for purposes of rate review only, definitions of “individual market” and “small group market” under State rate filing laws would govern even if those definitions departed from the definitions that otherwise apply under title XXVII of the Public Health Service Act (PHS Act). The preamble to the final rule requested comments on whether this policy should apply in cases in which State rate filing law definitions of “individual market” and “small group market” exclude association insurance policies that would be included in these definitions for other purposes under the PHS Act. In response to comments, this final rule amends the definitions of “individual market” and “small group market” that apply for rate review purposes to include coverage sold to individuals and small groups through

associations even if the State does not include such coverage in its definitions of individual and small group market. This final rule also updates standards for health insurance issuers regarding disclosure and review of unreasonable premium increases under section 2794 of the Public Health Service Act.

DATES: *Effective date.* This rule is effective on November 1, 2011.

FOR FURTHER INFORMATION CONTACT: Sally McCarty, (301) 492-4489 (or by e-mail: ratereview@hhs.gov).

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act (Pub. L. 111-148) was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (Pub. L. 111-152) was enacted on March 30, 2010. In this preamble, we refer to the two statutes collectively as the Affordable Care Act. The Affordable Care Act reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets.

Section 1003 of the Affordable Care Act adds a new section 2794 of the PHS Act, which directs the Secretary of the Department of Health and Human Services (the Secretary), in conjunction with the States, to establish a process for the annual review of “unreasonable increases in premiums for health insurance coverage.” The statute provides that health insurance issuers must submit to the Secretary and the applicable State justifications for unreasonable premium increases prior to the implementation of the increases. Section 2794 of the PHS Act does not apply to grandfathered health insurance coverage, nor does it apply to self-funded plans.

On December 23, 2010, we published a Notice of Proposed Rulemaking to implement section 2794. Among other things, because of unique characteristics of State rate review and for purposes of administrative efficiency, we proposed to adopt definitions of the individual and small group markets that would defer to definitions set forth in State rate filing laws. We did not discuss in the proposed rule, or anticipate, how association policies would be treated under the proposal. Regardless, we received a number of comments objecting to the definitions as they would apply to association plans. On May 23, 2011, we published a final rule with comment period (76 FR 29964), in which we specifically solicited further comments on amending the definitions

of “individual market” and “small group market” in § 154.102 to include coverage sold to individuals and small groups through associations in all cases.

We received 30 comments in the comment period. Commenters included the National Association of Insurance Commissioners (NAIC); a State insurance regulator; many consumer and public interest organizations; associations sponsoring insurance plans for their individual and employer members; health care providers; health insurance issuers and related trade associations (collectively, “industry”); and others. After consideration of the comments, we are amending the May 23, 2011 final rule to provide that individual and small employer policies sold through associations will be included in the rate review process, even if a State otherwise excludes such coverage from its definitions of individual and small group market coverage.

II. Provisions of the May 23, 2011 Final Rule With Comment and Responses to Comments

In the May 23, 2011 final rule, we solicited comments regarding whether to amend the definitions of “individual market” and “small group market” in § 154.102 to include coverage sold to individuals and small groups through associations in the rate review process, even if the State excludes such coverage from its definitions of individual and small group market coverage. Additionally, we solicited comments to address the following questions:

1. Do States currently review rate increases for association and out-of-State trust coverage sold to individuals and small groups, regardless of whether the policies are situated in or outside of their States?
2. How many rate filings do States receive for association and out-of-State trust coverage?
3. How prevalent are association and out-of-State trust coverage arrangements? What percentage of individual market and small group market business is sold through associations and out-of-State trusts?
4. In which States is association and out-of-State trust coverage commonly purchased by individuals and small groups? Where are out-of-State trusts typically situated?
5. Why do some individuals and small employers purchase coverage through associations and out-of-State trusts rather than through the traditional markets? Are there particular groups of individuals or types of small employers that typically purchase coverage through associations and out-of-State