

Supporting Statement For Paperwork Reduction Act Submissions

Specific Instructions

A. Background

The Centers for Medicare & Medicaid Services (CMS) is requesting approval to collect information from physicians and other eligible professionals related to significant hardships that would exempt them from a payment adjustment on their Medicare Part B Physician Fee Schedule (PFS) allowed charges for covered professional services furnished during the 2011 reporting period. In accordance with section 1848(a)(5)(A) of the Act, a PFS payment adjustment will begin in 2012 for those eligible professionals and group practices who are not successful electronic prescribers and will increase each year through 2014. 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.

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

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

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

Since publication of the CY 2011 PFS final rule with comment period, we have received numerous requests to expand the categories under the significant hardship exemption for the 2012 eRx payment adjustment. Some stakeholders have recommended specific circumstances of significant hardship for our consideration (for example, eligible professionals who have prescribing privileges but do not prescribe under their NPI, eligible professionals who

prescribe a high volume of narcotics, and eligible professionals who electronically prescribe but typically do not do so for any of the services included in the eRx measure's denominator), while others strongly suggested we consider increasing the number of specific hardship exemption categories. We believe that many of the circumstances raised by stakeholders may pose a significant hardship and limit eligible professionals and group practices in their ability to meet the requirements for being successful electronic prescribers either because of the nature of their practice or because of the limitations of the eRx measure itself, and as a result, such professionals might be unfairly penalized. Therefore, we are proposing to expand the categories under the significant hardship exemption for the 2012 eRx payment adjustment.

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

- a. Eligible Professionals Who Register to Participate in the Medicare or Medicaid EHR Incentive Programs and Adopt Certified EHR Technology
- b. Inability to Electronically Prescribe Due to Local, State, or Federal Law or Regulation
- c. Limited Prescribing Activity
- d. Insufficient Opportunities to Report the Electronic Prescribing Measure due to Limitations of the Measure's Denominator

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

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

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

hardship exemption request) to justify the request or make the determination of whether a significant hardship exists.

B. Justification

1. Need and Legal Basis

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 order to uphold the intent of section 1848(a)(5)(A) of the Act, CMS needs to collect information from eligible providers that will enable us to determine if they are legitimately exempt from the eRx payment adjustment.

2. Information Users

The collection of information under this extension is to be used to validate that compliance with the requirement for being a successful electronic prescriber would result in a significant hardship for the eligible professional (or group practice). If it is determined that a hardship would be incurred by the professional, CMS will grant the exemption and the professional will avoid being unfairly penalized. Alternatively, if it is deemed that a hardship is not incurred by the professional, CMS will apply the eRx payment adjustment as mandated by section 1848(a)(5)(A) of the Act. In addition to determining whether or not a hardship is valid, the information collected will provide CMS with insight on the current state and environment of electronic prescribing. This type of information will be valuable for future rule making as it relates to the eRx Incentive Program.

3. Use of Information Technology

It is our intent that eligible professionals or group practices would be able to submit significant hardship exemption requests using a web-based tool or interface. However, our ability to receive the significant hardship requests in this manner would be dependent on the development of such a website being completed prior to the publication of the final rule. In the event that such a website is not available, an eligible professional or group practice would be required to send us an application for a hardship exemption with such information by mail.

4. Duplication of Efforts

The information to be collected is specific to the Medicare eRx Incentive Program and is therefore not collected through any other programs or venues that would be accessible to CMS. Furthermore, the information is being collected exclusively for the purposes of exempting eligible professionals from the 2012 eRx payment adjustment. This is the first time that a payment adjustment has been mandated and as such, this information is not

currently available or being collected.

5. Small Businesses

Small businesses affected by this data collection effort would apply to those small or medium medical practices whose physicians or other eligible professionals for whom meeting the criteria for a successful electronic prescriber would cause a significant hardship.

6. Less Frequent Collection

The information is to be collected on an annual basis. Eligible professionals will submit for their exemption once during the reporting period. If the information were collected less frequently, CMS would not be able to obtain the information necessary to assess and grant exemptions to the eRx payment adjustment.

7. Special Circumstances

It is not anticipated that any of special circumstances specified would apply with the collection of this information. Eligible professionals who believe they have a significant hardship exemption code to submit will do so once in the program year by the date specified in the final rule. Eligible providers will have more than 30 days of notification of the deadline by which they must submit their hardship exemption code.

8. Federal Register/Outside Consultation

The proposed rule entitled, "Proposed Changes to the Electronic Prescribing (eRx) Incentive Program," will serve as the Federal Register of agency notice soliciting comments for this information collection. The proposed rule published on June 1, 2011 (76 FR 31574).

9. Payments/Gifts to Respondents

There will be no payment or gift to respondents.

10. Confidentiality

As a matter of policy, CMS will prevent the disclosure of personally identifiable information contained in the data submitted. The data collected will be for CMS internal use only and will not be published.

11. Sensitive Questions

The information collected will not include any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private or would cause any discomfort for the respondent.

12. Burden Estimates (Hours & Wages)

The burden estimate is based on the approximate number of physicians and eligible professionals (EPs) believed to be subject to the eRx penalty as well as the number of EPs we believe will actually submit a hardship exemption code. Providers could be exempt from the eRx payment adjustment for several reasons. Providers not eligible to participate in the eRx program are automatically exempt. Providers who are eligible to participate, but who are not an MD/DO, Nurse Practitioner, Physician's Assistant or Podiatrist are also automatically exempt. Providers who belong to these specialties may also be exempt from the adjustment if they 1) do not meet the denominator criteria (<100 eligible instances), 2) do not meet the Physician Fee Schedule (PFS) threshold (<10% of PFS charges are associated with eRx denominator codes) or 3) they have successfully reported (>10 numerator instances). Providers could be subject to the eRx payment adjustment if they have sufficient denominator counts (≥ 100), meet the PFS threshold (10% of charges in the eRx denominator) and fail to report sufficient numerator instances (≥ 10).

To most accurately estimate the number of EPs, several data sources need to be considered. Based on Medicare PFS data from January – June 2010, it is estimated that 209,323 eligible professionals will be non-exempt for (and therefore subject to) the eRx payment adjustment. 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 108,879 EPs would potentially submit a hardship exemption code as over 100,000 EPs are already participating in the program. Since the hardship exemptions represent specific circumstances that will not apply to all EPs, we believe that about 10% of EPs would actually request a hardship exemption code. This brings our minimum estimated number of EPs impacted to 10,888. Our maximum estimated number of EPs impacted is 209,323, which as previously stated is the number of EPs estimated to be subject to the payment adjustment. Since we are uncertain as to how many EPs the significant hardship exemption categories apply to, we are using the median (110,106) of our minimum (10,888) and maximum (209,323) estimated number of EPs impacted. The table below details our burden estimate using 1) the maximum number of providers subject to the eRx payment adjustment; 2) an estimate of the number of providers who will submit an exemption code for the eRx payment adjustment and 3) the median number of our minimum and maximum number of EPs impacted. It is estimated that the time needed to collect and report the information requested will be 2 hours. To collect and report the information, an EP would need to review the hardship exemption codes available, determine which code(s) applies to their particular situation, gather the information needed for the justification, and then complete and submit the web-based tool. Eligible professionals will only have to submit their information once during the program year. We assume an average hourly personnel cost of \$58.

Based on the above assumptions, we predict the annual burden cost to be between \$1,263,008

and \$24,281,468 For purposes of the burden estimate, we will use the median number of EPs who will be impacted resulting in a total cost of \$12,772,296 per year.

	# of Respondents	Hours/Response	Cost/Hour	Total Cost
Estimated # of EPs subject to payment adjustment (maximum # impacted)	209,323	2 hours	\$58	\$24,281,468
Estimated # EPs who will submit hardship (minimum # impacted)	10,888	2 hours	\$58	\$1,263,008
Estimated # of EPs who will be impacted (median of min and max)	110,106	2 hours	\$58	\$12,772,296

13. Capital Costs

There are not capital costs required for the collection of this information. Eligible professionals will either submit their hardship exemption information through a free web-based tool or mail. Eligible professionals will not be required to purchase or maintain any systems or capital equipments solely for the collection of this data.

14. Cost to Federal Government

The costs to the Federal Government to implement this data collection effort include CMS staff resources (0.25 full-time equivalent per year) to manage the project and review the data to determine if an exemption to the eRx payment adjustment can be granted and contractor costs to assist with initial review and any follow up communication needed with the eligible professionals. It is estimated that it will take a maximum of about 1 hour of contractor time at an hourly labor rate of \$22.63 to review the hardship exemptions and to contact the eligible professional to resolve any outstanding issues with the eligible professional’s submission. To calculate the costs to the government, we will use the median number of EPs who will be impacted by eRx payment adjustment. Median = 110,106

	2011	2012	2013	Total
CMS costs*	\$18,750	\$19,313	\$19,892	\$57,955
Contractor costs**	\$2,491,699	\$2,491,699	\$2,491,699	\$7,475,097
Total	\$2,510,499	\$2,511,012	\$2,511,591	\$7,533,052
Average/Year				\$2,511,017
*Estimated as .25 FTE per year, GS 12 (\$75,000/year including all salary and fringes); 3% annual inflation				
**Estimated as \$22.63 per hour x 110,106 calls				

15. Changes to Burden

This is the first time a burden estimate and PRA package has been submitted for the eRx Incentive Program – Submission of Significant Hardship Exemption to Avoid the eRx Payment Adjustment.

16. Publication/Tabulation Dates

There will be no publication of individual physician or other eligible professional specific information or data. All data and information collected will be used for internal CMS purpose, specifically to determine whether or not the eligible professional has a legitimate hardship and is therefore exempt from the eRx payment adjustment. Data may also be used internally by CMS to make future program decisions.

17. Expiration Date

CMS is seeking approval to use this web-based data collection tool for a period of 3 years from the original PRA package approval date. CMS would like an exemption from displaying the expiration date as these forms are intended to be used on a continuing basis.

18. Certification Statement

There are no exceptions to the certification statement.