

providing a 60-day public comment period.

Furthermore, in this final rule with comment period, we are making a technical revision to § 410.64 (Additional Preventive Services) to conform with section 1861(ddd)(1), as amended by section 4104 of the ACA. We are revising § 410.64(a) by removing the words “not otherwise described in this subpart” and adding the words “not described in subparagraphs (1) or (3) of § 410.2 of this subpart” in their place. This change reflects section 1861(ddd)(1) of the Act (as amended by section 4104(a)(2) of the ACA). While this change was not discussed in the CY 2011 PFS proposed rule (74 FR 40129), we are making this change pursuant to the “good cause” exception to APA notice and comment rulemaking. Under the good cause exception, public participation procedures are not required “when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest” (5 U.S.C. 553(b)). Section 410.64(a) previously reflected section 1861(ddd)(1) of the Act, which was subsequently amended. The revision to the regulations merely incorporates the new statutory language for consistency, and is not an interpretation or clarification. Therefore, we believe it is appropriate to waive advanced notice and public comment on this change for good cause, due to the technical nature of the revision to the regulations.

We ordinarily provide a 60-day delay in the effective date of the provisions of a rule in accordance with the Administrative Procedure Act (APA) (5 U.S.C. 553(d)), which requires a 30-day delayed effective date, and the Congressional Review Act (5 U.S.C. 801(a)(3)), which requires a 60-day delayed effective date for major rules. However, we can waive the delay in the effective date if the Secretary finds, for good cause, that the delay is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons in the rule issued (5 U.S.C. 553(d)(3); 5 U.S.C. 808(2)).

### IX. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and

approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

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

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

#### *A. ICRs Regarding Diagnostic X-ray Tests, Diagnostic Laboratory Tests, and Other Diagnostic Tests: Conditions (§ 410.32)*

Section 410.32(d)(2)(i) requires the physician or qualified nonphysician practitioner (as defined in § 410.32(a)(2)) who orders the service must maintain documentation of medical necessity in the beneficiary's medical record. In addition, both the medical record and the laboratory requisition (or order) would be required to be signed by the physician or qualified nonphysician practitioner (as defined in § 410.32(a)(2)) who orders the service. The burden associated with these requirements would be the time and effort necessary for a physician or qualified nonphysician practitioner to sign the medical record or laboratory requisition (or order). There is also a recordkeeping requirement associated with maintaining the documentation of medical necessity in the beneficiary medical record. While these recordkeeping and reporting requirements are subject to the PRA, we believe the associated burden is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2). We believe that the time, effort, and financial resources necessary to comply with the aforementioned information collection requirements is incurred by persons in the normal course of their activities and therefore considered to be usual and customary business practices.

#### *B. ICRs Regarding General Exceptions to the Referral Prohibition Related to Both Ownership/Investment and Compensation (§ 411.355)*

Section 411.355(b)(7)(i) states that with respect to magnetic resonance imaging, computed tomography, and

positron emission tomography, the referring physician must provide written notice to the patient at the time of the referral that the patient may receive the same services from a person other than one described in § 411.355(b)(1). The written notice must include a list of other suppliers (as defined in § 400.202 of this title) that provide the services for which the individual is being referred. In response to public comments received, we are finalizing this provision to require that the list must include a minimum of 5 suppliers within a 25-mile radius of the referring physician's office location at the time of the referral, rather than the proposed 10 suppliers. The notice should be written in a manner sufficient to be reasonably understood by all patients and should include for each supplier on the list, at a minimum, the supplier's name, address, and telephone number.

This rule finalizes section 411.355(b)(7)(ii) to state that if the referring physician makes a referral within an area with fewer than 5 other suppliers within the 25-mile radius of the physician's office location at the time of the referral, the physician shall list all of the other suppliers of the imaging service that are present within a 25-mile radius of the referring physician's office location. Provision of the written list of alternate suppliers will not be required if no other suppliers provide the services for which the individual is being referred within the 25-mile radius. These physicians must still disclose to the patient that the patient may receive these services from a person other than one described in § 411.355(b)(1) in a manner sufficient to reasonably be understood by all patients.

The burden associated with the requirements contained in this section would be the time and effort necessary for a physician to develop a standard disclosure. There would also be burden associated with the time and effort necessary for a physician to provide the disclosure to the patient. Based upon public comments received, we have removed the requirement that a physician must obtain the patient's signature on the disclosure and maintain a copy of this document in the medical record. Physicians must retain adequate assurance that the information was shared with the patient so that this information can be verified.

Our estimate that it would take 1 hour for a physician's office to develop a standard disclosure remains the same in this final rule with comment to account for physicians drafting the disclosure notice and listing the 5 alternate

suppliers. Our estimate that 71,000 physicians will be required to comply with these requirements remains unchanged from the proposed rule. The total burden associated with the development of the standard disclosure remains 71,000 hours at a cost of \$1,042,280. Although the physician no longer must have the patient sign the disclosure and enter it into the medical record, we have not changed the estimate that it will take each physician 1 minute to provide the disclosure to the patient. Each provider will make approximately 106 disclosures. The total estimated annual burden for this requirement remains 125,433 hours at a cost of \$10,536,400.

*C. ICRs Regarding Appeals Process for Termination of Competitive Bidding Contract (§ 414.423)*

Section 414.423(c)(1)(i) states that CMS has the option to allow a DMEPOS supplier to provide a written CAP to remedy the deficiencies identified in the notice, when CMS determines that the delay in the termination date caused by allowing a CAP will not cause harm to beneficiaries. As stated in § 414.423(c)(2)(i) a CAP must be submitted within 30 calendar days from the date on the notification letter. If the supplier decides not to submit a CAP the supplier may within 30 days of the date on the termination letter request a hearing by a CBIC hearing officer.

The burden associated with this requirement is the time and effort necessary for a supplier that has received a termination notice to develop and submit a CAP. We estimate that 10 suppliers will need to comply with this requirement annually. Similarly, we estimate that it will take a supplier an average of 3 hours to develop a CAP. The total estimated annual burden associated with this requirement is 30 hours at a cost of \$2,250.

Section 414.423(e)(2) requires that if CMS accepts the CAP, including supplier's designated timeframe for its completion, the supplier must provide a follow-up report within 5 days after the

supplier has fully implemented the CAP that verifies that all of the deficiencies identified in the CAP have been corrected in accordance with the timeframes accepted by CMS. The burden associated with this requirement is the time and effort necessary for a supplier to develop and submit a follow-up report. While this requirement is subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(h)(6). In accordance with 5 CFR 1320.3(h)(6), a request for facts or opinions addressed to a single person is not defined as information collection requirements and is therefore exempt from the PRA.

Section 414.423(f)(1) states that a supplier who has received a notice that CMS considers them in breach of contract or that their CAP is not acceptable has the right to request a hearing before a CBIC HO who was not involved with the original determination. Section 414.423(f)(2) further specifies that a supplier who wishes to appeal the termination notice must submit a written request to the CBIC. The request for a hearing must be received by the CBIC within 30 calendar days from the date of the notice to terminate.

The burden associated with this section is the time and effort necessary for a supplier to develop and submit a written request for a hearing by a CBIC Hearing Officer. We estimate that it will take a supplier 8 hours to develop and submit a request for a hearing. We believe 5 suppliers will be subject to this requirement on an annual basis. The total estimated annual burden associated with developing and submitting a written request for a hearing by a CBIC Hearing Officer is 40 hours at a cost of \$3,000.

Section 414.423 requires a contract supplier whose contract has been terminated to notify all beneficiaries who are receiving rented competitive bid items or competitive bid items received on a recurring basis, of the termination of their contract. The notice to the beneficiary from the supplier

whose contract was terminated must be provided within 5 days of receipt of the notice of termination. The notification to the beneficiaries must inform the beneficiaries that they are going to have to select a new contract supplier for these items.

The burden associated with this section is the time and effort necessary for a supplier to develop and distribute notification of its termination to all beneficiaries receiving rented competitive bid items or competitive bid items received on a recurring basis. We estimate that it will take a supplier 3 hours to develop and distribute a notice announcing its termination to all of its beneficiaries receiving rented competitive bid items or competitive bid items received on a recurring basis. We believe 2 suppliers will be subject to this requirement on an annual basis. The total estimated annual burden associated with this requirement is 6 hours at a cost of \$450.

*D. ICRs Regarding Additional Provider and Supplier Requirements for Enrolling and Maintaining Active Enrollment Status in the Medicare Program (§ 424.516)*

Section 424.516(e)(2) would require a provider or supplier to report a revocation or suspension to the applicable Medicare contractor within 30 days of any revocation or suspension of a Federal or State license or certification. Similarly, proposed § 424.516(e)(2) states that within 30 days of a voluntary withdrawal or involuntary termination from the Medicare program, the provider or supplier must report a voluntary withdrawal or involuntary termination to the applicable Medicare contractor. The burden associated with the requirements in § 424.516(e)(2) and (3) is the time and effort necessary for a provider or supplier to report the required information to the applicable Medicare contractor. While these requirements are subject to the PRA, each submission will be evaluated on a case-by-case basis.

TABLE 100—ESTIMATED ANNUAL RECORDKEEPING AND REPORTING BURDEN

Regulation section(s)	OMB control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting (in \$)	Total labor cost of reporting (in \$)	Total capital/maintenance costs (in \$)	Total cost (in \$)
§ 411.355 .....	0938—New .....	71,000	71,000	1	71,000	14.68	1,042,280	0	1,042,280
		71,000	7,454,760	0.0167	125,433	83.79	*10,536,400	0	10,536,400
§ 414.423 .....	0938—New .....	10	10	3	30	75.00	2,250	0	2,250
		5	5	8	40	75.00	3,000	0	3,000
		2	2	3	6	75.00	450	0	450

prevention plan, subject to the conditions and limitations specified in § 410.15 of this subpart.

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**Subpart J—Financial Relationships Between Physicians and Entities Furnishing Designated Health Services**

■ 19. Section 411.355 is amended by adding paragraph (b)(7) to read as follows:

**§ 411.355 General exceptions to the referral prohibition related to both ownership/investment and compensation.**

\* \* \* \* \*

(b) \* \* \*

(7) *Disclosure requirement for certain imaging services.*

(i) With respect to magnetic resonance imaging, computed tomography, and positron emission tomography services identified as “radiology and certain other imaging services” on the List of CPT/HCPCS Codes, the referring physician must provide written notice to the patient at the time of the referral that the patient may receive the same services from a person other than one described in paragraph (b)(1) of this section. Except as set forth in paragraph (b)(7)(ii) of this section, the written notice must include a list of at least 5 other suppliers (as defined in § 400.202 of this chapter) that provide the services for which the individual is being referred and which are located within a 25-mile radius of the referring physician’s office location at the time of the referral. The notice should be written in a manner sufficient to be reasonably understood by all patients and should include for each supplier on the list, at a minimum, the supplier’s name, address, and telephone number.

(ii) If there are fewer than 5 other suppliers located within a 25-mile radius of the physician’s office location at the time of the referral, the physician must list all of the other suppliers of the imaging service that are present within a 25-mile radius of the referring physician’s office location. Provision of the written list of alternate suppliers will not be required if no other suppliers provide the services for which the individual is being referred within the 25-mile radius.

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**PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES**

■ 20. The authority citation for part 413 continues to read as follows:

**Authority:** Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Public Law 106–133 (113 Stat. 1501A–332).

**Subpart E—Payments to Providers**

■ 21. Section 413.70 is amended by adding a sentence at the end of paragraph (b)(3)(ii)(B) to read as follows:

**§ 413.70 Payment for services of a CAH.**

\* \* \* \* \*

(b) \* \* \*

(3) \* \* \*

(ii) \* \* \*

(B) \* \* \* Effective for primary care services furnished by primary care practitioners (as defined in § 414.80(a)) and major surgical procedures furnished by general surgeons in health professional shortage areas (as defined in § 414.2) furnished on or after January 1, 2011 and before January 1, 2016, incentive payments specified under § 414.80 and § 414.67(b), respectively, of this title must not be included in determining payment made under this paragraph.

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

■ 22. 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 A—General Provisions**

■ 23. Section 414.2 is amended by adding the definitions of “Health Professional Shortage Area” and “Major surgical procedure” in alphabetical order to read as follows:

**§ 414.2 Definitions.**

\* \* \* \* \*

*Health Professional Shortage Area (HPSA)* means an area designated under section 332(a)(1)(A) of the Public Health Service Act as identified by the

Secretary prior to the beginning of such year.

*Major surgical procedure* means a surgical procedure for which a 10-day or 90-day global period is used for payment under the physician fee schedule and section 1848(b) of the Act.

\* \* \* \* \*

■ 24. Section 414.26 is amended by—

■ A. Redesignating paragraph (c) as paragraph (d).

■ B. Adding a new paragraph (c).

The addition reads as follows:

**§ 414.26 Determining the GAF.**

\* \* \* \* \*

(c) *Adjusting the practice expense index to account for the Frontier State floor.*

(1) *General criteria.* Effective on or after January 1, 2011, CMS will adjust the practice expense index for physicians’ services furnished in qualifying States to recognize the practice expense index floor established for Frontier States. A qualifying State must meet the following criteria:

(i) At least 50 percent of counties located within the State have a population density less than 6 persons per square mile.

(ii) The State does not receive a non-labor related share adjustment determined by the Secretary to take into account the unique circumstances of hospitals located in Alaska and Hawaii.

(2) *Amount of adjustment.* The practice expense value applied for physicians’ services furnished in a qualifying State will be not less than 1.00.

(3) *Process for determining adjustment.* (i) CMS will use the most recent population estimate data published by the U.S. Census Bureau to determine county definitions and population density. This analysis will be periodically revised, such as for updates to the decennial census data.

(ii) CMS will publish annually a listing of qualifying Frontier States receiving a practice expense index floor attributable to this provision.

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**Subpart B—Physicians and Other Practitioners**

■ 25. Section 414.54 is revised to read as follows:

**§ 414.54 Payment for certified nurse-midwives’ services.**

(a) For services furnished after December 31, 1991, allowed amounts under the fee schedule established under section 1833(a)(1)(K) of the Act for the payment of certified nurse-midwife services may not exceed 65