Renewal of OMB Approval for Information Collection
of Final Rule Concerning Physicians' Referrals
Including Regulations in 42 CFR 411.352 through 411.361
0938-0846

A. **Background**

CMS is requesting a renewal of OMB approval for the provisions of the January 4, 2001 interim final rule with comment period (Phase I) (66 FR 856), the March 26, 2004 interim final rule with comment period (Phase II) (69 FR 16054), and the September 5, 2007 final rule (Phase III) (72 FR 51012) that are subject to review under the Paperwork Reduction Act (PRA). Phase I, Phase II, and Phase III of this rulemaking are intended to be read together as a unified whole. Phase III interpreted and implemented the provisions of section 1877 of the Social Security Act (the Act). Under section 1877 of the Act, if a physician or a member of a physician's immediate family has a financial relationship with a health care entity (including an individual), the physician may not make referrals to that entity for the furnishing of designated health services (DHS) under the Medicare program, unless an exception applies. In addition, section 1877 of the Act provides that an entity may not present or cause to be presented a Medicare claim or bill to any individual, third party payer, or other entity for DHS furnished pursuant to a prohibited referral. Also, section 1877 of the Act prohibits us from making payment for a designated health service furnished under a prohibited referral. Paragraph (a) of section 1877 of the Act includes the general prohibition. Paragraph (b) of section 1877 of the Act includes exceptions that pertain to both ownership and compensation relationships, including the in-office ancillary services exception. Paragraph (b) of section 1877 of the Act authorizes us to create additional exceptions, provided that they do not create a risk of program or patient abuse. Paragraphs (c) and (d) include exceptions for ownership and investment interests in entities that furnish DHS. Paragraph (e) of section 1877 of the Act includes exceptions for compensation arrangements. Paragraph (f) of section 1877 includes reporting requirements. Paragraph (g) of section 1877 includes sanctions for violations of the prohibition on physician self-referral. Paragraph (h) of section 1877 includes definitions that are used throughout section 1877 of the Act, including the group practice definition and the definitions for each of the DHS.

B. **Justification**

1. **Need and Legal Basis**

We are requesting a renewal of OMB approval of the collection of information requirements contained in 42 CFR §411.352(d), §411.354(d), §411.355(e), §§411.357(a), (b), (d), (e), (h), (l), (p), and (s), and §411.361. CMS issued these regulations to interpret and implement the provisions of section 1877 of the Act that prohibit a physician from referring a patient to an entity for a designated health service, if the physician or an immediate family member has a financial relationship with the entity, unless an exception applies. The collection of information contained in 42 CFR §411.352(d), §411.354(d), §411.355(e), §§411.357(a), (b), (d), (e), (h), (l), (p), and (s), and §411.361 is necessary to allow CMS to implement section 1877 of the Act. As we indicated in the Phase III final rule, all collections of information contained in the physician

self-referral rules are exempt from the PRA. An explanation of each regulation and why the burdens from each regulation are exempt from the PRA is provided in section 12 below.

We have attached for your reference section 1877 of the Social Security Act and the regulations for which we are seeking a renewal of OMB approval of the collection of information requirements.

2. **Information Users**

The information would be read and analyzed by employees of CMS and other employees of the Department of Health and Human Services (HHS) when investigating a possible physician self-referral violation. The offices using the information will include CMS, the HHS Office of General Counsel, and the HHS Office of the Inspector General.

3. **Use of Information Technology**

This collection of information requires recordkeeping. The medium in which the recordkeeping is maintained may vary among physicians, suppliers, and providers, although the required information should be readily available in paper form.

4. **Duplication of Similar Information**

The information to be created does not duplicate any other effort, and the information cannot be obtained from any other source.

5. **Small Businesses**

Small businesses and other small entities are affected by this collection of information. We have minimized the impact of the recordkeeping by seeking only information that a business would have acquired in its routine operations. We will require small businesses and other small entities to report information to us only for purposes of determining compliance with the physician self-referral prohibitions in section 1877 of the Act. The information to be created and retained is the minimum necessary to determine compliance with section 1877 of the Act.

6. **Less Frequent Collection**

This collection of information is required by section 1877(f) of the Act only if the entity is under investigation for potential violations of the physician self-referral law. Failure to provide this information would prevent CMS and the Department from fulfilling the statutory obligation to enforce the prohibitions in section 1877 of the Act. We have reduced the burden of the collection of information to the lowest level possible while meeting our duty to investigate possible violations of the physician self-referral law. Physicians, other suppliers, and providers are asked to record and maintain the information necessary to determine whether a prohibited financial relationship exists.

7. **Special Circumstances**

The only special circumstance that may apply to this collection of information is that a physician, other supplier, or provider that is being investigated may need to provide confidential information about the entity's business relationships. The information we obtain from an investigation would be disclosed to the public only to the extent we are required to do so by the Freedom of Information Act (5 U.S.C. 552) or by other law.

8. **Federal Register Notice/Outside Consultation**

The 60-day Federal Register notice for this package was published on June 22, 2007 (72 FR 34467), and is attached.

A full and complete 60-day public comment period was process was undertaken with publication of the physician self-referral proposed rule on January 9, 1998. The comment period was extended for 30 days so that the public was provided with 120 days to comment on the proposed rule. In addition the public was given 150 days in which to comment on the Phase I interim final rule with comment period, beginning on January 4, 2001. The Phase II interim final rule with comment included a 90-day comment period, beginning on March 26, 2004.

9. **Payments/Gifts to Respondents**

We are not providing any payments or gifts to respondents in connection with this information collection.

10. **Confidentiality**

The documents that we review during an investigation will be subject to public disclosure only to the extent that we are required to do so by the Freedom of Information Act (FOIA) (5 U.S.C. 552) or by other law. We will ask physician, other suppliers, and providers to identify information that they believe is not subject to disclosure under the FOIA, such as items that the physicians, other suppliers, or providers believe are trade secrets or confidential commercial or financial information.

11. **Sensitive Questions**

The written agreements will contain no sensitive questions, such as those pertaining to sexual behavior and attitudes, religious beliefs, and other matters that we commonly consider private.

12. **Burden Estimate (Total Hours & Wages)**

For purposes of updating the estimated paperwork burden for the September 5, 2007 physician self-referral final rule (Phase III), we have used the statistics in 2007 CMS Statistics (Blue

Book) published annually by the Department.

Section 411.352 Group Practice

Under paragraph (d), a covered entity is required to document the total time each member of the group practice spends on patient care services, and to maintain and make available to the Secretary of HHS, upon request, documentation concerning compliance with the "substantially all" test at §411.352. (To qualify as a group practice, the group must meet certain conditions. One of these conditions, at §411.352(d), requires that substantially all (that is, at least 75 percent) of the total patient care services of the group practice members must be furnished through the group and billed under a billing number assigned to the group, and the amounts received must be treated as receipts of the group.) This paragraph also requires that a new member's employment with, or ownership interest in, the group practice be documented in writing no later than the beginning date of his or her new employment relationship or ownership or investment interest.

The burden associated with these requirements is that of documentation and making information available to the Secretary. This documentation may be in the form of time cards, appointment schedules, personal diaries, or any alternative measure that is reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, and verifiable. These types of records are usually kept by group practices in the normal course of business in order to allocate resources such as time, examination space, remuneration, and productivity bonuses, and, as such, the burden is not subject to the PRA under 5 CFR 1320.3(b)(5). To the extent this information is requested as part of an investigation, the burden of making the records available is exempt under 5 CFR 1320.4(a) as that incurred during an administrative action, investigation, or audit involving an agency against specific individuals or entities. In addition, this burden was found to be exempt from the requirements of the PRA in Phase I (66 FR 856).

Section 411.354 Financial Relationship, Compensation, and Ownership or Investment Interest

To qualify for an exception if a physician's compensation from a bona fide employer or under a managed care contract or other contract for personal services is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, a compensation arrangement must meet certain conditions. Section 411.354(d)(4) mandates that the requirement to make referrals to a particular provider, practitioner, or supplier be set forth in a written agreement signed by the parties.

We do not believe that this requirement imposes any additional burden. Where mandatory referral requirements are used, they are already routinely made part of a more comprehensive service agreement (for example, a contract between a physician and a managed care entity for the provision of physician services, or a preferred provider network agreement). We believe that this burden is a result of usual and customary business practice and, as such, is exempt from the PRA under 5 CFR 1320.3(b)(5).

Section 411.355 General Exceptions to the Referral Prohibition Related to Both Ownership/Investment and Compensation

Paragraph (e)(1)(iii) of this section requires that the relationship of the components of the academic medical center must be set forth in written agreement(s) or other written document(s) that have been adopted by the governing body of each component.

The burden associated with this requirement is that of documenting compliance, either in written documents or routine financial reports. The written documents, adopted by the governing body of each component, detailing the relationship of the components of the academic medical center may be any documents generated in the usual course of business, such as articles of incorporation or bylaws. Those academic medical centers will satisfy the requirement if transfers of funds between components of the academic medical center are reflected in routine financial reports generated in the usual course of business.

We believe that the burden imposed by §411.351(e)(1)(iii) is a result of usual and customary business practice and, as such, is exempt from the PRA under 5 CFR 1320.3(b)(5). In addition, this burden was found to be exempt from the requirements of the PRA in Phase I (66 FR 856, 949) and no revisions have been made since that time.

Section 411.357 Exceptions to the Referral Prohibition Related to Compensation Arrangements

This section contains several exceptions that require a written agreement signed by the parties. These are the exceptions for space and equipment rental agreements (§411.357(a) and (b)), arrangements for personal services (§411.357(d)), physician recruitment (§411.357(e)), certain group practice arrangements with a hospital (§411.357(h)), fair market value compensation (§411.357(l)), and indirect compensation (§411.357(p)).

The burden associated with these requirements is that of obtaining agreements in writing. The burden also includes a requirement that all separate personal service arrangements between an entity and a physician or an immediate family member of a physician must incorporate each other by reference, or the entity must maintain centrally a master list of contracts that is updated and preserves the historical record of the personal service contracts. The lease of space and equipment is usually and routinely set forth in a written agreement, as are personal service arrangements, recruitment agreements, and contracts between group practices and hospitals. Therefore, the requirement that these arrangements be set forth in a written agreement does not impose an additional burden beyond usual business practices, and, as such, is exempt from the PRA under 5 CFR 1320.3(b)(5). In addition, the burden that direct and indirect compensation arrangements be set forth in writing was formerly found to be exempt from the requirements of the PRA in the Phase I final rule (66 FR 856), and we also believe that the burden of these written agreements is a result of usual and customary business practice and, as such, is exempt from the PRA under 5 CFR 1320.3(b)(5).

In addition, in order for an arrangement to meet the requirements of the exception for professional courtesy (§411.357(s)), the entity's professional courtesy policy must be set out in writing. We believe that the burden of these written professional courtesy policy documents is a result of usual and customary business practice and, as such, is exempt from the PRA under 5 CFR 1320.3(b)(5). We are eliminating the requirement in §411.357(s) to notify insurance companies that an entity has a professional courtesy policy and has provided such personal courtesy. We are also eliminating the accompanying paperwork burden. Accordingly, we are decreasing the estimate made in the Federal Register notice, dated June 22, 2007, by 103,096 hours. (This paperwork burden estimate was that large because we estimated that as many as 75 percent of hospitals, 100 percent of physician practices and 10 percent of other health care entities would offer professional courtesy to their staff. We also assumed that each entity would have to create a model letter that would be tailored for each insurer of a staff member.)

Section 411.361 Reporting Requirements

This section requires that, subject to certain exceptions, all entities furnishing services for which payment may be made under Medicare must submit information to us concerning their financial relationships (as defined in the section), in the form, manner, and at the times that we specify. The information that we request can include the following:

(1) The name and unique physician identification number (UPIN) or National Provider Identifier (NPI) of each physician who has a financial relationship with the entity.

(2) The name and UPIN or NPI of each physician who has an immediate family member (as defined in §411.351) who has a financial relationship with the entity.

(3) The covered services furnished by the entity.

(4) With respect to specified physicians, the nature of the financial relationship (including the extent and/or value of the ownership or investment interest or the compensation arrangement) as evidenced in records that the entity knows or should know about in the course of prudently conducting business, including records that the entity is already required to retain to comply with the rules of the Internal Revenue Service and the Securities and Exchange Commission and other rules of the Medicare and Medicaid programs.

The first three requirements above are statutorily mandated. The fourth requirement was proposed in the 1998 proposed rule (63 FR 1659) and adopted as proposed in Phase II with no changes.

Entities that are subject to the requirements of this section must retain the information, and documentation sufficient to verify the information, and, upon request, must make that documentation available to us or to the OIG (depending upon which agency has requested the information).

The burden associated with these requirements is that of maintaining documentation and, if necessary, making it available to the Secretary. We believe that the information we are requiring entities to maintain is information that they would have and maintain already. In Phase II, the requirement was modified to require entities to make information available only upon request

and to maintain the information only for the length of time specified by the applicable regulatory requirements for the information (that is, IRS, SEC, Medicare, Medicaid, or other programs). This minimized the burden on entities, because this is information that is required to be maintained by other regulatory agencies in the usual course of business. We believe that this burden is a result of usual and customary business practice and, as such, is exempt from the PRA under 5 CFR 1320.3(b)(5).

Making information available to the Secretary would rarely be necessary and the information would be collected during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities, thus exempting the collection from the PRA under 5 CFR 1320.4(a).

13. **Capital Costs**

There are no capital costs associated with this collection.

14. **Cost to the Federal Government**

There are no additional costs to the Federal government.

15. **Program Changes**

In §411.357(s), we are eliminating the requirement to notify insurance companies that an entity has a professional courtesy policy and has provided such professional courtesy. We are also eliminating the accompanying paperwork burden for §411.357(s).

The reduction in burden hours for complying with the professional courtesy and personal service arrangements exceptions is 230,096. The original burden estimate was 422,008, which we cannot explain and which may have been an error. "

16. **Publication and Tabulation Dates**

There are no publication or tabulation dates.

17. **Expiration Date**

This collection does not lend itself to the displaying of an expiration date.

18. **Certification Statement**

There are no exceptions to the certification statement.