Supporting Statement – Part A
Disclosure Requirement for the In-Office Ancillary Services Exception
(CMS-10332, OMB 0938-1133)

Background

Section 1877 of the Social Security Act (the Act), also known as the physician self-referral law: (1) prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which the physician (or an immediate family member) has a financial relationship (ownership interest or compensation arrangement), unless an exception applies; and (2) prohibits the entity from submitting claims to Medicare or billing the beneficiary or third party payer for those referred services, unless an exception applies. The statute establishes a number of exceptions to the prohibition of physician self-referral.

Section 6003 of the Affordable Care Act (ACA) established a new disclosure requirement that a physician must perform for certain imaging services to meet the in-office ancillary services exception to the prohibition of the physician self-referral law. This section of the ACA amended section 1877(b)(2) of the Act by adding a requirement that the referring physician informs the patient, at the time of the referral and in writing, that the patient may receive the imaging service from another supplier. The imaging services affected by this requirement are: magnetic resonance imaging (MRI), computed tomography (CT), and positron emission tomography (PET). We implemented this requirement in the CY 2011 Physician Fee Schedule final rule by amending 42 CFR 411.355(b) with a new paragraph (7) requiring the physician to disclose to the patient that the services may be obtained from another supplier and to provide a list of other suppliers that provide the same imaging services (see 75 FR 73170). Physicians must retain adequate assurance that the information was shared with the patient so that this information can be verified.

The most recent approval of this information collection request (ICR) was issued by the Office of Management and Budget on August 10, 2021. We are now seeking to renew this approval before it expires on August 31, 2024. We have made no changes to the information being collected and are updating burden estimates to reflect changes in the number of physicians, number of disclosures, and the hourly wages of the personnel collecting the information.

A. Justification

1. Need and Legal Basis

Section 6003 of the ACA established a disclosure requirement for the in-office ancillary services exception to the prohibition of physician self-referral for certain imaging services.

This section of the ACA amended section 1877(b)(2) of the Social Security Act by adding a requirement that the referring physician informs the patient, at the time of the referral and in writing, that the patient may receive the imaging service from another supplier. The implementing regulations are at 42 CFR 411.355(b)(7).

2. Information Users

Physicians who provide certain imaging services (MRI, CT, and PET) under the in-office ancillary services exception to the physician self-referral prohibition are required to provide the disclosure notice as well as the list of other imaging suppliers to the patient. The patient will then be able to use the disclosure notice and list of suppliers in making an informed decision about his or her course of care for the imaging service.

CMS would use the collected information for enforcement purposes. Specifically, if we were investigating the referrals of a physician providing advanced imaging services under the in-office ancillary services exception, we would review the written disclosure in order to determine if it satisfied the requirement.

3. Use of Information Technology

The information is being created by the physician or group practice and then being communicated to the patient. We believe that gathering the list of suppliers to be provided to the patient will be conducted primarily electronically, via the Internet. The regulation requires that the disclosure be "written notice to the patient at the time of the referral" (See 42 CFR § 411.355(b)(7)). Thus, physicians must present the disclosure to the patient each time there is a referral for one of the advanced imaging services covered under the regulation. We expect that the physician will give the information to patients in hard copy; however, where verbal notification also occurs, mailing or e-mailing the disclosure to the patient are also acceptable methods to meet the disclosure requirement.

4. Duplication of Efforts

This information collection does not duplicate any other effort, and the information cannot be obtained from any other source.

5. Small Businesses

These information collection requirements do impact small businesses, which, as required by the statute, have the same disclosure requirements as other businesses.

6. Less Frequent Collection

This information will be distributed by a physician to their patients as the imaging services are ordered. There is no other way to change the frequency with which this information must be communicated.

7. Special Circumstances

There are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published in the Federal Register (89 FR) TBD

9. Payments/Gifts to Respondents

There will be no payment or gifts to respondents.

10. Confidentiality

CMS pledges to maintain privacy to the extent provided by law. If we need to review the agreements, we are prevented by the Trade Secrets Act, 18 U.S.C. 1905, from releasing to the public confidential business information, except to the extent permitted by law. We intend to protect from public disclosure, to the fullest extent permitted by Exemption 6 of the Freedom of Information Act, 5 U.S.C. 552(b)(6), any individual-specific information that we review.

11. Sensitive Questions

No sensitive information will be collected.

12. Burden Estimates (Wages & Hours)

There are two burdens associated with this disclosure requirement, each of which is discussed in more detail below. The first burden associated with this collection is a disclosure notice that must be prepared along with a list of alternative suppliers who can furnish the referred service. The second burden involves the act of the physician actually delivering the disclosure notice to the patient, either in hard copy or electronically.

With respect to each of these burdens, this collection affects only those physicians who are enrolled in the Medicare program and provide MRI, CT, PET services under the in-office ancillary services exception. Using Medicare fee-for-service Part B final action non-institutional claims data available from the CMS Chronic Condition Data Warehouse (www.ccwdata.org), we found that 972,654 Medicare beneficiaries received imaging services (MRI, CT, or PET) implicated by the disclosure requirement in 2022 (the most recent year for which data is available). These services were furnished by 20,691 unique National Provider Identifiers (NPIs). Of that total, 20,436 of the NPIs were affiliated with a physician group practice (PGP), meaning that the physician has reassigned his/her right to bill Medicare to a PGP for that NPI. The total number of PGPs that billed for a service furnished by a member physician was 1,471.

1) Preparation of the disclosure notice

We estimate that it will take an employee of the physician 1 hour to create the initial disclosure notice one time. This task primarily involves drafting the template form and researching the list of suppliers that furnish MRI, CT, or PET imaging services in the physician's service area. According to the Bureau of Labor Statistics (BLS), U.S. Department of Labor, Occupational Employment and Wages, May 2022, the hourly median wage for a healthcare support worker in a physician office (occupation code 319099) was $19.43. The wage data can be viewed on the BLS website here:

https://data.bls.gov/oes/#/home. We have added 100% of the hourly median wage to account for fringe and overhead benefits, which calculates to $38.86 per hour ($19.43 + $19.43).

As we noted above, 20,691 NPIs furnished an MRI, CT, or PET imaging service to a Medicare beneficiary in 2022. However, we believe that the number of physicians who have to create a unique disclosure notice is likely to be significantly lower than 20,691, given that 99% of the NPIs were affiliated with a PGP (20,436 / 20,691 = 99%). We understand that physicians in a PGP often share the cost of support staff who would be tasked with the preparation of a template form such as this disclosure notice; thus, we expect that multiple physicians in a PGP at the same location will be able to use the same disclosure document once it has been created.

A majority of physicians that furnish services to Medicare beneficiaries are members of a PGP. Although some PGPs are large, defined for purposes of this supporting statement only as more than 100 members, most PGPs have between 2 and 100 members. For example, MedPAC reported in 2016 that in analyzing 2014 claims data from nearly 600,000 physicians, it found that 68% of all Part B services to Medicare beneficiaries were furnished by physicians in PGPs comprising 2-100 members (http://www.medpac.gov/docs/default-source/meeting-materials/physician-affiliation-and-practice-size-final.pdf?sfvrsn=0). In the same study MedPAC noted that 22% of included services were furnished by individual physicians not members of a PGP, and that 12% of services were furnished by PGPs larger than 100 members. We believe that PGPs containing more than 1 physician member will implement processes to achieve greater efficiencies with respect to this disclosure requirement, by creating a template form for multiple physician members to share. As a result, we estimated the number of forms that would be created annually by calculating the following figures: the number of physicians who are members of a PGP and the number of physicians who are not a member of a PGP.

Again using the Medicare fee-for-service Part B final action non-institutional claims data available from the CMS Chronic Condition Data Warehouse (www.ccwdata.org), we found that 972,654 Medicare beneficiaries received imaging services (MRI, CT, or PET) implicated by the disclosure requirement in 2022, we first calculated the average number of physicians in a PGP that billed for an imaging service in 2022. Among 1,471 PGPs, there were 20,436 NPIs that were members of a PGP that furnished an imaging service. Thus, we estimate that the average PGP in this data set has 14 members (20,436 NPIs / 1,471 PGPs = 13.89 NPIs per PGP). Next, we calculated the number of physicians that furnished an imaging service that were not members of a PGP. We estimate that this figure is 255 (20,691 total NPIs – 20,436 NPIs that are PGP members = 255 physicians who are not members of a PGP). While larger PGPs are likely to require separate disclosure notices to account for the fact that member physicians may practice in diverse geographic areas, given that the average PGP in this data set is relatively small – calculated as having 14 members – we believe that most PGPs are likely to allocate the cost of an employee's time in researching and preparing the form among the member physicians. To account for the larger PGPs, we increase the number of PGPs

impacted by 12% to account for large PGPs with greater than 100 members (1,471 PGPs x 12% = 177). Thus, we estimate that 1,903 disclosure notices will be created annually (1,471 PGPs + 255 individual physicians + 177 to account for large PGPs that are greater than 100 members).

We estimate that approximately 1,903 notice templates will be created on an annual basis to meet this disclosure requirement. Thus, we estimate that the annual cost burden of creating the disclosure and list of alternative suppliers is $73,951 (1 hour x $38.86 wage x 1,903 forms). The annual hour burden for creating the disclosure notices is **1,903 hours** (1,903 notice templates x 1 hour).

2) Delivering disclosure notice to the patient

We estimate that it will take physicians 1 minute to provide the disclosure notice to the patient. We note that patients and physicians are not required to sign the disclosure notice, and that physicians need only retain adequate assurance that the information was shared with the patient so that this information can be verified. According to the BLS, U.S. Department of Labor, Occupational Employment and Wages, May 2022, the median hourly wage for a Family Medicine Physician (occupation code 291215) was $101.59. The wage data can be viewed on the BLS website here: https://data.bls.gov/oes/#/home. We have added 100% of the median hourly wage to account for fringe and overhead benefits, which calculates to $203.18 per hour ($101.59 + $101.59).

We estimate the annual burden of furnishing the required disclosure notice to the patient to be $3,292,413. We calculated this figure by multiplying the hourly wage of a family medicine physician by two figures: the time it takes to deliver the information to the patient (1 minute) and the total number of Medicare beneficiaries that had an imaging service in 2022 (972,654). Thus, we estimate that the annual cost burden of delivering the disclosure notice to the patient is $3,292,413 (.01666 hours x $203.18 wage x 972,654 disclosures). The annual hour burden for providing this information to patients is **16,204 hours** (972,654 disclosures x .01666 hours).

The total burden is **18,107 hours** for both the preparation of the disclosure notice and delivering the disclosure notice to the patient.

	Respondents	Responses per Respondent	Burden per Response	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($/hr.)	Total Cost ($)
Preparation of the disclosure notice	1,903	1	1hr	1,903	38.86	73,951
Delivering disclosure notice to the patient	972,654	1	.01666hr	16,204	203.18	3,292,413
TOTAL	974,557			18,107		3,366,364

13. Capital Costs

There are no capital costs related to this collection.

14. Cost to Federal Government

The total cost to the federal government associated with preparing the required documentation for this information collection in accordance with the Paperwork Reduction Act of 1995 is estimated to take a total of 30 hours and cost $1,505.79. Documentation preparation occurs every two years in advance of the three-year expiration of the Office of Management and Budget's approval of the collection. A CMS analyst gathers the data necessary to determine the burden estimate and drafts the required documentation for clearance. CMS staff then works in coordination with the Office of the Federal Register for notice publication.

Employees	**Hourly salary**	**# of Hours**	**Cost to Federal Government**
(1) GS-13, step 5	$48.07	25	$1,201.75
(1) GS-14, step 5	$56.80	3	$170.40
(2) GS-15, step 5	$66.82	2	$133.64
	TOTAL:	**30**	**$1,505.79**

15. Changes to Burden

We updated the burden estimates to reflect changes in the number of physicians, the number of disclosures, and the hourly wages of the personnel preparing and delivering the disclosure. However, we have made no changes to the information being collected.

We adjusted the average hourly wage for a healthcare support worker in a physician office from $19.24 to $19.43. We also fully loaded the hourly wage estimate by adding 100% to the median hourly wage to account for fringe and overhead benefits, which calculates to $38.86.

The revised annual cost burden of creating the disclosure and list of alternative suppliers is now $73,951, a decrease from the previous burden of $86,156. This decrease is a result of using more accurate information on the number of physicians impacted by this disclosure requirement and applying the hourly median wage for the respondent types. The adjusted annual burden for creating the disclosure notices is now 1,903 hours, a decrease from the previous burden hours of 2,239 hours.

We adjusted the average hourly rate for a family medicine physician from $102.53 to $101.59. We continue to use the BLS occupation code for family medicine physician (291215) because it most appropriately fits the respondent type. We also fully loaded the hourly wage estimate by adding 100% to the median hourly wage to account for fringe and overhead benefits, which calculates to $203.18. The revised annual cost burden to deliver the information to the patient is estimated to be $3,292,413, a decrease from the previous burden of $3,374,388. This decrease is a result of using more accurate data on the hourly wage estimate, including applying the hourly median wage for respondent types, to account for fringe and overhead benefits. The estimated annual hour burden for this disclosure requirement is 16,204 hours, a decrease from the previous burden hours of 16,455.

In summary, no changes have been made to this collection except to use updated data. As a result, there was a decrease in overall burden hours and costs due to a decrease in the number of beneficiaries receiving imaging services and the application of the hourly median wage for the respondent types. Therefore, the total annual cost burden for this collection is estimated to be $3,366,364, a decrease from the previous total annual cost burden of $3,460,544. The total adjusted annual burden for this collection is 18,107 hours, a decrease from the previous burden hours of 18,694 hours.

16. Publication/Tabulation Dates

No publication or tabulation of data expected.

17. Expiration Date

There is no collection data instrument used in the collection of this information. However, upon receiving OMB approval, CMS will publish a notice in the Federal Register to inform the public of both the approval as well as the expiration date.

18. Certification Statement

No exceptions.

B. Collections of Information Employing Statistical Methods

Not applicable. This collection does not employ statistical methods.