

Supporting Statement Part 405, Subpart D - Private Contracts and Supporting Regulations CMS-R-234 (OMB-0938-0730)

Background

Section 4507 of the Balanced Budget Act of 1997 (BBA 1997) amended section 1802 of the Social Security Act (the Act) to permit certain physicians and practitioners to opt-out of Medicare and to provide -- through private contracts -- services that Medicare would otherwise cover. Under such contracts, the mandatory claims submission and limiting charge rules of section 1848(g) of the Act would not apply. Part 405, subpart D and the supporting regulations contained in 42 CFR §§ 405.410, 405.430, 405.435, 405.440, 405.445, and 405.455 (hereafter “the applicable regulations,” except as otherwise noted), counters the effect of certain provisions of Medicare law that -- absent section 1802 of the Act -- preclude physicians and practitioners from contracting privately with Medicare beneficiaries to pay without regard to Medicare limits.

The most recent approval of this information collection request (ICR) was issued by the Office of Management and Budget on December 3, 2018. We now seek to reinstate the ICR that expired on December 31, 2021. We have made no changes to the information being collected. We updated our burden estimate to reflect changes in the number of physicians and practitioners who have opted out and to modify our methodology for estimating the burden associated with contracts. We have also updated the cost estimate to account for current Bureau of Labor Statistics (BLS) wage estimates and to include the estimated costs for Medicare Advantage plans.

A. Justification

1. Need and Legal Basis

Under section 1802 of the Act, certain physicians and practitioners are permitted to opt out of Medicare and furnish covered services to Medicare beneficiaries through private contracts.

2. Information Users

Physicians and practitioners use this information collection to comply with the applicable regulations. Physicians and practitioners entering private contracts with beneficiaries must file an affidavit with Medicare in which they agree to opt-out of Medicare for 2 years and to meet certain other criteria. In general, the applicable regulations require that during that 2-year period, physicians and practitioners who have filed affidavits opting out of Medicare must sign private contracts with all Medicare beneficiaries to whom they furnish services that Medicare would otherwise cover (except those who need emergency or urgently needed care). In addition, Medicare Administrative Contractors (MACs) use this information to determine if benefits should be paid or continued.

3. Use of Information Technology

These requirements do not lend themselves to information technology. Physicians and practitioners who opt out of Medicare need not use any required forms when opting out, terminating opt-out, or cancelling opt-out. The applicable regulations do not address the extent to which physicians or practitioners who opt-out can use information technology when entering private contracts with beneficiaries.

4. Duplication of Efforts

There are no other information collections that duplicate this effort.

5. Small Businesses

This data collection was carefully reviewed to minimize paperwork burden and capture only essential information. These requirements do not have a significant impact on small businesses.

6. Less Frequent Collection

Physicians and practitioners who are opting out need to submit affidavits to their MACs. The affidavit automatically renews every 2 years unless the physician or practitioner cancels the optout before the next 2-year period in accordance with the applicable regulations. A physician or practitioner who is opting out for the first time may submit a termination request within 90 days of the effective date of the opt-out. Physicians and practitioners must enter private contracts with beneficiaries every 2 years. If this information was collected less frequently, CMS would be noncompliant with the applicable regulations that require physicians and practitioners to: (1) file affidavits to opt-out; and (2) enter private contracts with beneficiaries.

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 Notice/Outside Consultation

The 60-day Federal Register notice (89 FR 53625) was published on 06/27/2024. No public comments were received.

The 30-day Federal Register (89 FR 73097) was published on 09/09/2024.

9. Payment/Gift to Respondent

The collection of information does not provide for any payment or gifts nor are there any financial benefits to physicians or practitioners.

10. Confidentiality

As required by section 106(a)(2) of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, CMS posts a list of physicians and practitioners who have opted out on the CMS website. CMS does not routinely collect copies of private contracts between physicians/practitioners and beneficiaries.

11. Sensitive Questions

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Burden Estimate (Hours & Wages)

Wage Estimates

To derive average costs, we used data from the U.S. BLS' May 2023 National Occupational Employment and Wage Estimates for all salary estimates

(https://www.bls.gov/oes/current/oes_nat.htm#00-0000). The following table presents the median hourly wage, the cost of fringe benefits, and the adjusted hourly wage.

Table 1 – Annual Wage Estimates

Occupation Title	Occupation Code	Median Hourly Wage (\$/hr)	Fringe Benefits and Overhead (\$/hr)	Adjusted Hourly Wage (\$/hr)
Medical Secretaries and Administrative Assistants	43-6013	19.54	19.54	39.08

We are using the above-referenced BLS occupation title because it has been our experience that affidavits are prepared by such personnel (hereafter occasionally referenced as “administrative personnel”) rather than physicians or practitioners themselves. Since the wage estimate for medical secretaries and administrative assistants is significantly less than that for physicians and practitioners, many of the costs outlined below will be less than before (when physician and practitioner wages may have been utilized).

Burden Estimates

a. § 405.410 Conditions for properly opting out of Medicare

(i) § 405.410(a)

Section 405.410(a) states that each private contract between a physician or practitioner and a Medicare beneficiary must meet the specifications of § 405.415.

The burden associated with these requirements is the time to prepare and complete the private contract. In 2022, 2,525 physicians and practitioners opted out. We will use this figure as a basis for our future estimates of the number of physicians and practitioners who will opt-out each year per this ICR. We also estimate that it takes 2 hours to create a contract, resulting in a total of 5,050 hours (2,525 x 2). Using the above-referenced wage estimate, the annual cost is \$197,354 (5,050 x \$39.08).

Each physician or practitioner who opts out must sign contracts with beneficiaries when first opting out and every 2 years thereafter. There are currently 29,011 opted out physicians and practitioners.

We do not have data indicating how many beneficiaries use opt-out physicians or practitioners. For purposes of this ICR, however, we will assume that each physician or practitioner serves approximately five such beneficiaries per year on average, for an estimated total of 145,055 beneficiaries (or 29,011 x 5). Of this amount, we project that half of them, or 72,528, will need to sign contracts each year. We also estimate that it will take 10 minutes for a beneficiary to read and sign the private contract. This results in a beneficiary hour total of 12,040 (or 72,528 x 0.166). In terms of beneficiary cost, we will use the federal minimum wage figure, which is \$7.25 (see <https://www.dol.gov/general/topic/wages/minimumwage>). Applying this to the beneficiary hour total leads to an annual beneficiary cost stemming from § 405.410(a) of \$87,290 (or 12,040 x \$7.25).

The combined annual burden for § 405.410(a) is thus 17,090 hours (5,050 + 12,040) at a cost of \$284,644 (\$197,354 + \$87,290).

(ii) § 405.410(b)

Section 405.410(b) states that the physician or practitioner must submit to each Medicare contractor with which he or she files claims an affidavit that meets the specifications of § 405.420. The burden associated with these requirements is the burden to prepare and submit the affidavit to the Medicare contractor, a task that administrative personnel will perform. Using our previously referenced estimates of 2,525 physicians/practitioners, 2 hours (the time we believe it will take to draft the affidavit), and \$39.08 hourly wage, this results in an annual burden associated with § 405.410(b) of 5,050 hours and \$197,354.

(iii) § 405.410

Given the foregoing, the total annual burden of § 405.410 is 22,140 hours (5,050 + 17,090) and \$481,998 (\$284,644 + \$197,354).

b. § 405.445 Cancellation of opt-out and early termination of opt-out

(i) § 405.445(a)

Section 405.445(a) states that a physician or practitioner may cancel his/her opt-out by submitting a written notice to each contractor to which he or she would file claims absent the optout. This

notice must be submitted no later than 30 days before the end of the current 2-year optout period. It also must indicate that the physician or practitioner does not want to extend the opt-out affidavit for a subsequent 2-year period.

The burden associated with this requirement is the time it takes to prepare and submit the written notice to the Medicare contractor. We estimate that 60 physicians and practitioners per year cancel their opt-out and that it takes approximately 10 minutes for their administrative personnel to do so. This results in an annual burden of 10 hours (60 x .166) at a cost of \$391 (10 x \$39.08).

(ii) Section 405.445(b)(2)

Section 405.445(b)(2) states that a physician or practitioner must notify all Medicare contractors with which he or she filed an affidavit of the termination of the opt-out no later than 90 days after the effective date of the opt-out period.

The burden associated with this requirement is the time it takes to prepare and submit the written notice to the Medicare contractor. Using our previous 60 physician/practitioner and 10minute estimates, this results in an annual burden of 10 hours (60 x .166) at a cost of \$391.

(iii) Section 405.445(b)(4)

Section 405.445(b)(4) states that a physician or practitioner must notify all beneficiaries with whom the physician or practitioner entered private contracts of: (1) the physician/practitioner's decision to terminate opt-out; and (2) the beneficiaries' right to have claims filed on their behalf with Medicare for the services furnished during the period between the effective date of the opt-out and the effective date of the termination of the opt-out period.

The burden associated with this requirement is the time it takes for the physician/practitioner -- through his/her administrative personnel -- to notify all beneficiaries of (1) and (2) in the previous paragraph. Utilizing our previous 60 physician/practitioner estimate -- as well as a projection that it will take the physician/practitioner's administrative personnel 2 hours to provide the above notice to their beneficiaries via bulk mailings --- this results in a total of 120 hours at a cost of \$4,690 (or 120 x \$3,908).

c. § 405.455 Application to Medicare Advantage contracts

Section 405.455(a) states that an organization that has a contract with CMS to provide one or more Medicare Advantage plans to beneficiaries must acquire and maintain information from Medicare contractors on physicians and practitioners who have opted-out of Medicare.

The burden associated with these requirements is the time associated with acquiring and maintaining information provided by Medicare contractors on physicians and practitioners who have opted out of Medicare. It is estimated that 500 organizations will spend 1 hour annually to acquire and maintain this information for a total of 500 hours. The organizations will make this information available to beneficiaries via telephone inquiries. The total annual burden for this requirement is therefore 500 hours at a cost of \$19,540 (or 500 x \$39.08).

d. Total Burden

The following chart summarizes the burden associated with this ICR.

Table 2 - Estimated Total Annual Burden of this ICR

	OMB Control No.	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting (\$) (includes 100% fringe benefits) *	Total Cost (\$)
§ 405.410(a) – Physician/Practitioner Burden	0938-0730	2,525	2,525	2	5,050	39.08	197,354
§ 405.410(a) – Beneficiary burden	0938-0730	72,528	72,528	.166	12,040	7.25	87,290
§ 405.410(b) - Physician/Practitioner Burden	0938-0730	2,525	2,525	2	5,050	39.08	197,354
§ 405.445(a) - Physician/Practitioner Burden	0938-0730	60	60	.166	10	39.08	391
§ 405.445(b)(2) - Physician/Practitioner Burden	0938-0730	60	60	.166	10	39.08	391

§ 405.445(b)(4) - Physician/Practitioner Burden	0938-0730	60	60	2	120	39.08	4,690
§ 405.455 – Medicare Advantage Organization Burden	0938-0730	500	500	1	500	39.08	19,540
Total	N/A	78,258	78,258	Varies	22,780	Varies	507,010

e. ICRs Approved under a different OMB Control Number:

While the following ICRs are subject to the Act, the associated burdens are captured under OMB control number 0938-0999 (CMS-1500) Health Insurance Claim Form.

§ 405.430 Failure to properly opt-out

Section 405.430(b)(2) states that the physician or practitioner must submit claims to Medicare for all Medicare-covered items and services furnished to Medicare beneficiaries.

§ 405.435 Failure to maintain opt-out

Section 405.435(b)(3) states that the physician or practitioner must submit claims to Medicare for all Medicare-covered items and services furnished to Medicare beneficiaries.

§ 405.440 Emergency and urgent care services

Section 405.440(b)(1) states that when a physician or practitioner furnishes emergency or urgent care services to a Medicare beneficiary with whom the physician or practitioner has not previously entered a private contract, the physician or practitioner must submit a claim to Medicare in accordance with both 42 CFR Part 424 and Medicare instruction (including but not limited to complying with proper coding of emergency or urgent care services furnished by physicians and practitioners who have opted-out of Medicare).

13. Capital Costs (Maintenance of Capital Costs)

There are no capital costs.

14. Cost to Federal Government

There are no additional costs to the federal government. MACs already process affidavits and opt-out termination notices, and we are not adding or requiring any new data elements to be reported thereon. Moreover, this ICR does not project that the MACs will receive an increased number of affidavits and termination notices.

15. Changes to Burden

Pursuant to the foregoing data, we project the following annual changes in burden associated with CMS-R-234:

CMS-R-234	Respondents	Total Responses	Total Annual Time (hours)	Total Annual Cost (\$)
Currently Approved	57,722	57,722	23,557	829,977
Requested Per This ICR	78,258	78,258	22,780	507,010
Net Change	+ 20,536	+ 20,536	-777	- 322,967

16. Publication/Tabulation Dates

N/A

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

There are no exceptions to the certification statement.

B. Collection of Information Employing Statistical Methods

These information collection requirements do not employ statistical methods.