Supporting Statement Part A
Subpart D - Private Contracts and Supporting Regulations Contained in 42 CFR 405.410, 405.430, 405.435, 405.440, 405.445, and 405.455
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 would otherwise be covered by Medicare. Under such contracts the mandatory claims submission and limiting charge rules of section 1848(g) of the Act would not apply. Subpart D and the supporting regulations contained in 42 CFR 405.410, 405.430, 405.435, 405.440, 405.445, and 405.455, 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 March 2, 2016. We are now seeking to renew this approval before it expires on March 31, 2019. 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 refinements to our methodology for estimating the burden associated with contracts. We have also updated the cost estimate to account for the 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 the law (i.e., 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/or practitioners use these information collection requirements to comply with the law. Physicians/practitioners entering into private contracts must file an affidavit with Medicare in which they agree to opt out of Medicare for a period of 2 years and to meet certain other criteria. In general, the law requires that during that 2-year period of time, physicians and practitioners who have filed affidavits opting out of Medicare must sign private contracts with <u>all</u> Medicare beneficiaries to whom they furnish services that would

otherwise be covered by Medicare, except those who are in need of emergency or urgently needed care. In addition, Medicare contractors 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 are not required to use any required forms when opting out of Medicare, terminating opt out, or cancelling opt-out. The regulations are silent on the extent to which physicians or practitioners who opt out can use information technology when entering into 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 Medicare Administrative Contractors. The affidavit automatically renews every 2 years unless the physician or practitioner cancels the opt-out before the next 2 year period in accordance with the regulations. A physician or practitioner who is opting out for the very first time may submit a termination request within 90 days of the effective date of the opt-out. Physicians and practitioners must enter into private contracts with beneficiaries every 2 years. If this information was collected less frequently, CMS would be out of compliance with the law because the law requires physicians/practitioners to file affidavits in order to opt-out and enter into 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 published on July 17, 2018 (83 FR 33223). The 30-day Federal Register notice published on October 4, 2018 (83 FR 50100). No comments.

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/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. Bureau of Labor Statistics' May 2017 National Occupational Employment and Wage Estimates for all salary estimates (https://www.bls.gov/oes/current/oes_nat.htm#00-0000). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits, and the adjusted hourly wage.

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Medical Secretaries	43-6013	17.25	17.25	34.50

Except where noted, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Burden Estimates

§ 405.410 Conditions for properly opting-out of Medicare

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

The burden associated with these requirements is the time to 1) draft and 2) read, sign, photocopy, and retain the private contract. We believe that physicians and practitioners will need to draft a model contract only one time: when they first opt out. In 2017, 3,771 physicians/practitioners opted out. We do not know how many physicians/practitioners will opt out in the future, but we will assume that 3,771 physicians/practitioners will opt out each year. It is estimated that it will take 3,771 physicians/practitioners 2 hours each to create a contract for a total of 7,542 hours.

Each physician/practitioner who opts out must sign contracts with beneficiaries when first opting out and every 2 years thereafter. There are currently 21,027 opt out physicians/practitioners. We do not know how many beneficiaries use opt-out physicians/practitioners, but we will assume that each physician/practitioner will serve between four and five beneficiaries on average, for an estimated total of approximately 100,000 beneficiaries. We also estimate that half of the beneficiaries, or 50,000 beneficiaries, will need to sign contracts each year. It is estimated that it will take 10 minutes each to read, sign, photocopy and retain the private contract for 50,000 beneficiaries for a total of 8,333 hours. The burden for these ICRs total 15,875 hours.

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 draft, sign and submit the affidavit to the Medicare contractor. It is estimated that it will take 3,771 physicians/practitioners approximately 2 hours each for a total of 7,542 burden hours.

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

Section 405.445(a) states that a physician or practitioner may cancel opt-out by submitting a written notice to each contractor to which he or she would file claims absent the opt-out, not later than 30 days before the end of the current 2-year opt-out period, indicating that the physician or practitioner does not want to extend the application of the opt-out affidavit for a subsequent 2-year period.

The burden associated with this requirement is the time to draft, sign and submit the writing to the Medicare contractor. We estimate it will take 60 physicians/practitioners approximately 10 minutes each for a total of 10 burden hours.

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 for the physician/practitioner to notify all Medicare contractors of the affidavit. It is estimated that it will take 60 physicians/practitioners 10 minutes each for a total of 10 hours.

Section 405.445(b)(4) states that a physician or practitioner must notify all beneficiaries with whom the physician or practitioner entered into private contracts of the physician's decision to terminate opt-out and of 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 for the physician/practitioner to notify all beneficiaries of his or her decision to terminate opt-out and of the beneficiaries' right to have claims filed on their behalf with Medicare. It is estimated that it will take 60 physicians/practitioners each 2 hours to notify their beneficiaries via bulk mailings for a total of 120 hours.

§ 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 burden for these ICRs is 500 hours.

Summary

The following chart summarizes the burden associated with the information collection requirements detailed in the need and legal basis section of this document.

Estimated Annual Burden for Physicians and Practitioners

CFR Section	Responses	Average Burden per response	Annual Burden Hours
405.410(a) - draft document - read, sign, photocopy, retain document 405.410(b)	3,771 50,000 3,771	2 hours 10 minutes 2 hours	7,542 hours 8,333 hours 7,542 hours
405.445(a)	60	10 minutes	10 hours
405.455(a)	500	1 hour	500 hours*
405.445(b)(2)	60	10 minutes	10 hours
405.445(b)(4)	60	2 hours	120 hours
Total	**58, 222**		**24, 057 hours**

*We estimate that it will cost the physicians and practitioners $812,716.50 (23,557 hours x $34.50/hr) to comply with these information collection requirements. We estimate that it will cost Medicare Advantage Plans $17,260 (500 hours x $34.50/hr).

ICRs Approved under a different OMB Control Number:

While the following ICRs are subject to the Act; the burden associated with this requirements 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 into 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. These requirements are a part of normal business practices.

15. Changes to Burden

We have not changed the information collection requirements in any way. We updated the burden estimate in section A.12 from the last burden estimate to reflect changes in the number of physicians and practitioners who have opted out and refinements to our methodology for estimating the burden associated with contracts. We have also updated the cost estimate to account for the current BLS wage estimates and to include the estimated costs for Medicare Advantage plans.

The previous estimate assumed that 600 physicians and practitioners would opt out each year. Current information posted on the CMS website (https://data.cms.gov/Medicare-Enrollment/Opt-Out-Affidavits/7yuw-754z) indicates that 3,771 physicians/practitioners opted out in 2017. For purposes of this estimate, we assume that 3,771 physicians/practitioners will opt out every year and will therefore need to create contracts and submit affidavits.

The previous estimate assumed that opt-out physicians/practitioners would create new contracts every 2 years. We have reconsidered that assumption and believe it is more likely that these physicians and practitioners create a model contract one time and use that model contract every time they sign new contracts with beneficiaries.

The previous estimate assumed that 25,000 beneficiaries annually sign contracts with physicians and practitioners who opted out. Current information posted on the CMS website (https://data.cms.gov/Medicare-Enrollment/Opt-Out-Affidavits/7yuw-754z) indicates there are 21,027 opt-out physicians and practitioners. We do not know how many beneficiaries use opt-out physicians/practitioners, but we assume that each physician/practitioner will serve between four and five beneficiaries on average, for an estimated total of 100,000 beneficiaries. We also estimate that half of the beneficiaries, or 50,000 beneficiaries, will need to sign contracts each year.

As a result of the updates to the number of physicians/practitioners who have opted out and the refinements to our methodology for estimating the burden associated with contracts, the total estimated annual burden changed from 6,307 hours to 23,557 hours.

The estimated average hourly wage for medical secretaries increased from $32.24 to $34.50. After applying the updated estimated hourly wave to the updated annual burden hours, the total estimated cost for physicians and practitioners increased from $203,337.68 to $812,716.50. The previous estimate did not reflect an estimated cost for Medicare Advantage organizations. We estimate that cost to be $17,260.

16. Publication/Tabulation Dates

There are no plans to publish the information for statistical use.

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.