

**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)**

This package is associated with a November 16, 2015, final rule (80 FR 70886) (CMS-1631-FC; RIN 0938-AS40).

**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 4507 of BBA 1997, preclude physicians and practitioners from contracting privately with Medicare beneficiaries to pay without regard to Medicare limits.

**A. Justification**

1. Need and Legal Basis

Under the law (i.e., section 4507 of BBA 1997), we are required to permit certain physicians and practitioners 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. 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.

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

If this information was collected less frequently, CMS would be out of compliance with the law.

7. Special Circumstances

The collection of information does not require any special circumstances.

8. Federal Register Notice/Outside Consultation

The NPRM served as the 60-day Federal Register notice which published on July 15, 2015 (80 FR 41685). The NPRM was placed on public inspection on July 8 whereby comments were due on Sept 8. No PRA-related comments were received.

The final rule is serving as the 30-day Federal Register notice (November 16, 2015; 80 FR 70886). The final rule was placed on public inspection on October 30 whereby comments are due on/by December 29, 2015.

Since these requirements have been in place for several years, we have not sought any additional outside consultations.

9. Payment/Gift To Respondent

The collection of information does not provide for any payment or gifts.

10. Confidentiality

Confidentiality of this information is assured.

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimate (Hours & Wages)

*Wage Estimates*

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2014 National Occupational Employment and Wage Estimates for all salary estimates ([www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm)). 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	16.12	16.12	32.24

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. It is estimated that it will take 600 physicians/practitioners 2 hours each to create a contract for a total of 1200 hours. It is estimated that it will take 10 minutes each to read, sign, photocopy and retain the private contract for 25,000 beneficiaries for a total of 4,167 hours. The burden for these ICRs total 5,367 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 150 physicians/practitioners approximately 2 hours each for a total of 300 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 new 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+Choice contracts

Section 405.455(a) states that an organization that has a contract with CMS to provide one or more Medicare+Choice (M+C) 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.

#### ICRs without burden:

The ICR below is subject to the Act. However, we believe the burden associated with this ICR is exempt since the burden is imposed by 405.410 and meets the specifications in 405.420.

#### Currently approved ICRs:

While the ICRs below are subject to the Act; the burden associated with this requirement is captured in the CMS-1500, Health Insurance Claim Form (OMB Control Number 0938-0999).

§ 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).

*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**

CFR Section	Responses	Average Burden per response	Annual Burden Hours
405.410(a)			
- draft document	(600)	2 hours	(1,200 hours)
- read, sign, photocopy, retain document	(25,000)	10 minutes	(4,167 hours)
<b>Sub-total</b>	<b>25,600</b>		<b>5,367 hours</b>
Part 405, subpart D	150	2 hours	300 hours (revised)
405.445(a)	60	10 minutes	10 hours (added)
405.445(b)(2)	60	10 minutes	10 hours
405.445(b)(4)	60	2 hours	120 hours

CFR Section	Responses	Average Burden per response	Annual Burden Hours
405.455(a)	500	1 hour	500 hours
<b>Total</b>	<b>26,430</b>		<b>6,307 hours</b>

We estimate that it will cost the public \$203,337.68 (6,307 hours x \$32.24/hr) to comply with these information collection requirements.

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

*Burden Adjustments*

Our cost estimate has been adjusted by accounting for the current BLS wage estimates and by factoring in our 100% fringe benefit adjustment.

*Program Changes*

Section 106(a) of MACRA indicates that valid opt-out affidavits filed on or after June 16, 2015, automatically renew every 2 years. Previously, physicians and practitioners wanting to renew their opt-out were required to file new valid affidavits with their Medicare Administrative Contractors (MAC).

To be consistent with section 106(a), we have revised 42 CFR part 405, subpart D governing the submission of opt-out affidavits. We estimate that 150 physicians/practitioners will submit new affidavits at 2 hr per submission or 300 hr (total). Previously, we estimated that 600 physicians/practitioners would submit renewal affidavits at 2 hr per submission or 1,200 hr (total). In this regard, the burden will decrease by -900 hr (300 hr - 1,200 hr) when physicians and practitioners no longer need to submit renewal affidavits starting on June 16, 2017. We also estimate that a Medical Secretary will perform this duty at \$32.24/hr for a savings of -\$29,016 (-900 hr x \$32.24/hr).

Under §405.445(a), physicians and practitioners that file valid opt-out affidavits on or after June 16, 2015 and do not want to extend their opt-out status at the end of a 2 year opt-out period may cancel by notifying us at least 30 days prior to the start of the next 2

year opt-out period. The burden associated with this new requirement is the time to draft, sign and submit the writing to the MAC. We estimate it will take 60 physicians/practitioners approximately 10 minutes each for a total of 10 burden hours. We also estimate that a Medical Secretary will perform this duty at \$32.24/hr for a cost of \$322.40 (10 hr x \$32.24/hr).

*Summary*

Section(s) in title 42 of the CFR	OMB No. (CMS ID No.)	Respondents	Responses (total)	Burden per Response	Total Annual Burden (hr)	Labor Rate for Reporting (\$/hr)	Total Cost (\$)
Part 405, subpart D	0938-0730 (CMS-R-234)	-450	-450	2 hr	-900	32.24	-29,016
405.445(a)	0938-0730 (CMS-R-234)	60	60	10 min	10	32.24	322.40

For Part 405, subpart D, the November 16, 2015, final rule reduces respondent burden by -900 hr (aggregate) since our currently approved burden estimates 1,200 hr and we now estimate 300 hr since respondents will no longer be required to submit a renewal affidavit.

With regard to §405.445(a) and the requirement to notify CMS, the final rule adds 10 hr (aggregate) to the respondent burden.

16. Publication/Tabulation Dates

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

17. Expiration Date

These information collection requirements do not lend themselves to an expiration date, therefore, this item does not apply.

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.