

Supporting Statement for Subpart D- Private Contracts
and Supporting Regulations Contained in
42 CFR 405.410, 405.430, 405.435, 405.440, 405.445,
And 405.455.

A. Background

Section 4507 of BBA 1997 amended section 1802 of the Social Security 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.

B. 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.

§ 405.410 Conditions for 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 carrier 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 carrier. It is estimated that it will take 600 physicians/practitioners approximately 2 hours each for a total of 1200 burden hours.

§ 405.445 Renewal and Early Termination of Opt-Out

Section 405.445(b)(2) states that a physician or practitioner must notify all Medicare carriers 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 carriers 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 Medicare+Choice

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 carriers 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 carriers 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.

§ Section 405.445 Renewal and Early Termination of Opt-Out

Section 405.445(a) states that a physician or practitioner may renew opt-out by filing an affidavit with each carrier to which an affidavit was submitted for the first opt-out period, (as specified in 405.420), and to each carrier to which a claim was submitted under 405.440 during the previous opt-out period, provided the affidavits are filed within 30 days after the current opt-out period expires.

Currently approved ICRs:

While the ICRs below are subject to the Act; the burden associated with this requirement is captured in the HCFA-1500, OMB Number 0938-0008, Medicare Common Claim Form, which expires on 5/31/2009.

§ Section 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.

§ Section 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.

§ Section 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).

2. Information Users

Physicians and/or practitioners use these information collection requirements to comply with the law. In addition, Medicare carriers use this information to determine if benefits should be paid or continued.

3. Improved Information Technology

These requirements do not lend themselves to improved information technology.

4. Duplication of Similar Information

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 60-day Federal Register notice was published on January 12, 2007, attached.

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 (Total Hours & Wages)

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	(1200 hours)
- read, sign, photocopy, retain document	(25,000)	10 minutes	(4,167 hours)
Sub-total	25,600		5,367 hours
405.410(b)	600	2 hours	1200 hours
405.445(b)(2)	60	10 minutes	10 hours
405.445(b)(4)	60	2 hours	120 hours
405.455(a)	500	1 hour	500 hours
Total	26,820		7,197 hours

It is estimated that it would cost the public \$179,925 (7,197 hours * \$25 per hour) 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. Program or Burden Changes

There are no program changes or changes to the burden.

16. Publication and 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.

C. Collection of Information Employing Statistical Methods

These information collection requirements do not employ statistical methods.