CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 92	Date: JUNE 27, 2008
	Change Request 6081

SUBJECT: Private Contracting/Opting out of Medicare

I. SUMMARY OF CHANGES: 42CFR405.435 was amended on November 21, 2005, in order to clarify that the consequences specified in 405.435(b) for the failure on the part of a physician or practitioner to maintain opt-out will apply regardless of whether or when a carrier notifies a physician or practitioner of the failure to maintain opt out. A new paragraph (d) was also added to 42CFR405.435 to clarify that in situations where a violation of 405.435(a) is not discovered by the carrier during the 2 year opt-out period when the violation actually occurred, then the requirements of 405.435(b)(1) through (b)(8) would be applicable from the date that the first violation of 405.435(a) occurred until the end of the opt-out period during which the violation occurred (unless the physician or practitioner takes good faith efforts to restore opt out conditions, for example, by refunding the amounts in excess of the charge limits to beneficiaries with whom he or she did not sign a private contract).

New / Revised Material

Effective Date: September 29, 2008

Implementation Date: September 29, 2008

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated) R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE						
R	15/40.5/When a Physician or Practitioner Opts Out of Medicare						
R	15/40.6/When Payment May be Made to a Beneficiary for Service of an Opt- Out Physician/Practitioner						
R	15/40.9/Requirements of the Opt-Out Affidavit						
R	15/40.11/Failure to Maintain Opt-Out						
R	15/40.13/Physician/Practitioner Who Has Never Enrolled in Medicare						
R	15/40.20/Maintaining Information on Opt-Out Physicians						
R	15/40.26/Registration and Identification of Physicians or Practitioners Who Opt Out						
R	15/40.35/Early Termination of Opt-Out						

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

SECTION B: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

*Unless otherwise specified, the effective date is the date of service.

Attachment – Business Requirements

Pub. 100-02 Transmittal: 92 Date: June 27, 2008 Change Request: 6081

SUBJECT: Private Contracting/Opting out of Medicare

Effective Date: September 29, 2008

Implementation Date: September 29, 2008

I. GENERAL INFORMATION

A. Background: Section 4507 of the Balanced Budget Act of 1997 amended section 1802 of the Social Security Act ("the Act") to permit certain physicians and practitioners to opt-out of Medicare if certain conditions were met, and to provide through private contracts services that would otherwise be covered by Medicare. Under these private contracts, the mandatory claims submission and limiting charge rules of section 1848(g) of the Act would not apply. The amendments to section 1802 of the Act, which were effective on January 1, 1998, made the provisions of the Medicare statute that would ordinarily preclude physicians and practitioners from contracting privately with Medicare beneficiaries to pay without regard to Medicare limits inapplicable if the conditions necessary for an effective "opt-out" are met.

Policy: 42 CFR §405.435 was amended on November 21, 2005, in order to clarify that the В. consequences specified in §405.435(b) for the failure on the part of a physician or practitioner to maintain opt-out will apply regardless of whether or when a carrier notifies a physician or practitioner of the failure to maintain opt-out. A new paragraph (d) was also added to 42 CFR §405.435 to clarify that in situations where a violation of §405.435(a) is not discovered by the carrier during the 2-year opt-out period when the violation actually occurred, then the requirements of §405.435(b)(1) through (b)(8) would be applicable from the date that the first violation of §405.435(a) occurred until the end of the opt-out period during which the violation occurred (unless the physician or practitioner takes good faith efforts to restore opt-out conditions, for example, by refunding the amounts in excess of the charge limits to beneficiaries with whom he or she did not sign a private contract). These good faith efforts must be made within 45 days of any notice by the carrier that the physician or practitioner has failed to maintain opt-out (where the carrier discovers the failure after the 2-year opt-out period has expired), or within 45 days after the physician or practitioner has discovered the failure to maintain opt-out, whichever is earlier. Therefore, because section 40.11 of Pub. 100-02, chapter 15 does not include the new policy outlined in 42 CFR §405.435, CMS is amending the manual so that it is consistent with that regulation as well as making some other minor changes to the private contracting/opt out section in order to bring it up-to-date.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement										
		A	D	F	C	R	Sł	ared-	Syste	m	OTHER
		/	M	I	A	H	Maintainers				
		В	Е		R	Н	F	M	V	C	
					R	I	I	C	M	W	
		M	M		I		S	S	S	F	
		A	A		Е		S				
		C	С		R						
6081.1	Medicare contractors/carriers shall apply the	X			X						
	rules specified in Pub. 100-02, chapter 15,										
	section 40.11 for the failure on the part of a										
	physician or practitioner to maintain opt-out.										

III. PROVIDER EDUCATION TABLE

Number	Requirement										
		A /	D M	F I	C A	R H	Shared-System Maintainers			OTHER	
		В	Е		R R	H I	F I	M C	V M	C W	
		M A C	M A C		I E R		S S	S	S	F	
6081.2	Contractors shall post this entire instruction, or a direct link to this instruction, on their Web site and include information about it in a listsery message within 1 week of the release of this instruction. In addition, the entire instruction must be included in your next regularly scheduled bulletin. Contractors are free to supplement it with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X			X						

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below:

Use "Should" to denote a recommendation.

X-Ref	Recommendations or other supporting information:
Requirement	
Number	

B. For all other recommendations and supporting information, use this space:

V. CONTACTS

Pre-Implementation Contact(s): Fred Grabau 410-786-0206 **Post-Implementation Contact(s):** Fred Grabau 410-786-0206

VI. FUNDING

A. For Fiscal Intermediaries and Carriers: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

B. For Medicare Administrative Contractors (MAC): The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

40.5 - When a Physician or Practitioner Opts Out of Medicare

(Rev. 92; Issued: 06-27-08; Effective/Implementation Date: 09-29-08)

When a physician/practitioner opts out of Medicare, Medicare covers no services provided by that individual and no Medicare payment can be made to that physician or practitioner directly or on a capitated basis. Additionally, no Medicare payment may be made to a beneficiary for items or services provided directly by a physician or practitioner who has opted out of the program.

EXCEPTION: In an emergency or urgent care situation, a physician/practitioner who opts out may treat a Medicare beneficiary with whom he/she does not have a private contract and bill for such treatment. In such a situation, the physician/practitioner may not charge the beneficiary more than what a nonparticipating physician/practitioner would be permitted to charge and must submit a claim to Medicare on the beneficiary's behalf. Payment will be made for Medicare covered items or services furnished in emergency or urgent situations when the beneficiary has not signed a private contract with that physician/practitioner. (See §40.28.)

Under the statute, the physician/practitioner cannot choose to opt out of Medicare for some Medicare beneficiaries but not others; or for some services but not others. The physician/practitioner who chooses to opt out of Medicare may provide covered care to Medicare beneficiaries only through private agreements.

Medicare will make payment for covered, medically necessary services that are ordered by a physician/practitioner who has opted out of Medicare if the ordering physician/practitioner has acquired *a National Provider Identifier (NPI)* and provided that the services are not furnished by another physician/practitioner who has also opted out. For example, if an opt-out physician/practitioner admits a beneficiary to a hospital, Medicare will reimburse the hospital for medically necessary care.

40.6 - When Payment May be Made to a Beneficiary for Service of an Opt-Out Physician/Practitioner

(Rev. 92; Issued: 06-27-08; Effective/Implementation Date: 09-29-08)

Payment may be made to a beneficiary for services of an opt out *physician/practitioner* in two cases:

- The services are emergency or urgent care services furnished by an opt-out physician/practitioner to a beneficiary with whom he/she has *not* previously *entered into* a private contract. (See §40.28 for further discussion of emergency and urgent care services by opt-out physicians and practitioners.); or
- The opt-out physician/practitioner failed to privately contract with the beneficiary for services that *he/she* provided that were not emergency or urgent care services. The CMS expects this case to come to the carrier's attention only in the course of a request for *a redetermination* of a denied claim or as a result of a complaint from a beneficiary or

the beneficiary's legal representative. If the carrier receives such a complaint, it must consider it to be a request for a *redetermination* of the denial of payment for services of the opt-out physician/practitioner. It must follow the procedures outlined in §40.11 for cases in which the physician/practitioner fails to maintain opt-out. If the physician/practitioner does not respond to the carrier's request for a copy of the private contract within 45 days, the carrier must make payment to the beneficiary based upon the payment for a nonparticipating physician/practitioner for that service. It must notify the beneficiary that the physician/practitioner who has opted out must privately contract with the beneficiary or the beneficiary's legal representative for services the physician/practitioner furnished and that no further payment will be made to the beneficiary for services furnished by the opt-out physician/practitioner after 15 days from the postmark of the notice.

40.9 - Requirements of the Opt-Out Affidavit

(Rev. 92; Issued: 06-27-08; Effective/Implementation Date: 09-29-08)

Under 1802(b)(3)(B) of the Act, a valid affidavit must:

- Be in writing and be signed by the physician/practitioner;
- Contain the physician's or practitioner's full name, address, telephone number, national provider identifier (NPI) or billing number (if one has been assigned), or, if an NPI has *not* been assigned, the physician's or practitioner's tax identification number (TIN);
- State that, except for emergency or urgent care services (as specified in §40.28), during the opt-out period the physician/practitioner will provide services to Medicare beneficiaries only through private contracts that meet the criteria of §40.8 for services that, but for their provision under a private contract, would have been Medicare-covered services;
- State that the physician/practitioner will not submit a claim to Medicare for any service furnished to a Medicare beneficiary during the opt-out period, nor will the physician/practitioner permit any entity acting on the physician's/practitioner's behalf to submit a claim to Medicare for services furnished to a Medicare beneficiary, except as specified in §40.28;
- State that, during the opt-out period, the physician/practitioner understands that the physician/practitioner may receive no direct or indirect Medicare payment for services that the physician/practitioner furnishes to Medicare beneficiaries with whom the physician/practitioner has privately contracted, whether as an individual, an employee of an organization, a partner in a partnership, under a reassignment of benefits, or as payment for a service furnished to a Medicare beneficiary under a Medicare Advantage plan;

- State that a physician/practitioner who opts out of Medicare acknowledges that, during the opt-out period, the physician's/practitioner's services are not covered under Medicare and that no Medicare payment may be made to any entity for the physician's/practitioner's services, directly or on a capitated basis;
- State on acknowledgment by the physician/practitioner to the effect that, during the opt-out period, the physician/practitioner agrees to be bound by the terms of both the affidavit and the private contracts that the physician/practitioner has entered into;
- Acknowledge that the physician/practitioner recognizes that the terms of the affidavit apply to all Medicare-covered items and services furnished to Medicare beneficiaries by the physician/practitioner during the opt-out period (except for emergency or urgent care services furnished to the beneficiaries with whom the physician/practitioner has not previously privately contracted) without regard to any payment arrangements the physician/practitioner may make;
- With respect to a physician/practitioner who has signed a Part B participation agreement, acknowledge that such agreement terminates on the effective date of the affidavit:
- Acknowledge that the physician/practitioner understands that a beneficiary who has not entered into a private contract and who requires emergency or urgent care services may not be asked to enter into a private contract with respect to receiving such services and that the rules of §40.28 apply if the physician/practitioner furnishes such services;
- Identify the physician/practitioner sufficiently so that the carrier can ensure that no payment is made to the physician/practitioner during the opt-out period; and
- Be filed with all carriers who have jurisdiction over claims the physician/practitioner would otherwise file with Medicare and be filed no later than 10 days after the first private contract to which the affidavit applies is entered into.

40.11 - Failure to Maintain Opt-Out

(Rev.92; Issued: 06-27-08; Effective/Implementation Date: 09-29-08)

A. Failure to maintain opt-out

A physician/practitioner fails to maintain opt-out under this section if during the opt-out period one of the following occurs:

• The physician/practitioner has filed an affidavit in accordance with §40.9 and has signed private contracts in accordance with §40.8 but, *t*he physician/practitioner knowingly and willfully submits a claim for Medicare payment (except as provided in §40.28) or *the physician/practitioner receives* Medicare payment directly or indirectly for

Medicare-covered services furnished to a Medicare beneficiary (except as provided in §40.28); *or*

- The physician/practitioner fails to enter into private contracts with Medicare beneficiaries for the purpose of furnishing items and services that would otherwise be covered by Medicare, or enters into private contracts that fail to meet the specifications of §40.8; or
- The physician/practitioner fails to comply with the provisions of §40.28 regarding billing for emergency care services or urgent care services; or
- The physician/practitioner fails to retain a copy of each private contract that the physician/practitioner has entered into for the duration of the opt-out period for which the contracts are applicable or fails to permit CMS to inspect them upon request.

B. Violation discovered by the carrier during the 2-year opt out period.

If a physician/practitioner fails to maintain opt-out in accordance with *the provisions* outlined in paragraph A. of this section, and fails to demonstrate within 45 days of a notice from the carrier that the physician/practitioner has taken good faith efforts to maintain opt-out (including by refunding amounts in excess of the charge limits to the beneficiaries with whom the physician/practitioner did not sign a private contract), the following will result effective 46 days after the date of the notice, **but only for the remainder of the opt-out period:**

- 1. All of the private contracts between the physician/practitioner and Medicare beneficiaries are deemed null and void.
- 2. The physician's or practitioner's opt-out of Medicare is nullified.
- 3. The physician or practitioner must submit claims to Medicare for all Medicare covered items and services furnished to Medicare beneficiaries.
- 4. The physician or practitioner or beneficiary will not receive Medicare payment on Medicare claims for the remainder of the opt-out period, except as stated above.
- 5. The physician or practitioner is subject to the limiting charge provisions as stated in §40.10.
- 6. The practitioner may not reassign any claim except as provided in the Medicare Claims Processing Manual, Chapter 1, "General Billing Requirements," §30.2.13.
- 7. The practitioner may neither bill nor collect any amount from the beneficiary except for applicable deductible and coinsurance amounts.

8. The physician or practitioner may not attempt to once more meet the criteria for properly opting out until the 2-year opt-out period expires.

C. Violation not discovered by the carrier during the 2-year opt out period.

In situations where a violation of paragraph (A) of this section is not discovered by the carrier during the 2-year opt-out period when the violation actually occurred, the requirements of paragraphs (B)(1) through (B)(8) of this section are applicable from the date that the first violation of paragraph (A) of this section occurred until the end of the opt-out period during which the violation occurred (unless the physician or practitioner takes good faith efforts, within 45 days of any notice from the carrier that the physician or practitioner failed to maintain opt-out, or within 45 days of the physician's or practitioner's discovery of the failure to maintain opt-out, whichever is earlier, to correct his or her violations of paragraph (A) of this section. Good faith efforts include, but are not necessarily limited to, refunding any amounts collected in excess of the charge limits from beneficiaries with whom he or she did not sign a private contract).

40.13 - Physician/Practitioner Who Has Never Enrolled in Medicare (Rev. 92; Issued: 06-27-08; Effective/Implementation Date: 09-29-08)

For a physician/practitioner who has never enrolled in the Medicare program and wishes to opt out of Medicare, the *physician/practitioner* must provide the *carrier* with *a National Provider Identifier (NPI)*. The carrier must annotate its in-house provider file that the physician/practitioner has opted out of the program. The carrier can get the full name, address, license number, and tax identification number from the *physician's/practitioner's opt out* affidavit. All other data requirements should be developed from other data sources (e.g., the American Medical Association, State Licensing Board, etc.). The physician/practitioner must not receive payment during the opt-out period (except in the case of emergency or urgent care services). If the carrier needs additional data elements and cannot obtain that information from another source, it may contact the physician/practitioner directly. It must notify the physician or practitioner that in order to refer or order services for a Medicare patient, the physician or practitioner must have an NPI.

If an opt-out physician/practitioner provides emergency or urgent care service to a beneficiary who has not signed a private contact with the physician or practitioner and the physician/practitioner submits an assigned claim, the physician or practitioner must complete Form CMS-855 and enroll in the Medicare program before receiving reimbursement. Under a similar circumstance, if the physician or practitioner submits an unassigned claim, the carrier must pay the beneficiary directly without requiring a completed Form CMS-855. It may use the information from the affidavit to begin the enrollment process.

40.20 - Maintaining Information on Opt-Out Physicians

(Rev.92; Issued: 06-27-08; Effective/Implementation Date: 09-29-08)

The carrier must maintain information on the opt-out physicians or practitioners. At a minimum, it must capture the name and *National Provider Identifier (NPI)* of the physician or practitioner, the effective date of the opt-out affidavit, and the end date of the opt-out period. The carrier may also include other provider-specific information it may need. If cost effective, it may house this information on its provider file.

40.26 - Registration and Identification of Physicians or Practitioners Who Opt Out

(Rev. 92; Issued: 06-27-08; Effective/Implementation Date: 09-29-08)

The carrier must use *a National Provider Identifier (NPI)* to identify opt-out physicians or practitioners nationwide.

40.35 - Early Termination of Opt-Out

(Rev.92; Issued: 06-27-08; Effective/Implementation Date: 09-29-08)

If a physician or practitioner changes his or her mind after the carrier has approved the affidavit, the opt-out may be terminated within 90 days of the effective date of the affidavit. To properly terminate an opt out, a physician or practitioner must:

- Not have previously opted out of Medicare;
- Notify all Medicare carriers, with which the physician or practitioner filed an affidavit, of the termination of the opt-out no later than 90 days after the effective date of the opt-out period;
- Refund to each beneficiary with whom the physician or practitioner has privately contracted all payment collected in excess of:
 - ^o The Medicare limiting charge (in the case of physicians or practitioners); or
 - ° The deductible and coinsurance (in the case of practitioners).
- Notify all beneficiaries with whom the physician or practitioner entered into private contracts of the physician's or practitioner's decision to terminate opt out and of the beneficiaries' rights to have claims filed on their behalf with Medicare for 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.

When the physician or practitioner properly terminates opt-out in accordance with the second bullet above, the physician or practitioner (*who was previously enrolled in Medicare*) will be reinstated in Medicare as if there had been no opt-out, and the provision of §40.3 must not apply unless the physician or practitioner subsequently properly opts out.