CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-02 Medicare Benefit Policy	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 160	**Date: October 26, 2012**
	Change Request 8100

SUBJECT: Effect of Beneficiary Agreements Not to Use Medicare Coverage and When Payment May be Made to a Beneficiary for Service of an Opt-Out Physician/Practitioner

I. SUMMARY OF CHANGES: The purpose of this CR is to modify the policy in chapter 15 regarding Medicare payments to physicians/practitioners who choose to opt out of the Medicare program to be consistent with regulations at 42CFR405.435(c).

EFFECTIVE DATE: January 28, 2013
IMPLEMENTATION DATE: January 28, 2013

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/Table of Contents
R	15/40/Effect of Beneficiary Agreements Not to Use Medicare Coverage
R	15/40.6/When Payment May be Made to a Beneficiary for Service of an Opt-Out Physician/Practitioner
R	15/40.8/Requirements of a Private Contract
R	15/40.9/Requirements of the Opt-Out Affidavit
R	15/40.11/Failure to Maintain Opt-Out
R	15/40.12/Actions to Take in Cases of Failure to Maintain Opt-Out
R	15/40.13/Physician/Practitioner Who Has Never Enrolled in Medicare
R	15/40.15/Excluded Physicians and Practitioners
R	15/40.16/Relationship Between Opt-Out and Medicare Participation Agreements
R	15/40.17/Participating Physicians and Practitioners
R	15/40.20/Maintaining Information on Opt-Out Physicians
R	15/40.21/Informing Medicare Managed Care Plans of the Identity of the Opt-Out Physicians or Practitioners

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	15/40.22/Informing the National Supplier Clearinghouse (NSC) of the Identity of the Opt-Out Physicians or Practitioners
R	15/40.26/Registration and Identification of Physicians or Practitioners Who Opt Out
R	15/40.27/System Identification
R	15/40.28/Emergency and Urgent Care Situations
R	15/40.30/Denial of Payment to Employers of Opt-Out Physicians and Practitioners
R	15/40.31/Denial of Payment to Beneficiaries and Others
R	15/40.32/Payment for Medically Necessary Services Ordered or Prescribed by an Opt-out Physician or Practitioner
R	15/40.34/Renewal of Opt-Out
R	15/40.35/Early Termination of Opt-Out
R	15/40.37/Application to the Medicare Advantage Program
R	15/40.38/Claims Denial Notices to Opt-Out Physicians and Practitioners
R	15/40.39/Claims Denial Notices to Beneficiaries

III. FUNDING:

For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:
No additional funding will be provided by CMS; Contractors activities are to be carried out with their operating budgets

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 obliged 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: 160	Date: October 26, 2012	Change Request: 8100

SUBJECT: Effect of Beneficiary Agreements Not to Use Medicare Coverage and When Payment May be Made to a Beneficiary for Service of an Opt-Out Physician/Practitioner

EFFECTIVE DATE: January 28, 2013
IMPLEMENTATION DATE: January 28, 2013

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.

B. Policy: Regulations at 42 C.F.R. §405.435(c) permit Medicare payment to be made for claims submitted by a beneficiary for the services of an opt out physician or practitioner when the physician or practitioner did not privately contract with the beneficiary for services that were not emergency care services or urgent care services and that were furnished no later than 15 days after the date of a notice by the Medicare contractor that the physician or practitioner has opted out of Medicare.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement.

Number	Requirement	Responsibility										
		A/B MAC		DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				Other
		Part A	Part B					FISS	MCS	VMS	CWF	
8100.1	Contractors shall refer Pub. 100-02, Medicare Benefit Policy Manual, chapter 15, sections 40 through 40.40 of for current information regarding Private Contracting/Opting Out.		X			X						
8100.2	Contractors shall permit Medicare payment to be made for claims submitted by a beneficiary for the services of an opt out physician or practitioner when the physician or practitioner did not privately contract with the beneficiary for services that were not emergency care services or urgent care services and that were furnished no later than 15 days after the date of a notice by the Medicare contractor that the physician or practitioner has opted out of Medicare.		X			X						

Number	Requirement	Responsibility										
		A/B MAC		DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				Other
		Part A	Part B					FISS	MCS	VMS	CWF	
8100.3	If a beneficiary indicates on an Advance Beneficiary Notice of Noncoverage (ABN) that he or she does not authorize a provider or supplier to submit a claim, contractors shall not consider the provider or supplier (in that situation) to be in violation of the mandatory claim submission rules of §1848(g)(4) of the Social Security Act.	X	X	X	X	X	X					
8100.4	Contractors shall permit physicians/practitioners who choose to opt out of Medicare to include his or her tax identification number (TIN) on the opt out affidavit if they have never enrolled in Medicare and do not have a National Provider Identifier (NPI).		X			X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility						
		A/B MAC		DME MAC	FI	CARRIER	RHHI	Other
		Part A	Part B					
8100.5	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X	X	X	X	X	

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Fred Grabau, 410-786-0206 or frederick.grabau@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR) or Contractor Manager, as applicable.

VI. FUNDING

Section A: For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs), and/or Carriers:
No additional funding will be provided by CMS; Contractors activities are to be carried out with 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 do 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.

Medicare Benefit Policy Manual

Chapter 15 – Covered Medical and Other Health Services

Table of Contents
(Rev. 160)

40 - Effect of Beneficiary Agreements Not to Use Medicare Coverage

(Rev. 160, Issued: 10-26-12, Effective: 01-28-13, Implementation: 01-28-13)

Normally physicians and practitioners are required to submit claims on behalf of beneficiaries for all items and services they provide for which Medicare payment may be made under Part B. Also, they are not allowed to charge beneficiaries in excess of the limits on charges that apply to the item or service being furnished.

However, a physician or practitioner (as defined in §40.4) may opt out of Medicare. A physician or practitioner who opts out is not required to submit claims on behalf of beneficiaries and also is excluded from limits on charges for Medicare covered services.

Only physicians and practitioners that are listed in §40.4 may opt out.

- The **only** situation in which non-opt-out physicians or practitioners, or other suppliers, are not required to submit claims to Medicare for covered services is where a beneficiary or the beneficiary's legal representative refuses, of his/her own free will, to authorize the submission of a bill to Medicare. However, the limits on what the physician, practitioner, or other supplier may collect from the beneficiary continue to apply to charges for the covered service, notwithstanding the absence of a claim to Medicare.

- In some circumstances, a non-opt-out physician/practitioner, or other supplier, *is required to* provide *an Advance Beneficiary Notice of Noncoverage (ABN) to* the beneficiary prior to rendering *an* item or service *that is usually covered by Medicare but may not be covered in this particular case. (See* the Medicare Claims Processing Manual, chapter 30 *for ABN policy and* §40.24 *of this chapter* for a description of the difference between an ABN and a private contract.) *The* ABN notifies the beneficiary that Medicare *will* likely deny the claim and *prompts the beneficiary to choose whether or not he/she will accept liability* for the full cost of the services *if Medicare does not pay*. *The beneficiary also indicates on the ABN whether or not a claim should be submitted to Medicare. Providers and suppliers must follow the beneficiary's directive for claim submission as indicated on the ABN. Providers and suppliers will not violate the mandatory claim submission rules of §1848(g)(4) of the Social Security Act when a claim is not submitted per a beneficiary's written request on an ABN.* Where a valid ABN is given *and a claim is submitted*, subsequent denial of the claim relieves the non-opt-out physician/practitioner, or other supplier, of the limitations on charges that would apply if the services were covered.

Opt-out physicians and practitioners must not use ABNs, because they use private contracts for any item or service that is, or may be, covered by Medicare (except for emergency or urgent care services (see §40.28)).

Where a physician/practitioner, or other supplier, fails to submit a claim to Medicare on behalf of a beneficiary for a covered Part B service within 1 year of providing the service,

or knowingly and willfully charges a beneficiary more than the applicable charge limits on a repeated basis, he/she/it may be subject to civil monetary penalties under §§1848(g)(1) and/or 1848(g)(3) of the Act. Congress enacted these requirements for the protection of all Part B beneficiaries. Application of these requirements cannot be negotiated between a physician/practitioner or other supplier and the beneficiary except where a physician/practitioner is eligible to opt out of Medicare under §40.4 and the remaining requirements of §§40.1 - 40.38 are met. Agreements with Medicare beneficiaries that are not authorized as described in these manual sections and that purport to waive the claims filing or charge limitations requirements, or other Medicare requirements, have no legal force and effect. For example, an agreement between a physician/practitioner, or other supplier and a beneficiary to exclude services from Medicare coverage, or to excuse mandatory assignment requirements applicable to certain practitioners, is ineffective.

The contractor will refer such cases to the OIG.

This subsection does not apply to noncovered charges.

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

(Rev. 160, Issued: 10-26-12, Effective: 01-28-13, Implementation: 01-28-13)

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 *Medicare contractor's* attention as a result of a complaint from a beneficiary or the beneficiary's legal representative*, or as a result of the beneficiary or the beneficiary's legal representative filing a claim for services furnished by an opt out physician/practitioner. Medicare payment may be made for the claims submitted by a beneficiary for the services of an opt out physician/practitioner when the physician/practitioner did not privately contract with the beneficiary for services that were not emergency care services or urgent care services and that were furnished no later than 15 days after the date of a notice by the Medicare contractor that the physician/practitioner has opted out of Medicare (see 42 C.F.R. 405.435(c)). Therefore, if the beneficiary submits a claim for a service that was furnished by an opt out physician/practitioner, then the Medicare contractor must contact the opt out physician/practitioner in order to ascertain whether the beneficiary entered into a private contract with the opt out physician/practitioner. (Note: The Medicare contractor should obtain a copy of the private contract from the opt out physician/practitioner before*

denying the beneficiary's claim if the beneficiary did, in fact, enter into a private contract with the physician/practitioner.) If the beneficiary did not enter into a private contract with the physician/practitioner and the beneficiary did not receive notice from the Medicare contractor that the physician/practitioner opted out of Medicare, then Medicare payment may be made to the beneficiary for the non-emergency and/or non-urgent care services (assuming that the services would otherwise be payable). On the other hand, if the beneficiary did enter into a private contract with the physician/practitioner for the services or received services from the physician/practitioner 15 days after the date of a notice by the Medicare contractor that the physician/practitioner has opted out of Medicare, then no Medicare payment may be made. Moreover, the Medicare contractor 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 *Medicare contractor's* request for a copy of the private contract within 45 days, the *Medicare contractor* 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.

40.8 - Requirements of a Private Contract

(Rev. 160, Issued: 10-26-12, Effective: 01-28-13, Implementation: 01-28-13)

A private contract under this section must:

- Be in writing and in print sufficiently large to ensure that the beneficiary is able to read the contract;
- Clearly state whether the physician/practitioner is excluded from Medicare under §§1128, 1156 or 1892 of the Act;
- State that the beneficiary or the beneficiary's legal representative accepts full responsibility for payment of the physician's or practitioner's charge for all services furnished by the physician/practitioner;
- State that the beneficiary or the beneficiary's legal representative understands that Medicare limits do not apply to what the physician/practitioner may charge for items or services furnished by the physician/practitioner;
- State that the beneficiary or the beneficiary's legal representative agrees not to submit a claim to Medicare or to ask the physician/practitioner to submit a claim to Medicare;
- State that the beneficiary or the beneficiary's legal representative understands that Medicare payment will not be made for any items or services furnished by

the physician/practitioner that would have otherwise been covered by Medicare if there was no private contract and a proper Medicare claim had been submitted;

- State that the beneficiary or the beneficiary's legal representative enters into the contract with the knowledge that the beneficiary has the right to obtain Medicare-covered items and services from physicians and practitioners who have not opted out of Medicare, and that the beneficiary is not compelled to enter into private contracts that apply to other Medicare-covered services furnished by other physicians or practitioners who have not opted out;

- State the expected or known effective date and expected or known expiration date of the opt-out period;

- State that the beneficiary or the beneficiary's legal representative understands that Medigap plans do not, and that other supplemental plans may elect not to, make payments for items and services not paid for by Medicare;

- Be signed by the beneficiary or the beneficiary's legal representative and by the physician/practitioner;

- Not be entered into by the beneficiary or by the beneficiary's legal representative during a time when the beneficiary requires emergency care services or urgent care services. (However, a physician/practitioner may furnish emergency or urgent care services to a Medicare beneficiary in accordance with §40.28;)

- Be provided (a photocopy is permissible) to the beneficiary or to the beneficiary's legal representative before items or services are furnished to the beneficiary under the terms of the contract;

- Be retained (original signatures of both parties required) by the physician/practitioner for the duration of the opt-out period;

- Be made available to CMS upon request; and

- Be entered into for each opt-out period.

In order for a private contract with a beneficiary to be effective, the physician/practitioner must file an affidavit with all Medicare *contractors* to which the physician/practitioner would submit claims, advising that the physician/practitioner has opted out of Medicare. The affidavit must be filed within 10 days of entering into the first private contract with a Medicare beneficiary. Once the physician/practitioner has opted out, such physician/practitioner must enter into a private contract with each Medicare beneficiary to whom the physician/practitioner furnishes covered services (even where Medicare payment would be on a capitated basis or where Medicare would pay an organization for the physician's or practitioner's services to the Medicare beneficiary), with the exception of a Medicare beneficiary needing emergency or urgent care.

If a physician/practitioner has opted out of Medicare, the physician/practitioner must use a private contract for items and services that are, or may be, covered by Medicare (except for emergency or urgent care services (see §40.28)). An opt-out physician/practitioner is not required to use a private contract for an item or service that is definitely excluded from coverage by Medicare.

A non-opt-out physician/practitioner, or other supplier, is required to submit a claim for any item or service that is, or may be, covered by Medicare. Where an item or service may be covered in some circumstances, but not in others, the physician/practitioner, or other supplier, may provide an Advance Beneficiary Notice to the beneficiary, which informs the beneficiary that Medicare may not pay for the item or service, and that if Medicare does not do so, the beneficiary is liable for the full charge. (See §§40, 40.24)

40.9 - Requirements of the Opt-Out Affidavit

(Rev. 160, Issued: 10-26-12, Effective: 01-28-13, Implementation: 01-28-13)

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 *Medicare contractor* can ensure that no payment is made to the physician/practitioner during the opt-out period; and

- Be filed with all *Medicare contractors* 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. 160, Issued: 10-26-12, Effective: 01-28-13, Implementation: 01-28-13)

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, the 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 *Medicare contractor* 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 *Medicare contractor* 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 <u>not</u> discovered by the *Medicare contractor* during the 2-year opt out period.

- In situations where a violation of paragraph (A) of this section is not discovered by the *Medicare contractor* 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 *Medicare contractor* 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).

40.12 - Actions to Take in Cases of Failure to Maintain Opt-Out

(Rev. 160, Issued: 10-26-12, Effective: 01-28-13, Implementation: 01-28-13)

If the *Medicare contractor* becomes aware that the physician/practitioner has failed to maintain opt-out as indicated in <u>§40.11</u>, it must send the physician/practitioner a letter advising the physician/practitioner that it has received a claim and believes that the physician/ practitioner may have inadvertently failed to maintain opt-out. It must describe the situation in §40.11 that it believes exists and its basis for its belief. It must ask the physician or practitioner to provide it with an explanation within 45 days of what happened and how the physician or practitioner will resolve it. (See the Medicare Claims Processing Manual, Chapter 1, "General Billing Requirements," §70.6, and the Medicare Program Integrity Manual for action when responses are not received within 45 days).

If the *Medicare contractor* received a claim from the opt-out physician/practitioner, it must ask the physician/practitioner if the received claim was: (a) an emergency or urgent situation, with missing documentation, **or** (b) filed in error. When the reason for the letter is that the physician/practitioner filed a claim that the physician/practitioner did not identify as an emergency or urgent care service, the *Medicare contractor* must request that the physician/practitioner submit the following information with the physician's/practitioner's response:

- Emergency/urgent care documentation if the claim was for a service furnished in an emergency or urgent situation but included no documentation to that effect; and/or

- If the claim was filed in error, the *Medicare contractor* must ask the physician/practitioner to explain whether the filing was an isolated incident or a systematic problem affecting a number of claims.

In the case of any potential failure to maintain opt-out (including but not limited to improper submission of a claim), the *Medicare contractor* must explain in its request to the physician or practitioner that it would like to resolve this matter as soon as possible. It must instruct the physician/practitioner to provide the information it requested within 45 days of the date of its development letter. It must provide the physician or practitioner with the name and telephone number of a contact person in case they have any questions.

If the violation was due to a systems problem, the *Medicare contractor* must ask the physician or practitioner to include with his or her response an explanation of the actions being taken to correct the problem and when the physician or practitioner expects the system error to be fixed. If the violation persists beyond the time period indicated in the physician's or practitioner's response, the *Medicare contractor* must contact the physician or practitioner again to ascertain why the problem still exists and when the physician or practitioner expects to have it corrected. It must repeat this process until the system problem is corrected.

Also, in the *Medicare contractor's* development request, it must advise the physician or practitioner that if no response is received by the due date, the *Medicare contractor* will assume that there has been no correction of the failure to maintain opt-out and that this could result in a determination that the physician/practitioner is once again subject to Medicare rules.

In the case of wrongly filed claims, the *Medicare contractor* must hold the claim and any others it receives from the physician or practitioner in suspense until it hears from the physician or practitioner or the response date lapses. In this case, if the physician or practitioner responds that the claim was filed in error, the *Medicare contractor* must continue processing the claim, deny the claim, and send the physician or practitioner the appropriate Remittance Advice and send the beneficiary a Medicare Summary Notice (MSN) with the appropriate language explaining that the claim was submitted erroneously and the beneficiary is responsible for the physician's or practitioner's charge. In other words, the limiting charge provision does not apply and the beneficiary is responsible for all charges. This process will apply to all claims until the physician or practitioner is able to get the problem fixed.

If the *Medicare contractor* does not receive a response from the physician or practitioner by the development letter due date or if it is determined that the opt-out physician or practitioner knowingly and willfully failed to maintain opt-out, it must notify the physician or practitioner that the effects of failure to maintain opt-out specified in §40.11 apply. **It must formally notify the physician/practitioner of this determination and of the rules that again apply (e.g., mandatory submission of claims, limiting charge, etc.)**. It must specifically include in this letter each of the effects of failing to opt out that are identified in §40.11.

The act of claims submission by the beneficiary for an item or service provided by a physician or practitioner who has opted out is **not** a violation by the physician or practitioner and does not nullify the contract with the beneficiary. However, if there are what the *Medicare contractor* considers to be a substantial number of claims submissions by beneficiaries for items or services by an opt-out physician or practitioner, it must investigate to ensure that contracts between the physician or practitioner and the beneficiaries exist and that the terms of the contracts meet the Medicare statutory requirements outlined in this instruction. If noncompliance with the opt-out affidavit is determined, it must develop claims submission or limiting charge violation cases, as appropriate, based on its findings.

In cases in which the beneficiary files an appeal of the denial of a beneficiary-filed claim for services from an opt-out physician or practitioner, and alleges that there was no private contract, the *Medicare contractor* must ask the physician/practitioner to provide it with a copy of the private contract. Where the physician or practitioner does not provide a copy of a private contract that *meets the requirements of §40.8 and* was signed by the beneficiary before the service was furnished, the *Medicare contractor* must make payment to the beneficiary and proceed as described above.

40.13 - Physician/Practitioner Who Has Never Enrolled in Medicare

(Rev. 160, Issued: 10-26-12, Effective: 01-28-13, Implementation: 01-28-13)

For a physician/practitioner who has never enrolled in the Medicare program and wishes to opt out of Medicare, *if* the physician/practitioner *does not have a National Provider Identifier (NPI), then the physician/practitioner* must *include his or her tax identification number (TIN) on the opt out affidavit*. The *Medicare contractor* must annotate its in-house provider file that the physician/practitioner has opted out of the program. The *Medicare contractor* 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 *Medicare contractor* 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 contract 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 *Medicare contractor* 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.

40.15 - Excluded Physicians and Practitioners

(Rev. 160, Issued: 10-26-12, Effective: 01-28-13, Implementation: 01-28-13)

An excluded physician or practitioner may opt out of Medicare by submitting the required documentation in accordance with §40.9. When determining effective dates of the exclusion versus the opt-out, the date of exclusion always takes precedence over the date the physician or practitioner opts out of Medicare. A physician or practitioner who has been excluded must comply with 42 CFR 1001.1901, "Scope and Effect of Exclusion."

If an excluded/opt-out physician or practitioner submits a claim to Medicare, the *Medicare contractor* must not make payment for services furnished, ordered, or prescribed on or after the effective date of the exclusion*, except in the limited circumstances stated in 42 CFR 1001.1901*.

The *Medicare contractor* must not make payment to a beneficiary who submits claims for services rendered by an excluded/opt-out physician or practitioner (except where payment would otherwise be made in accordance with the Medicare Program Integrity Manual). It must deny the claim and send the physician or practitioner the appropriate remittance and send the beneficiary a MSN as explained in §40.39.

40.16 - Relationship Between Opt-Out and Medicare Participation Agreements

(Rev. 160, Issued: 10-26-12, Effective: 01-28-13, Implementation: 01-28-13)

Participation agreements will terminate on the opt out effective date. See 40.17 for effective date provisions. Physicians and practitioners may not provide services under private contracts with beneficiaries earlier than the effective date of the affidavit. Nonparticipating physicians and practitioners may opt out at any time.

The *Medicare contractor* must update *the* system files so that it may timely pay participating physicians and practitioners at the correct payment amounts in effect for that part of the fee schedule year before they opt out and to pay them as nonparticipating for emergency or urgent care as of their opt out effective date.

40.17 - Participating Physicians and Practitioners

(Rev. 160, Issued: 10-26-12, Effective: 01-28-13, Implementation: 01-28-13)

Participating physicians and practitioners may opt out if they file an affidavit that meets the criteria and which is received by the *Medicare contractor* at least 30 days before the first day of the next calendar quarter showing an effective date of the first day in that quarter (i.e., January 1, April 1, July 1, October 1). They may not provide services under private contracts with beneficiaries earlier than the effective date of the affidavit.

The 30-day notice is required to allow sufficient time for the *Medicare contractor* to accomplish the appropriate system file updates before the effective date. The *Medicare contractor* must make participating physician status changes no less frequently than at the beginning of each calendar quarter. Therefore, participating physicians or practitioners must provide the *Medicare contractor* with 30 days notice that they intend to opt out at the beginning of the next calendar quarter.

Participating physicians or practitioners may sign private contracts only after the effective date of affidavits filed in accordance with §40.9. They may not provide services under private contracts with beneficiaries earlier than the effective date of the affidavit. It is necessary to treat nonparticipating physicians or practitioners differently from participating physicians or practitioners in order to assure that participating physicians or practitioners are paid properly for the services they furnish before the effective date of the affidavit.

Participating physicians or practitioners are paid at the full fee schedule for the services they furnish to Medicare beneficiaries. However, the law sets the payment amount for nonparticipating physicians or practitioners at 95 percent of the payment amount for participating physicians or practitioners.

Participating physicians or practitioners who opt out are treated as nonparticipating physicians or practitioners as of the effective date of the opt-out affidavit. When a participating physician/practitioner opts out of Medicare, the *Medicare contractor* must pay the physician/practitioner at the higher participating physician/practitioner rate for services rendered in the period before the effective date of the opt-out; and at the nonparticipating rate for services rendered on and after the opt-out date.

40.20 - Maintaining Information on Opt-Out Physicians

(Rev. 160, Issued: 10-26-12, Effective: 01-28-13, Implementation: 01-28-13)

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

40.21 - Informing Medicare Managed Care Plans of the Identity of the Opt-Out Physicians or Practitioners

(Rev. 160, Issued: 10-26-12, Effective: 01-28-13, Implementation: 01-28-13)

The *Medicare contractor* must develop data exchange mechanisms for furnishing Medicare managed care plans in its service area with timely information on physicians and practitioners who have opted out of Medicare. For example, it may wish to establish an Internet Web site “Home Page” which houses all of the information on physicians or practitioners who have opted out. It will need to negotiate appropriate opt out information exchange mechanisms with each managed care plan in its service area.

40.22 - Informing the National Supplier Clearinghouse (NSC) of the Identity of the Opt-Out Physicians or Practitioners

(Rev. 160, Issued: 10-26-12, Effective: 01-28-13, Implementation: 01-28-13)

The *Medicare contractor* must notify the NSC directly with timely information on physicians or practitioners who have opted out of Medicare. An Internet Web site "Home Page" is not an acceptable means of notifying the NSC. The NSC's address is as follows:

National Supplier Clearinghouse
P.O. Box 100142
Columbia, SC 29202-3142

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

(Rev. 160, Issued: 10-26-12, Effective: 01-28-13, Implementation: 01-28-13)

If the Medicare contractor has the physician's/practitioner's NPI, then the *Medicare contractor should* use *it in order* to identify opt-out physicians or practitioners nationwide. *However, if the physician/practitioner does not have an NPI, then the Medicare contractor must use the physician's or practitioner's TIN to identify opt-out physicians or practitioners nationwide.*

40.27 - System Identification

(Rev. 160, Issued: 10-26-12, Effective: 01-28-13, Implementation: 01-28-13)

The *Medicare contractor* must ensure that its system can automatically identify claims that include services furnished by providers or practitioners who have opted out of Medicare. It must not make payment to any opt-out physician/practitioner for items or services furnished on or after the effective date of the physician's or practitioner's opt out affidavit unless there are emergency or urgent care situations involved. In an emergency or urgent care situation, payment can be made for services furnished to a Medicare beneficiary if the beneficiary has no contract with the opt-out physician/practitioner. See the following section for related instructions.

40.28 - Emergency and Urgent Care Situations

(Rev. 160, Issued: 10-26-12, Effective: 01-28-13, Implementation: 01-28-13)

Payment may be made for services furnished by an opt-out physician or practitioner who has not signed a private contract with a Medicare beneficiary for emergency or urgent care items and services furnished to, or ordered or prescribed for, such beneficiary on or after the date the physician opted out.

Where a physician or a practitioner who has opted out of Medicare treats a beneficiary with whom the physician or practitioner does not have a private contract in an emergency or urgent *care* situation, the physician or practitioner may not charge the beneficiary more than the Medicare limiting charge for the service and must submit the claim to Medicare on behalf of the beneficiary for the emergency or urgent care. Medicare payment may be made to the beneficiary for the Medicare covered services furnished to the beneficiary.

In other words, where the physician or practitioner provides emergency or urgent *care* services to the beneficiary, the physician or practitioner must submit a claim to Medicare, and may collect no more than the Medicare limiting charge in the case of a physician, or the deductible and coinsurance in the case of a practitioner. This implements §1802(b)(2)(A)(iii) of the Act, which specifies that the contract may not be entered into when the beneficiary is in need of emergency or urgent care. Because the services are excluded from coverage under §1862(a)(19) of the Act only if they are furnished under private contract, CMS concludes that they are not excluded in this case where there i*s* no private contract, notwithstanding that they were furnished by an opt-out physician or practitioner. Hence, they are covered services furnished by a nonparticipating physician or practitioner, and the rules in effect absent the opt-out would apply in these cases. Specifically, the physician or practitioner may choose to take assignment (thereby agreeing to collect no more than the Medicare deductible and coinsurance based on the allowed amount from the beneficiary) or not to take assignment (and to collect no more than the Medicare limiting charge), but the practitioner must take assignment under §1842(b)(18) of the Act.

Therefore, in this circumstance the physician or practitioner must submit a completed Medicare claim on behalf of the beneficiary with the appropriate HCPCS code and HCPCS modifier that indicates the services furnished to the Medicare beneficiary were emergency or urgent *care services* and the beneficiary does not have a private *contract* with the physician or practitioner. If the physician or practitioner did not submit **GJ** national HCPCS modifier, then the *Medicare contractor* must deny the claim so that the beneficiary can appeal.

GJ = Opt-out physician/practitioner EMERGENCY OR URGENT SERVICES

This modifier must be used on claims for services rendered by an opt-out physician/ practitioner for an emergency/urgent *care* service. The use of this modifier indicates that the service was furnished by an opt-out physician/practitioner who has not signed a private contract with a Medicare beneficiary for emergency or urgent care items and services furnished to, or ordered or prescribed for, such beneficiary on or after the date the physician/practitioner opted out.

The *Medicare contractor* must deny payment for emergency or urgent care items and services to both an opt-out physician or practitioner and the beneficiary if these parties have previously entered into a private contract, i.e., prior to the furnishing of the

emergency or urgent care items or services but within the physician's or practitioner's opt out period.

Under the emergency and urgent care situation where an opt-out physician or practitioner renders emergency or urgent service to a Medicare beneficiary (e.g., a fractured leg) who has not entered into a private agreement with the physician or practitioner, as stated above the physician or practitioner is required to submit a claim to Medicare with the appropriate modifier (GJ and 54 as discussed further below) and is subject to all the rules and regulations of Medicare, including *the* limiting charge. However, if the opt-out physician or practitioner asks the beneficiary, with whom the physician or practitioner has no private contract, to return for a follow up visit (e.g., return within 5 to 6 weeks to remove the cast and examine the leg) the physician or practitioner must ask the beneficiary to sign a private contract. In other words, once a beneficiary no longer needs emergency or urgent care (i.e., non-urgent follow up care), Medicare cannot pay for the follow up care and the physician or practitioner can and must, under the opt-out affidavit agreement, ask the beneficiary to sign a private *contract* as a condition of further treatment.

The way this would work in the fractured leg example (see previous paragraph) is that the physician or practitioner would bill Medicare for the setting of the fractured leg with the emergency opt out CMS modifier **(GJ)** and the surgical care only modifier (54) to ensure that CMS does not pay the Evaluation and Management (E&M) that is in the global fee for the procedure. The physician or practitioner would then either have the beneficiary sign the private contract or refer the beneficiary to a Medicare physician or practitioner who would bill Medicare using the post op only modifier to be paid for the post op care in the global period.

If the beneficiary continues to be in a condition that requires emergency or urgent care (i.e., unconscious or unstable after surgery for an aneurysm) follow up care would continue to be paid under emergency or urgent care until such time as the beneficiary no longer needed such care. In the absence *of incontrovertible* evidence, CMS recommends accepting what the physician or practitioner says via the modifiers and doing post-pay records review of frequent users of the opt-out modifier.

40.30 - Denial of Payment to Employers of Opt-Out Physicians and Practitioners

(Rev. 160, Issued: 10-26-12, Effective: 01-28-13, Implementation: 01-28-13)

If an opt-out physician or practitioner is employed in a hospital setting and submits bills for which payment is prohibited, the *Medicare contractor* usually detects and investigates the situation. However, in some instances an opt-out physician or practitioner may have a salary arrangement with a hospital or clinic or work in a group practice and may not directly submit bills for payment. If the *Medicare contractor* detects this situation, it must recover the payment made for the opt-out physician/practitioner from the hospital/clinic/group practice, after appropriate notification.

40.31 - Denial of Payment to Beneficiaries and Others

(Rev. 160, Issued: 10-26-12, Effective: 01-28-13, Implementation: 01-28-13)

If a beneficiary submits a claim that includes items or services furnished by an opt-out physician or practitioner on dates on or after the effective date of opt out by such physician or practitioner, the *Medicare contractor* must deny such items or services *except as permitted by* §40.6.

40.32 - Payment for Medically Necessary Services Ordered or Prescribed by an Opt-out physician or Practitioner

(Rev. 160, Issued: 10-26-12, Effective: 01-28-13, Implementation: 01-28-13)

If claims are submitted for any items or services ordered or prescribed by an opt out physician or practitioner under §1802 of the Act, the *Medicare contractor* may pay for medically necessary services of the furnishing entity, provided the furnishing entity is not also a physician or practitioner that has opted out of the Medicare program.

40.34 - Renewal of Opt-Out

(Rev. 160, Issued: 10-26-12, Effective: 01-28-13, Implementation: 01-28-13)

A physician or practitioner may renew an opt out without interruption by filing an affidavit with each *Medicare contractor who has jurisdiction over claims the physician/practitioner would otherwise file with Medicare* (as specified in §40.9), provided the affidavits are filed within 30 days after the current opt-out period expires.

40.35 - Early Termination of Opt-Out

(Rev. 160, Issued: 10-26-12, Effective: 01-28-13, Implementation: 01-28-13)

If a physician or practitioner changes his or her mind after the *Medicare contractor* 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 *contractors*, 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:

    - 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.

40.37 - Application to *the* Medicare *Advantage Program*

(Rev. 160, Issued: 10-26-12, Effective: 01-28-13, Implementation: 01-28-13)

The Medicare Managed Care Manual contains instructions for *Medicare Advantage plans* about the impact on managed care.

The manual provides in general that *Medicare Advantage plans*:

- Must acquire and maintain information from Medicare *contractors* on physicians and practitioners who have opted out of Medicare.

- Must make no payment directly or indirectly for Medicare covered services furnished to a Medicare beneficiary by a physician or practitioner who has opted out of Medicare, except for emergency or urgent care services furnished to a beneficiary who has not previously entered into a private contract with the physician or practitioner, in accordance with §40.28.

The *Medicare contractor* must maintain mutually agreeable means of advising *Medicare Advantage plans* of who has opted out. Disputes with *Medicare Advantage plans* about the provision of opt out information should be referred to the regional office staff for resolution.

40.38 - Claims Denial Notices to Opt-Out Physicians and Practitioners

(Rev. 160, Issued: 10-26-12, Effective: 01-28-13, Implementation: 01-28-13)

To ensure that the notice denying payment to the opt-out physician or practitioner indicates the proper reason for denial of payment, the *Medicare contractor* must include language in the notice appropriate to particular circumstances as follows:

- When the claim is submitted **inadvertently** by the opt-out physician/practitioner, the *Medicare contractor* must use claim adjustment reason code 28 (coverage not in effect at the time service was provided) at the claim level with group code PR (patient responsibility) and the remark code MA47:

  > Our records show that you have opted out of Medicare, agreeing with the patient not to bill Medicare for services/tests/supplies

furnished. As a result, we cannot pay this claim. The patient is responsible for payment."

- The *Medicare contractor* uses the following message when the claim is submitted **knowingly and willfully** by the opt-out physician/practitioner. It must use claim adjustment reason code 28 (coverage not in effect at the time service was provided) at the claim level with group code PR (patient responsibility) and the claim level remark code MA56:

  Our records show that you have opted out of Medicare, agreeing with the patient not to bill Medicare for services/tests/supplies furnished. As a result, we cannot pay this claim. The patient is responsible for payment. Under Federal law you cannot charge more than the limiting charge amount.

40.39 - Claims Denial Notices to Beneficiaries

(Rev. 160, Issued: 10-26-12, Effective: 01-28-13, Implementation: 01-28-13)

To ensure that the notice to the beneficiary indicates the proper reason for denial of payment, the *Medicare contractor* must include language in the notice appropriate to particular circumstances as follows:

- It must use the following MSN message when the claim is submitted **inadvertently** by the opt-out physician/practitioner:

  MSN # 21.20 - "The provider decided to drop out of Medicare. No payment can be made for this service. You are responsible for this charge."

- It must use the following message when the claim is submitted **knowingly and willfully** by the opt-out physician/practitioner:

  MSN # 21.19 - "The provider decided to drop out of Medicare. No payment can be made for this service. You are responsible for this charge. Under Federal law your doctor cannot charge you more than the limiting charge amount."

- It must use the following message when the claim is submitted by the beneficiary for a service furnished by an opt-out physician/practitioner:

  MSN # 21.20 - "The provider decided to drop out of Medicare. No payment can be made for this service. You are responsible for this charge."