CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-02 Medicare Benefit Policy	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 222	**Date: May 13, 2016**
	Change Request 9616

SUBJECT: Revisions to Private Contracting/Opt-Out Manual Sections Due to the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to revise Publication 100-02, "Medicare Benefit Policy Manual" consistent with the Medicare Access and CHIP Reauthorization Act of 2015 amendments.

EFFECTIVE DATE: August 15 2016
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: August 15 2016

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	15/40.1/Private Contracts Between Beneficiaries and Physicians/Practitioners
R	15/40.2/General Rules of Private Contracts
R	15/40.5/When a Physician or Practitioner Opts-Out of Medicare
R	15/40.8/Requirements of a Private Contract
R	15/40.9/Requirements of the Opt-Out Affidavit
R	15/40.10/Failure to Properly Opt-Out
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	15/40.14/Nonparticipating Physicians or Practitioners Who Opt-Out of Medicare

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	15/40.18/Physicians or Practitioners Who Choose to Opt-Out of Medicare
R	15/40.19/Opt-Out Relationship to Noncovered Services
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	15/40.28/Emergency and Urgent Care Situations
R	15/40.33/Mandatory Claims Submission
R	15/40.34/Cancellation of Opt-Out
R	15/40.35/Early Termination of Opt-Out
R	15/40.36/Appeals
R	15/40.38/Claims Denial Notices to Opt-Out Physicians and Practitioners

III. FUNDING:

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

Attachment - Business Requirements

Pub. 100-02	Transmittal: 222	Date: May 13, 2016	Change Request: 9616

SUBJECT: Revisions to Private Contracting/Opt-Out Manual Sections Due to the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

EFFECTIVE DATE: August 15 2016

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

A. Background: The private contracting/opt-out provisions at section 1802(b) of the Social Security Act ("the Act") were recently amended by section 106(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10). Prior to the MACRA amendments, the law specified that physicians and practitioners may opt-out for a 2-year period. Individuals that wished to renew their opt-out at the end of a 2-year opt-out period were required to file new affidavits with their Medicare Administrative Contractor (MAC).

B. Policy: Section 106(a) of the MACRA amends section 1802(b)(3) of the Act to require that opt-out affidavits filed on or after June 16, 2015, automatically renew every 2 years. Therefore, physicians and practitioners that file opt-out affidavits on or after June 16, 2015, will no longer be required to file renewal affidavits to continue their opt-out status. The amendments and associated regulations further provide that physicians and practitioners who have filed opt-out affidavits on or after June 16, 2015, and who do not want their opt-out status to automatically renew at the end of a 2-year opt-out period may cancel the automatic extension by notifying each MAC to which he or she would file claims absent the opt-out in writing at least 30 days prior to the start of the next 2-year opt-out period. The purpose of this Change Request (CR) is to revise Publication 100-02, "Medicare Benefit Policy Manual" consistent with the MACRA amendments.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
9616.1	Medicare Contractors shall follow the new instructions in Pub. 100-02, Medicare Benefit Policy Manual chapter 15, section 40 et.al, regarding Private Contracting/Opt-Out.		X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
9616.2	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/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 5 business days after receipt of the notification from CMS announcing the availability of the 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			

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements:

"Should" denotes 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).

VI. FUNDING

Section A: 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.

ATTACHMENTS: 0

Medicare Benefit Policy Manual

Chapter 15 – Covered Medical and Other Health Services

Table of Contents

40.1 - Private Contracts Between Beneficiaries and Physicians/Practitioners

(Rev. 222, Issued: 05-13-16, Effective: 08-15-16, Implementation; 08-15-16)

Section 1802 of the Act, as amended by §4507 of the BBA of 1997 *and §106 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10)*, permits a physician/practitioner to opt-out of Medicare and enter into private contracts with Medicare beneficiaries if specific requirements of this instruction are met.

40.2 - General Rules of Private Contracts

(Rev. 222, Issued: 05-13-16, Effective: 08-15-16, Implementation; 08-15-16)

The following rules apply to physicians/practitioners who opt-out of Medicare:

- A physician/practitioner may enter into one or more private contracts with Medicare beneficiaries for the purpose of furnishing items or services that would otherwise be covered by Medicare (provided the conditions in §40.1 are met).

- A physician/practitioner who enters into at least one private contract with a Medicare beneficiary (under the conditions of §40.1) and who submits one or more affidavits in accordance with §40.9, opts-out of Medicare unless the opt-out is terminated early according to §40.35 or unless the physician/practitioner fails to maintain opt-out. (See §40.11.)

- *Valid opt-out affidavits signed on or after June 16, 2015, will automatically renew every 2 years. If physicians and practitioners who file affidavits effective on or after June 16, 2015, do not want their opt-out to automatically renew at the end of a 2 year opt-out period, they may cancel the renewal by notifying all contractors with which they filed an affidavit in writing at least 30 days prior to the start of the next opt-out period. Valid opt-out affidavits signed before June 16, 2015, will expire 2 years after the effective date of the opt-out. If physicians and practitioners that filed affidavits effective before June 16, 2015, want to extend their opt-out, they must submit a renewal affidavit within 30 days after the current opt-out period expires to all contractors with which they would have filed claims absent the opt-out*.

- Both the private contracts described in the first paragraph of this section and the physician's or practitioner's opt-out described in the second paragraph of this section are null and void if the physician/practitioner fails to properly opt-out in accordance with the conditions of these instructions.

- Both the private contracts described in the first paragraph of this section and the physician's or practitioner's opt-out described in the second paragraph of this section are null and void for the remainder of the opt-out period if the physician/practitioner fails to remain in compliance with the conditions of these instructions during the opt-out period.

- Services furnished under private contracts meeting the requirements of these instructions are not covered services under Medicare, and no Medicare payment will be made for such services either directly or indirectly.

40.5 - When a Physician or Practitioner Opts-Out of Medicare

(Rev. 222, Issued: 05-13-16, Effective: 08-15-16, Implementation; 08-15-16)

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 *contracts*.

Medicare will make payment for covered, medically necessary services that are ordered *or certified* by a physician/practitioner who has opted out of Medicare if the ordering *or certifying* physician/practitioner has acquired a National Provider Identifier (NPI)*, reports his/her Social Security Number, has a valid opt-out affidavit on file with his or her Medicare Administrative Contractor (MAC), is of a specialty that is eligible to order and certify,* 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.

40.8 - Requirements of a Private Contract

(Rev. 222, Issued: 05-13-16, Effective: 08-15-16, Implementation; 08-15-16)

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 *the* expected or known expiration date of the *current 2-year* 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 *current 2-year* opt-out period;

- Be made available to CMS upon request; and

- Be entered into for each *2-year* opt-out period.

In order for a private contract with a beneficiary to be effective, the physician/practitioner must *be opted out of Medicare. The physician/practitioner's initial 2-year opt-out period begins the date the affidavit meeting the requirements of §40.9 is signed, provided the affidavit is* filed within 10 days *after he or she signs his or her* 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. *When a 2-year opt-out period ends, the physician/practitioner must enter into new private contracts with each beneficiary for the new 2-year period. The new private contracts must state the expected or known effective date and the expected or known expiration date of the current 2-year opt-out period.*

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. 222, Issued: 05-13-16, Effective: 08-15-16, Implementation; 08-15-16)

The private contracting/opt-out provisions at section 1802(b) of the Act were amended by section 106(a) of MACRA. Prior to the MACRA amendments, the law specified that physicians and practitioners may opt-out for a 2-year period. Individuals that wished to renew their opt-out at the end of a 2-year opt-out period were required to file new affidavits with their MAC. Section 106(a) of the MACRA amends section 1802(b)(3) of the Act to require that opt-out affidavits filed on or after June 16, 2015, automatically renew every 2 years. Therefore, physicians and practitioners that filed opt-out affidavits on or after June 16, 2015, are not required to file renewal affidavits to continue their opt-

out status. Furthermore, physicians and practitioners who filed opt-out affidavits on or after June 16, 2015, and who do not want their opt-out status to automatically renew at the end of a 2-year opt-out period may cancel the automatic extension by notifying their MACs in writing at least 30 days prior to the start of the next 2-year opt-out period. Valid opt-out affidavits signed before June 16, 2015, will expire 2 years after the effective date of the opt-out. If physicians and practitioners that filed affidavits effective before June 16, 2015, want to extend their opt-out, they must submit a renewal affidavit within 30 days after the current opt-out period expires to all contractors with which they would have filed claims absent the opt-out.

Under 1802(b)(3)(B) *and (D)* of the Act *and Medicare regulations*, 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, 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 MACs who have jurisdiction over claims the physician/practitioner would otherwise file with Medicare, and *the initial 2-year opt-out period will begin the date the affidavit meeting the requirements of 42 C.F.R §405.420 is signed, provided the affidavit is filed within 10 days after the physician/practitioner signs his or her first private contract with a Medicare beneficiary.*

40.10 - Failure to Properly Opt-Out

(Rev. 222, Issued: 05-13-16, Effective: 08-15-16, Implementation; 08-15-16)

A. A physician/practitioner fails to properly opt-out for any of the following reasons:

- Any private contract between the physician/practitioner and a Medicare beneficiary that was entered into before the affidavit described in §40.9 was filed does not meet the specifications of §40.8; or

- The physician/practitioner fails to submit the affidavit(s) in accordance with §40.9.

B. If a physician/practitioner fails to properly opt-out in accordance with the above paragraphs of this section, the following will result:

- The physician's or practitioner's attempt to opt-out of Medicare is nullified, and all of the private contracts between the physician/practitioner and Medicare beneficiaries for the 2 year period covered by the attempted opt-out are deemed null and void;

- The physician/practitioner must submit claims to Medicare for all Medicare-covered items and services furnished to Medicare beneficiaries, including the items and services furnished under the nullified contracts. A nonparticipating physician/practitioner is subject to the limiting charge provision. For items or services paid under the physician fee schedule, the limiting charge is 115 percent of the approved amount for nonparticipating physicians or practitioners. A participating physician/practitioner is subject to the limitations on charges of the participation agreement the physician/practitioner signed;

- The physician/practitioner may not reassign any claim except as provided in the Medicare Claims Processing Manual, Chapter 1, "General Billing Requirements," §§30.2.12 and 30.2.13;

- The physician/practitioner may neither bill nor collect an amount from the beneficiary except for applicable deductible and coinsurance amounts; and

- The physician/practitioner may make another attempt to properly opt-out at any time.

40.11 - Failure to Maintain Opt-Out

(Rev. 222, Issued: 05-13-16, Effective: 08-15-16, Implementation; 08-15-16)

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 *current 2-year* 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 *current* 2-year 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 **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 Pub. 100-04, 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 *current* 2-year period expires.

C. Violation <u>not</u> discovered by the Medicare contractor during the *current* 2-year period.

- In situations where a violation of paragraph (A) of this section is not discovered by the Medicare contractor during the 2-year 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 *2-year* 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. 222, Issued: 05-13-16, Effective: 08-15-16, Implementation; 08-15-16)

If the Medicare contractor becomes aware that the physician/practitioner has failed to maintain opt-out as indicated in §40.11, 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 of what happened and how*, within 45 days,* the physician or practitioner will resolve it. (See *Pub. 100-04,* Medicare Claims Processing Manual, Chapter 1, "General Billing Requirements," §70.6).

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. 222, Issued: 05-13-16, Effective: 08-15-16, Implementation; 08-15-16)

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 *an* NPI, then the physician/practitioner must include his or her 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 *certify* or order services for a Medicare patient, the physician or practitioner must have a *valid* 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-*I* 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-*I*. It may use the information from the affidavit to begin the enrollment process.

40.14 - Nonparticipating Physicians or Practitioners Who Opt-Out of Medicare

(Rev. 222, Issued: 05-13-16, Effective: 08-15-16, Implementation; 08-15-16)

A nonparticipating physician or practitioner may opt-out of Medicare at any time in accordance with the following:

- The *initial* 2-year opt-out period begins the date the affidavit meeting the requirements of §40.9 is signed, provided the affidavit is filed within 10 days after the physician or practitioner signs his or her first private contract with a Medicare beneficiary.

- If the physician or practitioner does not timely file any required affidavit, the *initial* 2-year opt-out period begins when the last such affidavit is filed. Any private contract entered into before the last required affidavit is filed becomes effective upon the filing of the last required affidavit and the furnishing of any items or services to a Medicare beneficiary under such contract before the last required affidavit is filed is subject to standard Medicare rules.

40.18 - Physicians or Practitioners Who Choose to Opt-Out of Medicare

(Rev. 222, Issued: 05-13-16, Effective: 08-15-16, Implementation; 08-15-16)

If a physician/practitioner chooses to opt-out of Medicare, it means that the physician/ practitioner opts-out for all covered items and services that he or she furnishes. Physicians and practitioners cannot have private contracts that apply to some covered services they furnish but not to others. For example, if a physician or practitioner provides laboratory tests or durable medical equipment incident to his or her professional services and chooses to opt-out of Medicare, then the physician/practitioner has opted out of Medicare for payment of lab services and Durable Medical Equipment, Prosthetics, and Orthotics (DMEPOS) as well as for professional services. If a physician or practitioner *has a valid opt-out affidavit on file with the MAC, has a valid NPI, is a specialty that is eligible to order or certify, and* refers a beneficiary to a non-opt-out physician or practitioner for medically necessary services, such as laboratory, DMEPOS or inpatient hospitalization, Medicare would cover those services.

In addition, because suppliers of DMEPOS, independent diagnostic testing facilities, clinical laboratories, etc., cannot opt-out, the physician or practitioner owner of such suppliers cannot opt-out as such a supplier. Therefore, the participating physician or practitioner becomes a nonparticipating physician or practitioner for purposes of Medicare payment for emergency and urgent care services on the effective date of the opt-out. (See §40.28).

40.19 - Opt-Out Relationship to Noncovered Services

(Rev. 222, Issued: 05-13-16, Effective: 08-15-16, Implementation; 08-15-16)

Because Medicare's rules do not apply to items or services that are categorically not covered by Medicare, a private contract is not needed to furnish such items or services to Medicare beneficiaries, and Medicare's claims filing rules and limits on charges do not apply to such items or services. For example, because Medicare does not cover hearing aids, a physician or practitioner, or other supplier may furnish a hearing aid to a Medicare beneficiary and would not be required to file a claim with Medicare; further, the physician, practitioner, or other supplier would not be subject to any Medicare limit on the amount they could collect for the hearing aid.

If the item or service is one that is not categorically excluded from coverage by Medicare, but may be noncovered in a given case (for example, it is covered only where certain clinical criteria are met and there is a question as to whether the criteria are met), a non-opt-out physician/practitioner or other supplier is **not** relieved of his or her obligation to file a claim with Medicare. If the physician or practitioner or other supplier has given a proper Advance Beneficiary Notice (ABN), *he or she* may collect from the beneficiary the full charge if Medicare does deny the claim.

Where a physician or practitioner has opted out of Medicare, he or she must provide covered services only through private contracts that meet the criteria specified in §40.8 (including items and services that are not categorically excluded from coverage but may be excluded in a given case). An opt-out physician or practitioner is prohibited from submitting claims to Medicare (except for emergency or urgent care services furnished to a beneficiary with whom the physician or practitioner did not have a private contract). (See §40.12.)

40.20 - Maintaining Information on Opt-Out Physicians

(Rev. 222, Issued: 05-13-16, Effective: 08-15-16, Implementation; 08-15-16)

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 *automatic 2-year renewal date for affidavits filed on or after June 16, 2015. If the physician/practitioner cancels opt-out (see §40.34), then the Medicare contractor must also maintain the physician/practitioner's opt-out* end date *or cancellation date.* 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. 222, Issued: 05-13-16, Effective: 08-15-16, Implementation; 08-15-16)

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 *website* "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.

40.28 - Emergency and Urgent Care Situations

(Rev. 222, Issued: 05-13-16, Effective: 08-15-16, Implementation; 08-15-16)

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 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 is 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 *the* **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 *current 2-year* 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 *HCPCS* modifier **(GJ)** and the surgical care only modifier (54) to ensure that *Medicare* 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.

40.33 - Mandatory Claims Submission

(Rev. 222, Issued: 05-13-16, Effective: 08-15-16, Implementation; 08-15-16)

Section 1848(g)(4) of the Act, "Physician/Practitioner Submission of Claims," regarding mandatory claims submission, does not apply once a physician or practitioner signs and submits an affidavit to the Medicare *contractor* opting out of the Medicare program, for the duration of the physician's or practitioner's opt-out period, unless the physician or practitioner knowingly and willfully violates a term of the affidavit.

40.34 - *Cancellation* of Opt-Out

(Rev. 222, Issued: 05-13-16, Effective: 08-15-16, Implementation; 08-15-16)

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

40.35 - Early Termination of Opt-Out

(Rev. 222, Issued: 05-13-16, Effective: 08-15-16, Implementation; 08-15-16)

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 *initial 2-year* 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.

40.36 - Appeals

(Rev. 222, Issued: 05-13-16, Effective: 08-15-16, Implementation; 08-15-16)

A determination by CMS that a physician or practitioner has failed to properly opt-out, failed to maintain opt-out, failed to timely renew opt-out, failed to privately contract, failed to properly terminate opt-out*, or failed to properly cancel opt-out* is an initial determination for purposes of 42 CFR 498.3(b).

A determination by CMS that no payment can be made to a beneficiary for the services of a physician who has opted out is an initial determination for purposes of 42 CFR 405.924.

See the Medicare Claims Processing Manual, Chapter 29, "Appeals of Claims Decisions," for additional information on appeals.

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

(Rev. 222, Issued: 05-13-16, Effective: 08-15-16, Implementation; 08-15-16)

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 *27 (expenses incurred after coverage terminated)* 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 *27 (expenses incurred after coverage terminated)* at the claim level with group code PR (patient responsibility) and the *remittance advice* remark code MA*47 N771* :

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. *Alert:* Under Federal law you cannot charge more than the limiting charge amount.