

Medicare Benefit Policy Manual

Chapter 15 – Covered Medical and Other Health Services

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(Rev. 145, 07-08-11)

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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.

- If an item or service is one that Medicare may cover in some circumstances but not in others, a non-opt-out physician/practitioner, or other supplier, must still submit a claim to Medicare. However, the physician, practitioner or other supplier may choose to provide the beneficiary, prior to the rendering of the item or service, an Advance Beneficiary Notice (ABN) as described in the Medicare Claims Processing Manual Chapter 30. (Also see §40.24 for a description of the difference between an ABN and a private contract.) An ABN notifies the beneficiary that Medicare is likely to deny the claim and that if Medicare does deny the claim, the beneficiary will be liable for the full cost of the services. Where a valid ABN is given, 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 one 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.

40.1 - Private Contracts Between Beneficiaries and Physicians/Practitioners

(Rev. 1, 10-01-03)

B3-3044.1

Section 1802 of the Act, as amended by §4507 of the BBA of 1997, 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. 1, 10-01-03)

B3-3044.2

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 for a 2-year period unless the opt-out is terminated early according to §40.35 or unless the physician/practitioner fails to maintain opt-out. (See §40.11.) The physician's or practitioner's opt out may be renewed for subsequent 2-year periods.
- 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.

40.3 - Effective Date of the Opt-Out Provision

(Rev. 1, 10-01-03)

B3-3044.3

A physician/practitioner may enter into a private contract with a beneficiary for services furnished no earlier than January 1, 1998.

40.4 - Definition of Physician/Practitioner

(Rev. 62, Issued: 12-22-06, Effective: 11-13-06, Implementation: 04-02-07)

For purposes of this provision, the term “physician” is limited to doctors of medicine; doctors of osteopathy; doctors of dental surgery or of dental medicine; doctors of podiatric medicine; and doctors of optometry who are legally authorized to practice dentistry, podiatry, optometry, medicine, or surgery by the State in which such function or action is performed; no other physicians may opt out. Also, for purposes of this provision, the term “practitioner” means any of the following to the extent that they are legally authorized to practice by the State and otherwise meet Medicare requirements:

- Physician assistant;
- Nurse practitioner;
- Clinical nurse specialist;
- Certified registered nurse anesthetist;
- Certified nurse midwife;
- Clinical psychologist;
- Clinical social worker;
- Registered dietitian; or
- Nutrition Professional

The opt out law does not define “physician” to include chiropractors; therefore, they may not opt out of Medicare and provide services under private contract. Physical therapists in independent practice and occupational therapists in independent practice cannot opt out because they are not within the opt out law’s definition of either a “physician” or “practitioner”.

40.5 - When a Physician or Practitioner Opts Out of Medicare (Rev. 92; Issued: 06-27-08; Effective/Implementation Date: 09-29-08)

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

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

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

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

40.6 - When Payment May be Made to a Beneficiary for Service of an Opt-Out Physician/Practitioner (Rev. 92; Issued: 06-27-08; Effective/Implementation Date: 09-29-08)

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

- The services are emergency or urgent care services furnished by an opt-out physician/practitioner to a beneficiary with whom he/she has not previously entered into a private contract. (See §40.28 for further discussion of emergency and urgent care services by opt-out physicians and practitioners.); or
- The opt-out physician/practitioner failed to privately contract with the beneficiary for services that he/she provided that were not emergency or urgent care services. The CMS expects this case to come to the carrier's attention only in the course of a request for a redetermination of a denied claim or as a result of a complaint from a beneficiary or the beneficiary's legal representative. If the carrier receives such a complaint, it must consider it to be a request for a redetermination of the denial of payment for services of the opt-out physician/practitioner. It must follow the procedures outlined in §40.11 for cases in which the physician/ practitioner fails to maintain opt-out. If the physician/practitioner does not respond to the carrier's request for a copy of the private contract within 45 days, the carrier must make payment to the beneficiary based upon the payment for a nonparticipating physician/practitioner for that service. It must notify the beneficiary that the physician/practitioner who has opted out must privately contract with the beneficiary or the beneficiary's legal representative for services the physician/practitioner furnished and that no further payment will be made to the beneficiary for services furnished by the opt-out physician/practitioner after 15 days from the postmark of the notice.

40.7 - Definition of a Private Contract (Rev. 1, 10-01-03) B3-3044.7

A “private contract” is a contract between a Medicare beneficiary and a physician or other practitioner who has opted out of Medicare for two years for **all** covered items and services the physician/practitioner furnishes to Medicare beneficiaries. In a private contract, the Medicare beneficiary agrees to give up Medicare payment for services furnished by the physician/practitioner and to pay the physician/practitioner without regard to any limits that would otherwise apply to what the physician/practitioner could charge. Pursuant to the statute, once a physician/practitioner files an affidavit notifying the Medicare carrier that the he/she has opted out of Medicare, the physician/practitioner is out of Medicare for two years from the date the affidavit is signed (unless the opt-out is terminated early according to §40.35, or unless the he/she fails to maintain opt-out (See §40.11)). After those two years are over, a physician/practitioner could elect to return to Medicare or to opt out again. A beneficiary who signs a private contract with a physician/practitioner is not precluded from receiving services from other physicians and practitioners who have not opted out of Medicare.

Physicians or practitioners who provide services to Medicare beneficiaries enrolled in the new Medical Savings Account (MSA) demonstration created by the BBA of 1997 are not required to enter into a private contract with those beneficiaries and to opt out of Medicare under §1802 of the Act.

40.8 - Requirements of a Private Contract

(Rev. 1, 10-01-03)
B3-3044.8

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

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

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

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

40.10 - Failure to Properly Opt Out

(Rev. 1, 10-01-03)

B3-3044.10

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

A. Failure to maintain opt-out

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

- The physician/practitioner has filed an affidavit in accordance with §40.9 and has signed private contracts in accordance with §40.8 but, 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 carrier during the 2-year opt out period.

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

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

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

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

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

(Rev. 1, 10-01-03)

B3-3044.12

If the carrier 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 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 carrier 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 carrier 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 carrier 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 carrier 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 carrier 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 carrier 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 carrier's development request, it must advise the physician or practitioner that if no response is received by the due date, the carrier 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 carrier 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 carrier 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 carrier 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 carrier 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 carrier must ask the physician/practitioner to provide it with a copy of the private contract, but only if the beneficiary authorizes the carrier to do so. Where the physician or practitioner does not provide a copy of a private contract that was signed by the beneficiary before the service was furnished, the carrier must make payment to the beneficiary and proceed as described above.

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

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

If an opt-out physician/practitioner provides emergency or urgent care service to a beneficiary who has not signed a private 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 carrier must pay the beneficiary directly without requiring a completed Form CMS-855. It may use the information from the affidavit to begin the enrollment process.

40.14 - Nonparticipating Physicians or Practitioners Who Opt Out of Medicare (Rev. 1, 10-01-03) B3-3044.14

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

- The 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 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.

40.15 - Excluded Physicians and Practitioners

(Rev. 1, 10-01-03)

B3-3044.15

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 carrier must not make payment for services furnished, ordered, or prescribed on or after the effective date of the exclusion.

The carrier 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. 1, 10-01-03)

B3-3044.16

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 carrier must update carrier 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. 1, 10-01-03)

B3-3044.17

Participating physicians and practitioners may opt out if they file an affidavit that meets the criteria and which is received by the carrier 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 carrier to accomplish the appropriate system file updates before the effective date. The carrier 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 carrier 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 carrier 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.

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

(Rev. 1, 10-01-03)

B3-3044.18

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 who has opted out 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. 1, 10-01-03)

B3-3044.19

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

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

40.21 - Informing Medicare Managed Care Plans of the Identity of the Opt-Out Physicians or Practitioners
(Rev. 1, 10-01-03)
B3-3044.21

The carrier 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. 1, 10-01-03)
B3-3044.22

The carrier 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

40.23 - Organizations That Furnish Physician or Practitioner Services
(Rev. 1, 10-01-03)
B3-3044.23

The opt-out applies to all items or services the physician or practitioner furnishes to Medicare beneficiaries, regardless of the location where such items or services are furnished.

Where a physician or practitioner opts out and is a member of a group practice or otherwise reassigns his or her rights to Medicare payment to an organization, the organization may no longer bill Medicare or be paid by Medicare for services that the

physician or practitioner furnishes to Medicare beneficiaries. However, if the physician or practitioner continues to grant the organization the right to bill and be paid for the services the physician or practitioner furnishes to patients, the organization may bill and be paid by the beneficiary for the services that are provided under the private contract. The decision of a physician or practitioner to opt out of Medicare does not affect the ability of the group practice or organization to bill Medicare for the services of physicians and practitioners who have not opted out of Medicare.

Corporations, partnerships, or other organizations that bill and are paid by Medicare for the services of physicians or practitioners who are employees, partners, or have other arrangements that meet the Medicare reassignment-of-payment rules cannot opt out because they are neither physicians nor practitioners. Of course, if every physician and practitioner within a corporation, partnership, or other organization opts out, then such corporation, partnership, or other organization would have, in effect, opted out.

40.24 - The Difference Between Advance Beneficiary Notices (ABN) and Private Contracts

(Rev. 1, 10-01-03)

B3-3044.24

An Advance Beneficiary Notice (ABN) allows a beneficiary to make an informed consumer decision by knowing in advance that the beneficiary may have to pay out-of-pocket. An ABN is not needed where the item or service is categorically excluded from Medicare coverage or outside the scope of the benefit.

An ABN is used when the physician/practitioner believes that Medicare will not make payment, while private contracts are used for services that are covered by Medicare and for which payment might be made if a claim were to be submitted.

See the Medicare Claims Processing Manual, chapter 30, for a description of the ABN.

40.25 - Private Contracting Rules When Medicare is the Secondary Payer

(Rev. 1, 10-01-03)

B3-3044.25

The opt-out physician/practitioner must have a private contract with a Medicare beneficiary for all Medicare-covered services (see §40.7), notwithstanding that Medicare would be the secondary payer in a given situation. No Medicare primary **or** secondary payments will be made for items and services furnished by a physician/practitioner under the private contract.

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

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

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

40.27 - System Identification

(Rev. 1, 10-01-03)

B3-3044.27

The carrier 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. 1, 10-01-03)

B3-3044.28

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 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 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 and the beneficiary does not have a private agreement with the physician or practitioner. If the physician or practitioner did not submit **GJ** national HCPCS modifier, then the carrier 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 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 carrier 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 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 five to six 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., nonurgent 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 agreement 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 on controvertible 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.

40.29 - Definition of Emergency and Urgent Care Situations

(Rev. 1, 10-01-03)

B3-3044.29

Emergency services are defined as being services furnished to an individual who has an emergency medical condition as defined in 42 CFR 424.101. The CMS has adopted the definition of emergency medical condition in that section of the Code of Federal Regulations (CFR). However, it seemed clear that Congress intended that the term “emergency or urgent care services” not be limited to emergency services since they also included “urgent care services.” Urgent Care Services are defined in 42 CFR 405.400 as services furnished within 12 hours in order to avoid the likely onset of an emergency medical condition. For example, if a beneficiary has an ear infection with significant pain, CMS would view that as requiring treatment to avoid the adverse consequences of continued pain and perforation of the eardrum. The patient’s condition would not meet the definition of emergency medical condition because **immediate care** is not needed to avoid placing the health of the individual in serious jeopardy or to avoid serious impairment or dysfunction. However, although it does not meet the definition of emergency care, the beneficiary needs care within a relatively short period of time (which CMS defines as 12 hours) to avoid adverse consequences, and the beneficiary may not be able to find another physician or practitioner to provide treatment within 12 hours.

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

(Rev. 1, 10-01-03)

B3-3044.30

If an opt-out physician or practitioner is employed in a hospital setting and submits bills for which payment is prohibited, the Part B carrier 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 carrier 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. 1, 10-01-03)

B3-3044.31

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 carrier must deny such items or services. (See §40.6.) However, see §40.11 in cases in which the beneficiary appeals the denial on the basis that no private contract was signed.

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

(Rev. 1, 10-01-03)

B3-3044.32

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 carrier 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.

40.33 - Mandatory Claims Submission

(Rev. 1, 10-01-03)

B3-3044.33

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 carrier 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 - Renewal of Opt-Out

(Rev. 1, 10-01-03)

B3-3044.34

A physician or practitioner may renew an opt out without interruption by filing an affidavit with each carrier to which an affidavit was submitted for the first opt out (as specified in §40.9), and to each carrier to which a claim was submitted under §40.28 during the previous opt out period, provided the affidavits are filed within 30 days after the current opt-out period expires.

40.35 - Early Termination of Opt-Out

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

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

- Not have previously opted out of Medicare;

- Notify all Medicare carriers, with which the physician or practitioner filed an affidavit, of the termination of the opt-out no later than 90 days after the effective date of the opt-out period;
- Refund to each beneficiary with whom the physician or practitioner has privately contracted all payment collected in excess of:
 - 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. 1, 10-01-03)
B3-3044.36

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, or failed to properly terminate opt-out is an initial determination for purposes of 42 CFR 405.803.

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 405.803.

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

40.37 - Application to Medicare+Choice Contracts

(Rev. 1, 10-01-03)
B3-3044.37

The Medicare Managed Care Manual contains instructions for M+C organizations about the impact on managed care.

The manual provides in general that M+C organizations:

- Must acquire and maintain information from Medicare carriers 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 carrier must maintain mutually agreeable means of advising M+C organizations of who has opted out. Disputes with M+C organizations 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. 1, 10-01-03) B3-3044.38

To ensure that the notice denying payment to the opt-out physician or practitioner indicates the proper reason for denial of payment, the carrier 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 carrier 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 carrier 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. 1, 10-01-03)
B3-3044.39

To ensure that the notice to the beneficiary indicates the proper reason for denial of payment, the carrier 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.”

40.40 - Reporting

(Rev. 108; Issued: 07-31-09; Effective: 01-01-10; Implementation: 01-04-10)

Contractors shall report quarterly physician and non-physician practitioner opt outs to CMS beginning with providers who have approved affidavits with opt out effective dates of January 1, 2010 through March 31, 2010 via the CROWD system. The data will be entered into CROWD Form 8. Please refer to The Medicare Financial Management Manual, Publication 100-06, Chapter 6, Section 470 for complete instructions on how to enter data for quarterly opt out reporting.

The contractor shall maintain valid/approved affidavits in accordance with Section 40.9. The contractor must not count affidavits it receives for the opt out report that are invalid/not approved and must be returned to the physician/practitioner for clarification, incompleteness, etc. For the quarterly CROWD report, CMS only requires a count of the newly opted out physicians and non-physicians for the quarter. If no activity occurred, zeros will be entered for the report.

In CROWD contractors will report the number of providers who have opted out by specialty and quarter month. The quarter is based on a calendar year (e.g. for the first quarter, month # 1 (Jan), month # 2 (Feb) and month # 3 (Mar). No additional provider details (e.g., name, address, NPI) are required on the CROWD report. An example of the opt out reporting form in CROWD can be found in The Medicare Financial Management Manual, Publication 100-06, Chapter 6, Section 470.5.

Contractors shall also use CROWD to enter the total number of physicians and non-physician practitioners by specialty that it has on file to date flagged or identified as opt outs. For example, for specialty 01, the contractor would enter a number of all providers that have a status of opt out as of the close of the quarter.

The CMS will no longer accept faxed, e-mailed or mailed copies of the opt out report.

The report is due in CROWD 30 days after the end of each quarter (e.g., a report for the quarter April 1, 2010, through June 30, 2010, is due July 30, 2010.)

50 - Drugs and Biologicals

(Rev. 1, 10-01-03)

B3-2049, A3-3112.4.B, HO-230.4.B

The Medicare program provides limited benefits for outpatient drugs. The program covers drugs that are furnished “incident to” a physician’s service provided that the drugs are not usually self-administered by the patients who take them.

Generally, drugs and biologicals are covered only if all of the following requirements are met:

- They meet the definition of drugs or biologicals (see §50.1);
- They are of the type that are not usually self-administered. (see §50.2);
- They meet all the general requirements for coverage of items as incident to a physician’s services (see §§50.1 and 50.3);
- They are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice (see §50.4);
- They are not excluded as noncovered immunizations (see §50.4.4.2); and
- They have not been determined by the FDA to be less than effective. (See §§50.4.4).

Medicare Part B does generally not cover drugs that can be self-administered, such as those in pill form, or are used for self-injection. However, the statute provides for the