DEPARTMENT OF HEALTH & HUMAN SERVICES
Division of Financial Management & Fee for Service Operations
26 Federal Plaza
Room 38-130
New York, N.Y. 10278
Reference: MTN236833

January 7, 2013

Lawrence R. Huntoon, MD
Private Neurology
Chapel Park Villa
7008 Erie Road, Suite 6
Derby, NY 14047

Dear Dr. Huntoon:

This is in response to your inquiry concerning your dispute that our interpretation of 42 CFR §405.445(a) is incorrect in suggesting that providers are not allowed to file opt-out affidavits prior to expiring.

We have notified our Provider Enrollment Operations Group (PEOG) of your concerns about not being allowed to file your opt-out affidavit prior to it expiring since they initially provided us with guidance on this matter. PEOG suggested that we seek additional guidance on the interpretation of 42 CFR §405.445(a) from the Centers for Medicare (CM), the component of the Centers for Medicare & Medicaid Services responsible for writing this policy.

CM advised us that 42 CFR 405.445(a) and Pub. 100-2, Medicare Benefit Policy Manual, Chapter 15, Section 40.34 indicate that in order to renew an opt-out without interruption, the affidavit must be filed within 30 days after the current opt out period expires. CM further interprets this to mean that these sections do not require the opt-out physician to wait until his current opt-out period expires before filing a renewal opt-out affidavit. Therefore, you may file a renewal opt-out affidavit before your current opt-out period expires.

PEOG has instructed National Government Services (NGS) to follow CM's interpretations to allow an opt-out physician to file a renewal opt-out affidavit before his or her current opt-out period expires. We hope you find that your continued efforts to clarify the interpretation of 42 CFR §405.445(a) will make filing an opt-out affidavit with NGS seamless. We would like to thank you for bringing this matter to our attention.

We hope you find this information helpful. If you have any additional questions, please feel free to contact me at 212-616-2538.

Sincerely,

Melissa Towns

Melissa Towns
Health Insurance Specialist

U.S. Department of Health & Human Services
Centers for Medicare & Medicaid
Regional Office 2
Federal Building
26 Federal Plaza
New York, N.Y. 10278

OFFICIAL BUSINESS
PENALTY FOR PRIVATE USE, $300

FIRST CLASS

US OFFICIAL MAIL >> PENALTY FOR PRIVATE USE $300
PITNEY BOWES
ZIP 10278 02 1W $ 000.00⁰
0004887105 JAN 09 2014

FIRST CLASS

US OFFICIAL MAIL >> PENALTY FOR PRIVATE USE $300
PITNEY BOWES
ZIP 10278 02 1W $ 000.46⁰
0004887105 JAN 09 2014

Lawrence R. Huntoon, MD
Private Neurology
Chapel Park Villa
7008 Erie Road, Suite 6
Derby, NY 14047

14047$9596 R004

Lawrence R. Huntoon M.D., Ph.D., F.A.A.N.
Board-Certified Neurologist
Private Neurology
Chapel Park Villa
Suite 6
7008 Erie Rd.
Derby, NY 14047
Tel. 716-627-7759
www.PrivateNeurology.com

November 25, 2013

Ms. Melissa Towns
Health Insurance Specialist
CMS Region II Office
Division of Financial Management & Fee for Service Operations
26 Federal Plaza
Room 38-130
New York, NY 10278

Dear Ms. Towns:

I reviewed your letter, dated November 15, 2013 (enclosed), Reference MTN225432:229389:232398:232389.

Thank you for admitting that your rogue contractor, NGS, was incompetent in treating my Opt Out renewal as an application instead of what it obviously was – an Opt Out renewal.

I have reviewed 42 CFR §405.445(a) as referenced in your letter. I also have reviewed Transmittal 160 which you will find at: http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R160BP.pdf .

In your letter, you state: "Please note that you will need to adhere to submitting your next affidavit within 30 days after the next opt-out period expires."

However, you clearly have misinterpreted 42 CFR §405.445(a). Section 405.445(a) is a ***permissive*** requirement, not an exclusive requirement – that is, a physician is permitted to renew an opt-out as long as it is renewed within 30 days after the current opt out period expires. It is equivalent to a grace period following expiration of the current opt out period. It does not mean that a physician *mus*t ***exclusively*** submit an opt out renewal *after* the current opt out period expires. There is no prohibition of submitting an opt-out renewal prior to expiration of the current opt-out period. There is no time restriction for filing an opt-out renewal prior to the expiration of the current opt-out period.

You will find a similar ***permissive*** requirement under Section 40.9 – **Requirements of the Opt-Out Affidavit** – an opt out affidavit must "Be filed with all Medicare contractors who have jurisdiction over claims the physician/practitioner would otherwise file with Medicare and be filed ***no later than 10 days after the first private contractor to which the affidavit applies is entered into."*** That does not mean that the physician *must* submit the Opt Out affidavit within 10 days after entering into a private contract with a Medicare patient. Physicians can and do submit Opt Out affidavits well in advance of making a contract with a Medicare patient.

In addition to the fact that 42 CFR §405.445(a) is a ***permissive*** not ***exclusive*** requirement, it makes no logical sense whatsoever to wait until the current opt-out period expires to renew the opt-out. Ideally, a physician should not allow the opt-out to expire. Maintaining a continuous opt-out is best served by starting the process well in advance of the expiration of the current opt-out period. Allowing the opt-out to expire, and then submit an opt-out renewal is a prescription for disaster. As amply demonstrated via my many months of correspondence with your incompetent NGS contractor, just to accomplish a simple straight-forward opt-out renewal, Medicare contractors do not process or do anything in a timely or competent fashion. It has taken me over 3 months simply to accomplish my opt-out renewal for the 5th time!

Your gross misinterpretation of 42 CFR §405.445(a) will only create further confusion at NGS, a place where confusion and total incompetence are already rampant.

Lawrence R. Huntoon, M.D., Ph.D., F.A.A.N.

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

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

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

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

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

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

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

contract to furnish emergency care services or urgent care services to a Medicare beneficiary. Accordingly, a physician or practitioner will not be determined to have failed to maintain opt-out if he or she furnishes emergency care services or urgent care services to a Medicare beneficiary with whom the physician or practitioner has not previously entered into a private contract, provided the physician or practitioner complies with the billing requirements specified in paragraph (b) of this section.

(b) When a physician or practitioner who has not been excluded under sections 1128, 1156, or 1892 of the Social Security Act furnishes emergency care services or urgent care services to a Medicare beneficiary with whom the physician or practitioner has not previously entered into a private contract, he or she:

(1) Must submit a claim to Medicare in accordance with both 42 CFR part 424 and Medicare instructions (including but not limited to complying with proper coding of emergency or urgent care services furnished by physicians and practitioners who have opted-out of Medicare).

(2) May collect no more than—

(i) The Medicare limiting charge, in the case of a physician; or

(ii) The deductible and coinsurance, in the case of a practitioner.

(c) Emergency care services or urgent care services furnished to a Medicare beneficiary with whom the physician or practitioner has previously entered into a private contract (that is, entered into before the onset of the emergency medical condition or urgent medical condition), are furnished under the terms of the private contract.

(d) Medicare may make payment for emergency care services or urgent care services furnished by a physician or practitioner who has properly opted-out when the services are furnished and the claim for services is made in accordance with this section. A physician or practitioner who has been excluded must comply with the regulations at §1001.1901 (Scope and effect of exclusion) of this title when he or she furnishes emergency services to beneficiaries and may not bill and be paid for urgent care services.

§ 405.445 Renewal and early termination of opt-out.

(a) A physician or practitioner may renew opt-out by filing an affidavit with each carrier with which he or she would file claims absent completion of opt-out, provided the affidavits are filed within 30 days after the current opt-out period expires.

(b) To properly terminate opt-out a physician or practitioner must:

(1) Not have previously opted out of Medicare.

(2) Notify all Medicare carriers, with which he or she filed an affidavit, of the termination of the opt-out no later than 90 days after the effective date of the opt-out period.

(3) Refund to each beneficiary with whom he or she has privately contracted all payment collected in excess of:

(i) The Medicare limiting charge (in the case of physicians); or

(ii) The deductible and coinsurance (in the case of practitioners).

(4) 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' right to have claims filed on their behalf with Medicare for the services furnished during the period between the effective date of the opt-out and the effective date of the termination of the opt-out period.

(c) When the physician or practitioner properly terminates opt-out in accordance with paragraph (b), he or she will be reinstated in Medicare as if there had been no opt-out, and the provision of §405.425 shall not apply unless the physician or practitioner subsequently properly opts out.

(d) A physician or practitioner who has completed opt-out on or before January 1, 1999 may terminate opt-out during the 90 days following January 1, 1999 if he or she notifies all carriers to whom he or she would otherwise submit claims of the intent to terminate opt-out and complies with paragraphs (b)(3) and (4) of this section. Paragraph (c) of this section applies in these cases.

40.32 - Payment for Medically Necessary Services Ordered or Prescribed by an Opt-out physician or Practitioner
(Rev. 160, Issued: 10-26-12, Effective: 01-28-13, Implementation: 01-28-13)

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

40.33 - 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. 160, Issued: 10-26-12, Effective: 01-28-13, Implementation: 01-28-13)

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

40.35 - Early Termination of Opt-Out
(Rev. 160, Issued: 10-26-12, Effective: 01-28-13, Implementation: 01-28-13)

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

- Not have previously opted out of Medicare;

- Notify all Medicare contractors, with which the physician or practitioner filed an affidavit, of the termination of the opt-out no later than 90 days after the effective date of the opt-out period;

- Refund to each beneficiary with whom the physician or practitioner has privately contracted all payment collected in excess of:

    - The Medicare limiting charge (in the case of physicians or practitioners); or
    - The deductible and coinsurance (in the case of practitioners).

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

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

40.9 - Requirements of the Opt-Out Affidavit

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

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

- Be in writing and be signed by the physician/practitioner;

- Contain the physician's or practitioner's full name, address, telephone number, national provider identifier (NPI) or billing number (if one has been assigned), or, if an NPI has not been assigned, the physician's or practitioner's tax identification number (TIN);

- State that, except for emergency or urgent care services (as specified in §40.28), during the opt-out period the physician/practitioner will provide services to Medicare beneficiaries only through private contracts that meet the criteria of §40.8 for services that, but for their provision under a private contract, would have been Medicare-covered services;

- State that the physician/practitioner will not submit a claim to Medicare for any service furnished to a Medicare beneficiary during the opt-out period, nor will the physician/practitioner permit any entity acting on the physician's/practitioner's behalf to submit a claim to Medicare for services furnished to a Medicare beneficiary, except as specified in §40.28;

- State that, during the opt-out period, the physician/practitioner understands that the physician/practitioner may receive no direct or indirect Medicare payment for services that the physician/practitioner furnishes to Medicare beneficiaries with whom the physician/practitioner has privately contracted, whether as an individual, an employee of an organization, a partner in a partnership, under a reassignment of benefits, or as payment for a service furnished to a Medicare beneficiary under a Medicare Advantage plan;

• State that a physician/practitioner who opts out of Medicare acknowledges that, during the opt-out period, the physician's/practitioner's services are not covered under Medicare and that no Medicare payment may be made to any entity for the physician's/practitioner's services, directly or on a capitated basis;

• State on acknowledgment by the physician/practitioner to the effect that, during the opt-out period, the physician/practitioner agrees to be bound by the terms of both the affidavit and the private contracts that the physician/practitioner has entered into;

• Acknowledge that the physician/practitioner recognizes that the terms of the affidavit apply to all Medicare-covered items and services furnished to Medicare beneficiaries by the physician/practitioner during the opt-out period (except for emergency or urgent care services furnished to the beneficiaries with whom the physician/practitioner has not previously privately contracted) without regard to any payment arrangements the physician/practitioner may make;

• With respect to a physician/practitioner who has signed a Part B participation agreement, acknowledge that such agreement terminates on the effective date of the affidavit;

• Acknowledge that the physician/practitioner understands that a beneficiary who has not entered into a private contract and who requires emergency or urgent care services may not be asked to enter into a private contract with respect to receiving such services and that the rules of §40.28 apply if the physician/practitioner furnishes such services;

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

• Be filed with all *Medicare contractors* who have jurisdiction over claims the physician/practitioner would otherwise file with Medicare and be filed no later than 10 days after the first private contract to which the affidavit applies is entered into.

40.11 - Failure to Maintain Opt-Out

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

A. Failure to maintain opt-out

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

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