CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 926	**Date: November 22, 2019**
	Change Request 10939

SUBJECT: Additional Guidance on Private Contracting/Opting-out of Medicare and Entering Opt-out Affidavit Records in the Provider Enrollment, Chain and Ownership System (PECOS)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to provide instructions to the A/B Medicare Administrative Contractors (MACs Part B) to process physicians' and eligible non-physician practitioners' (known as eligible practitioners in this CR) affidavits to opt out of Medicare and appropriately create and maintain opt out affidavit records in the PECOS.

EFFECTIVE DATE: December 24, 2019
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: December 24, 2019

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-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	15/15.1/15.1.3/Medicare Contractor Duties
R	15/15.6/Timeliness and Accuracy Standards
R	15/15.6/15.6.1/Standards for Initial and Revalidation Applications and Opt-Out Affidavits
R	15/15.6/15.6.1.1/Paper Applications and Opt-Out Affidavit - Timeliness
R	15/15.6/15.6.1.1.2/Form CMS-855 and Form CMS-20134 Applications That Do Not Require a Site Visit and Opt-Out Affidavits
R	15/15.6/15.6.1.2/Paper Applications and Opt-Out Affidavits - Accuracy
R	15/15.6/15.6.2/Standards for Changes of Information
R	15/15.6/15.6.2.1/Paper Applications and Opt-Out Affidavit Changes of Information – Timeliness
R	15/15.6/15.6.2.2/Paper Applications and Opt-Out Affidavit Changes of Information – Accuracy
R	15/15.14/15.14.7/Opting-Out of Medicare
N	15/15.14/15.14.7.1/Who May Opt-Out of Medicare
N	15/15.14/15.14.7.2/Requirements of an Opt-Out Affidavit
N	15/15.14/15.14.7.2.1/Opting-Out and Ordering and Referring
N	15/15.14/15.14.7.2.2/Acceptable Opt-Out Affidavit Formats
N	15/15.14/15.14.7.2.2.1/Opt-Out Sample Form
N	15/15.14/15.14.7.3/Requirements of a Private Contract
N	15/15.14/15.14.7.4/Determining an Effective Date of an Opt-Out Period
N	15/15.14/15.14.7.5/Emergency and Urgent Care Services
N	15/15.14/15.14.7.6/Termination of an Opt-Out Affidavit
N	15/15.14/15.14.7.7/Opt Out Period Auto-Renewal and Cancellation of the Opt-Out Affidavit
N	15/15.14/15.14.7.7.1/Opt-out Period Auto-Renewal Report and Opt-Out Renewal Alert
N	15/15.14/15.14.7.8/Opting-Out vs. Enrolling for the Sole Purpose of Ordering and Referring and/or Prescribing
N	15/15.14/15.14.7.9/Failure to Properly Cancel or Terminate Opt-Out
N	15/15.24/15.24.16/Model Opt-Out Letters
N	15/15.24/15.24.16.1/Opt-Out Affidavit Development Letter
N	15/15.24/15.24.16.2/Opt-Out Rejection Letter
N	15/15.24/15.24.16.3/Opt-Out Return Letters

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N	15/15.24/15.24.16.3.1/Opt-Out Return Letter – Unlicensed Eligible Practitioners
N	15/15.24/15.24.16.3.2/Opt-Out Return Letter – Ineligible Practitioner Specialty
N	15/15.24/15.24.16.3.3/Opt-Out Return Letter – Submitted to the Incorrect MAC
N	15/15.24/15.24.16.3.4/Opt-Out Return Letter – Withdraw of Affidavit During Processing
N	15/15.24/15.24.16.4/Opt-Out Affidavit Approval Letters
N	15/15.24/15.24.16.4.1/Opt-Out Affidavit Approval Letter - Eligible Practitioner Approved to Order and Refer)
N	15/15.24/15.24.16.4.2/Opt-Out Affidavit Approval Letter - Eligible Practitioner May Not Order and Refer (Excluded by OIG)
N	15/15.24/15.24.16.4.3/Opt-Out Affidavit Approval Letter - Eligible Practitioner May Not Order and Refer (Ineligible Specialty to Order and Refer)
N	15/15.24/15.24.16.4.4/Opt-Out Affidavit Approval Letter - Eligible Practitioner May Not Order and Refer (Did Not Elect to Order and Refer)
N	15/15.24/15.24.16.4.5/Opt-Out Affidavit Approval Letter - Eligible Practitioner May Not Order and Refer (Eligible Practitioner Does Not Have an NPI)
N	15/15.24/15.24.16.5/Opt-Out Renewal Alert Letter
N	15/15.24/15.24.16.6/Opt-Out Affidavit Termination Letter
N	15/15.24/15.24.16.7/Opt-Out Affidavit Cancel Letter

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. 100-08	Transmittal: 926	Date: November 22, 2019	Change Request: 10939

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EFFECTIVE DATE: December 24, 2019
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I. GENERAL INFORMATION

A. Background: This CR will provide instructions to the A/B MACs (Part B) to process eligible practitioners' affidavits to opt out of Medicare and appropriately create and maintain opt out affidavit records in the PECOS by updating existing instructions in Publication (Pub.) 100-08, chapter 15.

Physicians and Other Practitioners Who May Opt-out of Medicare - The Medicare policy for opting out are found in chapter 15, section 40 of Pub. 100-02. The physicians and other practitioners listed below are permitted by statute to opt-out of the Medicare program:

Physicians who are --

- doctors of medicine or osteopathy;
- doctors of dental surgery or dental medicine;
- doctors of podiatry;
- doctors of optometry; and
- legally authorized to practice dentistry, podiatry, optometry, medicine, or surgery by the state in which such function or action is performed.

Practitioners who are --

- Physician assistants;
- Nurse practitioners;
- Clinical nurse specialists;
- Certified registered nurse anesthetists;
- Certified nurse midwives;
- Clinical psychologists;
- Clinical social workers;
- Registered dietitians or nutrition professionals; and
- legally authorized to practice by the state and otherwise meet Medicare requirements.

Opt-out Affidavit Basic Information

Eligible Practitioners who want to opt-out must file an affidavit with Medicare in which they agree to opt-out of Medicare for a period of two years and to meet certain other criteria. In general, the law requires that during that 2-year period of time, Eligible Practitioners who have filed affidavits opting out of Medicare must sign private contracts with all Medicare beneficiaries to whom they furnish services that would otherwise be covered by Medicare, except those who are in need of emergency or urgently needed care. They cannot sign such contracts with beneficiaries in need of emergency or urgent care services. Moreover, Eligible Practitioners who opt-out cannot choose to opt-out of Medicare for some Medicare

beneficiaries but not others; or for some services and not others.

The policy of the opt-out affidavit are in the Internet Only Manual Pub. 100-2, chapter 15, and section 40.9. Among other things, the affidavit must be in writing and signed by the Eligible Practitioner. It must include various statements to which the Eligible Practitioner must agree; for example, the Eligible Practitioner must agree not to submit claims to Medicare for any services furnished during the opt-out period except for emergency or urgent care services furnished to beneficiaries with whom the Eligible Practitioner has not previously entered into a private contract. It must identify the Eligible Practitioner sufficiently so that the MAC can ensure that no payment is made to the Eligible Practitioner during the opt-out period, and it must be filed with all MACs who have jurisdiction over the claims the Eligible Practitioner would have otherwise filed with Medicare and must be filed no later than 10 days after entering into the first private contract to which the affidavit applies. The following specific information must be included in the affidavit:

- The Eligible Practitioner's legal name
- Address (If the address in the affidavit is a P.O. Box, the MAC may request a different address) and Telephone number
- License Information
- Medicare Billing ID/Provider Transaction Number (PTAN) (if the was previously enrolled and one had been assigned)
- NPI (only if one has been assigned), and
- TIN (SSN) (required if an NPI has not been assigned)

Opt-out Affidavit Processing Information

Eligible Practitioners who have never enrolled in Medicare are <u>not</u> required to enroll in Medicare before they can opt-out of Medicare.

If a physician had been enrolled in Medicare and had signed a Part B participation agreement or a Non-Physician Practitioner (NPP) had been enrolled (all NPPs that are eligible to opt-out must participate in Medicare) and is now opting out, the participation agreement terminates at the same time the enrollment terminates. If an already-enrolled Eligible Practitioner is opting out, the existing PECOS enrollment record shall be end dated the day before the PECOS Affidavit Record is effective.

The effective date of the opt-out affidavit of an already-enrolled participating physician or eligible NPP shall be the beginning of any calendar quarter (i.e. January 1, April 1, July 1 or October 1), provided that the affidavit is submitted to the individual's MAC at least 30 days before the beginning of the selected calendar quarter. A private contract entered into before the beginning of the selected calendar quarter becomes effective at the beginning of the selected calendar quarter and the furnishing of any items or services to a Medicare beneficiary under such contract before the beginning of the selected calendar quarter is subject to standard Medicare rules.

The effective date of the opt-out affidavit of a nonparticipating physician or a previously non-enrolled Eligible Practitioner shall be the date the affidavit 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.

MACs shall review all affidavits on an on-going basis to ensure the opt-out affidavit information has been captured in PECOS. They must create an "Affidavit Record" (not an "Enrollment Record") in PECOS for each opt-out Eligible Practitioner who submits an acceptable opt-out affidavit.

MACs shall screen an opt-out affidavit to ensure completeness. MACs shall not create affidavit records in PECOS if the Eligible Practitioner does not have a valid State license, has a specialty that is ineligible to opt-out (such as: Chiropractic Medicine, Physical Therapy, Occupational Therapy, etc.) or if an Eligible Practitioner decides not to opt out of Medicare while their affidavit is in process, but not approved. Such affidavits shall be returned to the Eligible Practitioner. An opt-out affidavit that fails prescreening will be returned to the physician/practitioner.

However, a PECOS Logging and Tracking (L&T) record will capture the fact that the Eligible Practitioner submitted an opt-out affidavit that was rejected and the dates on which it was received and rejected. There will be no record of this opt-out affidavit in PECOS other than the L&T record.

When the opt-out affidavit passes screening, the MAC shall create an L&T and shall tie it to an affidavit record. The affidavit record in PECOS is for identification and tracking purposes.

The Affidavit Record must include the PTAN and that PTAN shall be added to the master provider file in the Multi-Carrier System (MCS). MACs shall not issue the PTAN added to the affidavit record or MCS provider file to the Eligible Practitioner.

MACs shall verify that the information in the opt-out affidavit meets the Medicare policy for opting out as found in chapter 15, and section 40.9 of Pub. 100-02. If MACs need to obtain missing data only one time, or they may obtain that information from other sources provided with the affidavit or they may contact the Eligible Practitioner directly. MACs shall provide Eligible Practitioners 30 days to provide the missing data. Missing information may be mailed, faxed or emailed. MACs shall **not** use Internet-Based PECOS or a CMS 855 form to obtain the information from the Eligible Practitioner, as the Eligible Practitioner is not enrolling in Medicare.

If the Eligible Practitioner is requested to submit missing information and fails to do so, the MAC shall reject the opt-out affidavit. The L&T will capture the fact that the opt-out affidavit was rejected.

An Eligible Practitioner’s opt-out status is not affected by a move or re-locating. Therefore, the opt-out start and end dates must not be changed by the new or incoming Medicare contractor. In addition, a change in practice location does not permit the opt-out Eligible Practitioners to terminate his or her opt-out early. The only way to terminate an opt-out early is if an Eligible Practitioners is eligible to utilize the early termination of opt-out procedures described in chapter 15, and section 40.35 of Pub. 100-02 or 42 Code of Federal Regulations (CFR) 405.445(b).

Contractors shall not change the affidavit record in PECOS to a deactivated status, if the Eligible Practitioner whose opt-out affidavit has exceeded the expiration date and who has not sent in an affidavit to renew the opt-out status or a CMS 855 to enroll in Medicare, as opt-out affidavits are automatically renewed on or after June 16, 2015.

The MACs shall use the Ordering/Referring Indicator (Y for Yes and N for No) in PECOS when creating affidavit records. The MAC shall set the Indicator to Y (Yes) (the Eligible Practitioner is permitted to and has indicated they intend to order or refer) or N (No) (the Eligible Practitioner is not permitted to or has chosen not to order or refer), as appropriate. The Ordering/Referring Indicator will only be used in PECOS for documentation purposes and for PECOS to determine which physicians or other practitioners should be included on the PECOS Ordering/Referring File(s) sent to the shared systems and the Ordering Referring Report on the CMS site.

Opt-out Eligible Practitioners Who May Order and Refer Services

There are differences between physicians and other practitioners who are permitted to opt-out and physicians and other practitioners who are permitted to order and refer services. The following Eligible Practitioners are permitted to order/refer:

- Physicians who are --
    - doctors of medicine or osteopathy;
    - doctors of dental surgery or dental medicine;
    - doctors of podiatry; and
    - doctors of optometry
- Practitioners who are --
    - physician assistants;
    - certified clinical nurse specialists;
    - nurse practitioners;
    - clinical psychologists;
    - certified nurse midwives; or
    - clinical social workers

If an Opted-out Eligible Practitioner elects to order and refer services, and the following information is not included with the Eligible Practitioner's affidavit, MACs shall develop for the following via an additional information request:

- An NPI (if one is not contained on the affidavit voluntarily)
- Confirmation if an Office of Inspector General (OIG) exclusion exists (if not contained on the Affidavit)
- Date of Birth
- Social Security Number (if not contained on the Affidavit)

MACs shall provide 30 days for the Eligible Practitioner to submit the additional information. If the information referenced in the previous paragraph is not obtained, the Eligible Practitioner will not be able to order and refer services. However, the Medicare contractor shall not reject that Eligible Practitioner's opt-out affidavit when the Eligible Practitioner refuses to report the information listed immediately above. In other words, if the Eligible Practitioner refuses to report the information listed immediately above, then the Eligible Practitioner cannot order and refer, but the failure to report this additional information does not affect the Eligible Practitioner's opt-out status.

MACs shall review the OIG website http://oig.hhs.gov/ and The System for Award Management (SAM) at www.sam.gov, to determine if the Eligible Practitioner has been excluded from enrollment in Medicare, Medicaid and other federal programs.

If an Eligible Practitioner reports his or her NPI on the opt-out affidavit, but does not report his or her SSN, then the contractor cannot reject or return the opt-out affidavit on this basis due to the requirements in 42 CFR 405.420. This requirement does not require the Eligible Practitioner to include both numbers. Thus, the Medicare contractor shall go back to the Eligible Practitioner and request him or her to submit the SSN, but if he or she has already included an NPI on the affidavit and the affidavit meets all of the other requirements in 42 CFR 405.420 to opt-out of Medicare, then the contractor cannot reject the affidavit when a Eligible Practitioner refuses to report his or her SSN. However, if no SSN is submitted when requested, the opt-out Eligible Practitioner cannot order and refer services.

An affidavit record shall be created even in the following three situations, assuming the required data is developed for by the Medicare contractor in addition to the opt-out affidavit. However, if the required data are not furnished upon request, the opt-out affidavit may be

processed, but the opt-out Eligible Practitioner may not order and refer services.

1. The opting-out Eligible Practitioner does not have an NPI. An Eligible Practitioner does not need to have an NPI to opt-out of the Medicare program. However, an Eligible Practitioner must have an NPI to order and refer items or services for Medicare beneficiaries. The MAC shall indicate in PECOS that the opt-out Eligible Practitioner does not have an NPI. Chapter 15, section 40.13 of Pub. 100-02, requires the MAC to notify the opting-out Eligible Practitioner that he/she is not permitted to order or refer items or services for Medicare beneficiaries if he/she does not have an NPI. The MAC shall set the PECOS Ordering/Referring Indicator to N (No) with the Reason: No NPI. The opting out Eligible Practitioner has been excluded by the Office of Inspector General (OIG) or SAM, including exclusions under sections 1128, 1156, or 1892 of the Social Security Act (the Act). An OIG exclusion does not prohibit an Eligible Practitioner from opting out of the Medicare program. However, CMS shall not pay claims for services submitted by or ordered by an Eligible Practitioner who is excluded under sections 1128, 1156, or 1892 of the Act except in the limited circumstances stated in 42C.F.R.1001.1901(c). The MAC shall set the PECOS Ordering/Referring Indicator to N (No) with the Reason: Excluded under 1128, 1156, or1892.
2. The private contract that an opt-out Eligible Practitioner must enter into with each Medicare beneficiary who he/she sees must indicate if the Eligible Practitioner was excluded under sections 1128, 1156, or 1892 of the Act. The Eligible Practitioner is required to furnish a copy of the private contract if the MAC requests it. In addition to requesting a copy of the private contract, MACs shall check the OIG website http://oig.hhs.gov/ and www.SAM.gov to determine if the Eligible Practitioner has been excluded under sections 1128, 1156, or 1892.
3. The opting-out Eligible Practitioner is not of a specialty that is permitted to order or refer. Registered dietitians, nutrition professionals, and certified registered nurse anesthetists may opt-out. However, they are not permitted to order or refer. The MAC shall set the PECOS Ordering/Referring Indicator to N (No) with the Reason: Specialty not permitted to order/refer.

For opt-out Eligible Practitioners, the Ordering/Referring Indicator of N in the affidavit record will distinguish those Eligible Practitioners in PECOS in an Opt-out status who are not permitted to order or refer. Those who have an Ordering/Referring Indicator of Y are permitted to order/refer and will be included in the appropriate daily PECOS file(s) for the shared systems and in the Ordering Referring Report on CMS website. Therefore, those who are described in items 1 and/or 3 above will have affidavit records in PECOS in Opt-out status but will not be included in any daily PECOS file(s) for the shared systems or on the Ordering and Referring Report on the CMS website (www.data.cms.gov) for ordering/referring purposes. As described in item 2 above, if an opt-out physician or Eligible Practitioner has been excluded by the OIG, then the contractor shall set the PECOS Ordering/Referring Indicator to N (No). This will result in any and all claims that are ordered or referred by an excluded Eligible Practitioner who has opted out being denied. Regulations in 42 CFR 405.425(j) and 42 CFR 1001.1901(c) include exceptions that would permit Medicare to make payment for some services that are ordered or referred by excluded Eligible Practitioners. In order for the claims that meet one of the exceptions described at 42 CFR 1001.1901(c) to be paid, the provider or supplier shall file an appeal of the claim to the MACs. The appeal shall follow the guidelines found in chapter 29, section 290 of Pub. 100-04 and should include documentation which proves that one of the exceptions described at 42 CFR 1001.1901(c) has been met.

For opt-out Eligible Practitioner who can no longer order/refer services, the MAC shall change the indicator to N so that the Ordering and Referring reports will be appropriately

updated.

Opt-out Affidavit Processing Timeliness Standards

An initial opt-out affidavit is considered an initial application and will be measured with the same timeliness metrics and accuracy standards as initial and revalidation CMS-855 and Internet-based PECOS applications, per Section 15.6. A of Pub. 100-08, opt-out affidavit change of information, early termination request or affidavit cancellation request are considered change of information applications and will be measured with the same timeliness metrics and accuracy standards as change of information CMS-855 and internet-based PECOS applications, per section 15.6 of Pub. 100-08.

Emergency or Urgent Care Services Provided by Opted-out Eligible Practitioners

If an opt-out Eligible Practitioner provides emergency or urgent care service to a beneficiary who has not signed a private contract with the Eligible Practitioner and the Eligible Practitioner submits an assigned claim, the Eligible Practitioner must enroll via internet-based PECOS or complete the appropriate Form CMS-855 and enroll in the Medicare program before receiving reimbursement.

Appeals of Opt-out Decisions

Regulations found in 42 CFR 405.450 state that approval of an opt-out, failure to properly terminate and failure to properly cancel an opt-out are considered initial decisions, per 42 CFR 498.3(b). Eligible practitioners shall be afforded appeal rights for these decisions.

B. Policy: There are no legislative or regulatory policies related to this CR

For additional information, MACs can also refer to 42 CFR 405.425, "Effects of opting-out of Medicare."

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
10939.1	MACs shall not require Eligible Practitioners who are permitted to opt-out to enroll in Medicare before they can opt-out of the Medicare program.		X							
10939.2	MACs shall maintain information on the Eligible Practitioners who opt-out within PECOS and their own tracking systems.		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
10939.3	MACs shall process initial opt-out affidavits as initial applications that do not require site visits and process within the appropriate amount of days of receipt according to chapter 15, section 15.6.1.1.2. of Pub. 100-08.		X							
10939.3.1	MACs shall process change of information opt-out affidavits or opt-out affidavit termination requests or cancellation requests as change of information applications and process within the appropriate amount of days of receipt according to chapter 15, section 15.6.2.1 of Pub. 100-08.		X							
10939.3.2	MACs shall process 98 percent of opt-out affidavits in full accordance with all of the instructions found in chapter 15 of Pub. 100-08.		X							
10939.4	MACs shall verify that the information in the opt-out affidavit meets the Medicare requirements for opting out and completing an Affidavit record in PECOS. The following specific information shall be included in the affidavit to opt-out: • The Eligible Practitioner's legal name, • Social Security Number (SSN), • Date of birth,		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	• Address (If the address in the affidavit is a P.O. Box, the MAC should request a different address) and telephone number, • Medicare Billing ID/Provider Transaction Number (PTAN) (if the physician or other practitioner was previously enrolled and one had been assigned) and • National Provider Identifier (NPI, only if one has been assigned).									
10939.4.1	If information listed in BR 10939.4 is missing, the MAC shall develop for the missing information in order to complete the PECOS Affidavit Record.		X							
10939.4.2	MACs shall reject the opt-out affidavit if the developed information is not returned within 30 days.		X							
10939.4.3	If information that is required for an Eligible Practitioner to be included on the ordering and referring list is not returned, but enough information is received to create an Affidavit Record in PECOS, the MAC shall create the record and indicate		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	"No" in the Ordering and Referring indicator.									
10939.5	If the opt-out affidavit contains all required data, the MAC shall process it with an L&T submittal reason of "opt-out" and create the affidavit record in PECOS with a status of opt-out.		X							
10939.6	In the event that an affidavit is incomplete, MACs shall attempt to obtain missing data <u>one time</u> in order to create the affidavit record.		X							
10939.6.1	MACs should obtain that information from other sources or they should contact the Eligible Practitioner.		X							
10939.6.2	MACs shall provide 30 days to the eligible practitioner to provide the missing information.		X							
10939.6.3	MACs shall return to the Eligible Practitioner an opt-out affidavit that is unable to be screened. Note: The only reasons for a return is if the physician/NPP does not have a valid State license, is a specialty that is ineligible to opt out (such as: Chiropractic Medicine, Physical Therapy, Occupational Therapy, etc.), submitted to an incorrect MAC, or if an eligible practitioner decides not to opt out of Medicare while their affidavit is in process, but not approved.		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
10939.6.4	MACs shall document their internal records with the exact reason for rejection or return and the date of rejection or return.		X							
10939.7	MACs shall create a PECOS L&T to capture the fact that the eligible practitioner submitted an opt-out affidavit that was rejected and dates on which it was received and rejected.		X							
10939.8	MACs shall not create an affidavit record in PECOS if the opt out affidavit is to be returned or if the eligible practitioner did not provide additional requested information.		X							
10939.9	MACs shall create an L&T and tie it to an "Affidavit record" (not an enrollment record) in PECOS if the opt-out affidavit passes screening.		X							
10939.10	Contractors shall **not** use an Internet-Based PECOS application or the CMS 855 form to obtain the information from the opt-out physician/non-physician practitioner, as the opt-out Eligible Practitioner is not enrolling in Medicare.		X							
10939.11	MACs shall determine if the opt-out Eligible Practitioner is excluded by the OIG (under sections 1128, 1156, or 1892 of the Act) and/or via the System for Award Management (SAM).		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
10939.11.1	If the MACs determine an Eligible Practitioner has obtained a waiver according to 42 CFR §1001.1901(c), the MAC shall continue processing the opt-out affidavit but shall notify the Eligible Practitioner via letter that he/she may not order or refer items or services for Medicare beneficiaries.		X							
10939.11.2	MACs shall set the Ordering/Referring Indicator to N and select the Reason (Excluded 1128, 1156 or 1892).		X							
10939.11.3	MACs shall be responsible for determining if a waiver exists based on 42 CFR §1001.1901(c) prior to adding the PECOS Ordering/Referring Indicator to N (No) as described in business requirement 10939.11.2.		X							
10939.12	If the opting out Eligible Practitioner does not have an NPI, the MAC shall continue processing the opt-out affidavit, as an NPI is not required in order to opt-out.		X							
10939.12.1	The MAC shall set the Ordering/Referring Indicator to N and select the Reason (No NPI).		X							
10939.13	MACs shall set the Ordering/Referring Indicator to N (No) and select the Reason (Specialty not permitted to order/refer) for opt-out Eligible Practitioners who are of a specialty that is permitted to opt-		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	out but is not permitted to order and refer (this includes Certified Registered Nurse Anesthetists and Registered Dietitians or Nutrition Professionals).									
10939.14	If an Eligible Practitioner who has validly opted out submits a renewal affidavit after June 16, 2015, the MACs shall close the affidavit and comment the MAC's internal file with the reason for closure.		X							
10939.14.1	If data in the renewal affidavit changes data that exists in the affidavit record in PECOS, the MAC shall update the PECOS affidavit record accordingly and treat the affidavit as a change of information and process per BR 10939.3.1.		X							
10939.15	MACs shall change the affidavit record in PECOS from "Opt-out" status to "Deactivated" status at the end of the Opt-Out period if the eligible practitioner submits a cancellation request at least 30 days prior to the end of his/her opt-out period.		X							
10939.16	MACs shall issue an Opt-Out development letter if an eligible practitioner submits a form CMS-855I (and/or a CMS-855R) prior to submitting a cancellation request or a termination request within 90 days of an		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	initial Opt-Out period. The development will request a cancellation (or termination) notice.									
10939.16.1	MACs shall process the cancellation request if it received at least 30 days prior to the auto-renewal date.		X							
10939.16.2	MACs shall allow the opt-out to renew if no cancellation request is received after 30 days from the issuance of the development letter and reject the application(s) to the eligible practitioner.		X							
10939.17	MACs shall contact their Provider Enrollment & Oversight Group Business Functional Lead in the case that a cancellation request was received within 30 days prior to the end of the opt-out period or after the opt-out period automatically renews.		X							
10939.18	MACs shall review the new Opt-out Report on the Share Point Ensemble site no later than the 15th of each month. CMS is providing this report monthly to the MACs to determine the eligible practitioners' opt-outs that will auto renew within the next 90 to 110 days.		X							
10939.18.1	MACs shall issue letters to all eligible practitioners to eligible practitioners 90 days prior to the opt-out auto-renewal date. These		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	letters will inform the eligible practitioners of the date they would need to submit a cancellation request, dates of their next opt-out period and appeal rights will be provided if the eligible practitioner was unable to submit a cancellation request.									
10939.19	MACs shall not separately maintain a list of opt-out Eligible Practitioners on their websites.		X							
10939.19.1	MACs shall instead provide the following link, which contains a list of Eligible Practitioners who have opted out of the Medicare program: https://data.cms.gov/Medicare-Enrollment/Opt-Out-Affidavits/7yuw-754z.		X							
10939.19.2	MACs shall refer the National Supplier Clearinghouse (NSC) to utilize PECOS or refer to https://data.cms.gov/Medicare-Enrollment/Opt-Out-Affidavits/7yuw-754z for timely information on Eligible Practitioners that have opted out of Medicare.		X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	None					

IV. SUPPORTING INFORMATION

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

"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): Michael Gooden, 410-786-1500 or Michael.Gooden@cms.hhs.gov , Andrew Stouder, 410-786-0222 or Andrew.Stouder@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 Program Integrity Manual
Chapter 15 - Medicare Enrollment

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(Rev. 926, 11-22-19)

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15.1.3 – Medicare Contractor Duties

(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

The contractor shall adhere to all of the instructions in this chapter 15 (hereafter generally referred to as "this chapter") and all other CMS provider enrollment directives (e.g., Technical Direction letters). The contractor shall also assign the appropriate number of staff to the Medicare enrollment function to ensure that all such instructions and directives - including application *and opt-out affidavit* processing timeframes and accuracy standards - are complied with and met.

A. Training

The contractor shall provide (1) training to new employees, and (2) refresher training (as necessary) to existing employees to ensure that each employee processes enrollment applications in a timely, consistent, and accurate manner. Training shall include, at a minimum:

- An overview of the Medicare program
- A review of all applicable regulations, manual instructions, and other CMS guidance
- A review of the contractor's enrollment processes and procedures
- Training regarding the Provider Enrollment, Chain and Ownership System (PECOS).

For new employees, the contractor shall also:

- Provide side-by-side training with an experienced provider enrollment analyst
- Test the new employee to ensure that he or she understands Medicare enrollment policy and contractor processing procedures, including the use of PECOS
- Conduct end-of-line quality reviews for 6 months after training or until the analyst demonstrates a clear understanding of Medicare enrollment policy, contractor procedures, and the proper use of PECOS.

B. PECOS

The contractor shall:

- Process all enrollment actions (e.g., initials, changes, revalidations) through PECOS
- Deactivate or revoke the provider or supplier's Medicare billing privileges in the Multi-Carrier System or the Fiscal Intermediary Shared System only if the provider or supplier is not in PECOS
- Close or delete any aged logging and tracking (L & T) records older than 120 days for which there is no associated enrollment application
- Participate in user acceptance testing for each PECOS release
- Attend scheduled PECOS training when requested

- Report PECOS validation and production processing problems through the designated tracking system for each system release

- Develop (and update as needed) a written training guide for new and current employees on the proper processing of Form CMS-855 or CMS-20134 applications and the appropriate entry of data into PECOS.

C. Validation and Processing

The contractor shall:

- Review the application *or opt-out affidavit* to determine whether it is complete and that all information and supporting documentation required for the applicant's provider/supplier type has been submitted on and with the appropriate enrollment application *or affidavit*. Unless stated otherwise in this chapter or in another CMS directive, the provider must complete all required data elements on the Form CMS-855 or CMS-20134 via the application itself.

- Unless stated otherwise in this chapter or in another CMS directive, verify and validate all information collected on the enrollment application *or opt-out affidavit*, provided that a data source is available.

- Coordinate with State survey/certification agencies and regional offices (ROs), as needed

- Collect and maintain the application's certification statement (in house) to verify and validate Electronic Funds Transfer (EFT) changes in accordance with the instructions in this chapter and all other CMS directives.

- Confirm that the applicant, all individuals and entities listed on the application, *eligible practitioner on an opt-out affidavit*, and any names or entities ascertained through other sources, are not presently excluded from the Medicare program by the HHS Office of the Inspector General (OIG) or through the System for Award Management *(as excluded individuals and entities may not enroll with Medicare and excluded eligible practitioners may opt-out, but cannot order and refer items and services)*.

D. Customer Service

Excluding matters pertaining to application processing (e.g., development for missing data) and appeals (e.g., appeal of revocation), the contractor is encouraged to respond to all enrollment-related provider/supplier correspondence (e.g., emails, letters, telephone calls) within 30 business days of receipt.

15.6 - Timeliness and Accuracy Standards

(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

Sections 15.6.1 through 15.6.3 of this chapter address the timeliness and accuracy standards applicable to the processing of Form CMS-855, Form CMS-20134 applications *and opt-out affidavits*. Even though the provisions of 42 CFR §405.818 contain processing timeframes that differ than those in sections 15.6.1 through 15.6.3, the contractor shall adhere to the standards specified in sections 15.6.1 through 15.6.3.

The processing of an application *or opt-out affidavit* generally includes, but is not limited to, the following activities:

- Receipt of the application *or opt-out affidavit* in the contractor's mailroom and forwarding it to the appropriate office for review.

- Prescreening the application *or opt-out affidavit*.

- Creating a logging and tracking (L & T) record and an enrollment *or opt-out affidavit* record in the Provider Enrollment, Chain and Ownership System (PECOS).

- Ensuring that the information on the application *or opt-out affidavit* is verified.

- Requesting and receiving clarifying information.

- Site visit (if necessary).

- Formal notification to the SA and/or RO of the contractor's approval, denial or recommendation for approval of the application.

15.6.1 – Standards for Initial and Revalidation Applications *and Opt-Out Affidavits*

(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

For purposes of sections 15.6.1.1 through 15.6.1.4 of this chapter, the term "initial applications" also includes:

1. Form CMS-855 or Form CMS-20134 change of ownership, acquisition/merger, and consolidation applications submitted by the new owner.

2. "Complete" Form CMS-855 or Form CMS-20134 applications submitted by enrolled providers: (a) voluntarily, (b) as part of any change request if the provider does not have an established enrollment record in the Provider Enrollment, Chain and Ownership System (PECOS), (c) as a Form CMS-855 or Form CMS-20134reactivation, or (d) as a revalidation.

3. Reactivation certification packages (as described in sections 15.27.1.2.1 and 15.27.1.2.2 of this chapter).

4. *Opt-out affidavits submitted for an eligible practitioner's first opt-out period.*

Initial and revalidation application *and opt-out affidavit* timeliness standards shall be reported together. Likewise, initial and revalidation *and opt-out affidavit* accuracy shall be reported together.

15.6.1.1 - Paper Applications *and Opt-Out Affidavits* - Timeliness

(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

For purposes of sections 15.6.1.1.2 through 15.6.1.1.4 below, the term "development" means that the contractor needs to contact the supplier for additional information. (A prescreening letter to the provider is considered to be the first developmental request.)

15.6.1.1.2 – Form CMS-855 and Form CMS-20134 Applications That Do Not Require a Site Visit *and Opt-Out Affidavits*

(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

The contractor shall process 80 percent of all Form CMS-855 and Form CMS-20134 initial and revalidation applications that do not require a site visit *and opt-out affidavits* within 60 calendar days of receipt, process 90 percent of all Form CMS-855 and Form CMS-20134 initial and revalidation applications that do not require a site visit *and opt-out affidavits* within 120 calendar days of receipt, and process 95 percent of all Form CMS-855 and Form CMS-20134 initial and revalidation applications that do not require a site visit *and opt-out affidavits* within 180 calendar days of receipt.

15.6.1.2 - Paper Applications *and Opt-Out Affidavits* – Accuracy

(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

The contractor shall process 98 percent of paper CMS-855 and Form CMS-20134 initial and revalidation applications *and opt-out affidavits* in full accordance with all of the instructions in this chapter (with the exception of the timeliness standards identified in sections 15.6.1.1.1 through 15.6.1.1.4 of this chapter) and all other applicable CMS directives.

15.6.2 – Standards for Changes of Information

(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

For purposes of timeliness, the term "changes of information" also includes:

1. Form CMS-855 and Form CMS-20134 change of ownership, acquisition/merger, and consolidation applications submitted by the old owner

2. Form CMS-588 changes submitted without a need for an accompanying complete Form CMS-855 or Form CMS-20134 application

3. Form CMS-855R applications submitted independently (i.e., without being part of a Form CMS-855I or Form CMS-855B package)

4. Form CMS-855 and Form CMS-20134 voluntary terminations

5. *Opt-out early termination requests (of initial opt-out affidavits), changes of information and cancellation requests*

15.6.2.1 - Paper Applications *and Opt-Out Changes of Information* - Timeliness

(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

The contractor shall process 80 percent of paper Form CMS-855 and Form CMS-20134 changes of information *and opt-out early termination requests, changes of information and cancellation requests* within 60 calendar days of receipt, and process 95 percent of paper Form CMS-855 and Form CMS-20134 changes of information *and opt-out early termination requests, changes of information and cancellation requests* within 120 calendar days of receipt. This process generally includes, but is not limited to, the following activities:

- Receipt of the change *or opt-out termination* request*, cancellation request, or other change of opt-out information* in the contractor's mailroom and forwarding it to the appropriate office for review.

- Prescreening the change request in accordance with existing instructions.

- Creating an L & T record and, if applicable, tying it to an enrollment *or opt-out affidavit* record in PECOS.

- Verification of the change request in accordance with existing instructions.

- Requesting and receiving clarifying information in accordance with existing instructions.

- Supplier site visit (if necessary).

- Formal notification of the contractor's decision or recommendation (and providing the appropriate appeal rights, as necessary).

15.6.2.2 - Paper Applications *and Opt-Out Changes of Information -* Accuracy

(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

The contractor shall process 98 percent of paper Form CMS-855 and Form CMS-20134 changes of information *and opt-out early termination requests, changes of information and cancellation requests* in full accordance with all of the instructions in this chapter (with the exception of the timeliness standards identified in section 15.6.2.1 above) and all other applicable CMS directives.

15.14.7 – Opt*ing-*Out *of Medicare*

(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

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

However, certain types of physicians and practitioners may "opt-out" of Medicare. A physician or practitioner who opts-out is not required to submit claims on behalf of beneficiaries and also is excluded from limits on charges for Medicare covered services. Medicare does not pay anyone for services (except for certain emergency and urgent care services) furnished by an opt-out physician or practitioner. Instead, opt-out physicians and practitioners sign private contracts with beneficiaries. Please refer to Pub. 100-02, Chapter 15, sections 40 – 40.39 for more information regarding maintaining opt-out affidavits and the effects of improper billing of claims during an opt-out period. The instruction included in this chapter is intended for processing opt-out affidavits by the Provider Enrollment staff at the Medicare Administrative Contractors (MACs).

15.14.7.1 – Who May Opt-out of Medicare

(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

Only certain physicians and non-physician practitioners (referred to as "eligible practitioners" in this section), but not organizations, can "opt-out" of Medicare.

Physicians who are:

- *Doctors of medicine or osteopathy,*
- *Doctors of dental surgery or dental medicine,*

- *Doctors of podiatry, or*
- *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.*

Non-Physician Practitioners who are

- *Physician assistants,*
- *Nurse practitioners,*
- *Clinical nurse specialists,*
- *Certified registered nurse anesthetists,*
- *Certified nurse midwives,*
- *Clinical psychologists,*
- *Clinical social workers, or*
- *Registered dietitians or nutrition professionals who are legally authorized to practice by the State and otherwise meet Medicare requirements.*

This means that neither the eligible practitioner nor the beneficiary submits the bill to Medicare for services performed. Instead, the beneficiary pays the physician out-of-pocket and neither party is reimbursed by Medicare. In fact, a private contract is signed between the eligible practitioner and the beneficiary that states, in essence, that neither one can receive payment from Medicare for the services that were performed. (The contract, of course, must be signed before the services are provided so the beneficiary is fully aware of the physician's opt-out status.) Moreover, the eligible practitioner must submit an affidavit to Medicare expressing his/her decision to opt-out of the program. The provider enrollment unit must process these affidavits.

*Eligible Practitioners that opt-out of Medicare are not the same as non-participating physicians/suppliers. Non-participating physicians/suppliers are enrolled in Medicare and choose on a claim-by-claim basis whether they want to accept assignment unless the service can only be paid on an assignment related basis as required by the law (e.g., for drugs, ambulance services, etc.). Therefore, non-participating physicians/suppliers must comply with Medicare's mandatory claim submission, assignment, and limiting charge rules. Conversely, opt-out physicians/practitioners are excused from the mandatory claim submission, assignment, and limiting charge rules but **only** when they maintain compliance with all of the requirements for opting out.*

In an emergency care or urgent care situation, an eligible practitioner who has opted-out may treat a Medicare beneficiary with whom he or she does not have a private contract. In those circumstances, the eligible practitioner must complete a CMS-855 application.

15.14.7.2 – Requirements for an Opt-out Affidavit

(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

As stated in Pub. 100-02, Chapter 15, Section 40.9, the affidavit shall state the following, that upon signing the affidavit, the eligible practitioner agrees to the following requirements:

1. *Except for emergency or urgent care services, during the opt out period the eligible practitioner will provide services to Medicare beneficiaries only through private contracts, but for their provision under a private contract, would have been Medicare-covered services;*

2. *The eligible practitioner will not submit a claim to Medicare for any service furnished to a Medicare beneficiary during the opt out period, nor will the eligible practitioner permit any entity acting on the eligible practitioner's behalf to submit a claim to*

Medicare for services furnished to a Medicare beneficiary;

3. *During the opt out period, the eligible practitioner understands that he/she may receive no direct or indirect Medicare payment for services that the eligible practitioner furnishes to Medicare beneficiaries with whom the eligible 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;*

4. *An eligible practitioner who opts out of Medicare acknowledges that, during the opt out period, the eligible practitioner's services are not covered under Medicare and that no Medicare payment may be made to any entity for the eligible practitioner's services, directly or on a capitated basis;*

5. *On acknowledgment by the eligible practitioner to the effect that, during the opt out period, the eligible practitioner agrees to be bound by the terms of both the affidavit and the private contracts that the eligible practitioner has entered into;*

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

7. *With respect to an eligible practitioner who has signed a Part B participation agreement, acknowledge that such agreement terminates on the effective date of the affidavit;*

8. *Acknowledge that the eligible 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;*

9. *Identify the eligible practitioner sufficiently so that the Medicare contractor can ensure that no payment is made to the eligible practitioner during the opt-out period; and*

10. *Be filed with all MACs who have jurisdiction over claims the eligible practitioner would otherwise file with Medicare, and 42 CFR §405.420 the initial 2-year opt-out period will begin the date the affidavit meeting the requirements of is signed, provided the affidavit is filed within 10 days after the eligible practitioner signs his or her first private contract with a Medicare beneficiary.*

MACs shall review initial opt-out affidavits to ensure that they contain the following information in order to create an affidavit record in PECOS:

The eligible practitioner's personal information:

- *Full name (first, middle and last),*
- *Birthdate,*
- *Address and telephone number,*
- *License information and*
- *NPI (if one has been obtained), and*
- *SSN (if no NPI has been issued).*

If MACs need to obtain any data that may be missing in an affidavit, in order to create a PECOS affidavit record, they may obtain that information from other sources (such as the state license board) or they should contact the eligible practitioner only ***one time*** *directly. Contractors shall* ***not*** *use Internet-Based PECOS or the CMS 855 form to obtain the information from the eligible practitioner, as the eligible practitioner* ***is not*** *enrolling in Medicare. If the eligible practitioner is requested to submit missing information to allow for processing of the affidavit and fails to do so within 30 days, the MAC shall reject the opt-out affidavit.*

15.14.7.2.1 – Opting-out and Ordering and Referring
(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

If an eligible practitioner that wishes to opt-out elects to order and refer items and services, the MACs shall develop for the following information (if not provided on the affidavit):

- *An NPI (if one is not contained on the affidavit voluntarily);*
- *Date of Birth, and;*
- *SSN (if not contained on the Affidavit).*

Note: MACs shall review the List of Excluded Individuals and Entities (LEIE) on the OIG's website and the Excluded Parties List on the GSA's System for Award Management (SAM) for all eligible practitioners that submit opt-out affidavits. Excluded eligible practitioners may opt-out of Medicare, but cannot order or refer.

If the information listed above is requested but not received, the eligible practitioner's affidavit can be processed, but the eligible practitioner cannot be listed as an ordering and referring provider.

15.14.7.2.2 – Acceptable Opt-out Affidavit Formats
(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

MACs may provide a sample opt-out affidavit form for eligible practitioners to complete. The opt-out affidavit form must provide spaces for the eligible practitioners to provide their personal information.

Eligible practitioners may also create their own affidavit. If the practitioner elects to do so, he/she should include information found in Section 15.14.7.2.2.1 to ensure timely processing of their opt-out affidavit.

15.14.7.2.2.1 – Opt Out Affidavit Sample Form
(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

MACs and eligible practitioners may use the information below as their opt-out affidavit form.

I, {Enter Physician/Non-Physician Practitioner Name}, being duly sworn, depose and say:

- *Opt-out is for a period of two years. At the end of the two year period, my opt-out status will automatically renew. If I wish to cancel the automatic extension, I understand that I must notify my Medicare Administrative Contractor (MAC) in writing at least 30 days prior to the start of the next two-year opt- out period.*
- *Except for emergency or urgent care services (as specified in the Medicare Benefit Policy Manual Publication 100-02, Chapter 15 §40.28), during the opt-out period I 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.

- *I will not submit a claim to Medicare for any service furnished to a Medicare beneficiary during the opt-out period, nor will I permit any entity acting on my behalf to submit a claim to Medicare for services furnished to a Medicare beneficiary, except as specified in §40.28.*
- *During the opt-out period, I understand that I may receive no direct or indirect Medicare payment for services that I furnish to Medicare beneficiaries with whom I have 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 Medicare Advantage.*
- *I acknowledge that during the opt-out period, my services are not covered under Medicare and that no Medicare payment may be made to any entity for my services, directly or on a capitated basis.*
- *I acknowledge and agree to be bound by the terms of both the affidavit and the private contracts that I have entered into during the opt-out period.*
- *I acknowledge and understand that the terms of the affidavit apply to all Medicare-covered items and services furnished to Medicare beneficiaries by myself during the opt-out period (except for emergency or urgent care services furnished to the beneficiaries with whom I have not previously privately contracted) without regard to any payment arrangements I may make.*
- *I acknowledge that if I have signed a Part B participation agreement, that such agreement terminates on the effective date of this affidavit.*
- *I acknowledge and understand 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 I furnish such services.*
- *I have identified myself sufficiently so that the MAC can ensure that no payment is made to me during the opt-out period. If I have already enrolled in Medicare, I have included my Medicare PTAN, if one has been assigned. If I have not enrolled in Medicare, I have included the information necessary to opt-out.*
- *I will file this affidavit with all MACs who have jurisdiction over claims that I would otherwise file with Medicare and the initial two- 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.*

Eligible practitioners should also be encouraged to include the following information (to complete an affidavit record in PECOS):

- *Eligible Practitioner's NPI*
- *Eligible Practitioner's Medicare Identification Number (if issued)*
- *Eligible Practitioner's Social Security Number*
- *Eligible Practitioner's Date of Birth*
- *Eligible Practitioner's Specialty*
- *Eligible Practitioner's E-mail Address*
- *Eligible Practitioner's request to Order & Refer*

15.14.7.3 – Requirements of a Private Contract

(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

In order to opt-out of Medicare, the eligible practitioner shall complete a "private contract" with their patients that are Medicare beneficiaries. Please refer to Pub. 100-02, Chapter 15, Section 40.8 for private contract definitions and requirements.

15.14.7.4 – Determining an Effective Date of an Opt-out Period

(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

As noted in Pub. 100-02, Chapter 15, Section 40.17, eligible practitioners receive effective dates based on their participation status.

A. Eligible practitioners that have never enrolled with Medicare

Eligible practitioners are not required to enroll prior to opting-out of Medicare. If a non-enrolled eligible practitioner submits an opt-out affidavit, the effective date of the opt-out period begins the date the affidavit is signed by the eligible practitioner.

B. Previously Enrolled Non-Participating Practitioners

If a previously enrolled eligible practitioner that is a non-participating physicians/suppliers decides to terminate their active Medicare billing enrollment and instead opt-out of Medicare, the effective date of the opt-out period begins the date the affidavit is signed by the eligible practitioner.

C. Previously Enrolled Participating Physicians/Suppliers

If a previously enrolled eligible practitioner that is a participating provider (one that accepts assignment for all their Medicare claims) decides to terminate his/her active Medicare billing enrollment and opt-out of Medicare, the effective date of the opt-out period begins the first day of the next calendar quarter. An opt-out affidavit must be received at least 30 days before the first day of the calendar quarter in order to receive January 1, April 1, July 1 or October 1 as their effective date. If the opt-out affidavit is received within 30 days prior to January 1, April 1, July 1 or October 1, the effective date would be the first day of the next calendar quarter. (For example, an enrolled participating eligible practitioner's opt-out affidavit was submitted on December 10th. The eligible practitioner's effective date could not be January 1, as the affidavit was not received 30 days prior to January 1. The effective date would be April 1.) The eligible practitioner would need to remain enrolled as a participating physician/supplier until the end of the next calendar quarter so that claims can be properly submitted until the opt-out period begins.

15.14.7.5 – Emergency and Urgent Care Services

(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

In the case that an eligible practitioner that has opted-out of Medicare provides emergency or urgent care services, that eligible practitioner must submit an application for enrollment via the Provider Enrollment Chain and Ownership System (PECOS) or a paper CMS-855I application. Once the eligible practitioner has received his/her Provider Transaction Access Number (PTAN), he/she must submit the claim(s) for any emergency or urgent care service provided. MACs shall contact their Provider Enrollment & Oversight Group Business Function Lead (PEOG BFL) for additional guidance when this type of situation arises.

Please refer to Pub. 100-02, Chapter 15, Section 40.28 for more information on Emergency and Urgent Care Services.

15.14.7.6 –Termination of an Opt Out Affidavit
(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

As noted in Pub. 100-02, Chapter 15, Section 40.35, an eligible practitioner who has not previously opted-out may terminate their opt-out period early, however notification must be given to the MAC, in writing, signed by the eligible practitioner no later than 90 days after the effective date of the initial 2-year opt-out period. In order to properly terminate an affidavit, the eligible practitioner must:

1. *Not have previously opted-out of Medicare (the eligible practitioner cannot terminate a renewal of his/her opt-out);*
2. *Notify all the MACs that the eligible practitioner has filed an affidavit no later than 90 days after the effective date of the affidavit;*
3. *Notify all beneficiaries (or their legal representation), that the eligible practitioner entered into private contracts with, of the eligible practitioner's decision to terminate their 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 and;*
4. *Refund to each beneficiary all payments collected in excess of the Medicare limiting charge or deductibles and coinsurance.*

For eligible practitioners that were previously enrolled to bill Medicare for services, the MAC shall reactivate the eligible practitioner's enrollment record in PECOS and reinstate his/her PTAN as if no opt-out affidavit existed. The physician or NPP may bill for services provided during the opt-out period.

For eligible practitioners that were not previously enrolled to bill Medicare for services, the MAC shall remove the affidavit record from PECOS so that the eligible practitioner can submit the appropriate application(s) (via PECOS or paper CMS-855 for individual and/or reassignment enrollment) in order to establish an enrollment record in PECOS, so the physician or NPP may bill for services rendered during the opt-out period.

15.14.7.7 – Opt-out Period Auto-Renewal and Cancellation of the Opt-out Affidavit
(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

Eligible practitioners that initially opted-out or renewed an affidavit on or after June 16, 2015 need not submit a renewal of their affidavit. The opt-out will be automatically renewed for another 2 year period. However, if the eligible practitioner decides to cancel his/her opt-out, he/she must submit a written, signed 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.

If the eligible practitioner decides to enroll in Medicare after his or her opt-out is canceled, he or she must submit an application via PECOS or a paper CMS-855I application. The effective date of enrollment cannot be before the cancellation date of the opt-out period. (For example, an eligible practitioner submits a cancellation of his or her opt-out to end the period on March 31, which is two years from the eligible practitioner's opt-out affidavit effective date. His/her requested Medicare effective date of enrollment cannot be before April 1.)

15.14.7.7.1 – Opt-out Period Auto-Renewal Report and Opt-Out Renewal Alert
(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

The MACs shall issue an Opt-Out Renewal Alert Letter (found in Section 15.24.16.6 of this chapter) to any eligible practitioners whose opt-out period is set to auto-renew.

To accomplish this, CMS will provide a monthly opt-out report to all contractors via the Share Point Ensemble site. The MACs shall access the report monthly through the Share Point Ensemble site. The MACs shall review the opt-out report for opted-out eligible practitioners that will auto-renew in the next 3 and a half months. MACs shall issue an Auto-Renewal Alert Letter to eligible practitioners at least 90 days prior to the auto-renewal date, so the eligible practitioner has at least 60 days prior to the date a cancellation notice must be submitted to cancel the current opt-out.

The Opt-out Auto-Renewal Alert Letter will provide the date the current opt-out period will be auto renewed and the date that the eligible practitioner will need to submit a cancellation request. The letter will provide the eligible practitioner appeal rights if he/she fails to submit a cancellation request and the opt-out renews.

The MACs shall complete the Opt-Out Renewal Alert Letter Report to include the date the Alert Letter was issued and post their reports no later than the 15th of the following month to the Share Point Ensemble site and email their PEOG BFL when the report has been posted.

If an eligible practitioner submits a CMS-855I and/or a CMS-855R (paper or web application) without submitting a cancellation request of his or her opt-out, the MACs shall issue a development for the cancellation notice. Once the cancellation notice is received, the MACs shall then process the application(s).

If the eligible practitioner submits a cancellation request (after development, as noted above, or without a prior application submission) at least 30 days before the end of the current opt-out period or after the opt-out period automatically renews, MACs shall contact their Provider Enrollment & Operations Group (PEOG) Business Function Lead (BFL) for guidance regarding the opt-out cancellation. This guidance will be issued on a case-by-case basis.

15.14.7.8 – Opting-out vs. Enrolling for the Sole Purpose of Ordering and Referring and/or Prescribing
(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

Physicians and certain non-physician practitioners (NPPs) who wish to enroll for the sole purpose of ordering and referring submit an application via PECOS or via the paper form CMS-855O application. These physicians and NPPs do not receive payments from Medicare, as they do not submit claims as performing providers.

An eligible practitioner that has opted out of Medicare does not need to additionally submit an application to enroll as an ordering and referring provider, if they indicate that they wish to order and refer (providing the necessary information on their affidavit as noted in Section 15.14.7.2).

15.14.7.9 – Failure to Properly Cancel or Terminate Opt-out
(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

Eligible practitioners that fail to properly cancel or terminate their opt-out shall be provided an opportunity to appeal the decision to continue the auto-renewal of the opt-out or continuation of the eligible practitioner's initial opt-out period.

The Opt-Out Approval letters include appeal rights for eligible practitioners that initially opt-out and fail to properly terminate the opt-out within 90 days of the approval.

15.24.16 – Model Opt-out Letters
(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

The MACs shall use the model letters in this section to respond to eligible practitioners' opt-out affidavits, request additional documentation, approve opt out affidavits and acknowledge the cancelation or early termination of an opt-out. The MACs shall not use these model letters to respond to Medicare enrollment applications or other correspondence. The MACs may issue the Model Opt-out Development Letter via fax, e-mail or mail to the eligible practitioner.

15.24.16.1 – Opt-out Affidavit Development Letter
(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

MACs shall use the following letter to request missing information from an eligible practitioner that wishes to opt-out of Medicare. This letter should be sent only one time and include a request for all missing information. The MAC may select the response type, either via mail, fax or email.

[month] [day], [year]

[Eligible Practitioner Name] [Address] [City] ST [Zip]

Reference: Case/Control Number

Dear [Eligible Practitioner]:

[Insert MAC] requires the following information to complete the processing of your Medicare opt-out affidavit:

[Specify information needed]

Submit the requested information within 30 calendar days of the postmark date of this letter [to the address listed below, via fax to (###-###-####), or via email to (enter PE analyst's email address here)]. We may reject your opt-out affidavit if you do not furnish the requested information within this timeframe.

[Name of MAC]

[Address]

[City], [ST] [Zip]

Attach a copy of this letter with your revised opt-out affidavit.

For questions concerning this letter, contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM.]

Sincerely,

[Name]
[Title]
[Company]

15.24.16.2 – Opt-out Rejection Letter
(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

In the event that an eligible practitioner does not respond timely or does not respond with needed information to complete an opt-out affidavit, the MACs shall issue this rejection letter.

[month] [day], [year]

[Eligible Practitioner Name] [Address] [City] ST [Zip]

Reference: Case/Control Number

Dear Eligible Practitioner Name:

[Insert MAC] is rejecting your Medicare opt-out affidavit, received on [insert date], for the following reason(s):

[List all reasons for rejection:]

To resubmit your opt-out affidavit include all information needed to process your opt-out request. Additional information on submitting a complete opt-out affidavit can be found at: [enter MAC website address].

Return the completed opt-out affidavit to:

[Name of MAC] [Address]
[City], [ST] [Zip]

For questions concerning this letter, contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Name]
[Title]
[Company]

15.24.16.3 – Opt-out Return Letters
(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

Opt-out affidavits should only be returned for the following reasons:

1. *The eligible practitioner requesting to opt-out of Medicare is not appropriately licensed by the state,*
2. *The practitioner is a specialty that is ineligible to opt-out (e.g., Chiropractic Medicine, Physical Therapy, Occupational Therapy, etc.),*
3. *The opt-out affidavit is filed with an incorrect MAC, or*
4. *The eligible practitioner decides not to opt out of Medicare while their opt-out affidavit is still in process, but not yet approved by the MAC.*

MACs shall issue the specific letter for the return reason.

15.24.16.3.1 – Opt-out Return Letter – Unlicensed Eligible Practitioner
(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

[month] [day], [year]

[Eligible Practitioner Name] [Address] [City] ST [Zip]

Reference: Case/Control Number

Dear [Eligible Practitioner Name]:

[Insert MAC] is returning your Medicare opt-out affidavit, submitted on [insert date], as you are not licensed by the state for the specialty type you indicated on your opt-out affidavit.

For questions concerning this letter, contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Name]
[Title]
[Company]

15.24.16.3.2 – Opt-out Return Letter – Ineligible Practitioner
(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

[month] [day], [year]

[Eligible Practitioner Name] [Address] [City] ST [Zip]

Reference: Case/Control Number

Dear [Eligible Practitioner Name]:

[Insert MAC] is returning your Medicare opt-out affidavit, submitted on [insert date], because you indicated a specialty that is ineligible to opt-out (e.g., Chiropractic Medicine, Physical Therapy, Occupational Therapy, etc.) of Medicare.

For questions concerning this letter, contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Name]
[Title]
[Company]

15.24.16.3.3 – Opt-out Return Letter – Submitted to Incorrect MAC
(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

[month] [day], [year]

[Eligible Practitioner Name] [Address] [City] ST [Zip]

Reference: Case/Control Number

Dear [Eligible Practitioner Name]:

[Insert MAC] is returning your Medicare opt-out affidavit, submitted on [insert date], because your opt-out affidavit was filed with an incorrect Medicare Administrative Contractor for the state that you are located in. Your affidavit should be resubmitted to the appropriate contractor for processing.

For questions concerning this letter, contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Name]
[Title]
[Company]

15.24.16.3.4 – Opt-out Return Letter – Withdraw of Affidavit During Processing
(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

[month] [day], [year]

[Eligible Practitioner Name] [Address] [City] ST [Zip]

Reference: Case/Control Number

Dear [Eligible Practitioner Name]:

[Insert MAC] is returning your Medicare opt-out affidavit, submitted on [insert date], because you have decided to withdraw your opt-out affidavit while it is still in process.

For questions concerning this letter, contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Name]
[Title]
[Company]

15.24.16.4 – Opt-out Affidavit Approval Letters
(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

The MACs shall issue an Opt-out Affidavit Approval ~~this~~ model letter when approving an opt-out affidavit and PECOS has been updated with the affidavit information. The approval letter shall be issued for the following reasons:

1. *Approved Opt-Out, Eligible Practitioner May Order & Refer*
2. *Approved Opt-Out, Eligible Practitioner May Not Order & Refer (OIG Exclusion)*
3. *Approved Opt-Out, Eligible Practitioner May Not Order & Refer (Ineligible Specialty)*
4. *Approved Opt-Out, Eligible Practitioner May Not Order & Refer (Did Not Elect to Order & Refer)*
5. *Approved Opt-Out, Eligible Practitioner May Not Order & Refer (Eligible Practitioner Does Not Have an NPI)*

The Opt-out approval letter shall include:

- *The eligible practitioner's personal information:*
    - *Name,*
    - *Address,*
    - *NPI,*
    - *Specialty, and*
    - *Eligibility to order and refer.*

- *The eligible practitioner's opt-out effective date.*

- *The date that the eligible practitioner can submit a request to cancel their opt-out affidavit (at least 30 days prior to the end-date of their current opt-out period) ~~and~~*

- *The date the eligible practitioner can terminate his/her opt-out early (if they are eligible to so, no later than 90 days after the effective date) of the eligible practitioner's initial 2-year opt-out period.*

15.24.16.4.1 – Opt-out Affidavit Approval Letter – Eligible Practitioner Approved to Order & Refer
(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

[month] [day], [year]

[Eligible Practitioner Name] [Address] [City] ST [Zip]

Reference: Case/Control Number

Dear [Eligible Practitioner Name]:

[Insert MAC] [approved or updated] your Medicare opt-out affidavit.

Opt-out Affidavit Information:

Eligible Practitioner Name:	*[Name]*
Address of File:	*[Address, City, State, Zip]*
National Provider Identifier (NPI):	*[NPI]*
Specialty:	*[Specialty]*
Ordering and Referring:	*You are eligible to Order and Refer*
Effective Date:	*[Effective date]*

Your opt-out will automatically renew every 2 years.

Since you are opting out for the very first time, you have a one-time, 90 day period to change your mind about opting out. If you decide to terminate during this 90 day period, you must submit your request, in writing and signed, no later than [Month DD, YYYY]. After this 90 day period ends, you can only cancel the opt-out at the end of a 2 year opt-out period. If you were unable to submit a termination request, you may appeal after the 90 day period ends. Please follow the Appeal Rights sections below.

To cancel opt-out, you must submit a cancellation request in writing and signed at least 30 days prior to the end of the opt-out period. For example, if you decide you want to cancel your opt-out at the end of this opt-out period, you must submit your cancellation request before [Month DD, YYYY].

APPEAL RIGHTS

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. Reconsideration requests must:

- *Be requested in writing within 60 calendar days of the postmark date of this letter (or within 60 calendar days after the 90-day period to terminate ends) and mailed to the address below.*
- *State the issues or findings of fact with which you disagree and the reasons for disagreement.*
- *Be signed by the eligible practitioner or an authorized legal representative.*
    - *If the authorized legal representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the legal representative.*

- *If the authorized legal representative is not an attorney, the eligible practitioner must file written notice of the appointment of its representative with the submission of the reconsideration request.*

Eligible practitioners may:

- *Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.*
- *Include an email address if you want to receive correspondence regarding your appeal via email.*

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

Send reconsideration requests to:

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
7500 Security Boulevard
Mailstop AR-18-50
Baltimore MD 21244-1850

For questions concerning this letter, contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Name]
[Title]
[Company]

15.24.16.4.2 – Opt-out Affidavit Approval Letter – Eligible Practitioner May Not Order & Refer (Excluded by the OIG)
(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

[month] [day], [year]

[Eligible Practitioner Name] [Address] [City] ST [Zip]

Reference: Case/Control Number

Dear [Eligible Practitioner Name]:

[Insert MAC] [approved or updated] your Medicare opt-out affidavit.

Opt-out Affidavit Information:

Eligible Practitioner Name: *[Name]*
Address of File: *[Address, City, State, Zip]*
National Provider Identifier (NPI): *[NPI]*
Specialty: *[Specialty]*
Ordering and Referring: *You are not eligible to Order and Refer**
Effective Date: *[Effective date]*

** You have been excluded by the OIG (and even if you have or have not obtained a waiver according to 42 CFR §1001.1901(c)), you may opt-out of Medicare, but you are not permitted to order and refer items and services to Medicare beneficiaries*

Your opt-out will automatically renew every 2 years.

Since you are opting out for the very first time, you have a one-time, 90 day period to change your mind about opting out. If you decide to terminate during this 90 day period, you must submit your request, in writing and signed, no later than [Month DD, YYYY]. After this 90 day period ends, you can only cancel the opt-out at the end of a 2 year opt-out period. If you were unable to submit a termination request, you may appeal after the 90 day period ends. Please follow the Appeal Rights sections below.

To cancel opt-out, you must submit a cancellation request in writing and signed at least 30 days prior to the end of the opt-out period. For example, if you decide you want to cancel your opt-out at the end of this opt-out period, you must submit your cancellation request before [Month DD, YYYY].

APPEAL RIGHTS

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. Reconsideration requests must:

- *Be requested in writing within 60 calendar days of the postmark date of this letter (or within 60 calendar days after the 90-day period to terminate ends) and mailed to the address below.*
- *State the issues or findings of fact with which you disagree and the reasons for disagreement.*
- *Be signed by the eligible practitioner or an authorized legal representative.*
    - *If the authorized legal representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the legal representative.*
    - *If the authorized legal representative is not an attorney, the eligible practitioner must file written notice of the appointment of its representative with the submission of the reconsideration request.*

Eligible practitioners may:

- *Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.*

- *Include an email address if you want to receive correspondence regarding your appeal via email.*

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

Send reconsideration requests to:

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
7500 Security Boulevard
Mailstop AR-18-50
Baltimore MD 21244-1850

For questions concerning this letter, contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Name]
[Title]
[Company]

15.24.16.4.3 – Opt-out Affidavit Approval Letter – Eligible Practitioner May Not Order & Refer (Ineligible Specialty)

(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

[month] [day], [year]

[Eligible Practitioner Name] [Address] [City] ST [Zip]

Reference: Case/Control Number

Dear [Eligible Practitioner Name]:

[Insert MAC] [approved or updated] your Medicare opt-out affidavit.

Opt-out Affidavit Information:

Eligible Practitioner Name:	*[Name]*
Address of File:	*[Address, City, State, Zip]*
National Provider Identifier (NPI):	*[NPI]*
Specialty:	*[Specialty]*
Ordering and Referring:	*You are not eligible to Order and Refer**
Effective Date:	*[Effective date]*

** You may opt-out of Medicare, but you are not permitted to order and refer items and services to Medicare beneficiaries, as your specialty is ineligible to order and refer.*

Your opt-out will automatically renew every 2 years.

Since you are opting out for the very first time, you have a one-time, 90 day period to change your mind about opting out. If you decide to terminate during this 90 day period,

you must submit your request, in writing and signed, no later than [Month DD, YYYY]. After this 90 day period ends, you can only cancel the opt-out at the end of a 2 year opt-out period. If you were unable to submit a termination request, you may appeal after the 90 day period ends. Please follow the Appeal Rights sections below.

To cancel opt-out, you must submit a cancellation request in writing and signed at least 30 days prior to the end of the opt-out period. For example, if you decide you want to cancel your opt-out at the end of this opt-out period, you must submit your cancellation request before [Month DD, YYYY].

APPEAL RIGHTS

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. Reconsideration requests must:

- *Be requested in writing within 60 calendar days of the postmark date of this letter (or within 60 calendar days after the 90-day period to terminate ends) and mailed to the address below.*
- *State the issues or findings of fact with which you disagree and the reasons for disagreement.*
- *Be signed by the eligible practitioner or an authorized legal representative.*
    - *If the authorized legal representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the legal representative.*
    - *If the authorized legal representative is not an attorney, the eligible practitioner must file written notice of the appointment of its representative with the submission of the reconsideration request.*

Eligible practitioners may:

- *Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.*
- *Include an email address if you want to receive correspondence regarding your appeal via email.*

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

Send reconsideration requests to:

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
7500 Security Boulevard
Mailstop AR-18-50
Baltimore MD 21244-1850

For questions concerning this letter, contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Name]
[Title]
[Company]

15.24.16.4.4 – Opt-out Affidavit Approval Letter – Eligible Practitioner May Not Order & Refer (Did Not Elect to Order and Refer)
(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

[month] [day], [year]

[Eligible Practitioner Name] [Address] [City] ST [Zip]

Reference: Case/Control Number

Dear [Eligible Practitioner Name]:

[Insert MAC] [approved or updated] your Medicare opt-out affidavit.

Opt-out Affidavit Information:

Eligible Practitioner Name:	*[Name]*
Address of File:	*[Address, City, State, Zip]*
National Provider Identifier (NPI):	*[NPI]*
Specialty:	*[Specialty]*
Ordering and Referring:	*You are not eligible to Order and Refer**
Effective Date:	*[Effective date]*

** You may opt-out of Medicare, but you are not permitted to order and refer items and services to Medicare beneficiaries as you did not elect to be and ordering and referring practitioner on your opt-out affidavit.*

Your opt-out will automatically renew every 2 years.

Since you are opting out for the very first time, you have a one-time, 90 day period to change your mind about opting out. If you decide to terminate during this 90 day period, you must submit your request, in writing and signed, no later than [Month DD, YYYY]. After this 90 day period ends, you can only cancel the opt-out at the end of a 2 year opt-out period. If you were unable to submit a termination request, you may appeal after the 90 day period ends. Please follow the Appeal Rights sections below.

To cancel opt-out, you must submit a cancellation request in writing and signed at least 30 days prior to the end of the opt-out period. For example, if you decide you want to cancel your opt-out at the end of this opt-out period, you must submit your cancellation request before [Month DD, YYYY].

APPEAL RIGHTS

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. Reconsideration requests must:

- *Be requested in writing within 60 calendar days of the postmark date of this letter (or within 60 calendar days after the 90-day period to terminate ends) and mailed to the address below.*
- *State the issues or findings of fact with which you disagree and the reasons for disagreement.*
- *Be signed by the eligible practitioner or an authorized legal representative.*
  - *If the authorized legal representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the legal representative.*
  - *If the authorized legal representative is not an attorney, the eligible practitioner must file written notice of the appointment of its representative with the submission of the reconsideration request.*

Eligible practitioners may:

- *Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.*
- *Include an email address if you want to receive correspondence regarding your appeal via email.*

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

Send reconsideration requests to:

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
7500 Security Boulevard
Mailstop AR-18-50
Baltimore MD 21244-1850

For questions concerning this letter, contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Name]
[Title]
[Company]

15.24.16.4.5 – Opt-out Affidavit Approval Letter – Eligible Practitioner May Not Order & Refer (Eligible Practitioner Does Not Have an NPI)

(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

[month] [day], [year]

[Eligible Practitioner Name] [Address] [City] ST [Zip]

Reference: Case/Control Number

Dear [Eligible Practitioner Name]:

[Insert MAC] [approved or updated] your Medicare opt-out affidavit.

Opt-out Affidavit Information:

Eligible Practitioner Name:	*[Name]*
Address of File:	*[Address, City, State, Zip]*
National Provider Identifier (NPI):	*[Not Provided]*
Specialty:	*[Specialty]*
Ordering and Referring:	*You are not eligible to Order and Refer**
Effective Date:	*[Effective date]*

** You may opt-out of Medicare, but you are not permitted to order and refer items and services to Medicare beneficiaries, as you have not obtained an NPI.*

Your opt-out will automatically renew every 2 years.

Since you are opting out for the very first time, you have a one-time, 90 day period to change your mind about opting out. If you decide to terminate during this 90 day period, you must submit your request, in writing and signed, no later than [Month DD, YYYY]. After this 90 day period ends, you can only cancel the opt-out at the end of a 2 year opt-out period. If you were unable to submit a termination request, you may appeal after the 90 day period ends. Please follow the Appeal Rights sections below.

To cancel opt-out, you must submit a cancellation request in writing and signed at least 30 days prior to the end of the opt-out period. For example, if you decide you want to cancel your opt-out at the end of this opt-out period, you must submit your cancellation request before [Month DD, YYYY].

APPEAL RIGHTS

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. Reconsideration requests must:

- *Be requested in writing within 60 calendar days of the postmark date of this letter (or within 60 calendar days after the 90-day period to terminate ends) and mailed to the address below.*
- *State the issues or findings of fact with which you disagree and the reasons for disagreement.*
- *Be signed by the eligible practitioner or an authorized legal representative.*
    - *If the authorized legal representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the legal representative.*
    - *If the authorized legal representative is not an attorney, the eligible practitioner must file written notice of the appointment of its representative with the submission of the reconsideration request.*

Eligible practitioners may:

- *Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.*
- *Include an email address if you want to receive correspondence regarding your appeal via email.*

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

Send reconsideration requests to:

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
7500 Security Boulevard
Mailstop AR-18-50
Baltimore MD 21244-1850

For questions concerning this letter, contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Name]
[Title]
[Company]

15.24.16.5 –Opt-out Renewal Alert Letter
(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

The MACs shall issue the following letter, informing the eligible practitioner that the opt-out is due to be automatically renewed.

[month] [day], [year]

[Eligible Practitioner Name] [Address] [City] ST [Zip]

Reference: Case/Control Number

Dear Eligible Practitioner Name:

We are writing to inform you that your opt-out will be automatically renewed for a new 2 year opt-out period, on [Month, DD, YYYY].

To cancel your opt-out in the future, you will need to submit a cancellation request at least 30 days prior to the end of your opt-out period, which is [Month DD, YYYY].

If your intention is to cancel your opt-out, but fail to submit a cancellation notice to us, please see the Appeal Rights section of this letter below.

APPEAL RIGHTS

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. Reconsideration requests must:

- *Be requested in writing within 60 calendar days of the auto-renewal date and mailed to the address below.*
- *State the issues or findings of fact with which you disagree and the reasons for disagreement.*
- *Be signed by the eligible practitioner or an authorized legal representative.*
  - *If the authorized legal representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the legal representative.*
  - *If the authorized legal representative is not an attorney, the eligible practitioner must file written notice of the appointment of its representative with the submission of the reconsideration request.*

Eligible practitioners may:

- *Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.*
- *Include an email address if you want to receive correspondence regarding your appeal via email.*

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

Send reconsideration requests to:

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
7500 Security Boulevard
Mailstop AR-18-50
Baltimore MD 21244-1850

For questions concerning this letter, contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Name]
[Title]
[Company]

15.24.16.6 – Opt-out Affidavit Termination Letter
(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

If an eligible practitioner timely terminates his/her initial opt-out, the MACs shall acknowledge this action by using this model letter.

Month DD, YYYY

[Eligible Practitioner Name] [Address] [City] ST [Zip]

Reference: Case/Control Number

Dear [Eligible Practitioner Name]:

[Insert MAC] completed your request to terminate your Medicare opt-out affidavit.

If you have not previously enrolled with Medicare and want to enroll as a Medicare billing provider or for the sole purpose of ordering and referring? Submit the appropriate Provider Enrollment Chain and Ownership System (PECOS) application or paper CMS-855 form.

APPEAL RIGHTS

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. Reconsideration requests must:

- *Be requested in writing within 60 calendar days of the postmark date of this letter and mailed to the address below.*
- *State the issues or findings of fact with which you disagree and the reasons for disagreement.*
- *Be signed by the eligible practitioner or an authorized legal representative.*
    - *If the authorized legal representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the legal representative.*
    - *If the authorized legal representative is not an attorney, the eligible practitioner must file written notice of the appointment of its representative with the submission of the reconsideration request.*

Eligible practitioners may:

- *Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.*
- *Include an email address if you want to receive correspondence regarding your appeal via email.*

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

Send reconsideration requests to:

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
7500 Security Boulevard
Mailstop AR-18-50
Baltimore MD 21244-1850

For questions concerning this letter, contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Name]
[Title]
[Company]

15.24.16.7 – Opt-out Affidavit Cancel Letter
(Rev. 926; Issued: 11-22-19; Effective: 12-24-19; Implementation: 12-24-19)

If an eligible practitioner timely submits an opt-out cancellation request, the MACs shall acknowledge this action by using this model letter.

Month DD, YYYY

[Eligible Practitioner Name] [Address] [City] ST [Zip]

Reference: Case/Control Number

Dear [Eligible Practitioner Name]:

[Insert MAC] completed your request to cancel your Medicare opt-out affidavit.

Your opt-out status will be canceled effective [Month DD, YYYY].

Want to enroll as a Medicare billing provider or for the sole purpose of ordering of referring? Submit the appropriate Provider Enrollment Chain and Ownership System (PECOS) application or paper CMS-855 form.

APPEAL RIGHTS

You may request a reconsideration of this determination. This is an independent review conducted by a person not involved in the initial determination. Reconsideration requests must:

- *Be requested in writing within 60 calendar days of the postmark date of this letter and mailed to the address below.*
- *State the issues or findings of fact with which you disagree and the reasons for disagreement.*
- *Be signed by the eligible practitioner or an authorized legal representative.*

- *If the authorized legal representative is an attorney, the attorney's statement that he or she has the authority to represent the provider or supplier is sufficient to accept this individual as the legal representative.*
- *If the authorized legal representative is not an attorney, the eligible practitioner must file written notice of the appointment of its representative with the submission of the reconsideration request.*

Eligible practitioners may:

- *Submit additional information with the reconsideration that may have a bearing on the decision. However, if you have additional information that you would like a Hearing Officer to consider during the reconsideration or, if necessary, an Administrative Law Judge (ALJ) to consider during a hearing, you must submit that information with your request for reconsideration. This is your only opportunity to submit information during the administrative appeals process unless an ALJ allows additional information to be submitted.*
- *Include an email address if you want to receive correspondence regarding your appeal via email.*

If a reconsideration is not requested, CMS deems this a waiver of all rights to further administrative review. More information regarding appeal rights can be found at 42 C.F.R. Part 498.

Send reconsideration requests to:

Centers for Medicare & Medicaid Services
Center for Program Integrity
Provider Enrollment & Oversight Group
7500 Security Boulevard
Mailstop AR-18-50
Baltimore MD 21244-1850

For questions concerning this letter, contact our office at [phone number] between the hours of [x:00 AM/PM] and [x:00 AM/PM].

Sincerely,

[Name]
[Title]
[Company]