

**§ 405.400 Definitions.**

For purposes of this subpart, the following definitions apply:

*Beneficiary* means an individual who is enrolled in Part B of Medicare.

*Emergency care services* means services furnished to an individual for treatment of an “emergency medical condition” as that term is defined in § 422.2 of this chapter.

*Legal representative* means one or more individuals who, as determined by applicable State law, has the legal authority to enter into the contract with the physician or practitioner on behalf of the beneficiary.

*Opt-out* means the status of meeting the conditions specified in § 405.410.

*Opt-out period* means the 2-year period beginning on the effective date of the affidavit as specified by § 405.410(c)(1) or § 405.410(c)(2), as applicable.

*Participating physician* means a “physician” as defined in this section who has signed an agreement to participate in Part B of Medicare.

*Physician* means a doctor of medicine or a doctor of osteopathy who is currently licensed as that type of doctor in each State in which he or she furnishes services to patients.

*Practitioner* means a physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, clinical psychologist, or clinical social worker, who is currently legally authorized to practice in that capacity by each State in which he or she furnishes services to patients or clients.

*Private contract* means a document that meets the criteria specified in § 405.415.

*Properly opt-out* means to complete, without defect, the requirements for opt-out as specified in § 405.410.

*Properly terminate opt-out* means to complete, without defect, the requirements for terminating opt-out as specified in § 405.445.

*Urgent care services* means services furnished to an individual who requires services to be furnished within 12 hours in order to avoid the likely onset of an emergency medical condition.

**§ 405.405 General rules.**

(a) A physician or practitioner may enter into one or more private contracts with Medicare beneficiaries for the purpose of furnishing items or services that would otherwise be covered by Medicare, provided the conditions of this subpart are met.

(b) A physician or practitioner who enters into at least one private contract with a Medicare beneficiary under the conditions of this subpart, and who submits one or more affidavits in accordance with this subpart, opt-out of Medicare for a 2-year period unless the opt-out is terminated early according to § 405.445. The physician’s or practitioner’s opt-out may be renewed for subsequent 2-year periods.

(c) Both the private contracts described in paragraph (a) of this section and the physician’s or practitioner’s opt-out described in paragraph (b) of this section are null and void if the physician or practitioner fails to properly opt-out in accordance with the conditions of this subpart.

(d) Both the private contracts described in paragraph (a) of this section and the physician’s or practitioner’s opt-out described in paragraph (b) of this section are null and void if the remainder of the opt-out period if the physician or practitioner fails to remain in compliance with the conditions of this subpart during the opt-out period.

(e) Services furnished under private contracts meeting the requirements of this subpart are not covered services under Medicare, and no Medicare payment will be made for such services either directly or indirectly, except as permitted in accordance with § 405.435(c).

**§ 405.410 Conditions for properly opting-out of Medicare.**

The following conditions must be met for a physician or practitioner to properly opt-out of Medicare:

(a) Each private contract between a physician or a practitioner and a Medicare beneficiary that is entered into prior to the submission of the affidavit described in paragraph (b) of this section must meet the specifications of § 405.415.

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(b) The physician or practitioner must submit an affidavit that meets the specifications of § 405.420 to each Medicare carrier with which he or she would file claims absent completion of opt-out.

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

(1) The 2-year opt-out period begins the date the affidavit meeting the requirements of § 405.420 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.

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

(d) A participating physician may properly opt-out of Medicare at the beginning of any calendar quarter, provided that the affidavit described in § 405.420 is submitted to the participating physician's Medicare carriers 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.

**§ 405.415 Requirements of the private contract.**

A private contract under this subpart must:

(a) Be in writing and in print sufficiently large to ensure that the beneficiary is able to read the contract.

(b) Clearly state whether the physician or practitioner is excluded from Medicare under sections 1128, 1156, or

1892 or any other section of the Social Security Act.

(c) State that the beneficiary or his or her legal representative accepts full responsibility for payment of the physician's or practitioner's charge for all services furnished by the physician or practitioner.

(d) State that the beneficiary or his or her legal representative understands that Medicare limits do not apply to what the physician or practitioner may charge for items or services furnished by the physician or practitioner.

(e) State that the beneficiary or his or her legal representative agrees not to submit a claim to Medicare or to ask the physician or practitioner to submit a claim to Medicare.

(f) State that the beneficiary or his or her legal representative understands that Medicare payment will not be made for any items or services furnished by the physician or practitioner that would have otherwise been covered by Medicare if there was no private contract and a proper Medicare claim had been submitted.

(g) State that the beneficiary or his or her legal representative enters into this contract with the knowledge that he or she has the right to obtain Medicare-covered items and services from physicians and practitioners who have not opted-out of Medicare, and that the beneficiary is not compelled to enter into private contracts that apply to other Medicare-covered services furnished by other physicians or practitioners who have not opted-out.

(h) State the expected or known effective date and expected or known expiration date of the opt-out period.

(i) State that the beneficiary or his or her legal representative understands that Medigap plans do not, and that other supplemental plans may elect not to, make payments for items and services not paid for by Medicare.

(j) Be signed by the beneficiary or his or her legal representative and by the physician or practitioner.

(k) Not be entered into by the beneficiary or by the beneficiary's legal representative during a time when the beneficiary requires emergency care services or urgent care services. (However, a physician or practitioner may