

## Centers for Medicare & Medicaid Services, HHS

## § 405.2401

involvement, received reimbursement or supplied goods.

(2) A medical review board member must not review the ESRD services of a facility in which he or she has a direct or indirect financial interest (as described in section 1126(a)(1) of the Act).

[51 FR 30361, Aug. 26, 1986, as amended at 53 FR 1620, Jan. 21, 1988]

### § 405.2114 [Reserved]

### §§ 405.2131–405.2184 [Reserved]

## Subparts V–W [Reserved]

## Subpart X—Rural Health Clinic and Federally Qualified Health Center Services

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 43 FR 8261, Mar. 1, 1978, unless otherwise noted.

### § 405.2400 Basis.

Subpart X is based on the provisions of the following sections of the Act:

(a) Section 1833—Amounts of payment for supplementary medical insurance services.

(b) Section 1861(aa)—Rural health clinic services and Federally qualified health center services covered by the Medicare program.

(c) Section 1834(o)—Federally qualified health center prospective payment system beginning October 1, 2014.

(d) Section 1834(y)—Payment for certain services furnished by rural health clinics.

[79 FR 25473, May 2, 2014, as amended at 88 FR 82176, Nov. 22, 2023]

### § 405.2401 Scope and definitions.

(a) *Scope*. This subpart establishes the requirements for coverage and reimbursement of rural health clinic and Federally qualified health center services under Medicare.

(b) *Definitions*. As used in this subpart, unless the context indicates otherwise:

*Allowable costs* means costs that are incurred by a RHC or FQHC that is authorized to bill based on reasonable costs and are reasonable in amount and

proper and necessary for the efficient delivery of RHC and FQHC services.

*Beneficiary* means an individual enrolled in the Supplementary Medical Insurance program for the Aged and Disabled (part of title XVIII of the Act).

*Certified nurse midwife (CNM)* means an individual who meets the applicable education, training, and other requirements of § 410.77(a) of this chapter.

*Clinical psychologist (CP)* means an individual who meets the applicable education, training, and other requirements of § 410.71(d) of this chapter.

*Clinical social worker (CSW)* means an individual who meets the applicable education, training, and other requirements of § 410.73(a) of this chapter.

*CMS* stands for Centers for Medicare & Medicaid Services.

*Coinsurance* means that portion of the RHC's charge for covered services or that portion of the FQHC's charge or PPS rate for covered services for which the beneficiary is liable (in addition to the deductible, where applicable).

*Covered services* means items or services for which the beneficiary is entitled to have payment made on his or her behalf under this subpart.

*Deductible* means the amount incurred by the beneficiary during a calendar year as specified in § 410.160 and § 410.161 of this chapter.

*Employee* means any individual who, under the common law rules that apply in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986), is considered to be employed by, or an employee of, an entity. (Application of these common law rules is discussed in 20 CFR 404.1007 and 26 CFR 31.3121(d)–1(c).)

*Federally qualified health center (FQHC)* means an entity that has entered into an agreement with CMS to meet Medicare program requirements under § 405.2434 and—

(1) Is receiving a grant under section 330 of the Public Health Service (PHS) Act, or is receiving funding from such a grant under a contract with the recipient of such a grant and meets the requirements to receive a grant under section 330 of the PHS Act;

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(2) Is determined by the HRSA to meet the requirements for receiving such a grant;

(3) Was treated by CMS, for purposes of Medicare Part B, as a comprehensive federally funded health center as of January 1, 1990; or

(4) Is an outpatient health program or facility operated by a tribe or tribal organizations under the Indian Self-Determination Act or by an Urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.

*HRSA* means the Health Resources and Services Administration.

*Intensive outpatient services* means a distinct and organized intensive ambulatory treatment program that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting and that furnishes the services as described in § 410.44 of this chapter.

*Marriage and family therapist (MFT)* means an individual who meets the applicable education, training, and other requirements of § 410.53 of this chapter.

*Medicare Administrative Contractor (MAC)* means an organization that has a contract with the Secretary to administer the benefits covered by this subpart as described in § 421.404 of this chapter.

*Mental health counselor (MHC)* means an individual who meets the applicable education, training, and other requirements of § 410.54 of this chapter.

*Nurse practitioner (NP)* means individuals who meet the applicable education, training, and other requirements of § 410.75(b) of this chapter.

*Physician assistant (PA)* means an individual who meet the applicable education, training, and other requirements of § 410.74(c) of this chapter.

*Prospective payment system (PPS)* means a method of payment in which Medicare payment is made based on a predetermined, fixed amount.

*Reporting period* generally means a period of 12 consecutive months specified by the MAC as the period for which a RHC or FQHC must report required costs and utilization information. The first and last reporting periods may be less than 12 months.

*Rural health clinic (RHC)* means a facility that has—

(1) Been determined by the Secretary to meet the requirements of section 1861(aa)(2) of the Act and part 491 of this chapter concerning RHC services and conditions for approval; and

(2) Filed an agreement with CMS that meets the requirements in § 405.2402 to provide RHC services under Medicare.

*Secretary* means the Secretary of Health and Human Services or his or her delegate.

*Visiting nurse services* means part-time or intermittent nursing care and related medical supplies (other than drugs or biologicals) furnished by a registered professional nurse or licensed practical nurse to a homebound patient.

(Secs. 1102, 1833, 1861(aa), 1871, 1902(a)(13), Social Security Act; 49 Stat. 647, 79 Stat. 302, 322, and 331, 91 Stat. 1485 (42 U.S.C. 1302, 1395l, 1395hh, 1395x(aa), and 1396(a)(13))

[43 FR 8261, Mar. 1, 1978, as amended at 43 FR 30526, July 14, 1978; 47 FR 21049, May 17, 1982; 47 FR 23448, May 28, 1982; 51 FR 41351, Nov. 14, 1986; 57 FR 24975, June 12, 1992; 59 FR 26958, May 25, 1994; 60 FR 63176, Dec. 8, 1995; 61 FR 14657, Apr. 3, 1996; 69 FR 74815, Dec. 24, 2003; 71 FR 55345, Sept. 22, 2006; 79 FR 25473, May 2, 2014; 83 FR 60072, Nov. 23, 2018; 88 FR 79523, Nov. 16, 2023; 88 FR 82176, Nov. 22, 2023]

### § 405.2402 Rural health clinic basic requirements.

(a) *Certification by the State survey agency.* The rural health clinic must be certified in accordance with part 491 of this chapter.

(b) *Acceptance of the clinic as qualified to furnish RHC services.* If the Secretary, after reviewing the survey agency or accrediting organization recommendation, as applicable, and other evidence relating to the qualifications of the clinic, determines that the clinic meets the requirements of this subpart and of part 491 of this chapter, the clinic is provided with—

(1) Written notice of the determination; and

(2) Two copies of the agreement to be filed as required by section 1861(aa)(1) of the Act.

(c) *Filing of agreement by the clinic.* If the clinic wishes to participate in the program, it must—

(1) Have both copies of the agreement signed by an authorized representative; and

(2) File them with the Secretary.

(d) *Acceptance by the Secretary.* If the Secretary accepts the agreement filed by the clinic, the Secretary returns to the clinic one copy of the agreement with a notice of acceptance specifying the effective date.

(e) *Appeal rights.* If CMS declines to enter into an agreement or if CMS terminates an agreement, the clinic is entitled to a hearing in accordance with § 498.3(b)(5) and (6) of this chapter.

[43 FR 8261, Mar. 1, 1978, as amended at 52 FR 22454, June 12, 1987; 79 FR 25474, May 2, 2014]

**§ 405.2403 Rural health clinic content and terms of the agreement with the Secretary.**

(a) Under the agreement, the RHC agrees to the following:

(1) *Maintaining compliance with conditions.* The RHC agrees to maintain compliance with the conditions set forth in part 491 of this chapter and to report promptly to CMS any failure to do so.

(2) *Charges to beneficiaries.* The RHC agrees not to charge the beneficiary or any other person for items and services for which the beneficiary is entitled to have payment made under the provisions of this part (or for which the beneficiary would have been entitled if the RHC had filed a request for payment in accordance with § 410.165 of this chapter), except for any deductible or coinsurance amounts for which the beneficiary is liable under § 405.2410.

(3) *Refunds to beneficiaries.* (i) The RHC agrees to refund as promptly as possible any money incorrectly collected from beneficiaries or from someone on their behalf.

(ii) As used in this section, *money incorrectly collected* means sums collected in excess of the amount for which the beneficiary was liable under § 405.2410. It includes amounts collected at a time when the beneficiary was believed not to be entitled to Medicare benefits but:

(A) The beneficiary is later determined to have been entitled to Medicare benefits; and

(B) The beneficiary's entitlement period falls within the time the RHC's agreement with the Secretary is in effect.

(4) *Beneficiary treatment.* (i) The RHC agrees to accept beneficiaries for care and treatment; and

(ii) The RHC agrees not to impose any limitations on the acceptance of beneficiaries for care and treatment that it does not impose on all other persons.

(b) *Additional provisions.* The agreement may contain any additional provisions that the Secretary finds necessary or desirable for the efficient and effective administration of the Medicare program.

[43 FR 8261, Mar. 1, 1978, as amended at 51 FR 41351, Nov. 14, 1986; 79 FR 25474, May 2, 2014]

**§ 405.2404 Termination of rural health clinic agreements.**

(a) *Termination by RHC—*(1) *Notice to Secretary.* If the RHC wishes to terminate its agreement it shall file with the Secretary a written notice stating the intended effective date of termination.

(2) *Action by the Secretary.* (i) The Secretary may approve the date proposed by the RHC, or set a different date no later than 6 months after the date of the RHC's notice.

(ii) The Secretary may approve a date which is less than 6 months after the date of notice if the Secretary determines that termination on that date would not:

(A) Unduly disrupt the furnishing of services to the community serviced by the RHC; or

(B) Otherwise interfere with the effective and efficient administration of the Medicare program.

(3) *Cessation of business.* If a RHC ceases to furnish services to the community, the Secretary deems it to be a voluntary termination of the agreement by the RHC, effective on the last day of business.

(b) *Termination by the Secretary—*(1) *Cause for termination.* The Secretary may terminate an agreement if he or she determines that the RHC:

(i) No longer meets the conditions for certification under part 491 of this chapter;

(ii) Is not in substantial compliance with the provisions of the agreement, the requirements of this subpart, any other applicable regulations of this part, or any applicable provisions of title XVIII of the Act; or

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(iii) Has undergone a change of ownership.

(2) *Notice of termination.* The Secretary gives notice of termination to the RHC at least 15 days before the effective date stated in the notice.

(3) *Appeal by the RHC.* A RHC may appeal the termination of its agreement in accordance with the provisions set forth in part 498 of this chapter.

(c) *Effect of termination.* Payment will not be available for RHC services furnished on or after the effective date of termination.

(d) *Notice to the public.* Prompt notice of the date and effect of termination must be given to the public by either of the following:

(1) The RHC, after the Secretary has approved or set a termination date.

(2) The Secretary, when he or she has terminated the agreement.

(e) *Conditions for reinstatement after termination of agreement by the Secretary.* When an agreement with a RHC is terminated by the Secretary, the RHC may not file another agreement to participate in the Medicare program unless the Secretary:

(1) Finds that the reason for the termination of the prior agreement has been removed; and

(2) Is assured that the reason for the termination will not recur.

[43 FR 8261, Mar. 1, 1978, as amended at 52 FR 22454, June 12, 1987; 79 FR 25474, May 2, 2014; 82 FR 38509, Aug. 14, 2017]

### § 405.2410 Application of Part B deductible and coinsurance.

(a) *Application of deductible.* (1) Medicare payment for RHC services begins only after the beneficiary has incurred the deductible.

(2) Medicare payment for services covered under the FQHC benefit is not subject to the usual Part B deductible.

(b) *Application of coinsurance.* Except for preventive services for which Medicare pays 100 percent under § 410.152(l) of this chapter, a beneficiary's responsibility is either of the following:

(1) For RHCs that are authorized to bill on the basis of the reasonable cost system—

(i) A coinsurance amount that does not exceed 20 percent of the RHC's reasonable customary charge for the covered service; and

(ii)(A) The beneficiary's deductible and coinsurance amount for any one item or service furnished by the RHC may not exceed a reasonable amount customarily charged by the RHC for that particular item or service; or

(B) For any one item or service furnished by a FQHC, a coinsurance amount that does not exceed 20 percent of a reasonable customary charge by the FQHC for that particular item or service.

(2) For FQHCs authorized to bill under the PPS, a coinsurance amount which is 20 percent of the lesser of—

(i) The FQHC's actual charge; or

(ii) The FQHC PPS rate for the covered service.

(c) *Application of deductible and coinsurance for RHCs and FQHCs paid on the basis of the special payment rule described under § 405.2462(j).* (1) For RHCs, a coinsurance amount that does not exceed 20 percent of the payment determined under § 405.2462(j)(1); or

(2) For FQHCs, a coinsurance amount that does not exceed 20 percent of the payment determined under § 405.2462(j)(2).

[71 FR 55345, Sept. 22, 2006, as amended at 79 FR 25474, May 2, 2014; 80 FR 71371, Nov. 16, 2015; 88 FR 82176, Nov. 22, 2023]

### § 405.2411 Scope of benefits.

(a) The following RHC and FQHC services are reimbursable under this subpart:

(1) The physicians' services specified in § 405.2412.

(2) Services and supplies furnished as an incident to a physician's professional service.

(3) The nurse practitioner or physician assistant services specified in § 405.2414.

(4) Services and supplies furnished as incident to the services of a nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor.

(5) Visiting nurse services when provided in accordance with 1861(aa)(1) of the Act and § 405.2416.

(6) Clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor services as specified in § 405.2450.

(7) Intensive outpatient services when provided in accordance with section 1861(ff)(4) of the Act and § 410.44 of this chapter.

(b) RHC and FQHC services are—

(1) Covered when furnished in a RHC, FQHC, or other outpatient setting, including a patient's place of residence;

(2) Covered when furnished during a Part A stay in a skilled nursing facility only when provided by a physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor employed or under contract with the RHC or FQHC at the time the services are furnished;

(3) Inclusive of hospice attending physician services, and are covered when furnished during a patient's hospice election only when provided by an RHC/FQHC physician, nurse practitioner, or physician assistant designated by the patient as his or her attending physician and employed or under contract with the RHC or FQHC at the time the services are furnished; and

(4) Not covered in a—

(i) Hospital as defined in section 1861(e) of the Act; or

(ii) Critical access hospital as defined in section 1861(mm)(1) of the Act.

[43 FR 8261, Mar. 1, 1978, as amended at 79 FR 25475, May 2, 2014; 86 FR 65660, Nov. 19, 2021; 88 FR 79523, Nov. 16, 2023; 88 FR 82176, Nov. 22, 2023]

#### § 405.2412 Physicians' services.

Physicians' services are professional services that are furnished by either of the following:

(a) By a physician at the RHC or FQHC.

(b) Outside of the RHC or FQHC by a physician whose agreement with the RHC or FQHC provides that he or she will be paid by the RHC or FQHC for such services and certification and cost reporting requirements are met.

[79 FR 25475, May 2, 2014]

#### § 405.2413 Services and supplies incident to a physician's services.

(a) Services and supplies incident to a physician's professional service are reimbursable under this subpart if the service or supply is:

(1) Of a type commonly furnished in physicians' offices;

(2) Of a type commonly rendered either without charge or included in the RHC's or FQHC's bill;

(3) Furnished as an incidental, although integral, part of a physician's professional services;

(4) Services and supplies must be furnished in accordance with applicable State law; and

(5) Furnished under the direct supervision of a physician, except that services and supplies furnished incident to Transitional Care Management, General Care Management, the Psychiatric Collaborative Care Model, and behavioral health services can be furnished under general supervision of a physician when these services or supplies are furnished by auxiliary personnel, as defined in § 410.26(a)(1) of this chapter.

(b) Only drugs and biologicals which cannot be self-administered are included within the scope of this benefit.

[43 FR 8261, Mar. 1, 1978, as amended at 78 FR 74810, Dec. 10, 2013; 79 FR 25475, May 2, 2014; 79 FR 68001, Nov. 13, 2014; 81 FR 80552, Nov. 15, 2016; 82 FR 53358, Nov. 15, 2017; 88 FR 79523, Nov. 16, 2023]

#### § 405.2414 Nurse practitioner, physician assistant, and certified nurse midwife services.

(a) Professional services are payable under this subpart if the services meet all of the following:

(1) Furnished by a nurse practitioner, physician assistant, or certified nurse midwife who is employed by, or receives compensation from, the RHC or FQHC.

(2) Furnished under the medical supervision of a physician.

(3) Furnished in accordance with any medical orders for the care and treatment of a patient prepared by a physician.

(4) Are of a type which the nurse practitioner, physician assistant or certified nurse midwife who furnished the service is legally permitted to perform by the State in which the service is rendered.

(5) The services would be covered if furnished by a physician.

(b) The physician supervision requirement is met if the conditions specified in § 491.8(b) of this chapter and

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any pertinent requirements of State law are satisfied.

(c) The services of nurse practitioners, physician assistants or certified nurse midwives are not covered if State law or regulations require that the services be performed under a physician's order and no such order was prepared.

[43 FR 8261, Mar. 1, 1978, as amended at 79 FR 25475, May 2, 2014]

#### § 405.2415 Incident to services and direct supervision.

(a) Services and supplies incident to the services of a nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor are payable under this subpart if the service or supply is all of the following:

(1) Of a type commonly furnished in physicians' offices.

(2) Of a type commonly rendered either without charge or included in the RHC's or FQHC's bill.

(3) Furnished as an incidental, although integral part of professional services furnished by a nurse practitioner, physician assistant, certified nurse-midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor.

(4) Furnished in accordance with applicable State law.

(5) Furnished under the direct supervision of a nurse practitioner, physician assistant, or certified nurse-midwife, except that services and supplies furnished incident to Transitional Care Management, General Care Management, the Psychiatric Collaborative Care model, and behavioral health services can be furnished under general supervision of a nurse practitioner, physician assistant, or certified nurse-midwife, when these services or supplies are furnished by auxiliary personnel, as defined in § 410.26(a)(1) of this chapter.

(b) The direct supervision requirement is met in the case of any of the following persons only if the person is permitted to supervise these services under the written policies governing the RHC or FQHC:

(1) Nurse practitioner.

(2) Physician assistant.

(3) Certified nurse-midwife.

(4) Clinical psychologist.

(5) Clinical social worker.

(6) Marriage and family therapist.

(7) Mental health counselor.

(c) Only drugs and biologicals which cannot be self-administered are included within the scope of this benefit.

[79 FR 25475, May 2, 2014, as amended at 79 FR 68001, Nov. 13, 2014; 81 FR 80552, Nov. 15, 2016; 82 FR 53358, Nov. 15, 2017; 88 FR 79523, Nov. 16, 2023]

#### § 405.2416 Visiting nurse services.

(a) Visiting nurse services are covered if the services meet all of the following:

(1) The RHC or FQHC is located in an area in which the Secretary has determined that there is a shortage of home health agencies.

(2) The services are rendered to a homebound individual.

(3) The services are furnished by a registered professional nurse or licensed practical nurse that is employed by, or receives compensation for the services from the RHC or FQHC.

(4) The services are furnished under a written plan of treatment that is both of the following:

(i)(A) Established and reviewed at least every 60 days by a supervising physician of the RHC or FQHC; or

(B)(I) Established by a nurse practitioner, physician assistant or certified nurse midwife; and

(2) Reviewed at least every 60 days by a supervising physician.

(ii) Signed by the supervising physician, nurse practitioner, physician assistant or certified nurse midwife of the RHC or FQHC.

(5) During a PHE, as defined in § 400.200 of this chapter, an area typically served by the RHC, and an area that is included in the FQHC's service area plan, is determined to have a shortage of home health agencies, and no request for this determination is required.

(b) The nursing care covered by this section includes the following:

(1) Services that must be performed by a registered professional nurse or licensed practical nurse if the safety of the patient is to be assured and the medically desired results achieved.

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(2) Personal care services, to the extent covered under Medicare as home health services. These services include helping the patient to bathe, to get in and out of bed, to exercise and to take medications.

(c) This benefit does not cover household and housekeeping services or other services that would constitute custodial care.

(d) For purposes of this section, *homebound* means an individual who is permanently or temporarily confined to his or her place of residence because of a medical or health condition. The individual may be considered homebound if he or she leaves the place of residence infrequently. For this purpose, “place of residence” does not include a hospital or long term care facility.

[43 FR 8261, Mar. 1, 1978, as amended at 79 FR 25475, May 2, 2014; 85 FR 19285, Apr. 6, 2020]

**§ 405.2417 Visiting nurse services: Determination of shortage of agencies.**

A shortage of home health agencies exists if the Secretary determines that the RHC or FQHC:

(a) Is located in a county, parish, or similar geographic area in which there is no participating home health agency or adequate home health services are not available to patients of the RHC or FQHC.

(b) Has (or expects to have) patients whose permanent residences are not within the area serviced by a participating home health agency.

(c) Has (or expects to have) patients whose permanent residences are not within a reasonable traveling distance, based on climate and terrain, of a participating home health agency.

[43 FR 8261, Mar. 1, 1978, as amended at 79 FR 25476, May 2, 2014]

**FEDERALLY QUALIFIED HEALTH CENTER SERVICES**

SOURCE: 57 FR 24978, June 12, 1992, unless otherwise noted.

**§ 405.2430 Basic requirements.**

(a) *Filing procedures.* (1) In response to a request from an entity that wishes to participate in the Medicare program, CMS enters into an agreement

with an entity when all of the following occur:

(i) HRSA approves the entity as meeting the requirements of section 330 of the PHS Act.

(ii) The entity assures CMS that it meets the requirements specified in this subpart and part 491 of this chapter, as described in § 405.2434(a).

(iii) The FQHC terminates other provider agreements, unless the FQHC assures CMS that it is not using the same space, staff and resources simultaneously as a physician’s office or another type of provider or supplier. A corporate entity may own other provider types as long as the provider types are distinct from the FQHC.

(2) CMS sends the entity a written notice of the disposition of the request.

(3) When the requirement of paragraph (a)(1) of this section is satisfied, CMS sends the entity two copies of the agreement. The entity must sign and return both copies of the agreement to CMS.

(4) If CMS accepts the agreement filed by the FQHC, CMS returns to the center one copy of the agreement with the notice of acceptance specifying the effective date (see § 489.11), as determined under § 405.2434.

(b) *Prior HRSA FQHC determination.* An entity applying to become a FQHC must do the following:

(1) Be determined by HRSA as meeting the applicable requirements of the PHS Act, as specified in § 405.2401(b).

(2) Receive approval by HRSA as a FQHC under section 330 of the PHS Act (42 U.S.C. 254b).

(c) *Appeals.* An entity is entitled to a hearing in accordance with part 498 of this chapter when CMS fails to enter into an agreement with the entity.

[57 FR 24978, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996; 79 FR 25476, May 2, 2014]

**§ 405.2434 Content and terms of the agreement.**

Under the agreement, the FQHC must agree to the following:

(a) *Maintain compliance with the requirements.* (1) The FQHC must agree to maintain compliance with the FQHC requirements set forth in this subpart and part 491, except that the provisions of § 491.3 do not apply.

(2) FQHCs must promptly report to CMS any changes that result in non-compliance with any of these requirements.

(b) *Effective date of agreement.* The effective date of the agreement is determined in accordance with the provisions of § 489.13 of this chapter.

(c) *Charges to beneficiaries.* (1) For non-FQHC services that are billed to Part B, the beneficiary is responsible for payment of a coinsurance amount which is 20 percent of the amount of Part B payment made to the FQHC for the covered services.

(2) The beneficiary is responsible for blood deductible expenses, as specified in § 410.161.

(3) The FQHC agrees not to charge the beneficiary (or any other person acting on behalf of a beneficiary) for any FQHC services for which the beneficiary is entitled to have payment made on his or her behalf by the Medicare program (or for which the beneficiary would have been entitled if the FQHC had filed a request for payment in accordance with § 410.165 of this chapter), except for coinsurance amounts.

(4) The FQHC may charge the beneficiary for items and services that are not FQHC services. If the item or service is covered under Medicare Part B, the FQHC may not charge the beneficiary more than 20 percent of the Part B payment amount.

(d) *Refunds to beneficiaries.* (1) The FQHC must agree to refund as promptly as possible any money incorrectly collected from Medicare beneficiaries or from someone on their behalf.

(2) As used in this section, “money incorrectly collected” means any amount for covered services that is greater than the amount for which the beneficiary was liable because of the coinsurance requirements specified in part 410, subpart E.

(3) Amounts also are considered incorrectly collected if the FQHC believed the beneficiary was not entitled to Medicare benefits but—

(i) The beneficiary was later determined to have been so entitled;

(ii) The beneficiary’s entitlement period fell within the time the FQHC’s agreement with CMS was in effect; and

(iii) The amounts exceed the beneficiary’s coinsurance liability.

(e) *Treatment of beneficiaries.* (1) The FQHC must agree to accept Medicare beneficiaries for care and treatment.

(2) The FQHC may not impose any limitations with respect to care and treatment of Medicare beneficiaries that it does not also impose upon all other persons seeking care and treatment from the FQHC. Failure to comply with this requirement is a cause for termination of the FQHC’s agreement with CMS in accordance with § 405.2436(d).

(3) If the FQHC does not furnish treatment for certain illnesses and conditions to patients who are not Medicare beneficiaries, it need not furnish such treatment to Medicare beneficiaries.

[57 FR 24978, June 12, 1992, as amended at 79 FR 25476, May 2, 2014]

**§ 405.2436 Termination of agreement.**

(a) *Termination by FQHC.* The FQHC may terminate its agreement by—

(1) Filing with CMS a written notice stating its intention to terminate the agreement; and

(2) Notifying CMS of the date on which the FQHC requests that the termination take effect.

(b) *Effective date.* (1) Upon receiving a FQHC’s notice of intention to terminate the agreement, CMS will set a date upon which the termination takes effect. This effective date may be—

(i) The date proposed by the FQHC in its notice of intention to terminate, if that date is acceptable to CMS; or

(ii) Except as specified in paragraph (2) of this section, a date set by CMS, which is no later than 6 months after the date CMS receives the FQHC’s notice of intention to terminate.

(2) The effective date of termination may be less than 6 months following CMS’s receipt of the FQHC’s notice of intention to terminate if CMS determines that termination on such a date would not—

(i) Unduly disrupt the furnishing of FQHC services to the community; or

(ii) Otherwise interfere with the effective and efficient administration of the Medicare program.

(3) The termination is effective at the end of the last day of business as a FQHC.

(c) *Termination by CMS.* (1) CMS may terminate an agreement with a FQHC if it finds that the FQHC—

(i) No longer meets the requirements specified in this subpart; or

(ii) Is not in substantial compliance with—

(A) The provisions of the agreement; or

(B) The requirements of this subpart, any other applicable regulations of this part, or any applicable provisions of title XVIII of the Act.

(2) *Notice by CMS.* CMS will notify the FQHC in writing of its intention to terminate an agreement at least 15 days before the effective date stated in the written notice.

(3) *Appeal.* A FQHC may appeal CMS's decision to terminate the agreement in accordance with part 498 of this chapter.

(d) *Effect of termination.* When a FQHC's agreement is terminated whether by the FQHC or CMS, payment will not be available for FQHC services furnished on or after the effective date of termination.

[57 FR 24978, June 12, 1992, as amended at 79 FR 25476, May 2, 2014]

#### § 405.2440 Conditions for reinstatement after termination by CMS.

When CMS has terminated an agreement with a FQHC, CMS does not enter into another agreement with the FQHC to participate in the Medicare program unless CMS—

(a) Finds that the reason for the termination no longer exists; and

(b) Is assured that the reason for the termination of the prior agreement will not recur.

[57 FR 24978, June 12, 1992, as amended at 79 FR 25476, May 2, 2014]

#### § 405.2442 Notice to the public.

(a) When the FQHC voluntarily terminates the agreement and an effective date is set for the termination, the FQHC must notify the public in the area serviced by the FQHC prior to a prospective effective date or on the actual day that business ceases, if no prospective date of termination has been set. The notice must include—

(1) Effective date of termination of the provision of services; and

(2) Effect of termination of the agreement.

(b) When CMS terminates the agreement, CMS will notify the public in the area serviced by the FQHC.

[57 FR 24978, June 12, 1992, as amended at 79 FR 25476, May 2, 2014; 82 FR 38509, Aug. 14, 2017]

#### § 405.2444 Change of ownership.

(a) *What constitutes change of ownership—*(1) *Incorporation.* The incorporation of an unincorporated FQHC constitutes change of ownership.

(2) *Merger.* The merger of the FQHC corporation into another corporation, or the consolidation of two or more corporations, one of which is the FQHC corporation, resulting in the creation of a new corporation, constitutes a change of ownership. (The merger of another corporation into the FQHC corporation does not constitute change of ownership.)

(3) *Leasing.* The lease of all or part of an entity constitutes a change of ownership of the leased portion.

(b) *Notice to CMS.* A FQHC which is contemplating or negotiating change of ownership must notify CMS.

(c) *Assignment of agreement.* When there is a change of ownership as specified in paragraph (a) of this section, the agreement with the existing FQHC is automatically assigned to the new owner if it continues to meet the conditions to be a FQHC.

(d) *Conditions that apply to assigned agreements.* An assigned agreement is subject to all applicable statutes and regulations and to the terms and conditions under which it was originally issued including, but not limited to, the following:

(1) Compliance with applicable health and safety standards.

(2) Compliance with the ownership and financial interest disclosure requirements of part 420, subpart C of this subchapter.

[57 FR 24978, June 12, 1992, as amended at 79 FR 25476, May 2, 2014]

#### § 405.2446 Scope of services.

(a) For purposes of this section, the terms rural health clinic and RHC

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when they appear in the cross references in paragraph (b) of this section also mean Federally qualified health centers and FQHCs.

(b) FQHC services that are paid for under this subpart are outpatient services that include the following:

(1) Physician services specified in § 405.2412.

(2) Services and supplies furnished as incident to a physician's professional service, as specified in § 405.2413.

(3) Nurse practitioner, physician assistant or certified nurse midwife services as specified in § 405.2414.

(4) Services and supplies furnished as incident to a nurse practitioner, physician assistant, or certified nurse midwife service, as specified in § 405.2415.

(5) Clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor services specified in § 405.2450.

(6) Services and supplies furnished as incident to the services of a clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor, as specified in § 405.2452.

(7) Visiting nurse services specified in § 405.2416.

(8) Preventive primary services specified in § 405.2448 of this subpart.

(9) Medical nutrition therapy services as specified in part 410, subpart G of this chapter, and diabetes outpatient self-management training services as specified in part 410, subpart H of this chapter.

(10) Intensive outpatient services when provided in accordance with section 1861(ff)(4) of the Act and § 410.44 of this chapter.

(c) FQHC services are covered when provided in outpatient settings only, including a patient's place of residence, which may be a skilled nursing facility or a nursing facility, other institution used as a patient's home, or are hospice attending physician services furnished during a hospice election.

(d) FQHC services are not covered in a hospital, as defined in section 1861(e)(1) of the Act.

[57 FR 24979, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996; 71 FR 69782, Dec. 1, 2006; 79 FR 25476, May 2, 2014; 86 FR 65660, Nov. 19, 2021; 88 FR 79524, Nov. 16, 2023; 88 FR 82176, Nov. 22, 2023]

## § 405.2448 Preventive primary services.

(a) Preventive primary services are those health services that—

(1) A FQHC is required to provide as preventive primary health services under section 330 of the PHS Act; and

(2) Are furnished by a or under the direct supervision of a physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor employed by or under contract with the FQHC.

(i) By a or under the direct supervision of a physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor; or

(ii) By a member of the FQHC's health care staff who is an employee of the FQHC or by a physician under arrangements with the FQHC.

(3) Except as specifically provided in section 1861(s) of the Act, include only drugs and biologicals that cannot be self-administered.

(b) Preventive primary services which may be paid for when provided by FQHCs are the following:

(1) Medical social services.

(2) Nutritional assessment and referral.

(3) Preventive health education.

(4) Children's eye and ear examinations.

(5) Prenatal and post-partum care.

(6) Perinatal services.

(7) Well child care, including periodic screening.

(8) Immunizations, including tetanus-diphtheria booster and influenza vaccine.

(9) Voluntary family planning services.

(10) Taking patient history.

(11) Blood pressure measurement.

(12) Weight.

(13) Physical examination targeted to risk.

(14) Visual acuity screening.

(15) Hearing screening.

(16) Cholesterol screening.

(17) Stool testing for occult blood.

(18) Dipstick urinalysis.

(19) Risk assessment and initial counseling regarding risks.

(20) Tuberculosis testing for high risk patients.

(21) For women only.

(i) Clinical breast exam.

(ii) Referral for mammography; and

(iii) Thyroid function test.

(c) Preventive primary services do not include group or mass information programs, health education classes, or group education activities, including media productions and publications.

(d) Screening mammography is not considered a FQHC service, but may be provided at a FQHC if the FQHC if the center meets the requirements applicable to that service specified in § 410.34 of this subchapter. Payment is made under applicable Medicare requirements.

(e) Preventive primary services do not include eyeglasses, hearing aids, or preventive dental services.

[57 FR 24980, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996; 79 FR 25477, May 2, 2014; 80 FR 71371, Nov. 16, 2015; 88 FR 79524, Nov. 16, 2023]

#### § 405.2449 Preventive services.

For services furnished on or after January 1, 2011, preventive services covered under the Medicare FQHC benefit are those preventive services defined in section 1861(ddd)(3) of the Act, and § 410.2 of this chapter. Specifically, these include the following:

(a) The specific services currently listed in section 1861(ww)(2) of the Act, with the explicit exclusion of electrocardiograms.

(b) The Initial Preventive Physical Examination (IPPE) (as specified by section 1861(ww)(1) of the Act as added by section 611 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108-173) and § 410.16 of this chapter).

(c) The Personalized Prevention Plan Services (PPPS), also known as the “Annual Wellness Visit” (as specified by section 1861(hhh) of the Act as added by section 4103 of the Affordable Care Act (Pub. L. 111-148) and § 410.15 of this chapter).

[75 FR 73613, Nov. 29, 2010, as amended at 79 FR 25477, May 2, 2014]

#### § 405.2450 Clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor services.

(a) For clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor professional services to be payable under this subpart, the services must be—

(1) Furnished by an individual who owns, is employed by, or furnishes services under contract to the FQHC;

(2) Of a type that the clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor who furnishes the services is legally permitted to perform by the State in which the service is furnished;

(3) Performed by a clinical social worker, clinical psychologist, marriage and family therapist, or mental health counselor who is legally authorized to perform such services under State law or the State regulatory mechanism provided by the law of the State in which such services are performed; and

(4) Covered if furnished by a physician.

(b) If State law prescribes a physician supervision requirement, it is met if the conditions specified in § 491.8(b) of this chapter and any pertinent requirements of State law are satisfied.

(c) The services of clinical psychologists, clinical social workers, marriage and family therapist, or mental health counselors are not covered if State law or regulations require that the services be performed under a physician's order and no such order was prepared.

[57 FR 24980, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996; 88 FR 79524, Nov. 16, 2023]

#### § 405.2452 Services and supplies incident to clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor services.

(a) Services and supplies incident to a clinical psychologist's, clinical social worker's, marriage and family therapist's, and mental health counselor's services are reimbursable under this subpart if the service or supply is —

(1) Of a type commonly furnished in a physician's office;

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(2) Of a type commonly furnished either without charge or included in the FQHC's bill;

(3) Furnished as an incidental, although integral part of professional services furnished by a clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor;

(4) Services and supplies must be furnished in accordance with applicable State law; and

(5) Furnished under the direct supervision of a clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor.

(b) The direct supervision requirement in paragraph (a)(5) of this section is met only if the clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor is permitted to supervise such services under the written policies governing the FQHC.

[43 FR 8261, Mar. 1, 1978, as amended at 78 FR 74810, Dec. 10, 2013; 79 FR 25477, May 2, 2014; 79 FR 68001, Nov. 13, 2014; 88 FR 79524, Nov. 16, 2023]

### PAYMENT FOR RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES

SOURCE: 57 FR 24976, 24977, June 12, 1992, unless otherwise noted.

#### § 405.2460 Applicability of general payment exclusions.

The payment conditions, limitations, and exclusions set out in subpart C of this part, part 410 and part 411 of this chapter are applicable to payment for services provided by RHCs and FQHCs, except that preventive primary services, as defined in § 405.2448, are statutorily authorized for FQHCs and not excluded by the provisions of section 1862(a) of the Act.

[79 FR 25477, May 2, 2014]

#### § 405.2462 Payment for RHC and FQHC services.

(a) *Payment to independent RHCs that are authorized to bill under the reasonable cost system.* (1) RHCs that are authorized to bill under the reasonable cost system are paid on the basis of an all-inclusive rate, subject to a payment limit per visit determined in paragraph

(b) of this section, for each beneficiary visit for covered services. This rate is determined by the Medicare Administration Contractor (MAC), in accordance with this subpart and general instructions issued by CMS.

(2) The amount payable by the MAC for a visit is determined in accordance with paragraphs (i)(1) and (2) of this section.

(b) *RHC payment limit per visit.* (1) In establishing limits on payment for rural health clinic services provided by rural health clinics the limit for services provided prior to April 1, 2021:

(i) In 1988, after March 31, at \$46 per visit; and

(ii) In a subsequent year (before April 1, 2021), at the limit established for the previous year increased by the percentage increase in the Medicare Economic Index (MEI) (as defined in section 1842(i)(3) of the Act) applicable to primary care services (as defined in section 1842(i)(4) of the Act) furnished as of the first day of that year.

(2) In establishing limits on payment for rural health services furnished on or after April 1, 2021, by rural health clinics or any rural health clinic that is enrolled on or after January 1, 2021 under section 1866(j) of the Act), the limit for services provided:

(i) In 2021, after March 31, at \$100 per visit;

(ii) In 2022, at \$113 per visit;

(iii) In 2023, at \$126 per visit;

(iv) In 2024, at \$139 per visit;

(v) In 2025, at \$152 per visit;

(vi) In 2026, at \$165 per visit;

(vii) In 2027, at \$178 per visit; and

(viii) In 2028, at \$190 per visit.

(ix) In a subsequent year, at the limit established for the previous year increased by the percentage increase in MEI applicable to primary care services furnished as of the first day of such year.

(3) In establishing limits on payment for rural health services furnished on or after April 1, 2021, by provider-based rural health clinics as described in section (c)(4) of this part, the limit for services provided:

(i) In 2021, after March 31, at an amount equal to the greater of:

(A) For rural health clinics that had an all-inclusive rate established for services furnished in 2020—

(1) The all-inclusive rate applicable to the rural health clinic for services furnished in 2020, increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of 2021, or

(2) The payment limit per visit applicable in paragraph (b)(2) of this section.

(B) For rural health clinics that did not have an all-inclusive rate established for services furnished in 2020—

(1) The all-inclusive rate applicable to the rural health clinic for services furnished in 2021, or

(2) The payment limit per visit applicable in paragraph (b)(2) of this section.

(ii) In a subsequent year, at an amount equal to the greater of:

(A) The amount established under paragraph (b)(3)(i)(A) or (B) of this section, as applicable for the previous year, increased by the percentage increase in MEI applicable to primary care services furnished as of the first day of such subsequent year, or

(B) The payment limit per visit applicable under paragraph (b)(2) of this section for such subsequent year.

(c) *Payment to provider-based RHCs that are authorized to bill under the reasonable cost system.* (1) An RHC that is authorized to bill under the reasonable cost system is paid in accordance with parts 405 and 413 of this subchapter, as applicable, if the RHC is—

(i) An integral and subordinate part of a hospital, skilled nursing facility or home health agency participating in Medicare (that is, a provider of services); and

(ii) Operated with other departments of the provider under common licensure, governance and professional supervision.

(2) An RHC, described in paragraph (c)(1) of this section, is paid on the basis of an all-inclusive rate, subject to a payment limit per visit, described in paragraphs (b)(1) and (2) of this section, for each beneficiary visit for covered services when in a hospital with greater than 50 beds as determined in § 412.105(b) of this subchapter. This all-inclusive rate is determined by the MAC, in accordance with this subpart and general instructions issued by CMS. The amount payable by the MAC

for a visit is determined in accordance with paragraphs (i)(1) and (2) of this section.

(3) Prior to April 1, 2021, an RHC, described in paragraph (c)(1) of this section, is paid on the basis of an all-inclusive rate and is not subject to a payment limit per visit described in paragraphs (b)(1) and (2) of this section for each beneficiary visit for covered services when in a hospital with less than 50 beds as determined in § 412.105(b) of this subchapter. This all-inclusive rate is determined by the MAC, in accordance with this subpart and general instructions issued by CMS. The amount payable by the MAC for a visit is determined in accordance with paragraphs (i)(1) and (2) of this section.

(4) On or after April 1, 2021, an RHC, described in paragraph (c)(1) of this section, is paid on the basis of an all-inclusive rate, subject to a payment limit per visit, described in paragraph (b)(3) of this section, for each beneficiary visit for covered services when it meets the specified qualifications in paragraph (d) of this section. This all-inclusive rate is determined by the MAC, in accordance with this subpart and general instructions issued by CMS. The amount payable by the MAC for a visit is determined in accordance with paragraphs (i)(1) and (2) of this section.

(d) *Specified qualifications.* A provider-based rural health clinic must meet the following qualifications to have a payment limit per visit established in accordance with paragraph (b)(3) of this section.

(1) As of December 31, 2020, was in a hospital with less than 50 beds (as determined in § 412.105(b) of this subchapter) and after December 31, 2020, in a hospital that continues to have less than 50 beds (not taking into account any increase in the number of beds pursuant to a waiver during the COVID-19 Public Health Emergency (PHE)); and one of the following circumstances:

(i) As of December 31, 2020, was enrolled under section 1866(j) of the Act (including temporary enrollment during the COVID-19 PHE); or

(ii) Submitted an application for enrollment under section 1866(j) of the Act (or a request for temporary enrollment during the COVID-19 PHE) that

was received not later than December 31, 2020.

(2) [Reserved]

(e) *Payment to FQHCs that are authorized to bill under the PPS.* A FQHC that is authorized to bill under the PPS is paid a single, per diem rate based on the prospectively set rate for each beneficiary visit for covered services. Except as noted in paragraph (f) of this section, this rate is adjusted for the following:

(1) Geographic differences in cost based on the Geographic Practice Cost Indices (GPCIs) in accordance with section 1848(e) of the Act and 42 CFR 414.2 and 414.26 are used to adjust payment under the physician fee schedule during the same period, limited to only the work and practice expense GPCIs.

(2) Furnishing of care to a beneficiary that is a new patient with respect to the FQHC, including all sites that are part of the FQHC. A new patient is one that has not been treated by the FQHC's organization within the previous 3 years.

(3) Furnishing of care to a beneficiary receiving a comprehensive initial Medicare visit (that is an initial preventive physical examination or an initial annual wellness visit) or a subsequent annual wellness visit.

(f) *Payment to grandfathered tribal FQHCs.* (1) A “grandfathered tribal FQHC” is a FQHC that:

(i) Is operated by a tribe or tribal organization under the Indian Self-Determination Education and Assistance Act (ISDEAA);

(ii) Was billing as if it were provider-based to an IHS hospital on or before April 7, 2000; and

(iii) Is not operating as a provider-based department of an IHS hospital.

(2) A grandfathered tribal FQHC is paid at the Medicare outpatient per visit rate as set annually by the IHS.

(3) The payment rate is not adjusted:

(i) By the FQHC Geographic Adjustment Factor;

(ii) For new patients, annual wellness visits, or initial preventive physical examinations; or

(iii) Annually by the Medicare Economic Index or a FQHC PPS market basket.

(4) The payment rate is adjusted annually by the IHS under the authority

of sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248 and 249(b)), Pub. L. 83–568 (42 U.S.C. 2001(a)), and the Indian Health Care Improvement Act (25 U.S.C. 1601 *et seq.*).

(g)(1) Except for preventive services for which Medicare pays 100 percent under § 410.152(l) of this chapter, Medicare pays—

(i) Eighty (80) percent of the lesser of the FQHC's actual charge or the PPS encounter rate for FQHCs authorized to bill under the PPS; or

(ii) Eighty (80) percent of the lesser of a grandfathered tribal FQHC's actual charge, or the outpatient rate for Medicare as set annually by the IHS for grandfathered tribal FQHCs that are authorized to bill at this rate.

(2) No deductible is applicable to FQHC services.

(h) For RHCs visits, payment is made in accordance with one of the following:

(1) If the deductible has been fully met by the beneficiary prior to the RHC visit, Medicare pays 80 percent of the all-inclusive rate.

(2) If the deductible has not been fully met by the beneficiary before the visit, and the amount of the RHC's reasonable customary charge for the services that is applied to the deductible is less than the all-inclusive rate, the amount applied to the deductible is subtracted from the all-inclusive rate and 80 percent of the remainder, if any, is paid to the RHC.

(3) If the deductible has not been fully met by the beneficiary before the visit, and the amount of the RHC's reasonable customary charge for the services that is applied to the deductible is equal to or exceeds the all-inclusive rate, no payment is made to the RHC.

(i) To receive payment, the RHC or FQHC must do all of the following:

(1) Furnish services in accordance with the requirements of subpart X of part 405 of this chapter and subpart A of part 491 of this chapter.

(2) File a request for payment on the form and manner prescribed by CMS.

(3) *HCPCS coding.* FQHCs and RHCs are required to submit HCPCS and other codes as required in reporting services furnished.

(j) *Payment amount for intensive outpatient services.* An RHC is paid the payment rate determined under § 419.21(a) of this chapter for services described under § 410.44 of this chapter. There are no adjustments to this rate.

(1) If the deductible has been fully met by the beneficiary prior to the RHC service, Medicare pays eighty (80) percent of the payment amount determined under paragraph (j)(1) of this section.

(2) If the deductible has not been fully met by the beneficiary prior to the RHC service, Medicare pays eighty (80) percent of the difference between the remaining deductible and the payment amount determined under paragraph (j)(1) of this section; or

(3) If the deductible has not been fully met by the beneficiary prior to the RHC service, no payment is made to the RHC if the deductible is equal to or exceeds the payment amount determined under paragraph (j)(1) of this section.

(4) FQHCs are paid the payment rate determined under § 419.21(a) of this chapter for services described under § 410.44 of this chapter. There are no adjustments to this rate, except that grandfathered tribal FQHCs are paid pursuant to paragraph (j)(4)(ii) of this section.

(i) Medicare pays eighty (80) percent of the lesser of the FQHC's actual charge or the payment rate determined under paragraph (j)(2) of this section; or

(ii) Medicare pays eighty (80) percent of the lesser of a grandfathered tribal FQHC's actual charge or the amount described under paragraphs (f)(2) and (3) of this section.

(iii) No deductible is applicable to FQHC services.

[79 FR 25477, May 2, 2014, as amended at 80 FR 71371, Nov. 16, 2015; 83 FR 60073, Nov. 23, 2018; 86 FR 65660, Nov. 19, 2021; 88 FR 82176, Nov. 22, 2023]

#### § 405.2463 What constitutes a visit.

(a) *Visit—General.* (1) For RHCs, a visit is either of the following:

(i) Face-to-face encounter (or, for mental health disorders only, an encounter that meets the requirements under paragraph (b)(3) of this section)

between an RHC patient and one of the following:

- (A) Physician.
- (B) Physician assistant.
- (C) Nurse practitioner.
- (D) Certified nurse midwife.
- (E) Visiting registered professional or licensed practical nurse.
- (G) Clinical psychologist.
- (H) Clinical social worker.
- (I) Marriage and family therapist.
- (J) Mental health counselor.
- (ii) Qualified transitional care management service.

(2) For FQHCs, a visit is either of the following:

(i) A visit as described in paragraph (a)(1)(i) or (ii) of this section.

(ii) A face-to-face encounter between a patient and either of the following:

(A) A qualified provider of medical nutrition therapy services as defined in part 410, subpart G, of this chapter.

(B) A qualified provider of outpatient diabetes self-management training services as defined in part 410, subpart H, of this chapter.

(b) *Visit—Medical.* (1) A medical visit is a face-to-face encounter between a RHC or FQHC patient and one of the following:

- (i) Physician.
- (ii) Physician assistant.
- (iii) Nurse practitioner.
- (iv) Certified nurse midwife.
- (v) Visiting registered professional or licensed practical nurse.

(2) A medical visit for a FQHC patient may be either of the following:

- (i) Medical nutrition therapy visit.
- (ii) Diabetes outpatient self-management training visit.

(3) *Visit—Mental health.* A mental health visit is a face-to-face encounter or an encounter furnished using interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where the patient is not capable of, or does not consent to, the use of video technology for the purposes of diagnosis, evaluation or treatment of a mental health disorder, including an in-person mental health service, beginning January 1, 2025, furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology)

must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record, between an RHC or FQHC patient and one of the following:

- (i) Clinical psychologist.
- (ii) Clinical social worker.
- (iii) Marriage and family therapist.
- (iv) Mental health counselor.
- (v) Other RHC or FQHC practitioner, in accordance with paragraph (b)(1) of this section, for mental health services.

(c) *Visit—Multiple.* (1) For RHCs and FQHCs that are authorized to bill under the reasonable cost system, encounters with more than one health professional and multiple encounters with the same health professional that take place on the same day and at a single location constitute a single visit, except when the patient—

- (i) Suffers an illness or injury subsequent to the first visit that requires additional diagnosis or treatment on the same day;
- (ii) Has a medical visit and a mental health visit or intensive outpatient services on the same day; or
- (iii) Has an initial preventive physical exam visit and a separate medical, mental health, or intensive outpatient services visit on the same day.

(2) For RHCs and FQHCs that are authorized to bill under the reasonable cost system, Medicare pays RHCs and FQHCs for more than 1 visit per day when the conditions in paragraph (c)(1) of this section are met.

(3) For FQHCs that are authorized to bill under the reasonable cost system, Medicare pays for more than 1 visit per day when a DSMT or MNT visit is furnished on the same day as a visit described in paragraph (c)(1) of this section are met.

(4) For FQHCs billing under the PPS, and grandfathered tribal FQHCs that are authorized to bill as a FQHC at the

outpatient per visit rate for Medicare as set annually by the Indian Health Service—

- (i) Suffers an illness or injury subsequent to the first visit that requires additional diagnosis or treatment on the same day; or
- (ii) Has a medical visit and a mental health visit or intensive outpatient services on the same day.

[79 FR 68001, Nov. 13, 2014, as amended at 80 FR 71372, Nov. 16, 2015; 86 FR 65661, Nov. 19, 2021; 87 FR 70222, Nov. 18, 2022; 88 FR 79524, Nov. 16, 2023; 88 FR 82176, Nov. 22, 2023]

**§ 405.2464 Payment rate.**

(a) *Payment rate for RHCs that are authorized to bill under the reasonable cost system.* (1) Except as specified in paragraphs (d) and (e) of this section, an RHC that is authorized to bill under the reasonable cost system is paid an all-inclusive rate that is determined by the MAC at the beginning of the cost reporting period.

(2) The rate is determined by dividing the estimated total allowable costs by estimated total visits for RHC services.

(3) The rate determination is subject to any tests of reasonableness that may be established in accordance with this subpart.

(4) The MAC, during each reporting period, periodically reviews the rate to assure that payments approximate actual allowable costs and visits and adjusts the rate if:

- (i) There is a significant change in the utilization of services;
- (ii) Actual allowable costs vary materially from allowable costs; or
- (iii) Other circumstances arise which warrant an adjustment.

(5) The RHC may request the MAC to review the rate to determine whether adjustment is required.

(b) *Payment rate for FQHCs that are authorized to bill under the prospective payment system.* (1) Except as specified in paragraphs (d) and (e) of this section, a per diem rate is calculated by CMS by dividing total FQHC costs by total FQHC daily encounters to establish an average per diem cost.

(2) The per diem rate is adjusted as follows:

- (i) For geographic differences in the cost of inputs according to § 405.2462(c)(1).

(ii) When the FQHC furnishes services to a new patient, as defined in § 405.2462(c)(2).

(iii) When a beneficiary receives either of the following:

(A) A comprehensive initial Medicare visit (that is, an initial preventive physical examination or an initial annual wellness visit).

(B) A subsequent annual wellness visit.

(c) *Payment for care management services.* For chronic care management services furnished between January 1, 2016 and December 31, 2017, payment to RHCs and FQHCs is at the physician fee schedule national non-facility payment rate. For care management services furnished between January 1, 2018 and December 31, 2023, payment to RHCs and FQHCs is at the rate set for each of the RHC and FQHC payment codes for care management services. For general care management services furnished on or after January 1, 2024, the payment amount is based on a weighted average of the services that comprise HCPCS code G0511 using the most recently available PFS utilization data.

(d) *Payment for FQHCs that are authorized to bill as grandfathered tribal FQHCs.* Grandfathered tribal FQHCs are paid at the outpatient per visit rate for Medicare as set annually by the Indian Health Service for each beneficiary visit for covered services. There are no adjustments to this rate.

(e) *Payment for communication technology-based and remote evaluation services.* For communication technology-based and remote evaluation services furnished on or after January 1, 2019, payment to RHCs and FQHCs is at the rate set for each of the RHC and FQHC payment codes for communication technology-based and remote evaluation services.

(f) *Payment for intensive outpatient services.* Payment to RHCs and FQHCs is at the rate determined under § 405.2462(j).

[79 FR 25478, May 2, 2014, as amended at 80 FR 71372, Nov. 16, 2015; 83 FR 60073, Nov. 23, 2018; 88 FR 79524, Nov. 16, 2023; 88 FR 82176, Nov. 22, 2023]

#### § 405.2466 Annual reconciliation.

(a) *General.* Payments made to RHCs or FQHCs that are authorized to bill under the reasonable cost system during a reporting period are subject to annual reconciliation to assure that those payments do not exceed or fall short of the allowable costs attributable to covered services furnished to Medicare beneficiaries during that period.

(b) *Calculation of reconciliation for RHCs or FQHCs that are authorized to bill under the reasonable cost system.* (1) The total reimbursement amount due the RHC or FQHC for covered services furnished to Medicare beneficiaries is based on the report specified in § 405.2470(c)(2) and is calculated by the MAC as follows:

(i) The average cost per visit is calculated by dividing the total allowable cost incurred for the reporting period by total visits for RHC or FQHC services furnished during the period. The average cost per visit is subject to tests of reasonableness which may be established in accordance with this subpart.

(ii) The total cost of RHC or FQHC services furnished to Medicare beneficiaries is calculated by multiplying the average cost per visit by the number of visits for covered RHC or FQHC services by beneficiaries.

(iii) The total payment due the RHC is 80 percent of the amount calculated by subtracting the amount of deductible incurred by beneficiaries that is attributable to RHC services from the cost of these services. FQHC services are not subject to a deductible and the payment computation for FQHCs does not include a reduction related to the deductible.

(iv) For RHCs and FQHCs, payment for pneumococcal, influenza, and COVID-19 vaccine and their administration is 100 percent of Medicare reasonable cost.

(2) The total reimbursement amount due is compared with total payments made to the RHC or FQHC for the reporting period, and the difference constitutes the amount of the reconciliation.

(c) *Notice of program reimbursement.* The MAC notifies the RHC or FQHC

that is authorized to bill under the reasonable-cost system:

(1) Setting forth its determination of the total reimbursement amount due the RHC or FQHC for the reporting period and the amount, if any, of the reconciliation; and

(2) Informing the RHC or FQHC of its right to have the determination reviewed at a hearing under the procedures set forth in subpart R of this part.

(d) *Payment of reconciliation amount—*

(1) *Underpayments.* If the total reimbursement due the RHC or FQHC that is authorized to bill under the reasonable cost system exceeds the payments made for the reporting period, the MAC makes a lump-sum payment to the RHC or FQHC to bring total payments into agreement with total reimbursement due the RHC or FQHC.

(2) *Overpayments.* If the total payments made to a RHC or FQHC for the reporting period exceed the total reimbursement due the RHC or FQHC for the period, the MAC arranges with the RHC or FQHC for repayment through a lump-sum refund, or, if that poses a hardship for the RHC or FQHC, through offset against subsequent payments or a combination of offset and refund. The repayment must be completed as quickly as possible, generally within 12 months from the date of the notice of program reimbursement. A longer repayment period may be agreed to by the MAC if the MAC is satisfied that unusual circumstances exist which warrant a longer period.

[57 FR 24976, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996; 79 FR 25478, May 2, 2014; 86 FR 65662, Nov. 19, 2021]

**§ 405.2467 Requirements of the FQHC PPS.**

(a) *Cost reporting.* For cost reporting periods beginning on or after October 1, 2014, FQHCs are paid the lesser of their actual charges or the FQHC PPS rate that does all of the following:

(1) Includes a process for appropriately describing the services furnished by FQHCs.

(2) Establishes payment rates for specific payment codes based on such appropriate descriptions of services.

(3) Takes into account the type, intensity and duration of services furnished by FQHCs.

(4) May include adjustments (such as geographic adjustments) determined by the Secretary.

(b) *Initial payments.* (1) Beginning October 1, 2014, for the first 15 months of the PPS, the estimated aggregate amount of PPS rates is equal to 100 percent of the estimated amount of reasonable costs that would have occurred for that period if the PPS had not been implemented.

(2) Payment rate is calculated based on the reasonable cost system, prior to productivity adjustments and any payment limitations.

(c) *Payments in subsequent years.* (1) Beginning January 1, 2016, PPS payment rates will be increased by the percentage increase in the Medicare economic index.

(2) Beginning January 1, 2017, PPS rates will be increased by the percentage increase in a market basket of FQHC goods and services as established through regulations, or, if not available, the Medicare economic index.

[79 FR 25479, May 2, 2014, as amended at 80 FR 71372, Nov. 16, 2015]

**§ 405.2468 Allowable costs.**

(a) *Applicability of general Medicare principles.* In determining whether and to what extent a specific type or item of cost is allowable, such as interest, depreciation, bad debts and owner compensation, the MAC applies the principles for reimbursement of provider costs, as set forth in part 413 of this subchapter.

(b) *Typical RHC and FQHC costs.* The following types and items of cost are included in allowable costs to the extent that they are covered and reasonable:

(1) Compensation for the services of a physician, physician assistant, nurse practitioner, certified nurse-midwife, visiting registered professional or licensed practical nurse, clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor who owns, is employed by, or furnishes services under contract to a FQHC or RHC.

(2) Compensation for the duties that a supervising physician is required to

perform under the agreement specified in § 491.8 of this chapter.

(3) Costs of services and supplies incident to the services of a physician, physician assistant, nurse practitioner, nurse-midwife, qualified clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor.

(4) Overhead costs, including RHC or FQHC administration, costs applicable to use and maintenance of the entity, and depreciation costs.

(5) Costs of services purchased by the RHC or FQHC.

(c) *Tests of reasonableness of cost and utilization.* Tests of reasonableness authorized by sections 1833(a) and 1861(v)(1)(A) of the Act may be established by CMS or the MAC with respect to direct or indirect overall costs, costs of specific items and services, or costs of groups of items and services. For RHCs and FQHCs that are authorized to bill under the reasonable cost system, these tests include, but are not limited to, screening guidelines and payment limits.

(d) *Screening guidelines.* (1) Costs in excess of amounts established by the guidelines are not included unless the RHC or FQHC that is authorized to bill under the reasonable cost system provides reasonable justification satisfactory to the MAC.

(2) Screening guidelines are used to assess the costs of services, including the following:

(i) Compensation for the professional and supervisory services of physicians and for the services of physician assistants, nurse practitioners, and nurse-midwives.

(ii) Services of physicians, physician assistants, nurse practitioners, nurse-midwives, visiting nurses, qualified clinical psychologists, clinical social workers, marriage and family therapists, and mental health counselors.

(iii) The level of administrative and general expenses.

(iv) Staffing (for example, the ratio of other RHC or FQHC personnel to physicians, physician assistants, and nurse practitioners).

(v) The reasonableness of payments for services purchased by the RHC or FQHC, subject to the limitation that the costs of physician services pur-

chased by the RHC or FQHC may not exceed amounts determined under the applicable provisions of subpart E of part 405 or part 415 of this chapter.

(e) *Payment limitations.* Limits on payments may be set by CMS, on the basis of costs estimated to be reasonable for the provision of such services.

(f) *Graduate medical education.* (1) Effective for portions of cost reporting periods occurring on or after January 1, 1999, if an RHC or an FQHC incurs “all or substantially all” of the costs for the training program in the nonhospital setting as defined in § 413.75(b) of this chapter, the RHC or FQHC may receive direct graduate medical education payment for those residents. However, in connection with cost reporting periods for which “all or substantially all of the costs for the training program in the nonhospital setting” is not defined in § 413.75(b) of this chapter, if an RHC or an FQHC incurs the salaries and fringe benefits (including travel and lodging where applicable) of residents training at the RHC or FQHC, the RHC or FQHC may receive direct graduate medical education payments for those residents.

(2) Direct graduate medical education costs are not included as allowable cost under § 405.2466(b)(1)(i); and therefore, are not subject to the limit on the all-inclusive rate for allowable costs.

(3) Allowable graduate medical education costs must be reported on the RHC’s or the FQHC’s cost report under a separate cost center.

(4) Allowable graduate medical education costs are non-reimbursable if payment for these costs are received from a hospital or a Medicare Advantage organization.

(5) Allowable direct graduate medical education costs under paragraphs (f)(6) and (f)(7)(i) of this section, are subject to reasonable cost principles under part 413 and the reasonable compensation equivalency limits in §§ 415.60 and 415.70 of this chapter.

(6) The allowable direct graduate medical education costs are those costs incurred by the nonhospital site for the educational activities associated with patient care services of an approved program, subject to the redistribution

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and community support principles in § 413.85(c).

(i) The following costs are allowable direct graduate medical education costs to the extent that they are reasonable—

(A) The costs of the residents' salaries and fringe benefits (including travel and lodging expenses where applicable).

(B) The portion of teaching physicians' salaries and fringe benefits that are related to the time spent teaching and supervising residents.

(C) Facility overhead costs that are allocated to direct graduate medical education.

(ii) The following costs are not allowable graduate medical education costs—

(A) Costs associated with training, but not related to patient care services.

(B) Normal operating and capital-related costs.

(C) The marginal increase in patient care costs that the RHC or FQHC experiences as a result of having an approved program.

(D) The costs associated with activities described in § 413.85(h) of this chapter.

(7) Payment is equal to the product of—

(i) The RHC's or the FQHC's allowable direct graduate medical education costs; and

(ii) Medicare's share, which is equal to the ratio of Medicare visits to the total number of visits (as defined in § 405.2463).

(8) Direct graduate medical education payments to RHCs and FQHCs made under this section are made from the Federal Supplementary Medical Insurance Trust Fund.

(g) *Intensive outpatient services.* (1) For RHCs, costs associated with intensive outpatient services are not used to determine the amount of payment for RHC services under the methodology for all-inclusive rates under section 1833(a)(3) of the Act as described in § 405.2464(a).

(2) For FQHCs, costs associated with intensive outpatient services are not used to determine the amount of payment for FQHC services under the prospective payment system under section

1834(o)(2)(B) of the Act as described in § 405.2464(b).

[43 FR 8261, Mar. 1, 1978. Redesignated and amended at 57 FR 24977, June 12, 1992; 60 FR 63176, Dec. 8, 1995; 61 FR 14658, Apr. 3, 1996; 63 FR 41002, July 31, 1998; 66 FR 39932, Aug. 1, 2001; 70 FR 47484, Aug. 12, 2005; 79 FR 25479, May 2, 2014; 79 FR 50351, Aug. 22, 2014; 88 FR 79525, Nov. 16, 2023; 88 FR 82176, Nov. 22, 2023]

**§ 405.2469 FQHC supplemental payments.**

(a) *Eligibility for supplemental payments.* FQHCs under contract (directly or indirectly) with MA organizations are eligible for supplemental payments for FQHC services furnished to enrollees in MA plans offered by the MA organization to cover the difference, if any, between their payments from the MA plan and what they would receive under one of the following:

(1) The PPS rate if the FQHC is authorized to bill under the PPS;

(2) The Medicare outpatient per visit rate as set annually by the Indian Health Service for grandfathered tribal FQHCs; or

(3) The payment rate as determined in § 405.2462(j).

(b) *Calculation of supplemental payment.* The supplemental payment for FQHC covered services provided to Medicare patients enrolled in MA plans is based on the difference between—

(1) Payments received by the FQHC from the MA plan as determined on a per visit basis and the FQHCs all-inclusive cost-based per visit rate as set forth in this subpart, less any amount the FQHC may charge as described in section 1857(e)(3)(B) of the Act; or

(2) Payments received by the FQHC from the MA plan as determined on a per visit basis and the FQHC PPS rate as set forth in this subpart, less any amount the FQHC may charge as described in section 1857(e)(3)(B) of the Act; or

(3) Payments received by the FQHC from the MA plan as determined on a per visit basis and the FQHC outpatient rate as set forth in this section under paragraph (a)(2) of this section, less any amount the FQHC may charge as described in section 1857(e)(3)(B) of the Act; or

(4) Payments received by the FQHC from the MA plan as determined on a

per visit basis and the payment rate as determined in § 405.2462(j), less any amount the FQHC may charge as described in section 1857(e)(3)(B) of the Act.

(c) *Financial incentives.* Any financial incentives provided to FQHCs under their MA contracts, such as risk pool payments, bonuses, or withholds, are prohibited from being included in the calculation of supplemental payments due to the FQHC.

(d) *Per visit supplemental payment.* A supplemental payment required under this section is made to the FQHC when a covered face-to-face encounter or an encounter furnished using interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where beneficiaries do not wish to use or do not have access to devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder occurs between a MA enrollee and a practitioner as set forth in § 405.2463. Additionally, beginning January 1, 2025, there must be an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record.

[79 FR 25479, May 2, 2014, as amended at 80 FR 71372, Nov. 16, 2015; 86 FR 65662, Nov. 19, 2021; 87 FR 70222, Nov. 18, 2022; 88 FR 79525, Nov. 16, 2023; 88 FR 82176, Nov. 22, 2023]

#### § 405.2470 Reports and maintenance of records.

(a) *Maintenance and availability of records.* The RHC or FQHC must:

(1) Maintain adequate financial and statistical records, in the form and

containing the data required by CMS, to allow the MAC to determine payment for covered services furnished to Medicare beneficiaries in accordance with this subpart;

(2) Make the records available for verification and audit by HHS or the General Accounting Office;

(3) Maintain financial data on an accrual basis, unless it is part of a governmental institution that uses a cash basis of accounting. In the latter case, appropriate depreciation on capital assets is allowable rather than the expenditure for the capital asset.

(b) *Adequacy of records.* (1) The MAC may suspend reimbursement if it determines that the RHC or FQHC does not maintain records that provide an adequate basis to determine payments under Medicare.

(2) The suspension continues until the RHC or FQHC demonstrates to the MAC's satisfaction that it does, and will continue to, maintain adequate records.

(c) *Reporting requirements*—(1) *Initial report.* At the beginning of its initial reporting period, the RHC or FQHC must submit an estimate of budgeted costs and visits for RHC or FQHC services for the reporting period, in the form and detail required by CMS, and such other information as CMS may require to establish the payment rate.

(2) *Annual reports.* Within 90 days after the end of its reporting period, the RHC or FQHC must submit, in such form and detail as may be required by CMS, a report of:

(i) Its operations, including the allowable costs actually incurred for the period and the actual number of visits for RHC or FQHC services furnished during the period; and

(ii) The estimated costs and visits for RHC services or FQHC services for the succeeding reporting period and such other information as CMS may require to establish the payment rate.

(3) *Late reports.* If the RHC or FQHC does not submit an adequate annual report on time, the MAC may reduce or suspend payments to preclude excess payment to the RHC or FQHC.

(4) *Inadequate reports.* If the RHC or FQHC does not furnish a report or furnishes a report that is inadequate for the MAC to make a determination of

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program payment, CMS may deem all payments for the reporting period to be overpayments.

(5) *Postponement of due date.* For good cause shown by the RHC or FQHC, the MAC may, with CMS's approval, grant a 30-day postponement of the due date for the annual report.

(6) *Reports following termination of agreement or change of ownership.* The report from a RHC or FQHC which voluntarily or involuntarily ceases to participate in the Medicare program or experiences a change in ownership (see §§ 405.2436–405.2438) is due no later than 45 days following the effective date of the termination of agreement or change of ownership.

(d) *Collection of additional claims data.* Beginning January 1, 2011, a Medicare FQHC must report on its Medicare claims such information as the Secretary determines is needed to develop and implement a prospective payment system for FQHCs including, but not limited to all pertinent HCPCS (Healthcare Common Procedure Coding System) code(s) corresponding to the service(s) provided for each Medicare FQHC visit (as defined in § 405.2463).

[43 FR 8261, Mar. 1, 1978, as amended at 75 FR 73613, Nov. 29, 2010; 79 FR 25479, May 2, 2014]

### § 405.2472 Beneficiary appeals.

A beneficiary may request a hearing by an intermediary (subject to the limitations and conditions set forth in subpart H of this part) if:

(a) The beneficiary is dissatisfied with a MAC's determination denying a request for payment made on his or her behalf by a RHC or FQHC;

(b) The beneficiary is dissatisfied with the amount of payment; or

(c) The beneficiary believes the request for payment is not being acted upon with reasonable promptness.

[43 FR 8261, Mar. 1, 1978, Redesignated and amended at 57 FR 24978, June 12, 1992; 79 FR 25480, May 2, 2014]

## PART 406—HOSPITAL INSURANCE ELIGIBILITY AND ENTITLEMENT

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AUTHORITY: 42 U.S.C. 1302, 1395i–2, 1395i–2a, 1395p, 1395q and 1395hh.

SOURCE: 48 FR 12536, Mar. 25, 1983, unless otherwise noted. Redesignated at 51 FR 41338, Nov. 14, 1986.

### Subpart A—General Provisions

#### § 406.1 Statutory basis.

Sections 226, 226A, 1818 and 1818A of the Social Security Act and section 103