

Centers for Medicare & Medicaid Services, HHS

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(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.

(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

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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

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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 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 and clinical social worker services specified in § 405.2450.

(6) Services and supplies furnished as incident to a clinical psychologist or clinical social worker service, 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.

(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

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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]

§ 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 or clinical social worker 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 or clinical social worker; 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]

§ 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 and clinical social worker services.

(a) For clinical psychologist or clinical social worker 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 or clinical social worker 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 or clinical psychologist 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 or clinical social workers 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]

§ 405.2452 Services and supplies incident to clinical psychologist and clinical social worker services.

(a) Services and supplies incident to a clinical psychologist's or clinical social worker's services are reimbursable under this subpart if the service or supply is—

- (1) Of a type commonly furnished in a physician's office;
- (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 or clinical social worker;

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

(5) Furnished under the direct supervision of a clinical psychologist or clinical social worker.

(b) The direct supervision requirement in paragraph (a)(5) of this section is met only if the clinical psychologist or clinical social worker 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]

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

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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—

(I) 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—