

#### § 405.2415

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.