

(2) A hospital-based laboratory that meets the requirements for participation in the Medicare program found in § 482.27 of this chapter;

(3) A rural health clinic, as defined in § 491.9 of this chapter; or

(4) A skilled nursing facility—based clinical laboratory, as defined in § 405.1128(a) of this chapter.

(b) Except as provided under paragraph (c), if a laboratory or other entity is requesting payment under Medicaid for testing for the presence of the human immunodeficiency virus (HIV) antibody or for the isolation and identification of the HIV causative agent as described in § 405.1316(f) (2) and (3) of this chapter, the laboratory records must contain the name and other identification of the person from whom the specimen was taken.

(c) An agency may choose to approve the use of alternative identifiers, in place of the requirement for patient's name, in paragraph (b) of this section for HIV antibody or causative agent testing of Medicaid recipients.

[54 FR 48647, Dec. 2, 1988. Redesignated at 63 FR 310, Jan. 5, 1998.]

**§ 441.18 Case management services.**

(a) If a State plan provides for case management services (including targeted case management services), as defined in § 440.169 of this chapter, the State must meet the following requirements:

(1) Allow individuals the free choice of any qualified Medicaid provider within the specified geographic area identified in the plan when obtaining case management services, in accordance with § 431.51 of this chapter, except as specified in paragraph (b) of this section.

(2) Not use case management (including targeted case management) services to restrict an individual's access to other services under the plan.

(3) Not compel an individual to receive case management services, condition receipt of case management (or targeted case management) services on the receipt of other Medicaid services, or condition receipt of other Medicaid services on receipt of case management (or targeted case management) services.

(4) Indicate in the plan that case management services provided in accordance with section 1915(g) of the Act will not duplicate payments made to public agencies or private entities under the State plan and other program authorities;

(5) Provide comprehensive case management services, on a one-to-one basis, to an individual through one case manager.

(6) Prohibit providers of case management services from exercising the agency's authority to authorize or deny the provision of other services under the plan.

(7) Require providers to maintain case records that document for all individuals receiving case management as follows:

(i) The name of the individual.  
(ii) The dates of the case management services.

(iii) The name of the provider agency (if relevant) and the person providing the case management service.

(iv) The nature, content, units of the case management services received and whether goals specified in the care plan have been achieved.

(v) Whether the individual has declined services in the care plan.

(vi) The need for, and occurrences of, coordination with other case managers.

(vii) A timeline for obtaining needed services.

(viii) A timeline for reevaluation of the plan.

(8) Include a separate plan amendment for each group receiving case management services that includes the following:

(i) Defines the group (and any subgroups within the group) eligible to receive the case management services.

(ii) Identifies the geographic area to be served.

(iii) Describes the case management services furnished, including the types of monitoring.

(iv) Specifies the frequency of assessments and monitoring and provides a justification for those frequencies.

(v) Specifies provider qualifications that are reasonably related to the population being served and the case management services furnished.

(vi) Specifies the methodology under which case management providers will

be paid and rates are calculated that employs a unit of service that does not exceed 15 minutes.

(vii) Specifies if case management services are being provided to Medicaid-eligible individuals who are in institutions (except individuals between ages 22 and 64 who are served in IMDs or individuals who are inmates of public institutions).

(viii) Specifies if case management services are being provided to individuals with long-term stays of 180 consecutive days or longer or to individuals with short-term stays of less than 180 consecutive days. When States choose to provide case management services to individuals in institutions to facilitate transition to the community, the State plan must include the following requirements:

(A) Specify the time period or other conditions under which case management may be provided in this manner. The time period that case management is provided in an institution must not exceed an individual's length of stay;

(B) Specify the case management activities and include an assurance that these activities are coordinated with and do not duplicate institutional discharge planning;

(C) Include an assurance that the amount, duration, and scope of the case management activities would be documented in an individual's plan of care which includes case management activities prior to and post-discharge, to facilitate a successful transition to community living; and

(D) Specify that case management is only provided by and reimbursed to community case management providers;

(E) Specify that Federal Financial Participation is only available to community providers and will not be claimed on behalf of an individual until discharge from the medical institution and enrollment in community services; and

(F) Describe the system and process the State will use to monitor providers' compliance with these provisions.

(9) Include a separate plan amendment for each subgroup within a group if any of the following differs among the subgroups:

(i) The case management services to be furnished;

(ii) The qualifications of case management providers; or

(iii) The methodology under which case management providers will be paid.

(b) If the State limits qualified providers of case management services for target groups of individuals with developmental disability or chronic mental illness, in accordance with § 431.51(a)(4) of this chapter, the plan must identify any limitations to be imposed on the providers and specify how these limitations enable providers to ensure that individuals within the target groups receive needed services.

(c) Case management does not include, and FFP is not available in expenditures for, services defined in § 440.169 of this chapter when any of the following conditions exist:

(1) Case management activities are an integral component of another covered Medicaid service.

(2) The case management activities constitute the direct delivery of underlying medical, educational, social, or other services to which an eligible individual has been referred, including, but not limited to, services under parole and probation programs, public guardianship programs, special education programs, child welfare/child protective services, and foster care programs.

(3) The activities are integral to the administration of foster care programs, including but not limited to the following:

(i) Research gathering and completion of documentation required by the foster care program.

(ii) Assessing adoption placements.

(iii) Recruiting or interviewing potential foster care parents.

(iv) Serving legal papers.

(v) Home investigations.

(vi) Providing transportation.

(vii) Administering foster care subsidies.

(viii) Making placement arrangements.

(4) The activities, for which an individual may be eligible, are integral to the administration of another non-medical program, such as a guardianship, child welfare/child protective services, parole, probation, or special

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education program except for case management that is included in an individualized education program or individualized family service plan consistent with section 1903(c) of the Act.

(5) Activities that meet the definition of case management services in § 440.169 and under the approved State plan cannot be claimed as administrative activities under § 433.15(b).

(d) After the State assesses whether the activities are within the scope of the case management benefit (applying the limitations described above), in determining the allowable costs for case management (or targeted case management) services that are also furnished by another federally-funded program, the State must use cost allocation methodologies, consistent with OMB Circular A-87, CMS policies, or any subsequent guidance and reflected in an approved cost allocation plan.

[72 FR 68092, Dec. 4, 2007]

### § 441.20 Family planning services.

For recipients eligible under the plan for family planning services, the plan must provide that each recipient is free from coercion or mental pressure and free to choose the method of family planning to be used.

### § 441.21 Nurse-midwife services.

If a State plan, under § 440.210 or 440.220 of this subchapter, provides for nurse-midwife services, as defined in § 440.165, the plan must provide that the nurse-midwife may enter into an independent provider agreement, without regard to whether the nurse-midwife is under the supervision of, or associated with, a physician or other health care provider.

[47 FR 21051, May 17, 1982]

### § 441.22 Nurse practitioner services.

With respect to nurse practitioner services that meet the definition of § 440.166(a) and the requirements of either § 440.166(b) or § 440.166(c), the State plan must meet the following requirements:

(a) Provide that nurse practitioner services are furnished to the categorically needy.

(b) Specify whether those services are furnished to the medically needy.

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(c) Provide that services furnished by a nurse practitioner, regardless of whether the nurse practitioner is under the supervision of, or associated with, a physician or other health care provider, may—

(1) Be reimbursed by the State Medicaid agency through an independent provider agreement between the State and the nurse practitioner; or

(2) Be paid through the employing provider.

[60 FR 19862, Apr. 21, 1995]

### § 441.25 Prohibition on FFP for certain prescribed drugs.

(a) FFP is not available in expenditures for the purchase or administration of any drug product that meets all of the following conditions:

(1) The drug product was approved by the Food and Drug Administration (FDA) before October 10, 1962.

(2) The drug product is available only through prescription.

(3) The drug product is the subject of a notice of opportunity for hearing issued under section 505(e) of the Federal Food, Drug, and Cosmetic Act and published in the FEDERAL REGISTER on a proposed order of FDA to withdraw its approval for the drug product because it has determined that the product is less than effective for all its labeled indications.

(4) The drug product is presently not subject to a determination by FDA, made under its efficacy review program (see 21 CFR 310.6 for an explanation of this program), that there is a compelling justification of the drug product's medical need.

(b) FFP is not available in expenditures for the purchase or administration of any drug product that is identical, related, or similar, as defined in 21 CFR 310.6, to a drug product that meets the conditions of paragraph (a) of this section.

[46 FR 48554, Oct. 1, 1981]

### § 441.30 Optometric services.

The plan must provide for payment of optometric services as physician services, whether furnished by an optometrist or a physician, if—