

are licensed by CMS or receive an exemption from the licensing requirement by the College of American Pathologists. (Hospital and physician laboratories may participate in competitive bidding only with regard to services to non-hospital patients and other physicians' patients, respectively.)

(3) Any laboratory from which a State purchases services under this section has no more than 75 percent of its charges based on services to Medicare beneficiaries and Medicaid recipients.

(e) *Lock-in of recipients who over-utilize Medicaid services.* If a Medicaid agency finds that a recipient has utilized Medicaid services at a frequency or amount that is not medically necessary, as determined in accordance with utilization guidelines established by the State, the agency may restrict that recipient for a reasonable period of time to obtain Medicaid services from designated providers only. The agency may impose these restrictions only if the following conditions are met:

(1) The agency gives the recipient notice and opportunity for a hearing (in accordance with procedures established by the agency) before imposing the restrictions.

(2) The agency ensures that the recipient has reasonable access (taking into account geographic location and reasonable travel time) to Medicaid services of adequate quality.

(3) The restrictions do not apply to emergency services furnished to the recipient.

(f) *Lock-out of providers.* If a Medicaid agency finds that a Medicaid provider has abused the Medicaid program, the agency may restrict the provider, through suspension or otherwise, from participating in the program for a reasonable period of time.

Before imposing any restriction, the agency must meet the following conditions:

(1) Give the provider notice and opportunity for a hearing, in accordance with procedures established by the agency.

(2) Find that in a significant number or proportion of cases, the provider has:

(i) Furnished Medicaid services at a frequency or amount not medically necessary, as determined in accordance with utilization guidelines established by the agency; or

(ii) Furnished Medicaid services of a quality that does not meet professionally recognized standards of health care.

(3) Notify CMS and the general public of the restriction and its duration.

(4) Ensure that the restrictions do not result in denying recipients reasonable access (taking into account geographic location and reasonable travel time) to Medicaid services of adequate quality, including emergency services.

§ 431.55 Waiver of other Medicaid requirements.

(a) *Statutory basis.* Section 1915(b) of the Act authorizes the Secretary to waive most requirements of section 1902 of the Act to the extent he or she finds proposed improvements or specified practices in the provision of services under Medicaid to be cost effective, efficient, and consistent with the objectives of the Medicaid program. Sections 1915 (f) and (h) prescribe how such waivers are to be approved, continued, monitored, and terminated. Section 1902(p)(2) of the Act conditions FFP in payments to an entity under a section 1915(b)(1) waiver on the State's provision for exclusion of certain entities from participation.

(b) *General requirements.* (1) General requirements for submittal of waiver requests, and the procedures that CMS follows for review and action on those requests are set forth in § 430.25 of this chapter.

(2) In applying for a waiver to implement an approvable project under paragraph (c), (d), (e), or (f) of this section, a Medicaid agency must document in the waiver request and maintain data regarding:

(i) The cost-effectiveness of the project;

(ii) The effect of the project on the accessibility and quality of services;

(iii) The anticipated impact of the project on the State's Medicaid program and;

(iv) Assurances that the restrictions on free choice of providers do not apply to family planning services.

(3) No waiver under this section may be granted for a period longer than 2 years, unless the agency requests a continuation of the waiver.

(4) CMS monitors the implementation of waivers granted under this section to ensure that requirements for such waivers are being met.

(i) If monitoring demonstrates that the agency is not in compliance with the requirements for a waiver under this section, CMS gives the agency notice and opportunity for a hearing.

(ii) If, after a hearing, CMS finds an agency to be out of compliance with the requirements of a waiver, CMS terminates the waiver and gives the agency a specified date by which it must demonstrate that it meets the applicable requirements of section 1902 of the Act.

(5) The requirements of section 1902(s) of the Act, with regard to adjustments in payments for inpatient hospital services furnished to infants who have not attained age 1 and to children who have not attained age 6 and who receive these services in disproportionate share hospitals, may not be waived under a section 1915(b) waiver.

(c) *Case-management system.* (1) Waivers of appropriate requirements of section 1902 of the Act may be authorized for a State to implement a primary care case-management system or specialty physician services system.

(i) Under a primary care case-management system the agency assures that a specific person or persons or agency will be responsible for locating, coordinating, and monitoring all primary care or primary care and other medical care and rehabilitative services on behalf of a recipient. The person or agency must comply with the requirements set forth in part 438 of this chapter for primary care case management contracts and systems.

(ii) A specialty physician services system allows States to restrict recipients of specialty services to designated providers of such services, even in the absence of a primary care case-management system.

(2) A waiver under this paragraph (c) may not be approved unless the State's request assures that the restrictions—

(i) Do not apply in emergency situations; and

(ii) Do not substantially impair access to medically necessary services of adequate quality.

(d) *Locality as central broker.* Waivers of appropriate requirements of section 1902 of the Act may be authorized for a State to allow a locality to act as a central broker to assist recipients in selecting among competing health care plans. States must ensure that access to medically necessary services of adequate quality is not substantially impaired.

(1) A locality is any defined jurisdiction, e.g., district, town, city, borough, county, parish, or State.

(2) A locality may use any agency or agent, public or private, profit or non-profit, to act on its behalf in carrying out its central broker function.

(e) *Sharing of cost savings.* (1) Waivers of appropriate requirements of section 1902 of the Act may be authorized for a State to share with recipients the cost savings resulting from the recipients' use of more cost-effective medical care.

(2) Sharing is through the provision of additional services, including—

(i) Services furnished by a plan selected by the recipient; and

(ii) Services expressly offered by the State as an inducement for recipients to participate in a primary care case-management system, a competing health care plan or other system that furnishes health care services in a more cost-effective manner.

(f) *Restriction of freedom of choice—*(1) Waiver of appropriate requirements of section 1902 of the Act may be authorized for States to restrict recipients to obtaining services from (or through) qualified providers or practitioners that meet, accept, and comply with the State reimbursement, quality and utilization standards specified in the State's waiver request.

(2) An agency may qualify for a waiver under this paragraph (f) only if its applicable State standards are consistent with access, quality and efficient and economic provision of covered care and services and the restrictions it imposes—

(i) Do not apply to recipients residing at a long-term care facility when a restriction is imposed unless the State

arranges for reasonable and adequate recipient transfer.

(ii) Do not discriminate among classes of providers on grounds unrelated to their demonstrated effectiveness and efficiency in providing those services; and

(iii) Do not apply in emergency circumstances.

(3) Demonstrated effectiveness and efficiency refers to reducing costs or slowing the rate of cost increase and maximizing outputs or outcomes per unit of cost.

(4) The agency must make payments to providers furnishing services under a freedom of choice waiver under this paragraph (f) in accordance with the timely claims payment standards specified in §447.45 of this chapter for health care practitioners participating in the Medicaid program.

(g) [Reserved]

(h) *Waivers approved under section 1915(b)(1) of the Act—(1) Basic rules.* (i) An agency must submit, as part of its waiver request, assurance that the entities described in paragraph (h)(2) of this section will be excluded from participation under an approved waiver.

(ii) FFP is available in payments to an entity that furnishes services under a section 1915(b)(1) waiver only if the agency excludes from participation any entity described in paragraph (h)(2) of this section.

(2) Entities that must be excluded. The agency must exclude an entity that meets any of the following conditions:

(i) Could be excluded under section 1128(b)(8) of the Act as being controlled by a sanctioned individual.

(ii) Has a substantial contractual relationship (direct or indirect) with an individual convicted of certain crimes, as described in section 1128(b)(8)(B) of the Act.

(iii) Employs or contracts directly or indirectly with one of the following:

(A) Any individual or entity that, under section 1128 or section 1128A of the Act, is precluded from furnishing health care, utilization review, medical social services, or administrative services.

(B) Any entity described in paragraph (h)(2)(i) of this section.

(3) Definitions. As used in this section, substantial contractual relationship means any contractual relationship that provides for one or more of the following services:

(i) The administration, management, or provision of medical services.

(ii) The establishment of policies, or the provision of operational support, for the administration, management, or provision of medical services.

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§ 431.56 Special waiver provisions applicable to American Samoa and the Northern Mariana Islands.

(a) *Statutory basis.* Section 1902(j) of the Act provides for waiver of all but three of the title XIX requirements, in the case of American Samoa and the Northern Mariana Islands.

(b) *Waiver provisions.* American Samoa or the Northern Mariana Islands may request, and CMS may approve, a waiver of any of the title XIX requirements except the following:

(1) The Federal medical assistance percentage specified in section 1903 of the Act and § 433.10(b) of this chapter.

(2) The limit imposed by section 1108(c) of the Act on the amount of Federal funds payable to American Samoa or the Northern Mariana Islands for care and services that meet the section 1905(a) definition for Medicaid assistance.

(3) The requirement that payment be made only with respect to expenditure made by American Samoa or the Northern Mariana Islands for care and services that meet the section 1905(a) definition of medical assistance.

§ 431.57 Waiver of cost-sharing requirements.

(a) Sections 1916(a)(3) and 1916(b)(3) of the Act specify the circumstances under which the Secretary is authorized to waive the requirement that cost-sharing amounts be nominal.

(b) For nonemergency services furnished in a hospital emergency room, the Secretary may by waiver permit a State to impose a copayment of up to double the “nominal” copayment amounts determined under § 447.54(a)(3) of this subchapter.