

§ 410.175 Alien absent from the United States.

(a) Medicare does not pay Part B benefits for services furnished to an individual who is not a citizen or a national of the United States if those services are furnished in any month for which the individual is not paid monthly social security cash benefits (or would not be paid if he or she were entitled to those benefits) because he or she has been outside the United States continuously for 6 full calendar months.

(b) Payment of benefits resumes with services furnished during the first full calendar month the alien is back in the United States.

[53 FR 6634, Mar. 2, 1988]

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Subpart A—General Exclusions and Exclusion of Particular Services

§ 411.1 Basis and scope.

(a) *Statutory basis.* Sections 1814(a) and 1835(a) of the Act require that a physician certify or recertify a patient's need for home health services but, in general, prohibit a physician from certifying or recertifying the need for services if the services will be furnished by an HHA in which the physician has a significant ownership interest, or with which the physician has a significant financial or contractual relationship. Sections 1814(c), 1835(d), and 1862 of the Act exclude from Medicare payment certain specified services. The Act provides special rules for payment of services furnished by the following: Federal providers or agencies (sections 1814(c) and 1835(d)); hospitals and physicians outside of the U.S. (sections 1814(f) and 1862(a)(4)); and hospitals and SNFs of the Indian Health Service (section 1880 of the Act). Section 1877 of the Act sets forth limitations on referrals and payment for designated health services furnished by entities with which the referring physician (or an immediate family member of the referring physician) has a financial relationship.

(b) *Scope.* This subpart identifies:

- (1) The particular types of services that are excluded;
- (2) The circumstances under which Medicare denies payment for certain services that are usually covered; and
- (3) The circumstances under which Medicare pays for services usually excluded from payment.

[54 FR 41734, Oct. 11, 1989, as amended at 60 FR 41978, Aug. 14, 1995; 60 FR 45361, Aug. 31, 1995; 66 FR 952, Jan. 4, 2001]

§ 411.2 Conclusive effect of QIO determinations on payment of claims.

If a utilization and quality control quality improvement organization (QIO) has assumed review responsibility, in accordance with part 466 of this chapter, for services furnished to Medicare beneficiaries, Medicare payment is not made for those services un-

less the conditions of subpart C of part 466 of this chapter are met.

§ 411.4 Services for which neither the beneficiary nor any other person is legally obligated to pay.

(a) *General rule.* Except as provided in § 411.8(b) (for services paid by a governmental entity), Medicare does not pay for a service if—

- (1) The beneficiary has no legal obligation to pay for the service; and
- (2) No other person or organization (such as a prepayment plan of which the beneficiary is a member) has a legal obligation to provide or pay for that service.

(b) *Special conditions for services furnished to individuals in custody of penal authorities.* Individuals who are in custody include, but are not limited to, individuals who are under arrest, incarcerated, imprisoned, escaped from confinement, under supervised release, on medical furlough, required to reside in mental health facilities, required to reside in halfway houses, required to live under home detention, or confined completely or partially in any way under a penal statute or rule. Payment may be made for services furnished to individuals or groups of individuals who are in the custody of police or other penal authorities or in the custody of a government agency under a penal statute only if the following conditions are met:

- (1) State or local law requires those individuals or groups of individuals to repay the cost of medical services they receive while in custody.
- (2) The State or local government entity enforces the requirement to pay by billing all such individuals, whether or not covered by Medicare or any other health insurance, and by pursuing collection of the amounts they owe in the same way and with the same vigor that it pursues the collection of other debts.

[54 FR 41734, Oct. 11, 1989, as amended at 72 FR 47410, Aug. 22, 2007]

§ 411.6 Services furnished by a Federal provider of services or other Federal agency.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, Medicare does not pay for services furnished by a

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Federal provider of services or other Federal agency.

(b) *Exceptions.* Payment may be made—

(1) For emergency hospital services, if the conditions of § 424.103 of this chapter are met;

(2) For services furnished by a participating Federal provider which CMS has determined is providing services to the public generally as a community institution or agency;

(3) For services furnished by participating hospitals and SNFs of the Indian Health Service; and

(4) For services furnished under arrangements (as defined in § 409.3 of this chapter) made by a participating hospital.

§ 411.7 Services that must be furnished at public expense under a Federal law or Federal Government contract.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, payment may not be made for services that any provider or supplier is obligated to furnish at public expense, in accordance with a law of, or a contract with, the United States.

(b) *Exception.* Payment may be made for services that a hospital or SNF of the Indian Health Service is obligated to furnish at public expense.

§ 411.8 Services paid for by a Government entity.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, Medicare does not pay for services that are paid for directly or indirectly by a government entity.

(b) *Exceptions.* Payment may be made for the following:

(1) Services furnished under a health insurance plan established for employees of the government entity.

(2) Services furnished under a title of the Social Security Act other than title XVIII.

(3) Services furnished in or by a participating general or special hospital that—

(i) Is operated by a State or local government agency; and

(ii) Serves the general community.

(4) Services furnished in a hospital or elsewhere, as a means of controlling in-

fectious diseases or because the individual is medically indigent.

(5) Services furnished by a participating hospital or SNF of the Indian Health Service.

(6) Services furnished by a public or private health facility that—

(i) Is not a Federal provider or other facility operated by a Federal agency;

(ii) Receives U.S. government funds under a Federal program that provides support to facilities that furnish health care services;

(iii) Customarily seeks payment for services not covered under Medicare from all available sources, including private insurance and patients' cash resources; and

(iv) Limits the amounts it collects or seeks to collect from a Medicare Part B beneficiary and others on the beneficiary's behalf to:

(A) Any unmet deductible applied to the charges related to the reasonable costs that the facility incurs in providing the covered services;

(B) Twenty percent of the remainder of those charges;

(C) The charges for noncovered services.

(7) Rural health clinic services that meet the requirements set forth in part 491 of this chapter.

[54 FR 41734, Oct. 11, 1989, as amended at 56 FR 2139, Jan. 22, 1991]

§ 411.9 Services furnished outside the United States.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, Medicare does not pay for services furnished outside the United States. For purposes of this paragraph (a), the following rules apply:

(1) The United States includes the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, The Northern Mariana Islands, and for purposes of services rendered on board ship, the territorial waters adjoining the land areas of the United States.

(2) Services furnished on board ship are considered to have been furnished in United States territorial waters if they were furnished while the ship was in a port of one of the jurisdictions listed in paragraph (a)(1) of this section, or within 6 hours before arrival

at, or 6 hours after departure from, such a port.

(3) A hospital that is not physically situated in one of the jurisdictions listed in paragraph (a)(1) of this section is considered to be outside the United States, even if it is owned or operated by the United States Government.

(b) *Exception.* Under the circumstances specified in subpart H of part 424 of this chapter, payment may be made for covered inpatient services furnished in a foreign hospital and, on the basis of an itemized bill, for covered physicians' services and ambulance service furnished in connection with those inpatient services, but only for the period during which the inpatient hospital services are furnished.

§411.10 Services required as a result of war.

Medicare does not pay for services that are required as a result of war, or an act of war, that occurs after the effective date of a beneficiary's current coverage for hospital insurance benefits or supplementary medical insurance benefits.

§411.12 Charges imposed by an immediate relative or member of the beneficiary's household.

(a) *Basic rule.* Medicare does not pay for services usually covered under Medicare if the charges for those services are imposed by—

(1) An immediate relative of the beneficiary; or

(2) A member of the beneficiary's household.

(b) *Definitions.* As used in this section—

Immediate relative means any of the following:

(1) Husband or wife.

(2) Natural or adoptive parent, child, or sibling.

(3) Stepparent, stepchild, stepbrother, or stepsister.

(4) Father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law.

(5) Grandparent or grandchild.

(6) Spouse of grandparent or grandchild.

Member of the household means any person sharing a common abode as part of a single family unit, including do-

mestic employees and others who live together as part of a family unit, but not including a mere roomer or boarder.

Professional corporation means a corporation that is completely owned by one or more physicians and is operated for the purpose of conducting the practice of medicine, osteopathy dentistry, podiatry, optometry, or chiropractic, or is owned by other health care professionals as authorized by State law.

(c) *Applicability of the exclusion.* The exclusion applies to the following charges in the specified circumstances:

(1) *Physicians' services.* (i) Charges for physicians' services furnished by an immediate relative of the beneficiary or member of the beneficiary's household, even if the bill or claim is submitted by another individual or by an entity such as a partnership or a professional corporation.

(ii) Charges for services furnished incident to a physician's professional services (for example by the physician's nurse or technician), only if the physician who ordered or supervised the services has an excluded relationship to the beneficiary.

(2) *Services other than physicians' services.* (i) Charges imposed by an individually owned provider or supplier if the owner has an excluded relationship to the beneficiary; and

(ii) Charges imposed by a partnership if any of the partners has an excluded relationship to the beneficiary.

(d) *Exception to the exclusion.* The exclusion does not apply to charges imposed by a corporation other than a professional corporation.

§411.15 Particular services excluded from coverage.

The following services are excluded from coverage:

(a) Routine physical checkups such as:

(1) Examinations performed for a purpose other than treatment or diagnosis of a specific illness, symptoms, complaint, or injury, except for screening mammography, colorectal cancer screening tests, screening pelvic exams, prostate cancer screening tests, glaucoma screening exams, ultrasound screening for abdominal aortic aneurysms (AAA), cardiovascular disease

screening tests, diabetes screening tests, a screening electrocardiogram, initial preventive physical examinations that meet the criteria specified in paragraphs (k)(6) through (k)(15) of this section, additional preventive services that meet the criteria in § 410.64 of this chapter, or annual wellness visits providing personalized prevention plan services.

(2) Examinations required by insurance companies, business establishments, government agencies, or other third parties.

(b) *Low vision aid exclusion*—(1) *Scope*. The scope of the eyeglass exclusion encompasses all devices irrespective of their size, form, or technological features that use one or more lens to aid vision or provide magnification of images for impaired vision.

(2) *Exceptions*. (i) Post-surgical prosthetic lenses customarily used during convalescence for eye surgery in which the lens of the eye was removed (for example, cataract surgery).

(ii) Prosthetic intraocular lenses and one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens.

(iii) Prosthetic lenses used by Medicare beneficiaries who are lacking the natural lens of the eye and who were not furnished with an intraocular lens.

(c) *Eye examinations* for the purpose of prescribing, fitting, or changing eyeglasses or contact lenses for refractive error only and procedures performed in the course of any eye examination to determine the refractive state of the eyes, without regard to the reason for the performance of the refractive procedures. Refractive procedures are excluded even when performed in connection with otherwise covered diagnosis or treatment of illness or injury.

(d) *Hearing aids* or examinations for the purpose of prescribing, fitting, or changing hearing aids.

(1) *Scope*. The scope of the hearing aid exclusion encompasses all types of air conduction hearing aids that provide acoustic energy to the cochlea via stimulation of the tympanic membrane with amplified sound and bone conduction hearing aids that provide mechanical stimulation of the cochlea via stimulation of the scalp with amplified

mechanical vibration or by direct contact with the tympanic membrane or middle ear ossicles.

(2) *Devices not subject to the hearing aid exclusion*. Paragraph (d)(1) of this section shall not apply to the following devices that produce the perception of sound by replacing the function of the middle ear, cochlea, or auditory nerve:

(i) Osseointegrated implants in the skull bone that provide mechanical energy to the cochlea via a mechanical transducer, or

(ii) Cochlear implants and auditory brainstem implants that replace the function of cochlear structures or auditory nerve and provide electrical energy to auditory nerve fibers and other neural tissue via implanted electrode arrays.

(e) *Immunizations, except for—*

(1) Vaccinations or inoculations directly related to the treatment of an injury or direct exposure such as antirabies treatment, tetanus antitoxin or booster vaccine, botulin antitoxin, antivenom sera, or immune globulin;

(2) Pneumococcal vaccinations that are reasonable and necessary for the prevention of illness;

(3) Hepatitis B vaccinations that are reasonable and necessary for the prevention of illness for those individuals, as defined in § 410.63(a) of this chapter, who are at high or intermediate risk of contracting hepatitis B;

(4) Influenza vaccinations that are reasonable and necessary for the prevention of illness; and

(5) COVID-19 vaccinations that are reasonable and necessary for the prevention of illness.

(f) *Orthopedic shoes* or other supportive devices for the feet, *except when* shoes are integral parts of leg braces.

(g) *Custodial care, except as necessary* for the palliation or management of terminal illness, as provided in part 418 of this chapter. (Custodial care is any care that does not meet the requirements for coverage as SNF care as set forth in §§ 409.31 through 409.35 of this chapter.)

(h) *Cosmetic surgery and related services*, except as required for the prompt repair of accidental injury or to improve the functioning of a malformed body member.

(i) *Dental services*—(1) *Basic rule.* *Dental services* in connection with the care, treatment, filling, removal, or replacement of teeth, or structures directly supporting the teeth.

(2) *Exception.* *Except* for inpatient hospital services in connection with such dental procedures when hospitalization is required because of—

(i) The individual's underlying medical condition and clinical status; or

(ii) The severity of the dental procedures.⁵⁷⁷

(3) *Inapplicability.* (i) Dental services that are inextricably linked to, and substantially related and integral to the clinical success of, a certain covered medical service are not excluded; payment may be made under Medicare Parts A and B for services furnished in the inpatient or outpatient setting. Such services include, but are not limited to:

(A) Dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered organ transplant, cardiac valve replacement, or valvuloplasty procedures; and, medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, the organ transplant, cardiac valve replacement, or valvuloplasty procedure.

(B) The reconstruction of a dental ridge performed as a result of and at the same time as the surgical removal of a tumor.

(C) The stabilization or immobilization of teeth in connection with the reduction of a jaw fracture, and dental splints only when used in conjunction with covered treatment of a covered medical condition such as dislocated jaw joints.

(D) The extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease.

(ii) Ancillary services and supplies furnished incident to covered dental services are not excluded, and Medicare payment may be made under Part A or Part B, as applicable, whether the serv-

ice is performed in the inpatient or outpatient setting, including, but not limited to the administration of anesthesia, diagnostic x-rays, use of operating room, and other related procedures.

(j) *Personal comfort services*, *except* as necessary for the palliation or management of terminal illness as provided in part 418 of this chapter. The use of a television set or a telephone are examples of personal comfort services.

(k) *Any services that are not reasonable and necessary* for one of the following purposes:

(1) For the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

(2) In the case of hospice services, for the palliation or management of terminal illness, as provided in part 418 of this chapter.

(3) In the case of pneumococcal vaccine for the prevention of illness.

(4) In the case of the patient outcome assessment program established under section 1875(c) of the Act, for carrying out the purpose of that section.

(5) In the case of hepatitis B vaccine, for the prevention of illness for those individuals at high or intermediate risk of contracting hepatitis B. (Section 410.63(a) of this chapter sets forth criteria for identifying those individuals.)

(6) In the case of screening mammography, for the purpose of early detection of breast cancer subject to the conditions and limitations specified in §410.34 of this chapter.

(7) In the case of colorectal cancer screening tests, for the purpose of early detection of colorectal cancer subject to the conditions and limitations specified in §410.37 of this chapter.

(8) In the case of screening pelvic examinations, for the purpose of early detection of cervical or vaginal cancer subject to the conditions and limitations specified in §410.56 of this chapter.

(9) In the case of prostate cancer screening tests, for the purpose of early detection of prostate cancer, subject to the conditions and limitations specified in §410.39 of this chapter.

(10) In the case of screening exams for glaucoma, for the purpose of early

⁵⁷⁷ Before July 1981, inpatient hospital care in connection with dental procedures was covered only when required by the patient's underlying medical condition and clinical status.

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detection of glaucoma, subject to the conditions and limitations specified in § 410.23 of this chapter.

(11) In the case of initial preventive physical examinations, with the goal of health promotion and disease prevention, subject to the conditions and limitations specified in § 410.16 of this chapter.

(12) In the case of ultrasound screening for abdominal aortic aneurysms, with the goal of early detection of abdominal aortic aneurysms, subject to the conditions and limitation specified in § 410.19 of this chapter.

(13) In the case of cardiovascular disease screening tests for the early detection of cardiovascular disease or abnormalities associated with an elevated risk for that disease, subject to the conditions specified in § 410.17 of this chapter.

(14) In the case of diabetes screening tests furnished to an individual at risk for diabetes for the purpose of the early detection of that disease, subject to the conditions specified in § 410.18 of this chapter.

(15) In the case of additional preventive services not otherwise described in this title, subject to the conditions and limitation specified in § 410.64 of this chapter.

(16) In the case of an annual wellness visit providing a personalized prevention plan, subject to the conditions and limitations specified in § 410.15 of this subpart.

(1) *Foot care*—(1) *Basic rule.* Except as provided in paragraph (1)(2) of this section, any services furnished in connection with the following:

(i) *Routine foot care*, such as the cutting or removal of corns, or calluses, the trimming of nails, routine hygienic care (preventive maintenance care ordinarily within the realm of self care), and any service performed in the absence of localized illness, injury, or symptoms involving the feet.

(ii) *The evaluation or treatment of subluxations of the feet* regardless of underlying pathology. (Subluxations are structural misalignments of the joints, other than fractures or complete dislocations, that require treatment only by nonsurgical methods.

(iii) *The evaluation or treatment of flattened arches* (including the prescription

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of supportive devices) regardless of the underlying pathology.

(2) *Exceptions.* (i) Treatment of warts is not excluded.

(ii) Treatment of mycotic toenails may be covered if it is furnished no more often than every 60 days or the billing physician documents the need for more frequent treatment.

(iii) The services listed in paragraph (1)(1) of this section are not excluded if they are furnished—

(A) As an incident to, at the same time as, or as a necessary integral part of a primary covered procedure performed on the foot; or

(B) As initial diagnostic services (regardless of the resulting diagnosis) in connection with a specific symptom or complaint that might arise from a condition whose treatment would be covered.

(m) *Services to hospital patients*—(1) *Basic rule.* Except as provided in paragraph (m)(3) of this section, any service furnished to an inpatient of a hospital or to a hospital outpatient (as defined in § 410.2 of this chapter) during an encounter (as defined in § 410.2 of this chapter) by an entity other than the hospital unless the hospital has an arrangement (as defined in § 409.3 of this chapter) with that entity to furnish that particular service to the hospital's patients. As used in this paragraph (m)(1), the term "hospital" includes a CAH.

(2) *Scope of exclusion.* Services subject to exclusion from coverage under the provisions of this paragraph (m) include, but are not limited to, clinical laboratory services; pacemakers and other prostheses and prosthetic devices (other than dental) that replace all or part of an internal body organ (for example, intraocular lenses); artificial limbs, knees, and hips; equipment and supplies covered under the prosthetic device benefits; and services incident to a physician service.

(3) *Exceptions.* The following services are not excluded from coverage:

(i) Physicians' services that meet the criteria of § 415.102(a) of this chapter for payment on a reasonable charge or fee schedule basis.

(ii) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the

Act, that are furnished after December 31, 1990.

(iii) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(iv) Certified nurse-midwife services, as defined in section 1861(ff) of the Act, that are furnished after December 31, 1990.

(v) Qualified psychologist services, as defined in section 1861(ii) of the Act, that are furnished after December 31, 1990.

(vi) Services of an anesthetist, as defined in §410.69 of this chapter.

(n) *Certain services of an assistant-at-surgery.* (1) Services of an assistant-at-surgery in a cataract operation (including subsequent insertion of an intra-ocular lens) unless, before the surgery is performed, the appropriate QIO or a carrier has approved the use of such an assistant in the surgical procedure based on the existence of a complicating medical condition.

(2) Services on an assistant-at-surgery in a surgical procedure (or class of surgical procedures) for which assistants-at-surgery on average are used in fewer than 5 percent of such procedures nationally.

(o) Experimental or investigational devices, except for certain devices.

(1) Categorized by the FDA as a Category B (Nonexperimental/investigational) device as defined in §405.201(b) of the chapter; and

(2) Furnished in accordance with the coverage requirements in §405.211(b).

(p) *Services furnished to SNF residents*—(1) *Basic rule.* Except as provided in paragraph (p)(2) of this section, any service furnished to a resident of an SNF during a covered Part A stay by an entity other than the SNF, unless the SNF has an arrangement (as defined in §409.3 of this chapter) with that entity to furnish that particular service to the SNF's residents. Services subject to exclusion under this paragraph include, but are not limited to—

(i) Any physical, occupational, or speech-language therapy services, regardless of whether the services are furnished by (or under the supervision of) a physician or other health care professional, and regardless of whether the resident who receives the services is in a covered Part A stay; and

(ii) Services furnished as an incident to the professional services of a physician or other health care professional specified in paragraph (p)(2) of this section.

(2) *Exceptions.* The following services are not excluded from coverage, provided that the claim for payment includes the SNF's Medicare provider number in accordance with §424.32(a)(5) of this chapter:

(i) Physicians' services that meet the criteria of §415.102(a) of this chapter for payment on a fee schedule basis.

(ii) Services performed under a physician's supervision by a physician assistant who meets the applicable definition in section 1861(aa)(5) of the Act.

(iii) Services performed by a nurse practitioner or clinical nurse specialist who meets the applicable definition in section 1861(aa)(5) of the Act and is working in collaboration (as defined in section 1861(aa)(6) of the Act) with a physician.

(iv) Services performed by a certified nurse-midwife, as defined in section 1861(gg) of the Act.

(v) Services performed by a qualified psychologist, as defined in section 1861(ii) of the Act.

(vi) Services performed by a certified registered nurse anesthetist, as defined in section 1861(bb) of the Act.

(vii) Dialysis services and supplies, as defined in section 1861(s)(2)(F) of the Act, and those ambulance services that are furnished in conjunction with them.

(viii) Erythropoietin (EPO) for dialysis patients, as defined in section 1861(s)(2)(O) of the Act.

(ix) Hospice care, as defined in section 1861(dd) of the Act.

(x) An ambulance trip that initially conveys an individual to the SNF to be admitted as a resident, or that conveys an individual from the SNF in connection with one of the circumstances specified in paragraphs (p)(3)(i) through (p)(3)(iv) of this section as ending the individual's status as an SNF resident.

(xi) The transportation costs of electrocardiogram equipment (HCPCS code R0076), but only with respect to those electrocardiogram test services furnished during 1998.

(xii) Services described in subparagraphs (p)(2)(i) through (vi) of this section when furnished via telehealth under section 1834(m)(4)(C)(ii)(VII) of the Act.

(xiii) Those chemotherapy items identified, as of July 1, 1999, by HCPCS codes J9000–J9020, J9040–J9151, J9170–J9185, J9200–J9201, J9206–J9208, J9211, J9230–J9245, and J9265–J9600, and as of January 1, 2004, by HCPCS codes A9522, A9523, A9533, and A9534 (as subsequently modified by CMS), and any additional chemotherapy items identified by CMS.

(xiv) Those chemotherapy administration services identified, as of July 1, 1999, by HCPCS codes 36260–36262, 36489, 36530–36535, 36640, 36823, and 96405–96542 (as subsequently modified by CMS), and any additional chemotherapy administration services identified by CMS.

(xv) Those radioisotope services identified, as of July 1, 1999, by HCPCS codes 79030–79440 (as subsequently modified by CMS), and any additional radioisotope services identified by CMS.

(xvi) Those customized prosthetic devices (including artificial limbs and their components) identified, as of July 1, 1999, by HCPCS codes L5050–L5340, L5500–L5611, L5613–L5986, L5988, L6050–L6370, L6400–6880, L6920–L7274, and L7362–L7366 (as subsequently modified by CMS) and any additional customized prosthetic devices identified by CMS, which are delivered for a resident's use during a stay in the SNF and intended to be used by the resident after discharge from the SNF.

(xvii) Those blood clotting factors indicated for the treatment of patients with hemophilia and other bleeding disorders identified, as of July 1, 2020, by HCPCS codes J7170, J7175, J7177–J7183, J7185–J7190, J7192–J7195, J7198–J7203, J7205, and J7207–J7211 (as subsequently modified by CMS) and items and services related to the furnishing of such factors, and any additional blood clotting factors identified by CMS and items and services related to the furnishing of such factors.

(xviii) Those RHC and FQHC services that are described in §405.2411(b)(2) of this chapter.

(3) *SNF resident defined.* For purposes of this paragraph, a beneficiary who is admitted to a Medicare-participating SNF is considered to be a resident of the SNF for the duration of the beneficiary's covered Part A stay. In addition, for purposes of the services described in paragraph (p)(1)(i) of this section, a beneficiary who is admitted to a Medicare-participating SNF is considered to be a resident of the SNF regardless of whether the beneficiary is in a covered Part A stay. Whenever the beneficiary leaves the facility, the beneficiary's status as an SNF resident for purposes of this paragraph (along with the SNF's responsibility to furnish or make arrangements for the services described in paragraph (p)(1) of this section) ends when one of the following events occurs—

(i) The beneficiary is admitted as an inpatient to a Medicare-participating hospital or CAH, or as a resident to another SNF;

(ii) The beneficiary receives services from a Medicare-participating home health agency under a plan of care;

(iii) The beneficiary receives outpatient services from a Medicare-participating hospital or CAH (but only for those services that CMS designates as being beyond the general scope of SNF comprehensive care plans, as required under §483.21(b) of this chapter); or

(iv) The beneficiary is formally discharged (or otherwise departs) from the SNF, unless the beneficiary is readmitted (or returns) to that or another SNF before the following midnight.

(q) *Assisted suicide.* Any health care service used for the purpose of causing, or assisting to cause, the death of any individual. This does not pertain to the withholding or withdrawing of medical treatment or care, nutrition or hydration or to the provision of a service for the purpose of alleviating pain or discomfort, even if the use may increase the risk of death, so long as the service is not furnished for the specific purpose of causing death.

(r) A home health service (including medical supplies described in section 1861(m)(5) of the Act, but excluding durable medical equipment to the extent provided for in such section) as defined

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in section 1861(m) of the Act furnished to an individual who is under a plan of care of an HHA, unless that HHA has submitted a claim for payment for such services.

(s) Unless § 414.404(d) or § 414.408(e)(2) of this subchapter applies, Medicare does not make payment if an item or service that is included in a competitive bidding program (as described in part 414, subpart F of this subchapter) is furnished by a supplier other than a contract supplier (as defined in § 414.402 of this subchapter).

[54 FR 41734, Oct. 11, 1989; 55 FR 1820, Jan. 19, 1990]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 411.15, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.gpo.gov.

EFFECTIVE DATE NOTE: At 88 FR 53345, Aug. 7, 2023, § 411.15 was amended by:

- a. Redesignating paragraphs (p)(2)(vi) through (xviii) as (p)(2)(viii) through (xx);
- b. Adding new paragraphs (p)(2)(vi) and (vii); and
- c. Revising newly redesignated paragraph (p)(2)(xiv), effective Jan. 1, 2024. For the convenience of the user, the added and revised text is set forth as follows:

§ 411.15 Particular services excluded from coverage.

* * * * *

(p) * * *

(2) * * *

(vi) Services performed by a marriage and family therapist, as defined in section 1861(l)(2) of the Act.

(vii) Services performed by a mental health counselor, as defined in section 1861(l)(4) of the Act.

* * * * *

(xiv) Services described in paragraphs (p)(2)(i) through (viii) of this section when furnished via telehealth under section 1834(m)(4)(C)(ii)(VII) of the Act.

* * * * *

Subpart B—Insurance Coverage That Limits Medicare Payment: General Provisions

§ 411.20 Basis and scope.

(a) *Statutory basis.* (1) Section 1862(b)(2)(A)(i) of the Act precludes

Medicare payment for services to the extent that payment has been made or can reasonably be expected to be made under a group health plan with respect to—

(i) A beneficiary entitled to Medicare on the basis of ESRD during the first 18 months of that entitlement;

(ii) A beneficiary who is age 65 or over, entitled to Medicare on the basis of age, and covered under the plan by virtue of his or her current employment status or the current employment status of a spouse of any age; or

(iii) A beneficiary who is under age 65, entitled to Medicare on the basis of disability, and covered under the plan by virtue of his or her current employment status or the current employment status of a family member.

(2) Section 1862(b)(2)(A)(ii) of the Act precludes Medicare payment for services to the extent that payment has been made or can reasonably be expected to be made under any of the following:

(i) Workers' compensation.

(ii) Liability insurance.

(iii) No-fault insurance.

(b) *Scope.* This subpart sets forth general rules that apply to the types of insurance specified in paragraph (a) of this section. Other general rules that apply to group health plans are set forth in subpart E of this part.

[60 FR 45361, Aug. 31, 1995, as amended at 71 FR 9470, Feb. 24, 2006]

§ 411.21 Definitions.

In this subpart B and in subparts C through H of this part, unless the context indicates otherwise—

Conditional payment means a Medicare payment for services for which another payer is responsible, made either on the bases set forth in subparts C through H of this part, or because the intermediary or carrier did not know that the other coverage existed.

Coverage or *covered services*, when used in connection with primary payments, means services for which a primary payer would pay if a proper claim were filed.

Monthly capitation payment means a comprehensive monthly payment that covers all physician services associated with the continuing medical management of a maintenance dialysis patient

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who dialyses at home or as an out-patient in an approved ESRD facility.

Plan means any arrangement, oral or written, by one or more entities, to provide health benefits or medical care or assume legal liability for injury or illness.

Primary payer means, when used in the context in which Medicare is the secondary payer, any entity that is or was required or responsible to make payment with respect to an item or service (or any portion thereof) under a primary plan. These entities include, but are not limited to, insurers or self-insurers, third party administrators, and all employers that sponsor or contribute to group health plans or large group health plans.

Primary payment means, when used in the context in which Medicare is the secondary payer, payment by a primary payer for services that are also covered under Medicare.

Primary plan means, when used in the context in which Medicare is the secondary payer, a group health plan or large group health plan, a workers' compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan), or no-fault insurance.

Prompt or promptly, when used in connection with primary payments, except as provided in § 411.50, for payments by liability insurers, means payment within 120 days after receipt of the claim.

Proper claim means a claim that is filed timely and meets all other claim filing requirements specified by the plan, program, or insurer.

Secondary, when used to characterize Medicare benefits, means that those benefits are payable only to the extent that payment has not been made and cannot reasonably be expected to be made under other coverage that is primary to Medicare.

Secondary payments means payments made for Medicare covered services or portions of services that are not payable under other coverage that is primary to Medicare.

[54 FR 41734, Oct. 11, 1989, as amended at 60 FR 45361, Aug. 31, 1995; 71 FR 9470, Feb. 24, 2006]

§ 411.22 Reimbursement obligations of primary payers and entities that received payment from primary payers.

(a) A primary payer, and an entity that receives payment from a primary payer, must reimburse CMS for any payment if it is demonstrated that the primary payer has or had a responsibility to make payment.

(b) A primary payer's responsibility for payment may be demonstrated by—

(1) A judgment;

(2) A payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary payer or the primary payer's insured; or

(3) By other means, including but not limited to a settlement, award, or contractual obligation.

(c) The primary payer must make payment to either of the following:

(1) To the entity designated to receive repayments if the demonstration of primary payer responsibilities is other than receipt of a recovery demand letter from CMS or designated contractor.

(2) As directed in a recovery demand letter.

[71 FR 9470, Feb. 24, 2006, as amended at 73 FR 9684, Feb. 22, 2008]

§ 411.23 Beneficiary's cooperation.

(a) If CMS takes action to recover conditional payments, the beneficiary must cooperate in the action.

(b) If CMS's recovery action is unsuccessful because the beneficiary does not cooperate, CMS may recover from the beneficiary.

§ 411.24 Recovery of conditional payments.

If a Medicare conditional payment is made, the following rules apply:

(a) *Release of information.* The filing of a Medicare claim by on or behalf of the beneficiary constitutes an express authorization for any entity, including State Medicaid and workers' compensation agencies, and data depositories, that possesses information pertinent to the Medicare claim to release that information to CMS. This information will be used only for Medicare

claims processing and for coordination of benefits purposes.

(b) *Right to initiate recovery.* CMS may initiate recovery as soon as it learns that payment has been made or could be made under workers' compensation, any liability or no-fault insurance, or an employer group health plan.

(c) *Amount of recovery.* (1) If it is not necessary for CMS to take legal action to recover, CMS recovers the lesser of the following:

(i) The amount of the Medicare primary payment.

(ii) The full primary payment amount that the primary payer is obligated to pay under this part without regard to any payment, other than a full primary payment that the primary payer has paid or will make, or, in the case of a primary payment beneficiary, the amount of the primary payment.

(2) If it is necessary for CMS to take legal action to recover from the primary payer, CMS may recover twice the amount specified in paragraph (c)(1)(i) of this section.

(d) *Methods of recovery.* CMS may recover by direct collection or by offset against any monies CMS owes the entity responsible for refunding the conditional payment.

(e) *Recovery from primary payers.* CMS has a direct right of action to recover from any primary payer.

(f) *Claims filing requirements.* (1) CMS may recover without regard to any claims filing requirements that the insurance program or plan imposes on the beneficiary or other claimant such as a time limit for filing a claim or a time limit for notifying the plan or program about the need for or receipt of services.

(2) However, CMS will not recover its payment for particular services in the face of a claims filing requirement unless it has filed a claim for recovery by the end of the year following the year in which the Medicare intermediary or carrier that paid the claim has notice that the third party is a primary plan to Medicare for those particular services. (A notice received during the last three months of a year is considered received during the following year.)

(g) *Recovery from parties that receive primary payments.* CMS has a right of action to recover its payments from

any entity, including a beneficiary, provider, supplier, physician, attorney, State agency or private insurer that has received a primary payment.

(h) *Reimbursement to Medicare.* If the beneficiary or other party receives a primary payment, the beneficiary or other party must reimburse Medicare within 60 days.

(i) *Special rules.* (1) In the case of liability insurance settlements and disputed claims under employer group health plans, workers' compensation insurance or plan, and no-fault insurance, the following rule applies: If Medicare is not reimbursed as required by paragraph (h) of this section, the primary payer must reimburse Medicare even though it has already reimbursed the beneficiary or other party.

(2) The provisions of paragraph (i)(1) of this section also apply if a primary payer makes its payment to an entity other than Medicare when it is, or should be, aware that Medicare has made a conditional primary payment.

(3) In situations that involve procurement costs, the rule of § 411.37(b) applies.

(j) *Recovery against Medicaid agency.* If a primary payment is made to a State Medicaid agency and that agency does not reimburse Medicare, CMS may reduce any Federal funds due the Medicaid agency (under title XIX of the Act) by an amount equal to the Medicare payment or the primary payment, whichever is less.

(k) *Recovery against Medicare contractor.* If a Medicare contractor, including an intermediary or carrier, also insures, underwrites, or administers as a third party administrator, a program or plan that is primary to Medicare, and does not reimburse Medicare, CMS may offset the amount owed against any funds due the intermediary or carrier under title XVIII of the Act or due the contractor under the contract.

(l) *Recovery when there is failure to file a proper claim—(1) Basic rule.* If Medicare makes a conditional payment with respect to services for which the beneficiary or provider or supplier has not filed a proper claim with a primary payer, and Medicare is unable to recover from the primary payer, Medicare may recover from the beneficiary

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or provider or supplier that was responsible for the failure to file a proper claim.

(2) *Exceptions.* (i) This rule does not apply in the case of liability insurance nor when failure to file a proper claim is due to mental or physical incapacity of the beneficiary.

(ii) CMS will not recover from providers or suppliers that are in compliance with the requirements of § 489.20 of this chapter and can show that the reason they failed to file a proper claim is that the beneficiary, or someone acting on his or her behalf, failed to give, or gave erroneous, information regarding coverage that is primary to Medicare.

(m) *Interest charges.* (1) With respect to recovery of payments for items and services furnished before October 31, 1994, CMS charges interest, exercising common law authority in accordance with 45 CFR 30.13, consistent with the Federal Claims Collection Act (31 U.S.C. 3711).

(2) In addition to its common law authority with respect to recovery of payments for items and services furnished on or after October 31, 1994, CMS charges interest in accordance with section 1862(b)(2)(B)(i) of the Act. Under that provision—

(i) CMS may charge interest if reimbursement is not made to the appropriate trust fund before the expiration of the 60-day period that begins on the date on which notice or other information is received by CMS that payment has been or could be made under a primary plan;

(ii) Interest may accrue from the date when that notice or other information is received by CMS, is charged until reimbursement is made, and is applied for full 30-day periods; and

(iii) The rate of interest is that provided at § 405.378(d) of this chapter.

[54 FR 41734, Oct. 11, 1989, as amended at 55 FR 1820, Jan. 19, 1990; 60 FR 45361, 45362, Aug. 31, 1995; 69 FR 45607, July 30, 2004; 71 FR 9470, Feb. 24, 2006]

§ 411.25 Primary payer's notice of primary payment responsibility.

(a) If it is demonstrated to a primary payer that CMS has made a Medicare primary payment for services for which the primary payer has made or should

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have made primary payment, it must provide notice about primary payment responsibility and information about the underlying MSP situation to the entity or entities designated by CMS to receive and process that information.

(b) The notice must describe the specific situation and the circumstances (including the particular type of insurance coverage as specified in § 411.20(a)) and, if appropriate, the time period during which the insurer is primary to Medicare.

(c) The primary payer must provide additional information to the designated entity or entities as the designated entity or entities may require this information to update CMS' system of records.

[54 FR 41734, Oct. 11, 1989, as amended at 55 FR 1820, Jan. 19, 1990; 73 FR 9684, Feb. 22, 2008]

§ 411.26 Subrogation and right to intervene.

(a) *Subrogation.* With respect to services for which Medicare paid, CMS is subrogated to any individual, provider, supplier, physician, private insurer, State agency, attorney, or any other entity entitled to payment by a primary payer.

(b) *Right to intervene.* CMS may join or intervene in any action related to the events that gave rise to the need for services for which Medicare paid.

§ 411.28 Waiver of recovery and compromise of claims.

(a) CMS may waive recovery, in whole or in part, if the probability of recovery, or the amount involved, does not warrant pursuit of the claim.

(b) General rules applicable to compromise of claims are set forth in subpart F of part 401 and § 405.376 of this chapter.

(c) Other rules pertinent to recovery are contained in subpart C of part 405 of this chapter.

[54 FR 41734, Oct. 11, 1989, as amended at 61 FR 63749, Dec. 2, 1996]

§ 411.30 Effect of primary payment on benefit utilization and deductibles.

(a) *Benefit utilization.* Inpatient psychiatric hospital and SNF care that is paid for by a primary payer is not

counted against the number of inpatient care days available to the beneficiary under Medicare Part A.

(b) *Deductibles.* Expenses for Medicare covered services that are paid for by primary payers are credited toward the Medicare Part A and Part B deductibles.

§ 411.31 Authority to bill primary payers for full charges.

(a) The fact that Medicare payments are limited to the DRG amount, or the reasonable charge, reasonable cost, capitation or fee schedule rate, does not affect the amount that a primary payer may pay.

(b) With respect to workers' compensation plans, no-fault insurers, and employer group health plans, a provider or supplier may bill its full charges and expect those charges to be paid unless there are limits imposed by laws other than title XVIII of the Act or by agreements with the primary payer.

§ 411.32 Basis for Medicare secondary payments.

(a) *Basic rules.* (1) Medicare benefits are secondary to benefits payable by a primary payer even if State law or the primary payer states that its benefits are secondary to Medicare benefits or otherwise limits its payments to Medicare beneficiaries.

(2) Except as provided in paragraph (b) of this section, Medicare makes secondary payments, within the limits specified in paragraph (c) of this section and in § 411.33, to supplement the primary payment if that payment is less than the charges for the services and, in the case of services paid on other than a reasonable charge basis, less than the gross amount payable by Medicare under § 411.33(e).

(b) *Exception.* Medicare does not make a secondary payment if the provider or supplier is either obligated to accept, or voluntarily accepts, as full payment, a primary payment that is less than its charges.

(c) *General limitation: Failure to file a proper claim.* When a provider or supplier, or a beneficiary who is not physically or mentally incapacitated, receives a reduced primary payment because of failure to file a proper claim,

the Medicare secondary payment may not exceed the amount that would have been payable under § 411.33 if the primary payer had paid on the basis of a proper claim.

The provider, supplier, or beneficiary must inform CMS that a reduced payment was made, and the amount that would have been paid if a proper claim had been filed.

§ 411.33 Amount of Medicare secondary payment.

(a) *Services for which CMS pays on a Medicare fee schedule or reasonable charge basis.* The Medicare secondary payment is the lowest of the following:

(1) The actual charge by the supplier (or the amount the supplier is obligated to accept as payment in full if that is less than the charges) minus the amount paid by the primary payer.

(2) The amount that Medicare would pay if the services were not covered by a primary payer.

(3) The higher of the Medicare fee schedule, Medicare reasonable charge, or other amount which would be payable under Medicare (without regard to any applicable Medicare deductible or coinsurance amounts) or the primary payer's allowable charge (without regard to any deductible or co-insurance imposed by the policy or plan) minus the amount actually paid by the primary payer.

(b) *Example:* An individual received treatment from a physician for which the physician charged \$175. The primary payer allowed \$150 of the charge and paid 80 percent of this amount or \$120. The Medicare fee schedule for this treatment is \$125. The individual's Part B deductible had been met. As secondary payer, Medicare pays the lowest of the following amounts:

(1) Excess of actual charge minus the primary payment: $\$175 - \$120 = \$55$.

(2) Amount Medicare would pay if the services were not covered by a primary payer: $.80 \times \$125 = \100 .

(3) Primary payer's allowable charge without regard to its coinsurance (since that amount is higher than the Medicare fee schedule in this case) minus amount paid by the primary payer: $\$150 - \$120 = \$30$.

The Medicare payment is \$30.

(c)-(d) [Reserved]

(e) *Services reimbursed on a basis other than fee schedule, reasonable charge, or monthly capitation rate.* The Medicare secondary payment is the lowest of the following:

(1) The gross amount payable by Medicare (that is, the amount payable without considering the effect of the Medicare deductible and coinsurance or the payment by the primary payer), minus the applicable Medicare deductible and coinsurance amounts.

(2) The gross amount payable by Medicare, minus the amount paid by the primary payer.

(3) The provider's charges (or the amount the provider is obligated to accept as payment in full, if that is less than the charges), minus the amount payable by the primary payer.

(4) The provider's charges (or the amount the provider is obligated to accept as payment in full if that is less than the charges), minus the applicable Medicare deductible and coinsurance amounts.

(f) *Examples:* (1) A hospital furnished 7 days of inpatient hospital care in 1987 to a Medicare beneficiary. The provider's charges for Medicare-covered services totaled \$2,800. The primary payer paid \$2,360. No part of the Medicare inpatient hospital deductible of \$520 had been met. If the gross amount payable by Medicare in this case is \$2,700, then as secondary payer, Medicare pays the lowest of the following amounts:

(i) The gross amount payable by Medicare minus the Medicare inpatient hospital deductible: $\$2,700 - \$520 = \$2,180$.

(ii) The gross amount payable by Medicare minus the primary payment: $\$2,700 - \$2,360 = \$340$.

(iii) The provider's charges minus the primary payment: $\$2,800 - \$2,360 = \$440$.

(iv) The provider's charges minus the Medicare deductible: $\$2,800 - \$520 = \$2,280$. Medicare's secondary payment is \$340 and the combined payment made by the primary payer and Medicare on behalf of the beneficiary is \$2,700. The \$520 deductible was satisfied by the primary payment so that the beneficiary incurred no out-of-pocket expenses.

(2) A hospital furnished 1 day of inpatient hospital care in 1987 to a Medicare beneficiary. The provider's

charges for Medicare-covered services totalled \$750. The primary payer paid \$450. No part of the Medicare inpatient hospital deductible had been met previously. The primary payment is credited toward that deductible. If the gross amount payable by Medicare in this case is \$850, then as secondary payer, Medicare pays the lowest of the following amounts:

(i) The gross amount payable by Medicare minus the Medicare deductible: $\$850 - \$520 = \$330$.

(ii) The gross amount payable by Medicare minus the primary payment: $\$850 - \$450 = \$400$.

(iii) The provider's charges minus the primary payment: $\$750 - \$450 = \$300$.

(iv) The provider's charges minus the Medicare deductible: $\$750 - \$520 = \$230$. Medicare's secondary payment is \$230, and the combined payment made by the primary payer and Medicare on behalf of the beneficiary is \$680. The hospital may bill the beneficiary \$70 (the \$520 deductible minus the \$450 primary payment). This fully discharges the beneficiary's deductible obligation.

(3) An ESRD beneficiary received 8 dialysis treatments for which a facility charged \$160 per treatment for a total of \$1,280. No part of the beneficiary's \$75 Part B deductible had been met. The primary payer paid \$1,024 for Medicare-covered services. The composite rate per dialysis treatment at this facility is \$131 or \$1,048 for 8 treatments. As secondary payer, Medicare pays the lowest of the following:

(i) The gross amount payable by Medicare minus the applicable Medicare deductible and coinsurance: $\$1,048 - \$75 - \$194.60 = \778.40 . (The coinsurance is calculated as follows: $\$1,048 \text{ composite rate} - \$75 \text{ deductible} = \$973 \times .20 = \$194.60$).

(ii) The gross amount payable by Medicare minus the primary payment: $\$1,048 - \$1,024 = \$24$.

(iii) The provider's charges minus the primary payment: $\$1,280 - \$1,024 = \$256$.

(iv) The provider's charge minus the Medicare deductible and coinsurance: $\$1,280 - \$75 - \$194.60 = \$1,010.40$. Medicare pays \$24. The beneficiary's Medicare deductible and coinsurance were met by the primary payment.

(4) A hospital furnished 5 days of inpatient care in 1987 to a Medicare beneficiary. The provider's charges for Medicare-covered services were \$4,000 and the gross amount payable was \$3,500. The provider agreed to accept \$3,000 from the primary payer as payment in full. The primary payer paid \$2,900 due to a deductible requirement under the primary plan. Medicare considers the amount the provider is obligated to accept as full payment (\$3,000) to be the provider charges. The Medicare secondary payment is the lowest of the following:

(i) The gross amount payable by Medicare minus the Medicare inpatient deductible: $\$3,500 - \$520 = \$2,980$.

(ii) The gross amount payable by Medicare minus the primary payment: $\$3,500 - \$2,900 = \$600$.

(iii) The provider's charge minus the primary payment: $\$3,000 - \$2,900 = \$100$.

(iv) The provider's charges minus the Medicare inpatient deductible: $\$3,000 - \$520 = \$2,480$. The Medicare secondary payment is \$100. When Medicare is the secondary payer, the combined payment made by the primary payer and Medicare on behalf of the beneficiary is \$3,000. The beneficiary has no liability for Medicare-covered services since the primary payment satisfied the \$520 deductible.

[54 FR 41734, Oct. 11, 1989, as amended at 55 FR 1820, Jan. 19, 1990; 60 FR 45362, Aug. 31, 1995; 71 FR 9470, Feb. 24, 2006]

§ 411.35 Limitations on charges to a beneficiary or other party when a workers' compensation plan, a no-fault insurer, or an employer group health plan is primary payer.

(a) *Definition.* As used in this section *Medicare-covered services* means services for which Medicare benefits are payable or would be payable except for the Medicare deductible and coinsurance provisions and the amounts payable by the primary payer.

(b) *Applicability.* This section applies when a workers' compensation plan, a no-fault insurer or an employer group health plan is primary to Medicare.

(c) *Basic rule.* Except as provided in paragraph (d) of this section, the amounts the provider or supplier may collect or seek to collect, for the Medicare-covered services from the bene-

ficiary or any entity other than the workers' compensation plan, the no-fault insurer, or the employer plan and Medicare, are limited to the following:

(1) The amount paid or payable by the primary payer to the beneficiary. If this amount exceeds the amount payable by Medicare (without regard to deductible or coinsurance), the provider or supplier may retain the primary payment in full without violating the terms of the provider agreement or the conditions of assignment.

(2) The amount, if any, by which the applicable Medicare deductible and coinsurance amounts exceed any primary payment made or due to the beneficiary or to the provider or supplier for the medical services.

(3) The amount of any charges that may be made to a beneficiary under § 413.35 of this chapter when cost limits are applied to the services, or under § 489.32 of this chapter when the services are partially covered, but only to the extent that the primary payer is not responsible for those charges.

(d) *Exception.* The limitations of paragraph (c) of this section do not apply if the services were furnished by a supplier that is not a participating supplier and has not accepted assignment for the services or claimed payment under § 424.64 of this chapter.

§ 411.37 Amount of Medicare recovery when a primary payment is made as a result of a judgment or settlement.

(a) *Recovery against the party that received payment—(1) General rule.* Medicare reduces its recovery to take account of the cost of procuring the judgment or settlement, as provided in this section, if—

(i) Procurement costs are incurred because the claim is disputed; and

(ii) Those costs are borne by the party against which CMS seeks to recover.

(2) *Special rule.* If CMS must file suit because the party that received payment opposes CMS's recovery, the recovery amount is as set forth in paragraph (e) of this section.

(b) *Recovery against the primary payer.* If CMS seeks recovery from the primary payer, in accordance with § 411.24(i), the recovery amount will be

no greater than the amount determined under paragraph (c) or (d) or (e) of this section.

(c) *Medicare payments are less than the judgment or settlement amount.* If Medicare payments are less than the judgment or settlement amount, the recovery is computed as follows:

(1) Determine the ratio of the procurement costs to the total judgment or settlement payment.

(2) Apply the ratio to the Medicare payment. The product is the Medicare share of procurement costs.

(3) Subtract the Medicare share of procurement costs from the Medicare payments. The remainder is the Medicare recovery amount.

(d) *Medicare payments equal or exceed the judgment or settlement amount.* If Medicare payments equal or exceed the judgment or settlement amount, the recovery amount is the total judgment or settlement payment minus the total procurement costs.

(e) *CMS incurs procurement costs because of opposition to its recovery.* If CMS must bring suit against the party that received payment because that party opposes CMS's recovery, the recovery amount is the lower of the following:

(1) Medicare payment.

(2) The total judgment or settlement amount, minus the party's total procurement cost.

§ 411.39 Automobile and liability insurance (including self-insurance), no-fault insurance, and workers' compensation: Final conditional payment amounts via Web portal.

(a) *Definitions.* For the purpose of this section the following definitions are applicable:

Applicable plan means the following laws, plans, or other arrangements, including the fiduciary or administrator for such law, plan or arrangement:

(1) Liability insurance (including self-insurance).

(2) No fault insurance.

(3) Workers' compensation laws or plans.

(b) *Accessing conditional payment information through the Medicare Secondary Payer Web portal—*(1) *Beneficiary access.* A beneficiary may access his or her Medicare Secondary Payer conditional payment information via the

Medicare Secondary Payer Recovery Portal (Web portal), provided the following conditions are met:

(i) The beneficiary creates an account to access his or her Medicare information through the CMS Web site.

(ii) The appropriate Medicare contractor has received initial notice of a pending liability insurance (including self-insurance), no-fault insurance, or workers' compensation settlement, judgment, award, or other payment and has posted the recovery case on the Web portal.

(2) *Beneficiary's attorney or other representative or applicable plan's access using the multifactor authentication process.* A beneficiary's attorney or other representative or an applicable plan may do the following:

(i) Access conditional payment information via the MSP Recovery Portal (Web portal).

(ii) Dispute claims.

(iii) Upload settlement information via the Web portal using multifactor authentication.

(c) *Obtaining a final conditional payment amount.* (1) A beneficiary, or his or her attorney or other representative, or an authorized applicable plan, may obtain a final conditional payment amount related to a pending liability insurance (including self-insurance), no-fault insurance, or workers' compensation settlement, judgment, award, or other payment using the following process:

(i) The beneficiary, his or her attorney or other representative, or an applicable plan, provides initial notice of a pending liability insurance (including self-insurance), no-fault insurance, and workers' compensation settlement, judgment, award, or other payment to the appropriate Medicare contractor before accessing information via the Web portal.

(ii) The Medicare contractor compiles claims for which Medicare has paid conditionally that are related to the pending settlement, judgment, award, or other payment within 65 days or less of receiving the initial notice of the pending settlement, judgment, award, or other payment and posts a recovery case on the Web portal.

(iii) If the underlying liability insurance (including self-insurance), no-

fault insurance, or workers' compensation claim derives from one of the following, the beneficiary, or his or her attorney or other representative, must provide notice to CMS' contractor via the Web portal in order to obtain a final conditional payment summary statement and amount through the Web portal:

(A) Alleged exposure to a toxic substance.

(B) Environmental hazard.

(C) Ingestion of pharmaceutical drug or other product or substance.

(D) Implantation of a medical device, joint replacement, or something similar.

(iv) Up to 120 days before the anticipated date of a settlement, judgment, award, or other payment, the beneficiary, or his or her attorney, other representative, or authorized applicable plan may notify CMS, once and only once, via the Web portal, that a settlement, judgment, award or other payment is expected to occur within 120 days or less from the date of notification.

(A) CMS may extend its response timeframe by an additional 30 days when it determines that additional time is required to address claims that Medicare has paid conditionally that are related to the settlement, judgment, award, or other payment in situations including, but not limited to, the following:

(1) A recovery case that requires manual filtering to ensure that associated claims are related to the pending settlement, judgment, award, or other payment.

(2) Internal CMS systems failures not otherwise considered caused by exceptional circumstances.

(B) In exceptional circumstances, CMS may further extend its response timeframe by the number of days required to address the issue that resulted from such exceptional circumstances. Exceptional circumstances include, but are not limited to the following:

(1) Systems failure(s) due to consequences of extreme adverse weather (loss of power, flooding, etc.).

(2) Security breaches of facilities or network(s).

(3) Terror threats; strikes and similar labor actions.

(4) Civil unrest, uprising, or riot.

(5) Destruction of business property (as by fire, etc.).

(6) Sabotage.

(7) Workplace attack on personnel.

(8) Similar circumstances beyond the ordinary control of government, private sector officers or management.

(v) The beneficiary, or his or her attorney, or other representative may then address discrepancies by disputing individual conditional payments, once and only once, if he or she believes that the conditional payment included in the most up-to-date conditional payment summary statement is unrelated to the pending liability insurance (including self-insurance), no-fault insurance, or workers' compensation settlement, judgment, award, or other payment.

(A) The dispute process is not an appeals process, nor does it establish a right of appeal regarding that dispute. There will be no administrative or judicial review related to this dispute process.

(B) The beneficiary, or his or her attorney or other representative may be required to submit supporting documentation in the form and manner specified by the Secretary to support his or her dispute.

(vi) Disputes submitted through the Web portal and after the beneficiary, or his or her attorney, other representative, or authorized applicable plan has notified CMS that he or she is 120 days or less from the anticipated date of a settlement, judgment, award, or other payment, are resolved within 11 business days of receipt of the dispute and any required supporting documentation.

(vii) When any disputes have been fully resolved, the beneficiary, or his or her attorney or other representative, may download or otherwise request a time and date stamped conditional payment summary statement through the Web portal.

(A) If the download or request is within 3 days of the date of settlement, judgment, award, or other payment, that conditional payment summary statement will constitute Medicare's final conditional payment amount.

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(B) If the beneficiary, or his or her attorney or other representative, is within 3 days of the date of settlement, judgment, award, or other payment and any claim disputes have not been fully resolved, he or she may not download or otherwise request a final conditional payment summary statement.

(viii) Within 30 days or less of securing a settlement, judgment, award, or other payment, the beneficiary, or his or her attorney or other representative, must submit through the Web portal documentation specified by the Secretary, including, but not limited to the following:

(A) The date of settlement, judgment, award, or other payment, including the total settlement amount, the attorney fee amount or percentage.

(B) Additional costs borne by the beneficiary to obtain his or her settlement, judgment, award, or other payment.

(I) If settlement information is not provided within 30 days or less of securing the settlement, the final conditional payment amount obtained through the Web portal is void.

(2) [Reserved]

(ix) Once settlement, judgment, award, or other payment information is received, CMS applies a pro rata reduction to the final conditional payment amount in accordance with § 411.37 and issues a final MSP recovery demand letter.

(2) An applicable plan may only obtain a final conditional payment amount related to a pending liability insurance (including self-insurance), no-fault insurance, or workers' compensation settlement, judgment, award, or other payment in the form and manner described in § 411.38(b) if the applicable plan has properly registered to use the Web portal and has obtained from the beneficiary, and submitted to the appropriate CMS contractor, proper proof of representation. The applicable plan may obtain read only access if the applicable plan obtains from the beneficiary, and submits to the appropriate CMS contractor, proper consent to release.

(d) *Obligations with respect to future medical items and services.* Final conditional payment amounts obtained via

the Web portal represent Medicare covered and otherwise reimbursable items and services that are related to the beneficiary's settlement, judgment, award, or other payment furnished before the time and date stamped on the final conditional payment summary form.

[78 FR 57804, Sept. 20, 2013, as amended at 81 FR 30492, May 17, 2016]

Subpart C—Limitations on Medicare Payment for Services Covered Under Workers' Compensation

§ 411.40 General provisions.

(a) *Definition.* “Workers’ compensation plan of the United States” includes the workers’ compensation plans of the 50 States, the District of Columbia, American Samoa, Guam, Puerto Rico, and the Virgin Islands, as well as the systems provided under the Federal Employees’ Compensation Act and the Longshoremen’s and Harbor Workers’ Compensation Act.

(b) *Limitations on Medicare payment.*
(1) Medicare does not pay for any services for which—

(i) Payment has been made, or can reasonably be expected to be made under a workers’ compensation law or plan of the United States or a state; or

(ii) Payment could be made under the Federal Black Lung Program, but is precluded solely because the provider of the services has failed to secure, from the Department of Labor, a provider number to include in the claim.

(2) If the payment for a service may not be made under workers’ compensation because the service is furnished by a source not authorized to provide that service under the particular workers’ compensation program, Medicare pays for the service if it is a covered service.

(3) Medicare makes secondary payments in accordance with §§ 411.32 and 411.33.

[54 FR 41734, Oct. 11, 1989, as amended at 71 FR 9470, Feb. 24, 2006]

§ 411.43 Beneficiary’s responsibility with respect to workers’ compensation.

(a) The beneficiary is responsible for taking whatever action is necessary to

obtain any payment that can reasonably be expected under workers' compensation.

(b) Except as specified in §411.45(a), Medicare does not pay until the beneficiary has exhausted his or her remedies under workers' compensation.

(c) Except as specified in §411.45(b), Medicare does not pay for services that would have been covered under workers' compensation if the beneficiary had filed a proper claim.

(d) However, if a claim is denied for reasons other than not being a proper claim, Medicare pays for the services if they are covered under Medicare.

§411.45 Basis for conditional Medicare payment in workers' compensation cases.

(a) A conditional Medicare payment may be made under either of the following circumstances:

(1) The beneficiary has filed a proper claim for workers' compensation benefits, but the intermediary or carrier determines that the workers' compensation carrier will not pay promptly. This includes cases in which a workers' compensation carrier has denied a claim.

(2) The beneficiary, because of physical or mental incapacity, failed to file a proper claim.

(b) Any conditional payment that CMS makes is conditioned on reimbursement to CMS in accordance with subpart B of this part.

[71 FR 9470, Feb. 24, 2006, as amended at 73 FR 9685, Feb. 22, 2008]

§411.46 Lump-sum payments.

(a) *Lump-sum commutation of future benefits.* If a lump-sum compensation award stipulates that the amount paid is intended to compensate the individual for all future medical expenses required because of the work-related injury or disease, Medicare payments for such services are excluded until medical expenses related to the injury or disease equal the amount of the lump-sum payment.

(b) *Lump-sum compromise settlement.* (1) A lump-sum compromise settlement is deemed to be a workers' compensation payment for Medicare purposes, even if the settlement agreement stip-

ulates that there is no liability under the workers' compensation law or plan.

(2) If a settlement appears to represent an attempt to shift to Medicare the responsibility for payment of medical expenses for the treatment of a work-related condition, the settlement will not be recognized. For example, if the parties to a settlement attempt to maximize the amount of disability benefits paid under workers' compensation by releasing the workers' compensation carrier from liability for medical expenses for a particular condition even though the facts show that the condition is work-related, Medicare will not pay for treatment of that condition.

(c) *Lump-sum compromise settlement: Effect on services furnished before the date of settlement.* Medicare pays for medical expenses incurred before the lump-sum compromise settlement only to the extent specified in §411.47.

(d) *Lump-sum compromise settlement: Effect on payment for services furnished after the date of settlement—(1) Basic rule.* Except as specified in paragraph (d)(2) of this section, if a lump-sum compromise settlement forecloses the possibility of future payment of workers' compensation benefits, medical expenses incurred after the date of the settlement are payable under Medicare.

(2) *Exception.* If the settlement agreement allocates certain amounts for specific future medical services, Medicare does not pay for those services until medical expenses related to the injury or disease equal the amount of the lump-sum settlement allocated to future medical expenses.

§411.47 Apportionment of a lump-sum compromise settlement of a workers' compensation claim.

(a) *Determining amount of compromise settlement considered as a payment for medical expenses.* (1) If a compromise settlement allocates a portion of the payment for medical expenses and also gives reasonable recognition to the income replacement element, that apportionment may be accepted as a basis for determining Medicare payments.

(2) If the settlement does not give reasonable recognition to both elements of a workers' compensation

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award or does not apportion the sum granted, the portion to be considered as payment for medical expenses is computed as follows:

(i) Determine the ratio of the amount awarded (less the reasonable and necessary costs incurred in procuring the settlement) to the total amount that would have been payable under workers' compensation if the claim had not been compromised.

(ii) Multiply that ratio by the total medical expenses incurred as a result of the injury or disease up to the date of the settlement. The product is the amount of the workers' compensation settlement to be considered as payment for medical expenses.

Example: As the result of a work injury, an individual suffered loss of income and incurred medical expenses for which the total workers' compensation payment would have been \$24,000 if the case had not been compromised. The medical expenses amounted to \$18,000. The workers' compensation carrier made a settlement with the beneficiary under which it paid \$8,000 in total. A separate award was made for legal fees. Since the workers' compensation compromise settlement was for one-third of the amount which would have been payable under workers' compensation had the case not been compromised ($\$8,000/\$24,000 = \frac{1}{3}$), the workers' compensation compromise settlement is considered to have paid for one-third of the total medical expenses ($\frac{1}{3} \times \$18,000 = \$6,000$).

(b) *Determining the amount of the Medicare overpayment.* When conditional Medicare payments have been made, and the beneficiary receives a compromise settlement payment, the Medicare overpayment is determined as set forth in this paragraph (b). The amount of the workers' compensation payment that is considered to be for medical expenses (as determined under paragraph (a) of this section) is applied, at the workers' compensation rate of payment prevailing in the particular jurisdiction, in the following order:

(1) First to any beneficiary payments for services payable under workers' compensation but not covered under Medicare.

(2) Then to any beneficiary payments for services payable under workers' compensation and also covered under Medicare Part B. (These include deductible and coinsurance amounts and,

in unassigned cases, the charge in excess of the reasonable charge.)

(3) Last to any beneficiary payments for services payable under workers' compensation and also covered under Medicare Part A. (These include Part A deductible and coinsurance amounts and charges for services furnished after benefits are exhausted.)

The difference between the amount of the workers' compensation payment for medical expenses and any beneficiary payments constitutes the Medicare overpayment. The beneficiary is liable for that amount.

Example: In the example in paragraph (a) of this section, it was determined that the workers' compensation settlement paid for \$6,000 of the total medical expenses. The \$18,000 in medical expenses included \$1,500 in charges for services not covered under Medicare, \$7,500 in charges for services covered under Medicare Part B, and \$9,000 in hospital charges for services covered under Medicare Part A. All charges were at the workers' compensation payment rate, that is, in amounts the provider or supplier must accept as payment in full.

The Medicare reasonable charge for physicians' services was \$7,000 and Medicare paid \$5,600 (80 percent of the reasonable charge). The Part B deductible had been met. The Medicare payment rate for the hospital services was \$8,000. Medicare paid the hospital \$7,480 (\$8,000—the Part A deductible of \$520).

In this situation, the beneficiary's payments totalled \$3,920:

Services not covered under Medicare	\$1,500
Excess of physicians' charges over reasonable charges	500
Medicare Part B coinsurance	1,400
Part A deductible	520
Total	3,920

The Medicare overpayment, for which the beneficiary is liable, would be \$2,080 (\$6,000—\$3,920).

Subpart D—Limitations on Medicare Payment for Services Covered Under Liability or No-Fault Insurance

§ 411.50 General provisions.

(a) *Limits on applicability.* The provisions of this subpart C do not apply to any services required because of accidents that occurred before December 5, 1980.

(b) *Definitions.*

Automobile means any self-propelled land vehicle of a type that must be registered and licensed in the State in which it is owned.

Liability insurance means insurance (including a self-insured plan) that provides payment based on legal liability for injury or illness or damage to property. It includes, but is not limited to, automobile liability insurance, uninsured motorist insurance, underinsured motorist insurance, homeowners' liability insurance, malpractice insurance, product liability insurance, and general casualty insurance.

Liability insurance payment means a payment by a liability insurer, or an out-of-pocket payment, including a payment to cover a deductible required by a liability insurance policy, by any individual or other entity that carries liability insurance or is covered by a self-insured plan.

No-fault insurance means insurance that pays for medical expenses for injuries sustained on the property or premises of the insured, or in the use, occupancy, or operation of an automobile, regardless of who may have been responsible for causing the accident. This insurance includes but is not limited to automobile, homeowners, and commercial plans. It is sometimes called "medical payments coverage", "personal injury protection", or "medical expense coverage".

Prompt or promptly, when used in connection with payment by a liability insurer means payment within 120 days after the earlier of the following:

(1) The date a claim is filed with an insurer or a lien is filed against a potential liability settlement.

(2) The date the service was furnished or, in the case of inpatient hospital services, the date of discharge.

Self-insured plan means a plan under which an individual, or a private or governmental entity, carries its own risk instead of taking out insurance with a carrier. This term includes a plan of an individual or other entity engaged in a business, trade, or profession, a plan of a non-profit organization such as a social, fraternal, labor, educational, religious, or professional organization, and the plan established by the Federal government to pay liability claims under the Federal Tort

Claims Act. An entity that engages in a business, trade, or profession is deemed to have a self-insured plan for purposes of liability insurance if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part.

Underinsured motorist insurance means insurance under which the policyholder's level of protection against losses caused by another is extended to compensate for inadequate coverage in the other party's policy or plan.

Uninsured motorist insurance means insurance under which the policyholder's insurer will pay for damages caused by a motorist who has no automobile liability insurance or who carries less than the amount of insurance required by law, or is underinsured.

(c) *Limitation on payment for services covered under no-fault insurance.* Except as provided under §§411.52 and 411.53 with respect to conditional payments, Medicare does not pay for the following:

(1) Services for which payment has been made or can reasonably be expected to be made under automobile no-fault insurance.

(2) Services furnished on or after November 13, 1989 for which payment has been made or can reasonably be expected to be made under any no-fault insurance other than automobile no-fault.

[54 FR 41734, Oct. 11, 1989, as amended at 55 FR 1820, Jan. 19, 1990; 71 FR 9470, Feb. 24, 2006]

§411.51 Beneficiary's responsibility with respect to no-fault insurance.

(a) The beneficiary is responsible for taking whatever action is necessary to obtain any payment that can reasonably be expected under no-fault insurance.

(b) Except as specified in §411.53, Medicare does not pay until the beneficiary has exhausted his or her remedies under no-fault insurance.

(c) Except as specified in §411.53, Medicare does not pay for services that would have been covered by the no-fault insurance if the beneficiary had filed a proper claim.

(d) However, if a claim is denied for reasons other than not being a proper

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claim, Medicare pays for the services if they are covered under Medicare.

§ 411.52 Basis for conditional Medicare payment in liability cases.

(a) A conditional Medicare payment may be made in liability cases under either of the following circumstances:

(1) The beneficiary has filed a proper claim for liability insurance benefits but the intermediary or carrier determines that the liability insurer will not pay promptly for any reason other than the circumstances described in § 411.32(a)(1). This includes cases in which the liability insurance carrier has denied the claim.

(2) The beneficiary has not filed a claim for liability insurance benefits.

(b) Any conditional payment that CMS makes is conditioned on reimbursement to CMS in accordance with subpart B of this part.

[71 FR 9470, Feb. 24, 2006]

§ 411.53 Basis for conditional Medicare payment in no-fault cases.

(a) A conditional Medicare payment may be made in no-fault cases under either of the following circumstances:

(1) The beneficiary has filed a proper claim for no-fault insurance benefits but the intermediary or carrier determines that the no-fault insurer will not pay promptly for any reason other than the circumstances described in § 411.32(a)(1). This includes cases in which the no-fault insurance carrier has denied the claim.

(2) The beneficiary, because of physical or mental incapacity, failed to meet a claim-filing requirement stipulated in the policy.

(b) Any conditional payment that CMS makes is conditioned on reimbursement to CMS in accordance with subpart B of this part.

[71 FR 9470, Feb. 24, 2006]

§ 411.54 Limitation on charges when a beneficiary has received a liability insurance payment or has a claim pending against a liability insurer.

(a) *Definition.* As used in this section, *Medicare-covered services* means services for which Medicare benefits are payable or would be payable except for applicable Medicare deductible and coinsurance provisions. Medicare benefits

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are payable notwithstanding potential liability insurance payments, but are recoverable in accordance with § 411.24.

(b) *Applicability.* This section applies when a beneficiary has received a liability insurance payment or has a claim pending against a liability insurer for injuries or illness allegedly caused by another party.

(c) *Itemized bill.* A hospital must, upon request, furnish to the beneficiary or his or her representative an itemized bill of the hospital's charges.

(d) *Exception—(1) Prepaid health plans.* If the services were furnished through an organization that has a contact under section 1876 of the Act (that is, an HMO or CMP), or through an organization that is paid under section 1833(a)(1)(A) of the Act (that is, through an HCPP) the rules of § 417.528 of this chapter apply.

(2) *Special rules for Oregon.* For the State of Oregon, because of a court decision, and in the absence of a reversal on appeal or a statutory clarification overturning the decision, there are the following special rules:

(i) The provider or supplier may elect to bill a liability insurer or place a lien against the beneficiary's liability settlement for Medicare covered services, rather than bill only Medicare for Medicare covered services, if the liability insurer pays within 120 days after the earlier of the following dates:

(A) The date the provider or supplier files a claim with the insurer or places a lien against a potential liability settlement.

(B) The date the services were provided or, in the case of inpatient hospital services, the date of discharge.

(ii) If the liability insurer does not pay within the 120-day period, the provider or supplier:

(A) Must withdraw its claim with the liability insurer and/or withdraw its lien against a potential liability settlement.

(B) May only bill Medicare for Medicare covered services.

(C) May bill the beneficiary only for applicable Medicare deductible and coinsurance amounts plus the amount of any charges that may be made to a beneficiary under 413.35 of this chapter (when cost limits are applied to these

services) or under 489.32 of this chapter (when services are partially covered).

[54 FR 41734, Oct. 11, 1989, as amended at 68 FR 43942, July 25, 2003]

Subpart E—Limitations on Payment for Services Covered Under Group Health Plans: General Provisions

SOURCE: 60 FR 45362, Aug. 31, 1995, unless otherwise noted.

§411.100 Basis and scope.

(a) *Statutory basis.* (1) Section 1862(b) of the Act provides in part that Medicare is secondary payer, under specified conditions, for services covered under any of the following:

(i) Group health plans of employers that employ at least 20 employees and that cover Medicare beneficiaries age 65 or older who are covered under the plan by virtue of the individual's current employment status with an employer or the current employment status of a spouse of any age. (Section 1862(b)(1)(A))

(ii) Group health plans (without regard to the number of individuals employed and irrespective of current employment status) that cover individuals who have ESRD. Except as provided in §411.163, group health plans are always primary payers throughout the first 18 months of ESRD-based Medicare eligibility or entitlement. (Section 1862(b)(1)(C))

(iii) Large group health plans (that is, plans of employers that employ at least 100 employees) and that cover Medicare beneficiaries who are under age 65, entitled to Medicare on the basis of disability, and covered under the plan by virtue of the individual's or a family member's current employment status with an employer. (Section 1862(b)(1)(B))

(2) Sections 1862(b)(1)(A), (B), and (C) of the Act provide that group health plans and large group health plans may not take into account that the individuals described in paragraph (a)(1) of this section are entitled to Medicare on the basis of age or disability, or eligible for, or entitled to Medicare on the basis of ESRD.

(3) Section 1862(b)(1)(A)(i)(II) of the Act provides that group health plans of employers of 20 or more employees must provide to any employee or spouse age 65 or older the same benefits, under the same conditions, that it provides to employees and spouses under 65. The requirement applies regardless of whether the individual or spouse 65 or older is entitled to Medicare.

(4) Section 1862(b)(1)(C)(ii) of the Act provides that group health plans may not differentiate in the benefits they provide between individuals who have ESRD and other individuals covered under the plan on the basis of the existence of ESRD, the need for renal dialysis, or in any other manner. Actions that constitute "differentiating" are listed in §411.161(b).

(b) *Scope.* This subpart sets forth general rules pertinent to—

(1) Medicare payment for services that are covered under a group health plan and are furnished to certain beneficiaries who are entitled on the basis of ESRD, age, or disability.

(2) The prohibition against taking into account Medicare entitlement based on age or disability, or Medicare eligibility or entitlement based on ESRD.

(3) The prohibition against differentiation in benefits between individuals who have ESRD and other individuals covered under the plan.

(4) The requirement to provide to those 65 or over the same benefits under the same conditions as are provided to those under 65.

(5) The appeals procedures for group health plans that CMS determines are nonconforming plans.

§411.101 Definitions.

As used in this subpart and in subparts F through H of this part—

COBRA stands for Consolidated Omnibus Budget Reconciliation Act of 1985.

Days means calendar days.

Employee (subject to the special rules in §411.104) means an individual who—

(1) Is working for an employer; or

(2) Is not working for an employer but is receiving payments that are subject to FICA taxes, or would be subject

to FICA taxes except that the employer is exempt from those taxes under the Internal Revenue Code.

Employer means, in addition to individuals (including self-employed persons) and organizations engaged in a trade or business, other entities exempt from income tax such as religious, charitable, and educational institutions, the governments of the United States, the individual States, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and the District of Columbia, and the agencies, instrumentalities, and political subdivisions of these governments.

FICA stands for the Federal Insurance Contributions Act, the law that imposes social security taxes on employers and employees under section 21 of the Internal Revenue Code.

Group health plan (GHP) means any arrangement made by one or more employers or employee organizations to provide health care directly or through other methods such as insurance or reimbursement, to current or former employees, the employer, others associated or formerly associated with the employer in a business relationship, or their families, that—

(1) Is of, or contributed to by, one or more employers or employee organizations.

(2) If it involves more than one employer or employee organization, provides for common administration.

(3) Provides substantially the same benefits or the same benefit options to all those enrolled under the arrangement.

The term includes self-insured plans, plans of governmental entities (Federal, State and local), and employee organization plans; that is, union plans, employee health and welfare funds or other employee organization plans. The term also includes employee-pay-all plans, which are plans under the auspices of one or more employers or employee organizations but which receive no financial contributions from them. The term does not include a plan that is unavailable to employees; for example, a plan only for self-employed persons.

IRC stands for Internal Revenue Code.

IRS stands for Internal Revenue Service.

Large group health plan (LGHP) means a GHP that covers employees of either—

(1) A single employer or employee organization that employed at least 100 full-time or part-time employees on 50 percent or more of its regular business days during the previous calendar year; or

(2) Two or more employers, or employee organizations, at least one of which employed at least 100 full-time or part-time employees on 50 percent or more of its regular business days during the previous calendar year.

MSP stands for Medicare secondary payer.

Multi-employer plan means a plan that is sponsored jointly by two or more employers (sometimes called a multiple-employer plan) or by employers and unions (sometimes under the Taft-Hartley law).

Self-employed person encompasses consultants, owners of businesses, and directors of corporations, and members of the clergy and religious orders who are paid for their services by a religious body or other entity.

Similarly situated individual means—

(1) In the case of employees, other employees enrolled or seeking to enroll in the plan; and

(2) In the case of other categories of individuals, other persons in any of those categories who are enrolled or seeking to enroll in the plan.

§ 411.102 Basic prohibitions and requirements.

(a) *ESRD*. (1) A group health plan of any size—(i) May not take into account the ESRD-based Medicare eligibility or entitlement of any individual who is covered or seeks to be covered under the plan; and

(ii) May not differentiate in the benefits it provides between individuals with ESRD and other individuals covered under the plan, on the basis of the existence of ESRD, or the need for dialysis, or in any other manner.

(2) The prohibitions of paragraph (a) of this section do not prohibit a plan from paying benefits secondary to Medicare after the first 18 months of ESRD-based eligibility or entitlement.

(b) *Age*. A GHP of an employer or employee organization of at least 20 employees—

(1) May not take into account the age-based Medicare entitlement of an individual or spouse age 65 or older who is covered (or seeks to be covered) under the plan by virtue of current employment status; and

(2) Must provide, to employees age 65 or older and to spouses age 65 or older of employees of any age, the same benefits under the same conditions as it provides to employees and spouses under age 65.

(c) *Disability*. A GHP of an employer or employee organization of at least 100 employees may not take into account the disability-based Medicare entitlement of any individual who is covered (or seeks to be covered) under the plan by virtue of current employment status.

§411.103 Prohibition against financial and other incentives.

(a) *General rule*. An employer or other entity (for example, an insurer) is prohibited from offering Medicare beneficiaries financial or other benefits as incentives not to enroll in, or to terminate enrollment in, a GHP that is, or would be, primary to Medicare. This prohibition precludes offering to Medicare beneficiaries an alternative to the employer primary plan (for example, coverage of prescription drugs) unless the beneficiary has primary coverage other than Medicare. An example would be primary coverage through his own or a spouse's employer.

(b) *Penalty for violation*. (1) Any entity that violates the prohibition of paragraph (a) of this section is subject to a civil money penalty of up to \$5,000 as adjusted annually under 45 CFR part 102 for each violation; and

(2) The provisions of section 1128A of the Act (other than subsections (a) and (b)) apply to the civil money penalty of up to \$5,000 as adjusted annually under 45 CFR part 102 in the same manner as the provisions apply to a penalty or proceeding under section 1128A(a).

[60 FR 45362, Aug. 31, 1995, as amended at 81 FR 61561, Sept. 6, 2016]

§411.104 Current employment status.

(a) *General rule*. An individual has current employment status if—

(1) The individual is actively working as an employee, is the employer (including a self-employed person), or is associated with the employer in a business relationship; or

(2) The individual is not actively working and—

(i) Is receiving disability benefits from an employer for up to 6 months (the first 6 months of employer disability benefits are subject to FICA taxes); or

(ii) Retains employment rights in the industry and has not had his employment terminated by the employer, if the employer provides the coverage (or has not had his membership in the employee organization terminated, if the employee organization provides the coverage), is not receiving disability benefits from an employer for more than 6 months, is not receiving disability benefits from Social Security, and has GHP coverage that is not pursuant to COBRA continuation coverage (26 U.S.C. 4980B; 29 U.S.C. 1161–1168; 42 U.S.C. 300bb–1 et seq.). Whether or not the individual is receiving pay during the period of nonwork is not a factor.

(b) *Persons who retain employment rights*. For purposes of paragraph (a)(2) of this section, persons who retain employment rights include but are not limited to—

(1) Persons who are furloughed, temporarily laid off, or who are on sick leave;

(2) Teachers and seasonal workers who normally do not work throughout the year; and

(3) Persons who have health coverage that extends beyond or between active employment periods; for example, based on an hours bank arrangement. (Active union members often have hours bank coverage.)

(c) *Coverage by virtue of current employment status*. An individual has coverage by virtue of current employment status with an employer if—

(1) the individual has GHP or LGHP coverage based on employment, including coverage based on a certain number of hours worked for that employer or a certain level of commissions earned

from work for that employer at any time; and

(2) the individual has current employment status with that employer, as defined in paragraph (a) of this section.

(d) *Special rule: Self-employed person.* A self-employed individual is considered to have GHP or LGHP coverage by virtue of current employment status during a particular tax year only if, during the preceding tax year, the individual's net earnings, from work in that year related to the employer that offers the group health coverage, are at least equal to the amount specified in section 211(b)(2) of the Act, which defines "self-employment income" for social security purposes.

(e) *Special Rule: members of religious orders and members of clergy—*(1) *Members of religious orders who have not taken a vow of poverty.* A member of a religious order who has not taken a vow of poverty is considered to have current employment status with the religious order if—

(i) The religious order pays FICA taxes on behalf of that member; or

(ii) The individual is receiving cash remuneration from the religious order.

(2) *Members of religious orders who have taken a vow of poverty.* A member of a religious order whose members are required to take a vow of poverty is not considered to be employed by the order if the services he or she performs as a member of the order are considered employment only because the order elects social security coverage under section 3121(r) of the IRC. This exemption applies retroactively to services performed as a member of the order, beginning with the effective dates of the MSP provisions for the aged and the disabled, respectively. The exemption does not apply to services performed for employers outside of the order.

(3) *Members of the clergy.* A member of the clergy is considered to have current employment status with a church or other religious organization if the individual is receiving cash remuneration from the church or other religious organization for services rendered.

(f) *Special rule: Delayed compensation subject to FICA taxes.* An individual who is not working is not considered an em-

ployee solely on the basis of receiving delayed compensation payments for previous periods of work even if those payments are subject to FICA taxes (or would be subject to FICA taxes if the employer were not exempt from paying those taxes). For example, an individual who is not working in 1993 and receives payments subject to FICA taxes for work performed in 1992 is not considered to be an employee in 1993 solely on the basis of receiving those payments.

§ 411.106 Aggregation rules.

The following rules apply in determining the number and size of employers, as required by the MSP provisions for the aged and disabled:

(a) All employers that are treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code (IRC) of 1986 (26 U.S.C. 52 (a) and (b)) are treated as a single employer.

(b) All employees of the members of an affiliated service group (as defined in section 414(m) of the IRC (26 U.S.C. 414m)) are treated as employed by a single employer.

(c) Leased employees (as defined in section 414(n)(2) of the IRC (26 U.S.C. 414(n)(2))) are treated as employees of the person for whom they perform services to the same extent as they are treated under section 414(n) of the IRC.

(d) In applying the IRC provisions identified in this section, CMS relies upon regulations and decisions of the Secretary of the Treasury respecting those provisions.

§ 411.108 Taking into account entitlement to Medicare.

(a) *Examples of actions that constitute "taking into account".* Actions by GHPs or LGHPs that constitute taking into account that an individual is entitled to Medicare on the basis of ESRD, age, or disability (or eligible on the basis of ESRD) include, but are not limited to, the following:

(1) Failure to pay primary benefits as required by subparts F, G, and H of this part 411.

(2) Offering coverage that is secondary to Medicare to individuals entitled to Medicare.

(3) Terminating coverage because the individual has become entitled to Medicare, except as permitted under COBRA continuation coverage provisions (26 U.S.C. 4980B(f)(2)(B)(iv); 29 U.S.C. 1162.(2)(D); and 42 U.S.C. 300bb-2.(2)(D)).

(4) In the case of a LGHP, denying or terminating coverage because an individual is entitled to Medicare on the basis of disability without denying or terminating coverage for similarly situated individuals who are not entitled to Medicare on the basis of disability.

(5) Imposing limitations on benefits for a Medicare entitled individual that do not apply to others enrolled in the plan, such as providing less comprehensive health care coverage, excluding benefits, reducing benefits, charging higher deductibles or coinsurance, providing for lower annual or lifetime benefit limits, or more restrictive pre-existing illness limitations.

(6) Charging a Medicare entitled individual higher premiums.

(7) Requiring a Medicare entitled individual to wait longer for coverage to begin.

(8) Paying providers and suppliers less for services furnished to a Medicare beneficiary than for the same services furnished to an enrollee who is not entitled to Medicare.

(9) Providing misleading or incomplete information that would have the effect of inducing a Medicare entitled individual to reject the employer plan, thereby making Medicare the primary payer. An example of this would be informing the beneficiary of the right to accept or reject the employer plan but failing to inform the individual that, if he or she rejects the plan, the plan will not be permitted to provide or pay for secondary benefits.

(10) Including in its health insurance cards, claims forms, or brochures distributed to beneficiaries, providers, and suppliers, instructions to bill Medicare first for services furnished to Medicare beneficiaries without stipulating that such action may be taken only when Medicare is the primary payer.

(11) Refusing to enroll an individual for whom Medicare would be secondary payer, when enrollment is available to similarly situated individuals for

whom Medicare would not be secondary payer.

(b) *Permissible actions.* (1) If a GHP or LGHP makes benefit distinctions among various categories of individuals (distinctions unrelated to the fact that the individual is disabled, based, for instance, on length of time employed, occupation, or marital status), the GHP or LGHP may make the same distinctions among the same categories of individuals entitled to Medicare whose plan coverage is based on current employment status. For example, if a GHP or LGHP does not offer coverage to employees who have worked less than one year and who are *not* entitled to Medicare on the basis of disability or age, the GHP or LGHP is not required to offer coverage to employees who have worked less than one year and who *are* entitled to Medicare on the basis of disability or age.

(2) A GHP or LGHP may pay benefits secondary to Medicare for an aged or disabled beneficiary who has current employment status if the plan coverage is COBRA continuation coverage because of reduced hours of work. Medicare is primary payer for this beneficiary because, although he or she has current employment status, the GHP coverage is by virtue of the COBRA law rather than by virtue of the current employment status.

(3) A GHP may terminate COBRA continuation coverage of an individual who becomes entitled to Medicare on the basis of ESRD, when permitted under the COBRA provisions.

[60 FR 45362, Aug. 31, 1995; 60 FR 53876, Oct. 18, 1995]

§411.110 Basis for determination of nonconformance.

(a) A “determination of nonconformance” is a CMS determination that a GHP or LGHP is a nonconforming plan as provided in this section.

(b) CMS makes a determination of nonconformance for a GHP or LGHP that, at any time during a calendar year, fails to comply with any of the following statutory provisions:

(1) The prohibition against taking into account that a beneficiary who is covered or seeks to be covered under the plan is entitled to Medicare on the

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basis of ESRD, age, or disability, or eligible on the basis of ESRD.

(2) The nondifferentiation clause for individuals with ESRD.

(3) The equal benefits clause for the working aged.

(4) The obligation to refund conditional Medicare primary payments.

(c) CMS may make a determination of nonconformance for a GHP or LGHP that fails to respond to a request for information, or to provide correct information, either voluntarily or in response to a CMS request, on the plan's primary payment obligation with respect to a given beneficiary, if that failure contributes to either or both of the following:

(1) Medicare erroneously making a primary payment.

(2) A delay or foreclosure of CMS's ability to recover an erroneous primary payment.

§ 411.112 Documentation of conformance.

(a) *Acceptable documentation.* CMS may require a GHP or LGHP to demonstrate that it has complied with the Medicare secondary payer provisions and to submit supporting documentation by an official authorized to act on behalf of the entity, under penalty of perjury. The following are examples of documentation that may be acceptable:

(1) A copy of the employer's plan or policy that specifies the services covered, conditions of coverage, benefit levels and limitations with respect to persons entitled to Medicare on the basis of ESRD, age, or disability as compared to the provisions applicable to other enrollees and potential enrollees.

(2) An explanation of the plan's allegation that it does not owe CMS any amount CMS claims the plan owes as repayment for conditional or mistaken Medicare primary payments.

(b) *Lack of acceptable documentation.* If a GHP or LGHP fails to provide acceptable evidence or documentation that it has complied with the MSP prohibitions and requirements set forth in § 411.110, CMS may make a determination of nonconformance for both the year in which the services were furnished and the year in which the request for information was made.

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§ 411.114 Determination of nonconformance.

(a) *Starting dates for determination of nonconformance.* CMS's authority to determine nonconformance of GHPs begins on the following dates:

(1) On January 1, 1987 for MSP provisions that affect the disabled.

(2) On December 20, 1989 for MSP provisions that affect ESRD beneficiaries and the working aged.

(3) On August 10, 1993 for failure to refund mistaken Medicare primary payments.

(b) *Special rule for failure to repay.* A GHP that fails to comply with § 411.110 (a)(1), (a)(2), or (a)(3) in a particular year is nonconforming for that year. If, in a subsequent year, that plan fails to repay the resulting mistaken primary payments (in accordance with § 411.110(a)(4)), the plan is also nonconforming for the subsequent year. For example, if a plan paid secondary for the working aged in 1991, that plan was nonconforming for 1991. If in 1994 CMS identifies mistaken primary payments attributable to the 1991 violation, and the plan refuses to repay, it is also nonconforming for 1994.

§ 411.115 Notice of determination of nonconformance.

(a) *Notice to the GHP or LGHP.* (1) If CMS determines that a GHP or an LGHP is nonconforming with respect to a particular calendar year, CMS mails to the plan written notice of the following:

(i) The determination.

(ii) The basis for the determination.

(iii) The right of the parties to request a hearing.

(iv) An explanation of the procedure for requesting a hearing.

(v) The tax that may be assessed by the IRS in accordance with section 5000 of the IRC.

(vi) The fact that if none of the parties requests a hearing within 65 days from the date of its notice, the determination is binding on all parties unless it is reopened in accordance with § 411.126.

(2) The notice also states that the plan must, within 30 days from the date on its notice, submit to CMS the names and addresses of all employers

and employee organizations that contributed to the plan during the calendar year for which CMS has determined nonconformance.

(b) *Notice to contributing employers and employee organizations.* CMS mails written notice of the determination, including all the information specified in paragraph (a)(1) of this section, to all contributing employers and employee organizations already known to CMS or identified by the plan in accordance with paragraph (a)(2) of this section. Employers and employee organizations have 65 days from the date of their notice to request a hearing.

§411.120 Appeals.

(a) *Parties to the determination.* The parties to the determination are CMS, the GHP or LGHP for which CMS determined nonconformance, and any employers or employee organizations that contributed to the plan during the calendar year for which CMS determined nonconformance.

(b) *Request for hearing.* (1) A party's request for hearing must be in writing (not in facsimile or other electronic medium) and in the manner stipulated in the notice of nonconformance; it must be filed within 65 days from the date on the notice.

(2) The request may include rationale showing why the parties believe that CMS's determination is incorrect and supporting documentation.

(3) A request is considered filed on the date it is received by the appropriate office, as shown by the receipt date stamped on the request.

§411.121 Hearing procedures.

(a) *Nature of hearing.* (1) If any of the parties requests a hearing within 65 days from the date on the notice of the determination of nonconformance, the CMS Administrator appoints a hearing officer.

(2) If no party files a request within the 65-day period, the initial determination of nonconformance is binding upon all parties unless it is reopened in accordance with §411.126.

(3) If more than one party requests a hearing the hearing officer conducts a single hearing in which all parties may participate.

(4) *On the record review.* Ordinarily, the hearing officer makes a decision based upon review of the data and documents on which CMS based its determination of nonconformance and any other documentation submitted by any of the parties within 65 days from the date on the notice.

(5) *Oral hearing.* The hearing officer may provide for an oral hearing either on his or her own motion or in response to a party's request if the party demonstrates to the hearing officer's satisfaction that an oral hearing is necessary. Within 30 days of receipt of the request, the hearing officer gives all known parties written notice of the request and whether the request for oral hearing is granted.

(b) *Notice of time and place of oral hearing.* If the hearing officer provides an oral hearing, he or she gives all known parties written notice of the time and place of the hearing at least 30 days before the scheduled date.

(c) *Prehearing discovery.* (1) The hearing officer may permit prehearing discovery if it is requested by a party at least 10 days before the scheduled date of the hearing.

(2) If the hearing officer approves the request, he or she—

(i) Provides a reasonable time for inspection and reproduction of documents; and

(ii) In ruling on discovery matters, is guided by the Federal Rules of Civil Procedure. (28 U.S.C.A. Rules 26–37)

(3) The hearing officer's orders on all discovery matters are final.

(d) *Conduct of hearing.* The hearing officer determines the conduct of the hearing, including the order in which the evidence and the allegations are presented.

(e) *Evidence at hearing.* (1) The hearing officer inquires into the matters at issue and may receive from all parties documentary and other evidence that is pertinent and material, including the testimony of witnesses, and evidence that would be inadmissible in a court of law.

(2) Evidence may be received at any time before the conclusion of the hearing.

(3) The hearing officer gives the parties opportunity for submission and

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consideration of evidence and arguments and, in ruling on the admissibility of evidence, excludes irrelevant, immaterial, or unduly repetitious evidence.

(4) The hearing officer's ruling on admissibility of evidence is final and not subject to further review.

(f) *Subpoenas.* (1) The hearing officer may, either on his or her own motion or upon the request of any party, issue subpoenas for either or both of the following if they are reasonably necessary for full presentation of the case:

(i) The attendance and testimony of witnesses.

(ii) The production of books, records, correspondence, papers, or other documents that are relevant and material to any matter at issue.

(2) A party that wishes the issuance of a subpoena must, at least 10 days before the date fixed for the hearing, file with the hearing officer a written request that identifies the witnesses or documents to be produced and describes the address or location in sufficient detail to permit the witnesses or documents to be found.

(3) The request for a subpoena must state the pertinent facts that the party expects to establish by the witnesses or documents and whether those facts could be established by other evidence without the use of a subpoena.

(4) The hearing officer issues the subpoenas at his or her discretion, and CMS assumes the cost of the issuance and the fees and mileage of any subpoenaed witness, in accordance with section 205(d) of the Act (42 U.S.C. 405(d)).

(g) *Witnesses.* Witnesses at the hearing testify under oath or affirmation, unless excused by the hearing officer for cause. The hearing officer may examine the witnesses and shall allow the parties to examine and cross-examine witnesses.

(h) *Record of hearing.* A complete record of the proceedings at the hearing is made and transcribed in all cases. It is made available to the parties upon request. The record is not closed until a decision has been issued.

(i) *Sources of hearing officer's authority.* In the conduct of the hearing, the hearing officer complies with all the provisions of title XVIII of the Act and implementing regulations, as well as

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with CMS Rulings issued under § 401.108 of this chapter. The hearing officer gives great weight to interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS.

§ 411.122 Hearing officer's decision.

(a) *Timing.* (1) If the decision is based on a review of the record, the hearing officer mails the decision to all known parties within 120 days from the date of receipt of the request for hearing.

(2) If the decision is based on an oral hearing, the hearing officer mails the decision to all known parties within 120 days from the conclusion of the hearing.

(b) *Basis, content, and distribution of hearing decision.* (1) The written decision is based on substantial evidence and contains findings of fact, a statement of reasons, and conclusions of law.

(2) The hearing officer mails a copy of the decision to each of the parties, by certified mail, return receipt requested, and includes a notice that the administrator may review the hearing decision at the request of a party or on his or her own motion.

(c) *Effect of hearing decision.* The hearing officer's decision is the final Departmental decision and is binding upon all parties unless the Administrator chooses to review that decision in accordance with § 411.124 or it is reopened by the hearing officer in accordance with § 411.126.

§ 411.124 Administrator's review of hearing decision.

(a) *Request for review.* A party's request for review of a hearing officer's decision must be in writing (not in facsimile or other electronic medium) and must be received by the Administrator within 25 days from the date on the decision.

(b) *Office of the Attorney Advisor responsibility.* The Office of the Attorney Advisor examines the hearing officer's decision, the requests made by any of the parties or CMS, and any submission made in accordance with the provisions of this section in order to assist the Administrator in deciding whether to review the decision.

(c) *Administrator's discretion.* The Administrator may—

(1) Review or decline to review the hearing officer's decision;

(2) Exercise this discretion on his or her own motion or in response to a request from any of the parties; and

(3) Delegate review responsibility to the Deputy Administrator. (As used in this section, the term "Administrator" includes "Deputy Administrator" if review responsibility has been delegated.)

(d) *Basis for decision to review.* In deciding whether to review a hearing officer's decision, the Administrator considers—

(1) Whether the decision—

(i) Is based on a correct interpretation of law, regulation, or CMS Ruling;

(ii) Is supported by substantial evidence;

(iii) Presents a significant policy issue having a basis in law and regulations;

(iv) Requires clarification, amplification, or an alternative legal basis for the decision; and

(v) Is within the authority provided by statute, regulation, or CMS Ruling; and

(2) Whether review may lead to the issuance of a CMS Ruling or other directive needed to clarify a statute or regulation.

(e) *Notice of decision to review or not to review.* (1) The Administrator gives all parties prompt written notice of his or her decision to review or not to review.

(2) The notice of a decision to review identifies the specific issues the Administrator will consider.

(f) *Response to notice of decision to review.* (1) Within 20 days from the date on a notice of the Administrator's decision to review a hearing officer's decision, any of the parties may file with the Administrator any or all of the following:

(i) Proposed findings and conclusions.

(ii) Supporting views or exceptions to the hearing officer's decision.

(iii) Supporting reasons for the proposed findings and exceptions.

(iv) A rebuttal to another party's request for review or to other submissions already filed with the Administrator.

(2) The submissions must be limited to the issues the Administrator has decided to review and confined to the record established by the hearing officer.

(3) All communications from the parties concerning a hearing officer's decision being reviewed by the Administrator must be in writing (not in facsimile or other electronic medium) and must include a certification that copies have been sent to all other parties.

(4) The Administrator does not consider any communication that does not meet the requirements of this paragraph.

(g) *Administrator's review decision.* (1) The Administrator bases his or her decision on the following:

(i) The entire record developed by the hearing officer.

(ii) Any materials submitted in connection with the hearing or under paragraph (f) of this section.

(iii) Generally known facts not subject to reasonable dispute.

(2) The Administrator mails copies of the review decision to all parties within 120 days from the date of the hearing officer's decision.

(3) The Administrator's review decision may affirm, reverse, or modify the hearing decision or may remand the case to the hearing officer.

(h) *Basis and effect of remand.*—(1) *Basis.* The bases for remand do not include the following:

(i) Evidence that existed at the time of the hearing and that was known or could reasonably have been expected to be known.

(ii) A court case that was either not available at the time of the hearing or was decided after the hearing.

(iii) Change of the parties' representation.

(iv) An alternative legal basis for an issue in dispute.

(2) *Effect of remand.* (i) The Administrator may instruct the hearing officer to take further action with respect to the development of additional facts or new issues or to consider the applicability of laws or regulations other than those considered during the hearing.

(ii) The hearing officer takes the action in accordance with the Administrator's instructions in the remand notice and again issues a decision.

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(iii) The Administrator may review or decline to review the hearing officer's remand decision in accordance with the procedures set forth in this section.

(i) *Finality of decision.* The Administrator's review decision, or the hearing officer's decision following remand, is the final Departmental decision and is binding on all parties unless the Administrator chooses to review the decision in accordance with this section, or the decision is reopened in accordance with § 411.126.

§ 411.126 Reopening of determinations and decisions.

(a) A determination that a GHP or LGHP is a nonconforming GHP or the decision or revised decision of a hearing officer or of the CMS Administrator may be reopened within 12 months from the date on the notice of determination or decision or revised decision, for any reason by the entity that issued the determination or decision.

(b) The decision to reopen or not to reopen is not appealable.

§ 411.130 Referral to Internal Revenue Service (IRS).

(a) *CMS responsibility.* After CMS determines that a plan has been a nonconforming GHP in a particular year, it refers its determination to the IRS, but only after the parties have exhausted all CMS appeal rights with respect to the determination.

(b) *IRS responsibility.* The IRS administers section 5000 of the IRC, which imposes a tax on employers (other than governmental entities) and employee organizations that contribute to a nonconforming GHP. The tax is equal to 25 percent of the employer's or employee organization's expenses, incurred during the calendar year in which the plan is a nonconforming GHP, for each GHP, both conforming and nonconforming, to which the employer or employee organization contributes.

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Subpart F—Special Rules: Individuals Eligible or Entitled on the Basis of ESRD, Who Are Also Covered Under Group Health Plans

§ 411.160 Scope.

This subpart sets forth special rules that apply to individuals who are eligible for, or entitled to, Medicare on the basis of ESRD. (Section 406.13 of this chapter contains the rules for eligibility and entitlement based on ESRD.)

[60 FR 45367, Aug. 31, 1995]

§ 411.161 Prohibition against taking into account Medicare eligibility or entitlement or differentiating benefits.

(a) *Taking into account—(1) Basic rule.* A GHP may not take into account that an individual is eligible for or entitled to Medicare benefits on the basis of ESRD during the coordination period specified in § 411.162(b) and (c). Examples of actions that constitute taking into account Medicare entitlement are listed in § 411.108(a).

(2) *Applicability.* This prohibition applies for ESRD-based Medicare eligibility to the same extent as for ESRD-based Medicare entitlement. An individual who has ESRD but who has not filed an application for entitlement to Medicare on that basis is eligible for Medicare based on ESRD for purposes of paragraphs (b)(2) and (c)(2) through (c)(4) of § 411.162 if the individual meets the other requirements of § 406.13 of this chapter.

(3) *Relation to COBRA continuation coverage.* This rule does not prohibit the termination of GHP coverage under title X of COBRA when termination of that coverage is expressly permitted, upon entitlement to Medicare, under 26 U.S.C. 4980B(f)(2)(B)(iv); 29 U.S.C. 1162.(2)(D); or 42 U.S.C. 300bb–2.(2)(D).¹ (Situations in which Medicare

¹COBRA requires that certain group health plans offer continuation of plan coverage for 18 to 36 months after the occurrence of certain “qualifying events,” including loss of employment or reduction of employment hours. Those are events that otherwise would result in loss of group health plan coverage

is secondary to COBRA continuation coverage are set forth in §411.162(a)(3).)

(b) *Nondifferentiation*. (1) A GHP may not differentiate in the benefits it provides between individuals who have ESRD and others enrolled in the plan, on the basis of the existence of ESRD, or the need for renal dialysis, or in any other manner.

(2) GHP actions that constitute differentiation in plan benefits (and that may also constitute “taking into account” Medicare eligibility or entitlement) include, but are not limited to the following:

(i) Terminating coverage of individuals with ESRD, when there is no basis for such termination unrelated to ESRD (such as failure to pay plan premiums) that would result in termination for individuals who do not have ESRD.

(ii) Imposing on persons who have ESRD, but not on others enrolled in the plan, benefit limitations such as less comprehensive health plan coverage, reductions in benefits, exclusions of benefits, a higher deductible or coinsurance, a longer waiting period, a lower annual or lifetime benefit limit, or more restrictive preexisting illness limitations.

(iii) Charging individuals with ESRD higher premiums.

(iv) Paying providers and suppliers less for services furnished to individuals who have ESRD than for the same services furnished to those who do not have ESRD, such as paying 80 percent of the Medicare rate for renal dialysis on behalf of a plan enrollee who has ESRD and the usual, reasonable and customary charge for renal dialysis on behalf of an enrollee who does not have ESRD.

unless the individual is given the opportunity to elect, and does so elect, to continue plan coverage at his or her own expense. With one exception, the COBRA amendments expressly permit termination of continuation coverage upon entitlement to Medicare. The exception is that the plan may not terminate continuation coverage of an individual (and his or her qualified dependents) if the individual retires on or before the date the employer substantially eliminates regular plan coverage by filing for Chapter 11 bankruptcy (26 U.S.C. 4980B(g)(1)(D) and 29 U.S.C. 1167.(3)(C)).

(v) Failure to cover routine maintenance dialysis or kidney transplants, when a plan covers other dialysis services or other organ transplants.

(c) *Uniform Limitations on particular services permissible*. A plan is not prohibited from limiting covered utilization of a particular service as long as the limitation applies uniformly to all plan enrollees. For instance, if a plan limits its coverage of renal dialysis sessions to 30 per year for all plan enrollees, the plan would not be differentiating in the benefits it provides between plan enrollees who have ESRD and those who do not.

(d) *Benefits secondary to Medicare*. (1) The prohibition against differentiation of benefits does not preclude a plan from paying benefits secondary to Medicare after the expiration of the coordination period described in §411.162(b) and (c), but a plan may not otherwise differentiate, as described in paragraph (b) of this section, in the benefits it provides.

(2) Example—

Mr. Smith works for employer A, and he and his wife are covered through employer A's GHP (Plan A). Neither is eligible for Medicare nor has ESRD. Mrs. Smith works for employer B, and is also covered by employer B's plan (Plan B). Plan A is more comprehensive than Plan B and covers certain items and services which Plan B does not cover, such as prescription drugs. If Mrs. Smith obtains a medical service, Plan B pays primary and Plan A pays secondary. That is, Plan A covers Plan B copayment amounts and items and services that Plan A covers but that Plan B does not.

Mr. Jones also works for employer A, and he and his wife are covered by Plan A. Mrs. Jones does not have other GHP coverage. Mrs. Jones develops ESRD and becomes entitled to Medicare on that basis. Plan A pays primary to Medicare during the first 18 months of Medicare entitlement based on ESRD. When Medicare becomes the primary payer, the plan converts Mrs. Jones' coverage to a Medicare supplement policy. That policy pays Medicare deductible and coinsurance amounts but does not pay for items and services not covered by Medicare, which plan A would have covered. That conversion is impermissible because the plan is providing a lower level of coverage for Mrs. Jones, who has ESRD, than it provides for Mrs. Smith, who does not. In other words, if Plan A pays secondary to primary payers other than Medicare, it must provide the same level of secondary benefits when Medicare is primary

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in order to comply with the nondifferentiation provision.

[60 FR 45368, Aug. 31, 1995]

§ 411.162 Medicare benefits secondary to group health plan benefits.

(a) *General provisions*—(1) *Basic rule.* Except as provided in § 411.163 (with respect to certain individuals who are also entitled on the basis of age or disability), Medicare is secondary to any GHP (including a retirement plan), with respect to benefits that are payable to an individual who is entitled to Medicare on the basis of ESRD, for services furnished during any coordination period determined in accordance with paragraphs (b) and (c) of this section. (No Medicare benefits are payable on behalf of an individual who is eligible but not yet entitled.)

(2) *Medicare benefits secondary without regard to size of employer and beneficiary's employment status.* The size of employer and employment status requirements of the MSP provisions for the aged and disabled do not apply with respect to ESRD beneficiaries.

(3) *COBRA continuation coverage.* Medicare is secondary payer for benefits that a GHP—

(i) Is required to keep in effect under COBRA continuation requirements (as explained in the footnote to § 411.161(a)(3)), even after the individual becomes entitled to Medicare; or

(ii) Voluntarily keeps in effect after the individual becomes entitled to Medicare on the basis of ESRD, even though not obligated to do so under the COBRA provisions.

(4) *Medicare payments during the coordination period.* During the coordination period, CMS makes Medicare payments as follows:

(i) Primary payments only for Medicare covered services that are—

(A) Furnished to Medicare beneficiaries who have declined to enroll in the GHP;

(B) Not covered under the plan;¹

(C) Covered under the plan but not available to particular enrollees because they have exhausted their benefits; or

(D) Furnished to individuals whose COBRA continuation coverage has been terminated because of the individual's Medicare entitlement.

(ii) Secondary payments, within the limits specified in §§ 411.32 and 411.33, to supplement the amount paid by the GHP if that plan pays only a portion of the charge for the services.

(b) *Beginning of coordination period.*

(1) For individuals who start a course of maintenance dialysis or who receive a kidney transplant before December 1989, the coordination period begins with the earlier of—

(i) The month in which the individual initiated a regular course of renal dialysis; or

(ii) In the case of an individual who received a kidney transplant, the first month in which the individual became entitled to Medicare, or, if earlier, the first month for which the individual would have been entitled to Medicare benefits if he or she had filed an application for such benefits.

(2) For individuals other than those specified in paragraph (b)(1) of this section, the coordination period begins with the earlier of—

(i) The first month in which the individual becomes entitled to Medicare part A on the basis of ESRD; or

(ii) The first month the individual would have become entitled to Medicare part A on the basis of ESRD if he or she had filed an application for such benefits.

(c) *End of coordination period.* (1) For individuals who start a regular course of renal dialysis or who receive a kidney transplant before December 1989, the coordination period ends with the earlier of the end of the 12th month of dialysis or the end of the 12th month of a transplant. The 12th month of dialysis may be any time from the 9th month through the 12th month of Medicare entitlement, depending on the extent to which the individual was subject to a waiting period before becoming entitled to Medicare.

(2) The coordination period for the following individuals ends with the earlier of the 12th month of eligibility or the 12th month of entitlement to Medicare part A:

(i) Individuals, other than those specified in paragraph (c)(1) of this section,

¹ CMS does not pay if noncoverage of services constitutes differentiation as prohibited by § 411.161(b).

who became entitled to Medicare part A solely on the basis of ESRD during December 1989 and January 1990.

(ii) Individuals, other than those specified in paragraph (c)(1) of this section, who could have become entitled to Medicare Part A solely on the basis of ESRD during December 1989 and January 1990 if they had filed an application.

(iii) Individuals who become entitled to Medicare part A on the basis of ESRD after September 1997.

(iv) Individuals who can become entitled to Medicare part A on the basis of ESRD after September 1997.

(3) The coordination period for the following individuals ends with the earlier of the end of the 18th month of eligibility or the 18th month of entitlement to Medicare part A:

(i) Individuals, other than those specified in paragraph (c)(1) of this section, who become entitled to Medicare part A on the basis of ESRD from February 1990 through April 1997.

(ii) Individuals, other than those specified in paragraph (c)(1) of this section, who could become entitled to Medicare part A on the basis of ESRD from February 1990 through April 1997 if they would file an application.

(4) The coordination periods for the following individuals ends September 30, 1998:

(i) Individuals who become entitled to Medicare part A on the basis of ESRD from May 1997, through September 1997.

(ii) Individuals who could become entitled to Medicare part A on the basis of ESRD from May 1997, through September 1997, if they would file an application.

(d) *Examples.* Based on the rules specified in paragraphs (b) and (c) of this section and the rules specified in §406.13 of this subchapter, the following examples illustrate how to determine, in different situations, the number of months during which Medicare is secondary payer.

(1) An individual began dialysis on November 4, 1989. He did not initiate a course in self-dialysis training nor did he receive a kidney transplant during the first 3 calendar months of dialysis. Thus, he became entitled to Medicare on February 1, 1990. Since this indi-

vidual began dialysis before December 1989, the 12-month period began with the first month of dialysis, November 1989, and ended October 31, 1990. The coordination period in this case is 9 months, February 1990 through October 1990.

(2) An individual began dialysis on January 29, 1990. He did not initiate a course in self-dialysis training nor did he receive a kidney transplant during the first 3 calendar months of dialysis. Thus, he became entitled to Medicare on April 1, 1990. Since the individual began dialysis after November 1989, and became entitled to Medicare after January 1990, the coordination period began with the first month of entitlement, April 1990, and ended September 30, 1991, the end of the 18th month of entitlement.

(3) An individual began a regular course of maintenance dialysis on February 10, 1990. He did not initiate a course of self-dialysis training nor did he receive a kidney transplant during the first 3 calendar months of dialysis. Thus, he became entitled to Medicare on May 1, 1990. Medicare is secondary payer from May 1, 1990 through October 1991, a total of 18 months.

(4) The same facts exist as in the example under paragraph (d)(3), except that the individual began a course of self-dialysis training during the first 3 calendar months of dialysis. Thus, the effective date of his Medicare entitlement is February 1, 1990, and Medicare is secondary payer from February 1, 1990 through July 1991, a total of 18 months.

(5) An individual began dialysis on September 15, 1990. He did not initiate a course of self-dialysis training nor did he receive a kidney transplant during the first 3 calendar months of dialysis. Thus, he became entitled to Medicare effective December 1, 1990. Medicare is secondary payer from December 1, 1990 through May 1992, a total of 18 months.

(6) An individual began dialysis on November 17, 1990. He initiates a course of self-dialysis training in January 1991, and thus becomes entitled to Medicare effective November 1, 1990. Medicare is secondary payer from November 1, 1990, through April 1992, a total of 18 months.

(7) An individual began a regular course of dialysis on December 10, 1990. He does not initiate a course of self-dialysis training nor does he receive a kidney transplant. He decides to delay his enrollment in Medicare because his employer group health plan pays charges in full and he does not wish to incur part B premiums at this time. However, in March 1992, he files for part A and part B Medicare entitlement, and stipulates that he wants his Medicare entitlement to be effective March 1, 1992 (one year later than he could have become entitled). Since this individual could have been entitled to Medicare as early as March 1, 1991, Medicare is secondary payer only from March 1, 1992, through August 1992, a period of 6 months.

(While Medicare is secondary payer for only the last 6 months of this period, the Medicare program is effectively secondary payer for the full coordination period, due to the fact that the individual delayed his Medicare enrollment on account of his employer plan coverage and Medicare made no payments at all during the deferred period.)

(8) The same facts exist as in the example under paragraph (d)(7) of this section, except that the individual defers Medicare entitlement beyond August 1992. (For purposes of this example, Medicare entitlement is not retroactive, but rather takes effect after August 1992.) There would be no period during which Medicare is secondary payer in this situation. This is because Medicare entitlement does not begin until after the 18-month period expires as specified in paragraph (c)(3)(ii) of this section. Medicare would become primary payer as of the effective date of Medicare entitlement. The employer plan is required to pay primary from December 1, 1990, through August 1992, a total of 21 months.

(9) An individual becomes entitled to Medicare on December 1, 1997. The employer plan is primary payer, and Medicare is secondary payer, from December 1, 1997, through November 30, 1998, a period of 12 months. Medicare becomes primary payer on December 1, 1998, because the extension of the coordination period from 12 to 18 months

applies only to items and services furnished before October 1, 1998.

(10) An individual becomes entitled to Medicare on August 1, 1997. Medicare is secondary payer from August 1, 1997, through September 30, 1998, a period of 14 months. Medicare becomes primary payer on October 1, 1998, because the coordination period has expired.

(e) [Reserved]

(f) *Determinations for subsequent periods of ESRD eligibility.* If an individual has more than one period of eligibility based on ESRD, a coordination period will be determined for each period of eligibility in accordance with this section.

[57 FR 36015, Aug. 12, 1992; 57 FR 45113, Sept. 30, 1992. Redesignated and amended at 60 FR 45362, 45368, Aug. 31, 1995]

§411.163 Coordination of benefits: Dual entitlement situations.

(a) *Basic rule.* Coordination of benefits is governed by this section if an individual is eligible for or entitled to Medicare on the basis of ESRD and also entitled on the basis of age or disability.

(b) *Specific rules.*¹ (1) *Coordination period ended before August 1993.* If the first 18 months of ESRD-based eligibility or entitlement ended before August 1993, Medicare was primary payer from the first month of dual eligibility or entitlement, regardless of when dual eligibility or entitlement began.

(2) *First month of ESRD-based eligibility or entitlement and first month of dual eligibility/entitlement after February 1992 and before August 10, 1993.* Except as provided in paragraph (b)(4) of this section, if the first month of ESRD-based eligibility or entitlement and

¹ A lawsuit was filed in United States District Court for the District of Columbia on May 5, 1995 (*National Medical Care, Inc. v. Shalala*, Civil Action No. 95-0860), challenging the implementation of one aspect of the OBRA '93 provisions with respect to group health plan retirement coverage. The court issued a preliminary injunction order on June 6, 1995, which enjoins the Secretary from applying the rule contained in §411.163(b)(4) for items and services furnished between August 10, 1993 and April 24, 1995, pending the court's decision on the merits. CMS will modify the rules, if required, based on the final ruling by the court.

first month of dual eligibility/entitlement were after February 1992 and before August 10, 1993, Medicare—

(i) Is primary payer from the first month of dual eligibility/entitlement through August 9, 1993;

(ii) Is secondary payer from August 10, 1993, through the 18th month of ESRD-based eligibility or entitlement; and

(iii) Again becomes primary payer after the 18th month of ESRD-based eligibility or entitlement.

(3) *First month of ESRD-based eligibility or entitlement after February 1992 and first month of dual eligibility/entitlement after August 9, 1993.* Except as provided in paragraph (b)(4) of this section, if the first month of ESRD-based eligibility or entitlement is after February 1992, and the first month of dual eligibility/entitlement is after August 9, 1993, the rules of §411.162(b) and (c) apply; that is, Medicare—

(i) Is secondary payer during the first 18 months of ESRD-based eligibility or entitlement; and

(ii) Becomes primary after the 18th month of ESRD-based eligibility or entitlement.

(4) *Medicare continues to be primary after an aged or disabled beneficiary becomes eligible on the basis of ESRD.* (i) *Applicability of the rule.* Medicare remains the primary payer when an individual becomes eligible for Medicare based on ESRD if all of the following conditions are met:

(A) The individual is already entitled on the basis of age or disability when he or she becomes eligible on the basis of ESRD.

(B) The MSP prohibition against “taking into account” age-based or disability-based entitlement does not apply because plan coverage was not “by virtue of current employment status” or the employer had fewer than 20 employees (in the case of the aged) or fewer than 100 employees (in the case of the disabled).

(C) The plan is paying secondary to Medicare because the plan had justifiably taken into account the age-based or disability-based entitlement.

(ii) *Effect of the rule.* The plan may continue to pay benefits secondary to Medicare under paragraph (b)(4)(i) of this section. However, the plan may

not differentiate in the services covered and the payments made between persons who have ESRD and those who do not.

(c) *Examples.* (1) (Rule (b)(1).) Mr. A, who is covered by a GHP, became entitled to Medicare on the basis of ESRD in January 1992. On December 20, 1992, Mr. A attained age 65 and became entitled on the basis of age. Since prior law was still in effect (OBRA '93 amendment was effective in August 1993), Medicare became primary payer as of December 1992, when dual entitlement began.

(2) (Rule (b)(2).) Miss B, who has GHP coverage, became entitled to Medicare on the basis of ESRD in July 1992, and also entitled on the basis of disability in June 1993. Medicare was primary payer from June 1993 through August 9, 1993, because the plan permissibly took into account the ESRD-based entitlement (ESRD was not the “sole” basis of Medicare entitlement); secondary payer from August 10, 1993, through December 1993, the 18th month of ESRD-based entitlement (the plan is no longer permitted to take into account ESRD-based entitlement that is not the “sole” basis of Medicare entitlement); and again became primary payer beginning January 1994.

(3) (Rule (b)(3).) Mr. C, who is 67 years old and entitled to Medicare on the basis of age, has GHP coverage by virtue of current employment status. Mr. C is diagnosed as having ESRD and begins a course of maintenance dialysis on June 27, 1993. Effective September 1, 1993, Mr. C. is eligible for Medicare on the basis of ESRD. Medicare, which was secondary because Mr. C's GHP coverage was by virtue of current employment, continues to be secondary payer through February 1995, the 18th month of ESRD-based eligibility, and becomes primary payer beginning March 1995.

(4) (Rule (b)(3).) Mr. D retired at age 62 and maintained GHP coverage as a retiree. In January 1994, at the age of 64, Mr. D became entitled to Medicare based on ESRD. Seven months into the 18-month coordination period (July 1994) Mr. D turned age 65. The coordination period continues without regard

to age-based entitlement, with the retirement plan continuing to pay primary benefits through June 1995, the 18th month of ESRD-based entitlement. Thereafter, Medicare becomes the primary payer.

(5) (Rule (b)(3).) Mrs. E retired at age 62 and maintained GHP coverage as a retiree. In July 1994, she simultaneously became eligible for Medicare based on ESRD (maintenance dialysis began in April 1994) and entitled based on age. The retirement plan must pay benefits primary to Medicare from July 1994 through December 1995, the first 18 months of ESRD-based eligibility. Thereafter, Medicare becomes the primary payer.

(6) (Rule (b)(3).) Mr. F, who is 67 years of age, is working and has GHP coverage because of his employment status, subsequently develops ESRD, and begins a course of maintenance dialysis in October 1994. He becomes eligible for Medicare based on ESRD effective January 1, 1995. Under the working aged provision, the plan continues to pay primary to Medicare through December 1994. On January 1, 1995, the working aged provision ceases to apply and the ESRD MSP provision takes effect. In September 1995, Mr. F retires. The GHP must ignore Mr. F's retirement status and continue to pay primary to Medicare through June 1996, the end of the 18-month coordination period.

(7) (Rule (b)(4).) Mrs. G, who is 67 years of age, is retired. She has GHP retirement coverage through her former employer. Her plan permissibly took into account her age-based Medicare entitlement when she retired and is paying benefits secondary to Medicare. Mrs. G subsequently develops ESRD and begins a course of maintenance dialysis in October 1995. She automatically becomes eligible for Medicare based on ESRD effective January 1, 1996. The plan continues to be secondary on the basis of Mrs. G's age-based entitlement as long as the plan does not differentiate in the services it provides to Mrs. G and does not do anything else that would constitute "taking into account" her ESRD-based eligibility.

[60 FR 45369, Aug. 31, 1995; 60 FR 53876, Oct. 18, 1995]

§ 411.165 Basis for conditional Medicare payments.

(a) *General rule.* Except as specified in paragraph (b) of this section, the Medicare intermediary or carrier may make a conditional payment if—

(1) The beneficiary, the provider, or the supplier that has accepted assignment files a proper claim under the group health plan and the plan denies the claim in whole or in part; or

(2) The beneficiary, because of physical or mental incapacity, fails to file a proper claim.

(b) *Exception.* Medicare does not make conditional primary payments under either of the following circumstances:

(1) The claim is denied for one of the following reasons:

(i) It is alleged that the group health plan is secondary to Medicare.

(ii) The group health plan limits its payments when the individual is entitled to Medicare.

(iii) Failure to file a proper claim if that failure is for any reason other than the physical or mental incapacity of the beneficiary.

(2) The group health plan fails to furnish information requested by CMS and necessary to determine whether the employer plan is primary to Medicare.

[57 FR 36015, Aug. 12, 1992. Redesignated and amended at 60 FR 45362, 45370, Aug. 31, 1995; 60 FR 53877, Oct. 18, 1995]

Subpart G—Special Rules: Aged Beneficiaries and Spouses Who Are Also Covered Under Group Health Plans

§ 411.170 General provisions.

(a) *Basis.* (1) This subpart is based on certain provisions of section 1862(b) of the Act, which impose specific requirements and limitations with respect to—

(i) Individuals who are entitled to Medicare on the basis of age; and

(ii) GHPs of at least one employer of 20 or more employees that cover those individuals.

(2) Under these provisions, the following rules apply:

(i) An employer is considered to employ 20 or more employees if the employer has 20 or more employees for

each working day in each of 20 or more calendar weeks in the current calendar year or the preceding calendar year.

(ii) The plan may not take into account the Medicare entitlement of—

(A) An individual age 65 or older who is covered or seeks to be covered under the plan by virtue of current employment status; or

(B) The spouse, including divorced or common-law spouse age 65 or older of an individual (of any age) who is covered or seeks to be covered by virtue of current employment status. (Section 411.108 gives examples of actions that constitute “taking into account.”)

(iii) Regardless of whether entitled to Medicare, employees and spouses age 65 or older, including divorced or common-law spouses of employees of any age, are entitled to the same plan benefits under the same conditions as employees and spouses under age 65.

(b) [Reserved]

(c) *Determination of “aged”.* (1) An individual attains a particular age on the day preceding the anniversary of his or her birth.

(2) The period during which an individual is considered to be “aged” begins on the first day of the month in which that individual attains age 65.

(3) For services furnished before May 1986, the period during which an individual is considered “aged” ends as follows:

(i) For services furnished before July 18, 1984, it ends on the last day of the month in which the individual attains age 70.

(ii) For services furnished between July 18, 1984 and April 30, 1986, it ends on the last day of the month *before* the month the individual attains age 70.

(4) For services furnished on or after May 1, 1986, the period has no upper age limit.

[54 FR 41734, Oct. 11, 1989. Redesignated and amended at 60 FR 45362, 45370, Aug. 31, 1995]

§411.172 Medicare benefits secondary to group health plan benefits.

(a) *Conditions that the individual must meet.* Medicare Part A and Part B benefits are secondary to benefits payable by a GHP for services furnished during any month in which the individual—

(1) Is aged;

(2) Is entitled to Medicare Part A benefits under §406.10 of this chapter; and

(3) Meets one of the following conditions:

(i) Is covered under a GHP of an employer that has at least 20 employees (including a multi-employer plan in which at least one of the participating employers meets that condition), and coverage under the plan is by virtue of the individual's current employment status.

(ii) Is the aged spouse (including a divorced or common-law spouse) of an individual (of any age) who is covered under a GHP described in paragraph (a)(3)(i) of this section by virtue of the individual's current employment status.

(b) *Special rule for multi-employer plans.* The requirements and limitations of paragraph (a) of this section and of (a)(2)(iii) of §411.170 do not apply with respect to individuals enrolled in a multi-employer plan if—

(1) The individuals are covered by virtue of current employment status with an employer that has fewer than 20 employees; and

(2) The plan requests an exception and identifies the individuals for whom it requests the exception as meeting the conditions specified in paragraph (b)(1) of this section.

(c) *Refusal to accept group health plan coverage.* An employee or spouse may refuse the health plan offered by the employer. If the employee or spouse refuses the plan—

(1) Medicare is primary payer for that individual; and

(2) The plan may not offer that individual coverage complementary to Medicare.

(d) *Reemployed retiree or annuitant.* A reemployed retiree or annuitant who is covered by a GHP and who performs sufficient services to qualify for coverage on that basis (that is, other employees in the same category are provided health benefits) is considered covered “by reason of current employment status” even if:

(1) The employer provides the same GHP coverage to retirees; or

(2) The premiums for the plan are paid from a retirement or pension fund.

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(e) *Secondary payments.* Medicare pays secondary benefits, within the limitations specified in §§ 411.32 and 411.33, to supplement the primary benefits paid by the group health plan if that plan pays only a portion of the charge for the services.

(f) *Disabled aged individuals who are considered employed.* (1) For services furnished on or after November 12, 1985, and before July 17, 1987, a disabled, nonworking individual age 65 or older was considered employed if he or she—

(i) Was receiving, from an employer, disability payments that were subject to tax under the Federal Insurance Contributions Act (FICA); and

(ii) For the month before the month of attainment of age 65, was not entitled to disability benefits under title II of the Act and 20 CFR 404.315 of the SSA regulations.

(2) For services furnished on or after July 17, 1987, an individual is considered employed if he or she receives, from an employer, disability benefits that are subject to tax under FICA, even if he or she was entitled to Social Security disability benefits before attaining age 65.

(g) *Individuals entitled to Medicare on the basis of age who are also eligible for or entitled to Medicare on the basis of ESRD.* If an aged individual is, or could upon filing an application become, entitled to Medicare on the basis of ESRD, the coordination of benefits rules of subpart F of this part apply.

[54 FR 41734, Oct. 11, 1989, as amended at 55 FR 1820, Jan. 19, 1990. Redesignated and amended at 60 FR 45362, 45370, Aug. 31, 1995; 60 FR 53877, Oct. 18, 1995]

§ 411.175 Basis for Medicare primary payments.

(a) *General rule.* CMS makes Medicare primary payments for covered services that are—

(1) Furnished to Medicare beneficiaries who have declined to enroll in the GHP;

(2) Not covered by the plan for any individuals or spouses who are enrolled by virtue of the individual's current employment status;

(3) Covered under the plan but not available to particular individuals or spouses enrolled by virtue of current employment status because they have

exhausted their benefits under the plan;

(4) Furnished to individuals whose COBRA continuation coverage has been terminated because of the individual's Medicare entitlement; or

(5) Covered under COBRA continuation coverage notwithstanding the individual's Medicare entitlement.

(b) *Conditional Medicare payments: Basic rule.* Except as provided in paragraph (c) of this section, Medicare may make a conditional primary payment if—

(1) The beneficiary, the provider, or the supplier that has accepted assignment has filed a proper claim under the group health plan and the plan has denied the claim in whole or in part; or

(2) The beneficiary, because of physical or mental incapacity, failed to file proper claim.

(c) *Conditional primary payments: Exception.* Medicare does not make conditional primary payments under either of the following circumstances:

(1) The claim is denied for one of the following reasons:

(i) It is alleged that the group health plan is secondary to Medicare.

(ii) The plan limits its payments when the individual is entitled to Medicare.

(iii) The plan covers the services for individuals or spouses who are enrolled in the plan by virtue of current employment status and are under age 65 but not for individuals and spouses who are enrolled on the same basis but are age 65 or older.

(iv) Failure to file a proper claim if that failure is for any reason other than physical or mental incapacity of the beneficiary.

(2) The group health plan fails to furnish information requested by CMS and necessary to determine whether the employer plan is primary to Medicare.

[54 FR 41734, Oct. 11, 1989. Redesignated and amended at 60 FR 45362, 45371, Aug. 31, 1995]

Subpart H—Special Rules: Disabled Beneficiaries Who Are Also Covered Under Large Group Health Plans

SOURCE: 60 FR 45371, Aug. 31, 1995, unless otherwise noted.

§ 411.200 Basis.

(a) This subpart is based on certain provisions of section 1862(b) of the Act, which impose specific requirements and limitations with respect to—

(1) Individuals who are entitled to Medicare on the basis of disability; and

(2) Large group health plans (LGHPs) that cover those individuals.

(b) Under these provisions, the LGHP may not take into account the Medicare entitlement of a disabled individual who is covered (or seeks to be covered) under the plan by virtue of his or her own current employment status or that of a member of his or her family. (§411.108 gives examples of actions that constitute taking into account.)

§ 411.201 Definitions.

As used in this subpart—

Entitled to Medicare on the basis of disability means entitled or deemed entitled on the basis of entitlement to social security disability benefits or railroad retirement disability benefits. (§406.12 of this chapter explains the requirements an individual must meet in order to be entitled or deemed to be entitled to Medicare on the basis of disability.)

Family member means a person who is enrolled in an LGHP based on another person's enrollment; for example, the enrollment of the named insured individual. Family members may include a spouse (including a divorced or common-law spouse), a natural, adopted, foster, or stepchild, a parent, or a sibling.

§ 411.204 Medicare benefits secondary to LGHP benefits.

(a) Medicare benefits are secondary to benefits payable by an LGHP for services furnished during any month in which the individual—

(1) Is entitled to Medicare Part A benefits under §406.12 of this chapter;

(2) Is covered under an LGHP; and

(3) Has LGHP coverage by virtue of his or her own or a family member's current employment status.

(b) *Individuals entitled to Medicare on the basis of disability who are also eligible for, or entitled to, Medicare on the basis of ESRD.* If a disabled individual is, or could upon filing an application become, entitled to Medicare on the basis

of ESRD, the coordination of benefits rules of subpart F of this part apply.

§ 411.206 Basis for Medicare primary payments and limits on secondary payments.

(a) *General rule.* CMS makes Medicare primary payments for services furnished to disabled beneficiaries covered under the LGHP by virtue of their own or a family member's current employment status if the services are—

(1) Furnished to Medicare beneficiaries who have declined to enroll in the GHP;

(2) Not covered under the plan for the disabled individual or similarly situated individuals;

(3) Covered under the plan but not available to particular disabled individuals because they have exhausted their benefits under the plan;

(4) Furnished to individuals whose COBRA continuation coverage has been terminated because of the individual's Medicare entitlement; or

(5) Covered under COBRA continuation coverage notwithstanding the individual's Medicare entitlement.

(b) *Conditional primary payments: Basic rule.* Except as provided in paragraph (c) of this section, CMS may make a conditional Medicare primary payment for any of the following reasons:

(1) The beneficiary, the provider, or the supplier that has accepted assignment has filed a proper claim with the LGHP and the LGHP has denied the claim in whole or in part.

(2) The beneficiary, because of physical or mental incapacity, failed to file a proper claim.

(c) *Conditional primary payments: Exceptions.* CMS does not make conditional Medicare primary payments if—

(1) The LGHP denies the claim in whole or in part for one of the following reasons:

(i) It is alleged that the LGHP is secondary to Medicare.

(ii) The LGHP limits its payments when the individual is entitled to Medicare.

(iii) The LGHP does not provide the benefits to individuals who are entitled to Medicare on the basis of disability and covered under the plan by virtue of current employment status but does

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provide the benefits to other similarly situated individuals enrolled in the plan.

(iv) The LGHP takes into account entitlement to Medicare in any other way.

(v) There was failure to file a proper claim for any reason other than physical or mental incapacity of the beneficiary.

(2) The LGHP, an employer or employee organization, or the beneficiary fails to furnish information that is requested by CMS and that is necessary to determine whether the LGHP is primary to Medicare.

(d) *Limit on secondary payments.* The provisions of § 411.172(e) also apply to services furnished to the disabled under this subpart.

Subpart I [Reserved]

Subpart J—Financial Relationships Between Physicians and Entities Furnishing Designated Health Services

SOURCE: 69 FR 16126, Mar. 26, 2004, unless otherwise noted.

§ 411.350 Scope of subpart.

(a) This subpart implements section 1877 of the Act, which generally prohibits a physician from making a referral under Medicare for designated health services to an entity with which the physician or a member of the physician's immediate family has a financial relationship.

(b) This subpart does not provide for exceptions or immunity from civil or criminal prosecution or other sanctions applicable under any State laws or under Federal law other than section 1877 of the Act. For example, although a particular arrangement involving a physician's financial relationship with an entity may not prohibit the physician from making referrals to the entity under this subpart, the arrangement may nevertheless violate another provision of the Act or other laws administered by HHS, the Federal Trade Commission, the Securities and Exchange Commission, the Internal Revenue Service, or any other Federal or State agency.

(c) This subpart requires, with some exceptions, that certain entities furnishing covered services under Medicare report information concerning ownership, investment, or compensation arrangements in the form, in the manner, and at the times specified by CMS.

(d) This subpart does not alter an individual's or entity's obligations under—

(1) The rules regarding reassignment of claims (§ 424.80 of this chapter);

(2) The rules regarding purchased diagnostic tests (§ 414.50 of this chapter);

(3) The rules regarding payment for services and supplies incident to a physician's professional services (§ 410.26 of this chapter); or

(4) Any other applicable Medicare laws, rules, or regulations.

[85 FR 77656, Dec. 2, 2020]

§ 411.351 Definitions.

The definitions in this subpart apply only for purposes of section 1877 of the Act and this subpart. As used in this subpart, unless the context indicates otherwise:

Centralized building means all or part of a building, including, for purposes of this subpart only, a mobile vehicle, van, or trailer that is owned or leased on a full-time basis (that is, 24 hours per day, 7 days per week, for a term of not less than 6 months) by a group practice and that is used exclusively by the group practice. Space in a building or a mobile vehicle, van, or trailer that is shared by more than one group practice, by a group practice and one or more solo practitioners, or by a group practice and another provider or supplier (for example, a diagnostic imaging facility) is not a centralized building for purposes of this subpart. This provision does not preclude a group practice from providing services to other providers or suppliers (for example, purchased diagnostic tests) in the group practice's centralized building. A group practice may have more than one centralized building.

Clinical laboratory services means the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from

the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings, including procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body, as specifically identified by the List of CPT/HCPSC Codes. All services so identified on the List of CPT/HCPSC Codes are clinical laboratory services for purposes of this subpart. Any service not specifically identified as a clinical laboratory service on the List of CPT/HCPSC Codes is not a clinical laboratory service for purposes of this subpart.

Commercially reasonable means that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.

Consultation means a professional service furnished to a patient by a physician if the following conditions are satisfied:

- (1) The physician's opinion or advice regarding evaluation or management or both of a specific medical problem is requested by another physician.
- (2) The request and need for the consultation are documented in the patient's medical record.
- (3) After the consultation is provided, the physician prepares a written report of his or her findings, which is provided to the physician who requested the consultation.
- (4) With respect to radiation therapy services provided by a radiation oncologist, a course of radiation treatments over a period of time will be considered to be pursuant to a consultation, provided that the radiation oncologist communicates with the referring physician on a regular basis about the patient's course of treatment and progress.

Cybersecurity means the process of protecting information by preventing, detecting, and responding to cyberattacks.

Designated health services (DHS) means any of the following services (other than those provided as emergency physician services furnished outside of the U.S.), as they are defined in this section:

- (1)(i) Clinical laboratory services.
- (ii) Physical therapy, occupational therapy, and outpatient speech-language pathology services.
- (iii) Radiology and certain other imaging services.
- (iv) Radiation therapy services and supplies.
- (v) Durable medical equipment and supplies.
- (vi) Parenteral and enteral nutrients, equipment, and supplies.
- (vii) Prosthetics, orthotics, and prosthetic devices and supplies.
- (viii) Home health services.
- (ix) Outpatient prescription drugs.
- (x) Inpatient and outpatient hospital services.

(2) Except as otherwise noted in this subpart, the term "designated health services" or DHS means only DHS payable, in whole or in part, by Medicare. DHS do not include services that are paid by Medicare as part of a composite rate (for example, SNF Part A payments or ASC services identified at §416.164(a)), except to the extent that services listed in paragraphs (1)(i) through (1)(x) of this definition are themselves payable under a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS). For services furnished to inpatients by a hospital, a service is not a designated health service payable, in whole or in part, by Medicare if the furnishing of the service does not increase the amount of Medicare's payment to the hospital under any of the following prospective payment systems (PPS):

- (i) Acute Care Hospital Inpatient (IPPS);
- (ii) Inpatient Rehabilitation Facility (IRF PPS);
- (iii) Inpatient Psychiatric Facility (IPF PPS); or
- (iv) Long-Term Care Hospital (LTCH PPS).

Does not violate the anti-kickback statute, as used in this subpart only, means that the particular arrangement—

(1)(i) Meets a safe harbor under the anti-kickback statute, as set forth at § 1001.952 of this title, “Exceptions”;

(ii) Has been specifically approved by the OIG in a favorable advisory opinion issued to a party to the particular arrangement (for example, the entity furnishing DHS) with respect to the particular arrangement (and not a similar arrangement), provided that the arrangement is conducted in accordance with the facts certified by the requesting party and the opinion is otherwise issued in accordance with part 1008 of this title, “Advisory Opinions by the OIG”; or

(iii) Does not violate the anti-kickback provisions in section 1128B(b) of the Act.

(2) For purposes of this definition, a favorable advisory opinion means an opinion in which the OIG opines that—

(i) The party’s specific arrangement does not implicate the anti-kickback statute, does not constitute prohibited remuneration, or fits in a safe harbor under § 1001.952 of this title; or

(ii) The party will not be subject to any OIG sanctions arising under the anti-kickback statute (for example, under sections 1128A(a)(7) and 1128(b)(7) of the Act) in connection with the party’s specific arrangement.

Downstream contractor means a “first tier contractor” as defined at § 1001.952(t)(2)(iii) of this title or a “downstream contractor” as defined at § 1001.952(t)(2)(i) of this title.

Durable medical equipment (DME) and supplies has the meaning given in section 1861(n) of the Act and § 414.202 of this chapter.

Electronic health record means a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions.

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).)

Entity means—

(1) A physician’s sole practice or a practice of multiple physicians or any other person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, nonprofit corporation, or unincorporated association that furnishes DHS. An entity does not include the referring physician himself or herself, but does include his or her medical practice. A person or entity is considered to be furnishing DHS if it—

(i) Is the person or entity that has performed services that are billed as DHS; or

(ii) Is the person or entity that has presented a claim to Medicare for the DHS, including the person or entity to which the right to payment for the DHS has been reassigned in accordance with § 424.80(b)(1) (employer) or (b)(2) (payment under a contractual arrangement) of this chapter (other than a health care delivery system that is a health plan (as defined at § 1001.952(l) of this title), and other than any managed care organization (MCO), provider-sponsored organization (PSO), or independent practice association (IPA) with which a health plan contracts for services provided to plan enrollees).

(2) A health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier under § 424.80(b)(1) and (b)(2) of this chapter, with respect to any DHS provided by that supplier.

(3) For purposes of this subpart, “entity” does not include a physician’s practice when it bills Medicare for the technical component or professional component of a diagnostic test for which the anti-markup provision is applicable in accordance with § 414.50 of this chapter and Pub. 100–04, Medicare Claims Processing Manual, Chapter 1, Section 30.2.9.

Fair market value means—

(1) *General*. The value in an arm’s-length transaction, consistent with the general market value of the subject transaction.

(2) *Rental of equipment*. With respect to the rental of equipment, the value in an arm’s-length transaction of rental

property for general commercial purposes (not taking into account its intended use), consistent with the general market value of the subject transaction.

(3) *Rental of office space.* With respect to the rental of office space, the value in an arm's-length transaction of rental property for general commercial purposes (not taking into account its intended use), without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee, and consistent with the general market value of the subject transaction.

General market value means—

(1) *Assets.* With respect to the purchase of an asset, the price that an asset would bring on the date of acquisition of the asset as the result of *bona fide* bargaining between a well-informed buyer and seller that are not otherwise in a position to generate business for each other.

(2) *Compensation.* With respect to compensation for services, the compensation that would be paid at the time the parties enter into the service arrangement as the result of *bona fide* bargaining between well-informed parties that are not otherwise in a position to generate business for each other.

(3) *Rental of equipment or office space.* With respect to the rental of equipment or the rental of office space, the price that rental property would bring at the time the parties enter into the rental arrangement as the result of *bona fide* bargaining between a well-informed lessor and lessee that are not otherwise in a position to generate business for each other.

Home health services means the services described in section 1861(m) of the Act and part 409, subpart E of this chapter.

Hospital means any entity that qualifies as a “hospital” under section 1861(e) of the Act, as a “psychiatric hospital” under section 1861(f) of the Act, or as a “critical access hospital” under section 1861(mm)(1) of the Act, and refers to any separate legally organized operating entity plus any sub-

sidiary, related entity, or other entities that perform services for the hospital's patients and for which the hospital bills. However, a “hospital” does not include entities that perform services for hospital patients “under arrangements” with the hospital.

HPSA means, for purposes of this subpart, an area designated as a health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act for primary medical care professionals (in accordance with the criteria specified in part 5 of this title).

Immediate family member or member of a physician's immediate family means husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

“Incident to” services or services “incident to” means those services and supplies that meet the requirements of section 1861(s)(2)(A) of the Act, §410.26 of this chapter, and Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, Sections 60, 60.1, 60.2, 60.3, and 60.4.

Inpatient hospital services means those services defined in section 1861(b) of the Act and §409.10(a) and (b) of this chapter and include inpatient psychiatric hospital services listed in section 1861(c) of the Act and inpatient critical access hospital services, as defined in section 1861(mm)(2) of the Act. “Inpatient hospital services” do not include emergency inpatient services provided by a hospital located outside of the U.S. and covered under the authority in section 1814(f)(2) of the Act and part 424, subpart H of this chapter, or emergency inpatient services provided by a nonparticipating hospital within the U.S., as authorized by section 1814(d) of the Act and described in part 424, subpart G of this chapter. “Inpatient hospital services” also do not include dialysis furnished by a hospital that is not certified to provide end-stage renal dialysis (ESRD) services under subpart U of part 405 of this chapter. “Inpatient hospital services” include services that are furnished either by the hospital directly or under arrangements made by the hospital

with others. “Inpatient hospital services” do not include professional services performed by physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists and qualified psychologists if Medicare reimburses the services independently and not as part of the inpatient hospital service (even if they are billed by a hospital under an assignment or reassignment).

Interoperable means—

(1) Able to securely exchange data with and use data from other health information technology; and

(2) Allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law.

Isolated financial transaction—(1) Isolated financial transaction means a one-time transaction involving a single payment between two or more persons or a one-time transaction that involves integrally related installment payments, provided that—

(i) The total aggregate payment is fixed before the first payment is made and does not take into account the volume or value of referrals or other business generated by the physician; and

(ii) The payments are immediately negotiable, guaranteed by a third party, secured by a negotiable promissory note, or subject to a similar mechanism to ensure payment even in the event of default by the purchaser or obligated party.

(2) An isolated financial transaction includes a one-time sale of property or a practice, single instance of forgiveness of an amount owed in settlement of a *bona fide* dispute, or similar one-time transaction, but does not include a single payment for multiple or repeated services (such as payment for services previously provided but not yet compensated).

Laboratory means an entity furnishing biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of

any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Entities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

List of CPT/HCPCS Codes means the list of CPT and HCPCS codes that identifies those items and services that are DHS under section 1877 of the Act or that may qualify for certain exceptions under section 1877 of the Act. It is updated annually and posted on the CMS website at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.

Locum tenens physician (or substitute physician) means a physician who substitutes in exigent circumstances for another physician, in accordance with section 1842(b)(6)(D) of the Act and Pub. 100–04, Medicare Claims Processing Manual, Chapter 1, Section 30.2.11.

Member of the group or member of a group practice means, for purposes of this subpart, a direct or indirect physician owner of a group practice (including a physician whose interest is held by his or her individual professional corporation or by another entity), a physician employee of the group practice (including a physician employed by his or her individual professional corporation that has an equity interest in the group practice), a *locum tenens* physician (as defined in this section), or an on-call physician while the physician is providing on-call services for members of the group practice. A physician is a member of the group during the time he or she furnishes “patient care services” to the group as defined in this section. An independent contractor or a leased employee is not a member of the group (unless the leased employee meets the definition of an “employee” under this section).

Outpatient hospital services means the therapeutic, diagnostic, and partial hospitalization services listed under sections 1861(s)(2)(B) and (s)(2)(C) of the Act; outpatient services furnished by a

psychiatric hospital, as defined in section 1861(f) of the Act; and outpatient critical access hospital services, as defined in section 1861(mm)(3) of the Act. “Outpatient hospital services” do not include emergency services furnished by nonparticipating hospitals and covered under the conditions described in section 1835(b) of the Act and subpart G of part 424 of this chapter. “Outpatient hospital services” include services that are furnished either by the hospital directly or under arrangements made by the hospital with others. “Outpatient hospital services” do not include professional services performed by physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, certified registered nurse anesthetists, and qualified psychologists if Medicare reimburses the services independently and not as part of the outpatient hospital service (even if they are billed by a hospital under an assignment or reassignment).

Outpatient prescription drugs means all drugs covered by Medicare Part B or D, except for those drugs that are “covered ancillary services,” as defined at §416.164(b) of this chapter, for which separate payment is made to an ambulatory surgical center.

Parenteral and enteral nutrients, equipment, and supplies means the following services (including all HCPCS level 2 codes for these services):

(1) *Parenteral nutrients, equipment, and supplies*, meaning those items and supplies needed to provide nutriment to a patient with permanent, severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients to maintain strength commensurate with the patient’s general condition, as described in Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Section 180.2, as amended or replaced from time to time; and

(2) *Enteral nutrients, equipment, and supplies*, meaning items and supplies needed to provide enteral nutrition to a patient with a functioning gastrointestinal tract who, due to pathology to or nonfunction of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate

with his or her general condition, as described in Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Section 180.2.

Patient care services means any task(s) performed by a physician in the group practice that address the medical needs of specific patients or patients in general, regardless of whether they involve direct patient encounters or generally benefit a particular practice. Patient care services can include, for example, the services of physicians who do not directly treat patients, such as time spent by a physician consulting with other physicians or reviewing laboratory tests, or time spent training staff members, arranging for equipment, or performing administrative or management tasks.

Physical therapy, occupational therapy, and outpatient speech-language pathology services means those particular services so identified on the List of CPT/HCPCS Codes. All services so identified on the List of CPT/HCPCS Codes are physical therapy, occupational therapy, and outpatient speech-language pathology services for purposes of this subpart. Any service not specifically identified as physical therapy, occupational therapy or outpatient speech-language pathology on the List of CPT/HCPCS Codes is not a physical therapy, occupational therapy, or outpatient speech-language pathology service for purposes of this subpart. The list of codes identifying physical therapy, occupational therapy, and outpatient speech-language pathology services for purposes of this regulation includes the following:

(1) *Physical therapy services*, meaning those outpatient physical therapy services described in section 1861(p) of the Act that are covered under Medicare Part A or Part B, regardless of who provides them, if the services include—

(i) Assessments, function tests, and measurements of strength, balance, endurance, range of motion, and activities of daily living;

(ii) Therapeutic exercises, massage, and use of physical medicine modalities, assistive devices, and adaptive equipment; or

(iii) Establishment of a maintenance therapy program for an individual whose restoration potential has been

reached; however, maintenance therapy itself is not covered as part of these services.

(2) *Occupational therapy services*, meaning those services described in section 1861(g) of the Act that are covered under Medicare Part A or Part B, regardless of who provides them, if the services include—

- (i) Teaching of compensatory techniques to permit an individual with a physical or cognitive impairment or limitation to engage in daily activities;
- (ii) Evaluation of an individual's level of independent functioning;
- (iii) Selection and teaching of task-oriented therapeutic activities to restore sensory-integrative function; or
- (iv) Assessment of an individual's vocational potential, except when the assessment is related solely to vocational rehabilitation.

(3) *Outpatient speech-language pathology services*, meaning those services as described in section 1861(ll)(2) of the Act that are for the diagnosis and treatment of speech, language, and cognitive disorders that include swallowing and other oral-motor dysfunctions.

Physician has the meaning set forth in section 1861(r) of the Act. A physician and the professional corporation of which he or she is a sole owner are the same for purposes of this subpart.

Physician in the group practice means a member of the group practice, as well as an independent contractor physician during the time the independent contractor is furnishing patient care services (as defined in this section) for the group practice under a contractual arrangement directly with the group practice to provide services to the group practice's patients in the group practice's facilities. The contract must contain the same restrictions on compensation that apply to members of the group practice under § 411.352(g) (or the contract must satisfy the requirements of the personal service arrangements exception in § 411.357(d)), and the independent contractor's arrangement with the group practice must comply with the reassignment rules in § 424.80(b)(2) of this chapter (see also Pub. L. 100–04, Medicare Claims Processing Manual, Chapter 1, Section 30.2.7, as amended or

replaced from time to time). Referrals from an independent contractor who is a physician in the group practice are subject to the prohibition on referrals in § 411.353(a), and the group practice is subject to the limitation on billing for those referrals in § 411.353(b).

Physician incentive plan means any compensation arrangement between an entity (or downstream contractor) and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services furnished with respect to individuals enrolled with the entity.

Physician organization means a physician, a physician practice, or a group practice that complies with the requirements of § 411.352.

Plan of care means the establishment by a physician of a course of diagnosis or treatment (or both) for a particular patient, including the ordering of services.

Professional courtesy means the provision of free or discounted health care items or services to a physician or his or her immediate family members or office staff.

Prosthetics, Orthotics, and Prosthetic Devices and Supplies means the following services (including all HCPCS level 2 codes for these items and services that are covered by Medicare):

(1) *Orthotics*, meaning leg, arm, back, and neck braces, as listed in section 1861(s)(9) of the Act.

(2) *Prosthetics*, meaning artificial legs, arms, and eyes, as described in section 1861(s)(9) of the Act.

(3) *Prosthetic devices*, meaning devices (other than a dental device) listed in section 1861(s)(8) of the Act that replace all or part of an internal body organ, including colostomy bags, and one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens.

(4) *Prosthetic supplies*, meaning supplies that are necessary for the effective use of a prosthetic device (including supplies directly related to colostomy care).

Radiation therapy services and supplies means those particular services and supplies, including (effective January 1, 2007) therapeutic nuclear medicine services and supplies, so identified on

the List of CPT/HCPCS Codes. All services and supplies so identified on the List of CPT/HCPCS Codes are radiation therapy services and supplies for purposes of this subpart. Any service or supply not specifically identified as radiation therapy services or supplies on the List of CPT/HCPCS Codes is not a radiation therapy service or supply for purposes of this subpart. The list of codes identifying radiation therapy services and supplies is based on section 1861(s)(4) of the Act and §410.35 of this chapter.

Radiology and certain other imaging services means those particular services so identified on the List of CPT/HCPCS Codes. All services identified on the List of CPT/HCPCS Codes are radiology and certain other imaging services for purposes of this subpart. Any service not specifically identified as radiology and certain other imaging services on the List of CPT/HCPCS Codes is not a radiology or certain other imaging service for purposes of this subpart. The list of codes identifying radiology and certain other imaging services includes the professional and technical components of any diagnostic test or procedure using x-rays, ultrasound, computerized axial tomography, magnetic resonance imaging, nuclear medicine (effective January 1, 2007), or other imaging services. All codes identified as radiology and certain other imaging services are covered under section 1861(s)(3) of the Act and §§410.32 and 410.34 of this chapter, but do not include—

(1) X-ray, fluoroscopy, or ultrasound procedures that require the insertion of a needle, catheter, tube, or probe through the skin or into a body orifice;

(2) Radiology or certain other imaging services that are integral to the performance of a medical procedure that is not identified on the list of CPT/HCPCS codes as a radiology or certain other imaging service and is performed—

(i) Immediately prior to or during the medical procedure; or

(ii) Immediately following the medical procedure when necessary to confirm placement of an item placed during the medical procedure.

(3) Radiology and certain other imaging services that are “covered ancillary

services,” as defined at §416.164(b), for which separate payment is made to an ASC.

Referral—

(1) Means either of the following:

(i) Except as provided in paragraph (2) of this definition, the request by a physician for, or ordering of, or the certifying or recertifying of the need for, any designated health service for which payment may be made under Medicare Part B, including a request for a consultation with another physician and any test or procedure ordered by or to be performed by (or under the supervision of) that other physician, but not including any designated health service personally performed or provided by the referring physician. A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person, including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

(ii) Except as provided in paragraph (2) of this definition, a request by a physician that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of a plan of care by a physician that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but not including any designated health service personally performed or provided by the referring physician. A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

(2) Does not include a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, by a radiologist for diagnostic radiology services, and by a radiation oncologist for radiation therapy or ancillary services necessary for, and integral to, the provision of radiation therapy, if—

(i) The request results from a consultation initiated by another physician (whether the request for a consultation was made to a particular physician or to an entity with which the physician is affiliated); and

(ii) The tests or services are furnished by or under the supervision of the pathologist, radiologist, or radiation oncologist, or under the supervision of a pathologist, radiologist, or radiation oncologist, respectively, in the same group practice as the pathologist, radiologist, or radiation oncologist.

(3) Can be in any form, including, but not limited to, written, oral, or electronic.

(4) A referral is not an item or service for purposes of section 1877 of the Act and this subpart.

Referring physician means a physician who makes a referral as defined in this section or who directs another person or entity to make a referral or who controls referrals made by another person or entity. A referring physician and the professional corporation of which he or she is a sole owner are the same for purposes of this subpart.

Remuneration means any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind, except that the following are not considered remuneration for purposes of this section:

(1) The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors.

(2) The furnishing of items, devices, or supplies that are, in fact, used solely for one or more of the following purposes:

(i) Collecting specimens for the entity furnishing the items, devices or supplies;

(ii) Transporting specimens for the entity furnishing the items, devices or supplies;

(iii) Processing specimens for the entity furnishing the items, devices or supplies;

(iv) Storing specimens for the entity furnishing the items, devices or supplies;

(v) Ordering tests or procedures for the entity furnishing the items, devices or supplies; or

(vi) Communicating the results of tests or procedures for the entity furnishing the items, devices or supplies.

(3) A payment made by an insurer or a self-insured plan (or a subcontractor of the insurer or self-insured plan) to a physician to satisfy a claim, submitted on a fee-for-service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if—

(i) The health services are not furnished, and the payment is not made, under a contract or other arrangement between the insurer or the self-insured plan (or a subcontractor of the insurer or self-insured plan) and the physician;

(ii) The payment is made to the physician on behalf of the covered individual and would otherwise be made directly to the individual; and

(iii) The amount of the payment is set in advance, does not exceed fair market value, and is not determined in any manner that takes into account the volume or value of referrals.

Rural area means an area that is not an urban area as defined at § 412.64(b) of this chapter.

Rural emergency hospital has the meaning set forth in section 1861(kkk)(2) of the Act and § 419.91 of this chapter.

Same building means a structure with, or combination of structures that share, a single street address as assigned by the U.S. Postal Service, excluding all exterior spaces (for example, lawns, courtyards, driveways, parking lots) and interior loading docks or parking garages. For purposes of this section, the “same building” does not include a mobile vehicle, van, or trailer.

Specialty hospital means:

(1) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Act) that is primarily or exclusively engaged in the care and treatment of one of the following:

(i) Patients with a cardiac condition;

(ii) Patients with an orthopedic condition;

(iii) Patients receiving a surgical procedure; or

(iv) Any other specialized category of services that the Secretary designates as inconsistent with the purpose of permitting physician ownership and investment interests in a hospital.

(2) A “specialty hospital” does not include any hospital—

(i) Determined by the Secretary to be in operation before or under development as of November 18, 2003;

(ii) For which the number of physician investors at any time on or after such date is no greater than the number of such investors as of such date;

(iii) For which the type of categories described above is no different at any time on or after such date than the type of such categories as of such date;

(iv) For which any increase in the number of beds occurs only in the facilities on the main campus of the hospital and does not exceed 50 percent of the number of beds in the hospital as of November 18, 2003, or 5 beds, whichever is greater; and

(v) That meets such other requirements as the Secretary may specify.

Target patient population means an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that—

(1) Are set out in writing in advance of the commencement of the value-based arrangement; and

(2) Further the value-based enterprise’s value-based purpose(s).

Transaction means an instance of two or more persons or entities doing business.

Value-based activity means any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise:

(1) The provision of an item or service;

(2) The taking of an action; or

(3) The refraining from taking an action.

Value-based arrangement means an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are—

(1) The value-based enterprise and one or more of its VBE participants; or

(2) VBE participants in the same value-based enterprise.

Value-based enterprise (VBE) means two or more VBE participants—

(1) Collaborating to achieve at least one value-based purpose;

(2) Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise;

(3) That have an accountable body or person responsible for the financial and operational oversight of the value-based enterprise; and

(4) That have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).

Value-based purpose means any of the following:

(1) Coordinating and managing the care of a target patient population;

(2) Improving the quality of care for a target patient population;

(3) Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or

(4) Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

VBE participant means a person or entity that engages in at least one value-based activity as part of a value-based enterprise.

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§411.352 Group practice.

For purposes of this subpart, a group practice is a physician practice that meets the following conditions:

(a) *Single legal entity.* The group practice must consist of a single legal entity operating primarily for the purpose of being a physician group practice in any organizational form recognized by the State in which the group practice achieves its legal status, including, but not limited to, a partnership, professional corporation, limited liability company, foundation, nonprofit corporation, faculty practice plan, or similar association. The single legal entity may be organized by any party or parties, including, but not limited

to, physicians, health care facilities, or other persons or entities (including, but not limited to, physicians individually incorporated as professional corporations). The single legal entity may be organized or owned (in whole or in part) by another medical practice, provided that the other medical practice is not an operating physician practice (and regardless of whether the medical practice meets the conditions for a group practice under this section). For purposes of this subpart, a single legal entity does not include informal affiliations of physicians formed substantially to share profits from referrals, or separate group practices under common ownership or control through a physician practice management company, hospital, health system, or other entity or organization. A group practice that is otherwise a single legal entity may itself own subsidiary entities. A group practice operating in more than one State will be considered to be a single legal entity notwithstanding that it is composed of multiple legal entities, provided that—

(1) The States in which the group practice is operating are contiguous (although each State need not be contiguous to every other State);

(2) The legal entities are absolutely identical as to ownership, governance, and operation; and

(3) Organization of the group practice into multiple entities is necessary to comply with jurisdictional licensing laws of the States in which the group practice operates.

(b) *Physicians.* The group practice must have at least two physicians who are members of the group (whether employees or direct or indirect owners), as defined at § 411.351.

(c) *Range of care.* Each physician who is a member of the group, as defined at § 411.351, must furnish substantially the full range of patient care services that the physician routinely furnishes, including medical care, consultation, diagnosis, and treatment, through the joint use of shared office space, facilities, equipment, and personnel.

(d) *Services furnished by group practice members.* (1) Except as otherwise provided in paragraphs (d)(3) through (6) of this section, substantially all of the patient care services of the physicians

who are members of the group (that is, at least 75 percent of the total patient care services of the group practice members) must be furnished through the group and billed under a billing number assigned to the group, and the amounts received must be treated as receipts of the group. *Patient care services* must be measured by one of the following:

(i) The total time each member spends on patient care services documented by any reasonable means (including, but not limited to, time cards, appointment schedules, or personal diaries). (For example, if a physician practices 40 hours a week and spends 30 hours a week on patient care services for a group practice, the physician has spent 75 percent of his or her time providing patient care services for the group.)

(ii) Any alternative measure that is reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, verifiable, and documented.

(2) The data used to calculate compliance with this *substantially all* test and related supportive documentation must be made available to the Secretary upon request.

(3) The *substantially all* test set forth in paragraph (d)(1) of this section does not apply to any group practice that is located solely in a HPSA, as defined at § 411.351.

(4) For a group practice located outside of a HPSA (as defined at § 411.351), any time spent by a group practice member providing services in a HPSA should not be used to calculate whether the group practice has met the *substantially all* test, regardless of whether the member's time in the HPSA is spent in a group practice, clinic, or office setting.

(5) During the *start up* period (not to exceed 12 months) that begins on the date of the initial formation of a new group practice, a group practice must make a reasonable, good faith effort to ensure that the group practice complies with the *substantially all* test requirement set forth in paragraph (d)(1) of this section as soon as practicable, but no later than 12 months from the date of the initial formation of the group practice. This paragraph (d)(5)

does not apply when an existing group practice admits a new member or reorganizes.

(6)(i) If the addition to an existing group practice of a new member who would be considered to have relocated his or her medical practice under §411.357(e)(2) would result in the existing group practice not meeting the *substantially all* test set forth in paragraph (d)(1) of this section, the group practice will have 12 months following the addition of the new member to come back into full compliance, provided that—

(A) For the 12-month period the group practice is fully compliant with the *substantially all* test if the new member is not counted as a member of the group for purposes of §411.352; and

(B) The new member's employment with, or ownership interest in, the group practice is documented in writing no later than the beginning of his or her new employment, ownership, or investment.

(ii) This paragraph (d)(6) does not apply when an existing group practice reorganizes or admits a new member who is not relocating his or her medical practice.

(e) *Distribution of expenses and income.* The overhead expenses of, and income from, the practice must be distributed according to methods that are determined before the receipt of payment for the services giving rise to the overhead expense or producing the income. Nothing in this section prevents a group practice from adjusting its compensation methodology prospectively, subject to restrictions on the distribution of revenue from DHS under paragraph (i) of this section.

(f) *Unified business.* (1) The group practice must be a unified business having at least the following features:

(i) Centralized decision-making by a body representative of the group practice that maintains effective control over the group's assets and liabilities (including, but not limited to, budgets, compensation, and salaries); and

(ii) Consolidated billing, accounting, and financial reporting.

(2) Location and specialty-based compensation practices are permitted with respect to revenues derived from services that are not DHS and may be permitted with respect to revenues de-

rived from DHS under paragraph (i) of this section.

(g) *Volume or value of referrals.* No physician who is a member of the group practice directly or indirectly receives compensation based on the volume or value of his or her referrals, except as provided in paragraph (i) of this section.

(h) *Physician-patient encounters.* Members of the group must personally conduct no less than 75 percent of the physician-patient encounters of the group practice.

(i) *Special rules for profit shares and productivity bonuses—*(1) *Overall profits.*

(i) Notwithstanding paragraph (g) of this section, a physician in the group may be paid a share of overall profits that is not directly related to the volume or value of the physician's referrals.

(ii) Overall profits means the profits derived from all the designated health services of any component of the group that consists of at least five physicians, which may include all physicians in the group. If there are fewer than five physicians in the group, overall profits means the profits derived from all the designated health services of the group.

(iii) Overall profits must be divided in a reasonable and verifiable manner. The share of overall profits will be deemed not to directly relate to the volume or value of referrals if one of the following conditions is met:

(A) Overall profits are divided per capita (for example, per member of the group or per physician in the group).

(B) Overall profits are distributed based on the distribution of the group's revenues attributed to services that are not designated health services and would not be considered designated health services if they were payable by Medicare.

(C) Revenues derived from designated health services constitute less than 5 percent of the group's total revenues, and the portion of those revenues distributed to each physician in the group constitutes 5 percent or less of his or her total compensation from the group.

(2) *Productivity bonuses.* (i) Notwithstanding paragraph (g) of this section, a physician in the group may be paid a productivity bonus based on services

that he or she has personally performed, or services “incident to” such personally performed services, that is not directly related to the volume or value of the physician’s referrals (except that the bonus may directly relate to the volume or value of the physician’s referrals if the referrals are for services “incident to” the physician’s personally performed services).

(ii) A productivity bonus must be calculated in a reasonable and verifiable manner. A productivity bonus will be deemed not to relate directly to the volume or value of referrals if one of the following conditions is met:

(A) The productivity bonus is based on the physician’s total patient encounters or the relative value units (RVUs) personally performed by the physician.

(B) The services on which the productivity bonus is based are not designated health services and would not be considered designated health services if they were payable by Medicare.

(C) Revenues derived from designated health services constitute less than 5 percent of the group’s total revenues, and the portion of those revenues distributed to each physician in the group constitutes 5 percent or less of his or her total compensation from the group.

(3) *Value-based enterprise participation.* Notwithstanding paragraph (g) of this section, profits from designated health services that are directly attributable to a physician’s participation in a value-based enterprise, as defined at § 411.351, may be distributed to the participating physician.

(4) *Supporting documentation.* Supporting documentation verifying the method used to calculate the profit share or productivity bonus under paragraphs (i)(1), (2), and (3) of this section, and the resulting amount of compensation, must be made available to the Secretary upon request.

[85 FR 77656, 76682, Dec. 2, 2020]

§ 411.353 Prohibition on certain referrals by physicians and limitations on billing.

(a) *Prohibition on referrals.* Except as provided in this subpart, a physician who has a direct or indirect financial relationship with an entity, or who has an immediate family member who has

a direct or indirect financial relationship with the entity, may not make a referral to that entity for the furnishing of DHS for which payment otherwise may be made under Medicare. A physician’s prohibited financial relationship with an entity that furnishes DHS is not imputed to his or her group practice or its members or its staff. However, a referral made by a physician’s group practice, its members, or its staff may be imputed to the physician if the physician directs the group practice, its members, or its staff to make the referral or if the physician controls referrals made by his or her group practice, its members, or its staff.

(b) *Limitations on billing.* An entity that furnishes DHS pursuant to a referral that is prohibited by paragraph (a) of this section may not present or cause to be presented a claim or bill to the Medicare program or to any individual, third party payer, or other entity for the DHS performed pursuant to the prohibited referral.

(c) *Denial of payment for services furnished under a prohibited referral.* (1) Except as provided in paragraph (e) of this section, no Medicare payment may be made for a designated health service that is furnished pursuant to a prohibited referral.

(2) When payment for a designated health service is denied on the basis that the service was furnished pursuant to a prohibited referral, and such payment denial is appealed—

(i) The ultimate burden of proof (burden of persuasion) at each level of appeal is on the entity submitting the claim for payment to establish that the service was not furnished pursuant to a prohibited referral (and not on CMS or its contractors to establish that the service was furnished pursuant to a prohibited referral); and

(ii) The burden of production on each issue at each level of appeal is initially on the claimant, but may shift to CMS or its contractors during the course of the appellate proceeding, depending on the evidence presented by the claimant.

(d) *Refunds.* An entity that collects payment for a designated health service that was performed pursuant to a

prohibited referral must refund all collected amounts on a timely basis, as defined at §1003.110 of this title.

(e) *Exception for certain entities.* Payment may be made to an entity that submits a claim for a designated health service if—

(1) The entity did not have actual knowledge of, and did not act in reckless disregard or deliberate ignorance of, the identity of the physician who made the referral of the designated health service to the entity; and

(2) The claim otherwise complies with all applicable Federal and State laws, rules, and regulations.

(f) *Exception for certain arrangements involving temporary noncompliance.* (1) Except as provided in paragraphs (f)(2) through (4) of this section, an entity may submit a claim or bill and payment may be made to an entity that submits a claim or bill for a designated health service if—

(i) The financial relationship between the entity and the referring physician fully complied with an applicable exception under §411.355, 411.356, or 411.357 for at least 180 consecutive calendar days immediately preceding the date on which the financial relationship became noncompliant with the exception; and

(ii) The financial relationship has fallen out of compliance with the exception for reasons beyond the control of the entity, and the entity promptly takes steps to rectify the noncompliance.

(2) Paragraph (f)(1) of this section applies only to DHS furnished during the period of time it takes the entity to rectify the noncompliance, which must not exceed 90 consecutive calendar days following the date on which the financial relationship became noncompliant with an exception.

(3) Paragraph (f)(1) may be used by an entity only once every 3 years with respect to the same referring physician.

(4) Paragraph (f)(1) does not apply if the exception with which the financial relationship previously complied was §411.357(k) or (m).

(g) [Reserved]

(h) *Special rule for reconciling compensation.* An entity may submit a claim or bill and payment may be made to an entity that submits a claim

or bill for a designated health service if—

(1) No later than 90 consecutive calendar days following the expiration or termination of a compensation arrangement, the entity and the physician (or immediate family member of a physician) that are parties to the compensation arrangement reconcile all discrepancies in payments under the arrangement such that, following the reconciliation, the entire amount of remuneration for items or services has been paid as required under the terms and conditions of the arrangement; and

(2) Except for the discrepancies in payments described in paragraph (h)(1) of this section, the compensation arrangement fully complies with an applicable exception in this subpart.

[85 FR 77656, Dec. 2, 2020, as amended at 88 FR 59328, Aug. 28, 2023]

§411.354 Financial relationship, compensation, and ownership or investment interest.

(a) *Financial relationships*—(1) *Financial relationship* means—

(i) A direct or indirect ownership or investment interest (as defined in paragraph (b) of this section) in any entity that furnishes DHS; or

(ii) A direct or indirect compensation arrangement (as defined in paragraph (c) of this section) with an entity that furnishes DHS.

(2) *Types of financial relationships.* (i) A *direct* financial relationship exists if remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities between the entity furnishing DHS and the referring physician (or a member of his or her immediate family).

(ii) An *indirect* financial relationship exists under the conditions described in paragraphs (b)(5) and (c)(2) of this section.

(b) *Ownership or investment interest.* An ownership or investment interest in the entity may be through equity, debt, or other means, and includes an interest in an entity that holds an ownership or investment interest in any entity that furnishes DHS.

(1) An ownership or investment interest includes, but is not limited to,

stock, stock options other than those described in paragraph (b)(3)(ii) of this section, partnership shares, limited liability company memberships, as well as loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue.

(2) An ownership or investment interest in a subsidiary company is neither an ownership or investment interest in the parent company, nor in any other subsidiary of the parent, unless the subsidiary company itself has an ownership or investment interest in the parent or such other subsidiaries. It may, however, be part of an indirect financial relationship.

(3) Ownership and investment interests do not include, among other things—

(i) An interest in an entity that arises from a retirement plan offered by that entity to the physician (or a member of his or her immediate family) through the physician's (or immediate family member's) employment with that entity;

(ii) Stock options and convertible securities received as compensation until the stock options are exercised or the convertible securities are converted to equity (before this time the stock options or convertible securities are compensation arrangements as defined in paragraph (c) of this section);

(iii) An unsecured loan subordinated to a credit facility (which is a compensation arrangement as defined in paragraph (c) of this section);

(iv) An “under arrangements” contract between a hospital and an entity owned by one or more physicians (or a group of physicians) providing DHS “under arrangements” with the hospital (such a contract is a compensation arrangement as defined in paragraph (c) of this section);

(v) A security interest held by a physician in equipment sold by the physician to a hospital and financed through a loan from the physician to the hospital (such an interest is a compensation arrangement as defined in paragraph (c) of this section);

(vi) A titular ownership or investment interest that excludes the ability or right to receive the financial benefits of ownership or investment, includ-

ing, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment; or

(vii) An interest in an entity that arises from an employee stock ownership plan (ESOP) that is qualified under Internal Revenue Code section 401(a).

(4) An ownership or investment interest that meets an exception set forth in § 411.355 or § 411.356 need not also meet an exception for compensation arrangements set forth in § 411.357 with respect to profit distributions, dividends, or interest payments on secured obligations.

(5)(i) An *indirect ownership or investment interest* exists if—

(A) Between the referring physician (or immediate family member) and the entity furnishing DHS there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests; and

(B) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the entity furnishing the DHS.

(ii) An indirect ownership or investment interest exists even though the entity furnishing DHS does not know, or acts in reckless disregard or deliberate ignorance of, the precise composition of the unbroken chain or the specific terms of the ownership or investment interests that form the links in the chain.

(iii) Notwithstanding anything in this paragraph (b)(5), common ownership or investment in an entity does not, in and of itself, establish an indirect ownership or investment interest by one common owner or investor in another common owner or investor.

(iv) An indirect ownership or investment interest requires an unbroken chain of ownership interests between the referring physician and the entity furnishing DHS such that the referring physician has an indirect ownership or investment interest *in* the entity furnishing DHS.

(c) *Compensation arrangement.* A compensation arrangement is any arrangement involving remuneration, direct or indirect, between a physician (or a member of a physician's immediate family) and an entity. An "under arrangements" contract between a hospital and an entity providing DHS "under arrangements" to the hospital creates a compensation arrangement for purposes of these regulations. A compensation arrangement does not include the portion of any business arrangement that consists solely of the remuneration described in section 1877(h)(1)(C) of the Act and in paragraphs (1) through (3) of the definition of the term "remuneration" at §411.351. (However, any other portion of the arrangement may still constitute a compensation arrangement.)

(1)(i) A direct compensation arrangement exists if remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities.

(ii) Except as provided in paragraph (c)(3)(ii)(C) of this section, a physician is deemed to "stand in the shoes" of his or her physician organization and have a direct compensation arrangement with an entity furnishing DHS if—

(A) The only intervening entity between the physician and the entity furnishing DHS is his or her physician organization; and

(B) The physician has an ownership or investment interest in the physician organization.

(iii) A physician (other than a physician described in paragraph (c)(1)(ii)(B) of this section) is permitted to "stand in the shoes" of his or her physician organization and have a direct compensation arrangement with an entity furnishing DHS if the only intervening entity between the physician and the entity furnishing DHS is his or her physician organization.

(2) An *indirect compensation arrangement* exists if all of the conditions of paragraphs (c)(2)(i) through (iii) of this section exist:

(i) Between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS

there exists an unbroken chain of any number (but not fewer than one) of persons or entities that have financial relationships (as defined in paragraph (a) of this section) between them (that is, each link in the chain has either an ownership or investment interest or a compensation arrangement with the preceding link).

(ii)(A)(1) The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS; and

(2) The amount of compensation that the physician (or immediate family member) receives per individual unit—

(i) Is not fair market value for items or services actually provided;

(ii) Could increase as the number or value of the physician's referrals to the entity furnishing DHS increases, or could decrease as the number or value of the physician's referrals to the entity decreases;

(iii) Could increase as the amount or value of the other business generated by the physician for the entity furnishing DHS increases, or could decrease as the amount or value of the other business generated by the physician for the entity furnishing DHS decreases; or

(iv) Is payment for the lease of office space or equipment or for the use of premises or equipment.

(B) For purposes of applying paragraph (c)(2)(ii)(A)(2) of this section, the individual unit is:

(1) Item, if the physician (or immediately family member) is compensated solely per item provided.

(2) Service, if the physician (or immediate family member) is compensated solely per service provided, which includes arrangements where the "service" provided includes both items and services.

(3) Time, if the conditions of paragraph (c)(2)(ii)(B)(1) or (2) of this section are not met.

(C) If the financial relationship between the physician (or immediate

family member) and the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest, the nonownership or non-investment interest closest to the referring physician (or immediate family member) is used to determine whether the aggregate compensation varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS and whether the amount of compensation that the physician (or immediate family member) receives per individual unit meets the conditions in paragraph (c)(2)(ii)(A)(2) of this section. (For example, if a referring physician has an ownership interest in company A, which owns company B, which has a compensation arrangement with company C, which has a compensation arrangement with entity D that furnishes DHS, we would look to the aggregate compensation between company B and company C for purposes of this paragraph (c)(2)(ii).

(iii) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.

(iv)(A) For purposes of paragraph (c)(2)(i) of this section, except as provided in paragraph (c)(3)(ii)(C) of this section, a physician is deemed to “stand in the shoes” of his or her physician organization if the physician has an ownership or investment interest in the physician organization.

(B) For purposes of paragraph (c)(2)(i) of this section, a physician (other than a physician described in paragraph (c)(2)(iv)(A) of this section) is permitted to “stand in the shoes” of his or her physician organization.

(3)(i) For purposes of paragraphs (c)(1)(ii) and (c)(2)(iv) of this section, a physician who “stands in the shoes” of his or her physician organization is deemed to have the same compensation arrangements (with the same parties and on the same terms) as the physi-

cian organization. When applying the exceptions in §§ 411.355 and 411.357 to arrangements in which a physician stands in the shoes of his or her physician organization, the “parties to the arrangements” are considered to be—

(A) With respect to a signature requirement, the physician organization and any physician who “stands in the shoes” of the physician organization as required under paragraph (c)(1)(ii) or (c)(2)(iv)(A) of this section; and

(B) With respect to all other requirements of the exception, including the relevant referrals and other business generated between the parties, the entity furnishing DHS and the physician organization (including all members, employees, and independent contractor physicians).

(ii) The provisions of paragraphs (c)(1)(ii) and (c)(2)(iv)(A) of this section—

(A) Need not apply during the original term or current renewal term of an arrangement that satisfied the requirements of § 411.357(p) as of September 5, 2007 (see 42 CFR parts 400–413, revised as of October 1, 2007);

(B) Do not apply to an arrangement that satisfies the requirements of § 411.355(e); and

(C) Do not apply to a physician whose ownership or investment interest is titular only. A titular ownership or investment interest is an ownership or investment interest that excludes the ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment.

(iii) An arrangement structured to comply with an exception in § 411.357 (other than § 411.357(p)), but which would otherwise qualify as an indirect compensation arrangement under this paragraph as of August 19, 2008, need not be restructured to satisfy the requirements of § 411.357(p) until the expiration of the original term or current renewal term of the arrangement.

(4)(i) *Exceptions applicable to indirect compensation arrangements—General.* Except as provided in this paragraph

(c)(4) of this section, only the exceptions at §§411.355 and 411.357(p) are applicable to indirect compensation arrangements.

(ii) *Special rule for indirect compensation arrangements involving a MCO or IPA and a referring physician.* Only the exceptions at §§411.355, 411.357(n), and 411.357(p) are applicable in the case of an indirect compensation arrangement in which the entity furnishing DHS described in paragraph (c)(2)(i) of this section is a MCO or IPA.

(iii) *Special rule for indirect compensation arrangements involving value-based arrangements.* When an unbroken chain described in paragraph (c)(2)(i) of this section includes a value-based arrangement (as defined at §411.351) to which the physician (or the physician organization in whose shoes the physician stands under this paragraph) is a direct party—

(A) Only the exceptions at §§411.355, 411.357(p), and 411.357(aa) are applicable to the indirect compensation arrangement if the entity furnishing DHS is not a MCO or IPA; and

(B) Only the exceptions at §§411.355, 411.357(n), 411.357(p), and 411.357(aa) are applicable to the indirect compensation arrangement if the entity furnishing DHS is a MCO or IPA.

(d) *Special rules on compensation.* The following special rules apply only to compensation under section 1877 of the Act and subpart J of this part:

(1) *Set in advance.* (i) Compensation is deemed to be “set in advance” if the aggregate compensation, a time-based or per-unit of service-based (whether per-use or per-service) amount, or a specific formula for calculating the compensation is set out in writing before the furnishing of the items, services, office space, or equipment for which the compensation is to be paid. The formula for determining the compensation must be set forth in sufficient detail so that it can be objectively verified.

(ii) Notwithstanding paragraph (d)(1)(i) of this section, compensation (or a formula for determining the compensation) may be modified at any time during the course of a compensation arrangement and satisfy the requirement that it is “set in advance” if all of the following conditions are met:

(A) All requirements of an applicable exception in §§411.355 through 411.357 are met on the effective date of the modified compensation (or the formula for determining the modified compensation).

(B) The modified compensation (or the formula for determining the modified compensation) is determined before the furnishing of the items, services, office space, or equipment for which the modified compensation is to be paid.

(C) Before the furnishing of the items, services, office space, or equipment for which the modified compensation is to be paid, the formula for the modified compensation is set forth in writing in sufficient detail so that it can be objectively verified. Paragraph (e)(4) of this section does not apply for purposes of this paragraph (d)(1)(ii)(C).

(2) *Unit-based compensation and the volume or value standard.* Unit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account the volume or value of referrals if the compensation is fair market value for items or services actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals of designated health services. This paragraph (d)(2) does not apply for purposes of paragraphs (d)(5)(i) and (6)(i) of this section.

(3) *Unit-based compensation and the other business generated standard.* Unit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account other business generated between the parties or other business generated by the referring physician if the compensation is fair market value for items and services actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals or other business generated by the referring physician, including private pay health care business (except for services personally performed by the referring physician, which are not considered “other business generated” by the referring physician). This paragraph (d)(3) does not

apply for purposes of paragraphs (d)(5)(ii) and (d)(6)(ii) of this section.

(4) *Directed referral requirement.* If a physician's compensation under a *bona fide* employment relationship, personal service arrangement, or managed care contract is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, all of the following conditions must be met.

(i) The compensation, or a formula for determining the compensation, is set in advance for the duration of the arrangement. Any changes to the compensation (or the formula for determining the compensation) must be made prospectively.

(ii) The compensation is consistent with the fair market value of the physician's services.

(iii) The compensation arrangement otherwise satisfies the requirements of an applicable exception at § 411.355 or § 411.357.

(iv) The compensation arrangement complies with both of the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

(v) The required referrals relate solely to the physician's services covered by the scope of the employment, personal service arrangement, or managed care contract, and the referral requirement is reasonably necessary to effectuate the legitimate business purposes of the compensation arrangement. In no event may the physician be required to make referrals that relate to services that are not provided by the physician under the scope of his or her employment, personal service arrangement, or managed care contract.

(vi) Regardless of whether the physician's compensation takes into account the volume or value of referrals by the physician as set forth at paragraph

(d)(5)(i) of this section, neither the existence of the compensation arrangement nor the amount of the compensation is contingent on the number or value of the physician's referrals to the particular provider, practitioner, or supplier. The requirement to make referrals to a particular provider, practitioner, or supplier may require that the physician refer an established percentage or ratio of the physician's referrals to a particular provider, practitioner, or supplier.

(5) *Compensation to a physician.* (i) Compensation from an entity furnishing designated health services to a physician (or immediate family member of the physician) takes into account the volume or value of referrals only if the formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals to the entity.

(ii) Compensation from an entity furnishing designated health services to a physician (or immediate family member of the physician) takes into account the volume or value of other business generated only if the formula used to calculate the physician's (or immediate family member's) compensation includes other business generated by the physician for the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the physician's generation of other business for the entity.

(iii) For purposes of applying this paragraph (d)(5), a positive correlation between two variables exists when one variable decreases as the other variable decreases, or one variable increases as the other variable increases.

(iv) This paragraph (d)(5) does not apply for purposes of applying the special rules in paragraphs (d)(2) and (3) of this section or the exceptions at § 411.357(m), (s), (u), (v), (w), and (bb).

(6) *Compensation from a physician.* (i) Compensation from a physician (or immediate family member of the physician) to an entity furnishing designated health services takes into account the volume or value of referrals only if the formula used to calculate the entity's compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the entity's compensation that negatively correlates with the number or value of the physician's referrals to the entity.

(ii) Compensation from a physician (or immediate family member of the physician) to an entity furnishing designated health services takes into account the volume or value of other business generated only if the formula used to calculate the entity's compensation includes other business generated by the physician for the entity as a variable, resulting in an increase or decrease in the entity's compensation that negatively correlates with the physician's generation of other business for the entity.

(iii) For purposes of applying this paragraph (d)(6), a negative correlation between two variables exists when one variable increases as the other variable decreases, or when one variable decreases as the other variable increases.

(iv) This paragraph (d)(6) does not apply for purposes of applying the special rules in paragraphs (d)(2) and (3) of this section or the exceptions at §411.357(m), (s), (u), (v), (w), and (bb).

(e) *Special rule on compensation arrangements—(1) Application.* This paragraph (e) applies only to compensation arrangements as defined in section 1877 of the Act and this subpart.

(2) *Writing requirement.* In the case of any requirement in this subpart for a compensation arrangement to be in writing, such requirement may be satisfied by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties.

(3) *Signature requirement.* In the case of any signature requirement in this subpart, such requirement may be satisfied by an electronic or other signature that is valid under applicable Federal or State law.

(4) *Special rule on writing and signature requirements.* In the case of any requirement in this subpart for a compensation arrangement to be in writing and signed by the parties, the writing requirement or the signature requirement is satisfied if—

(i) The compensation arrangement between the entity and the physician fully complies with an applicable exception in this subpart except with respect to the writing or signature requirement of the exception; and

(ii) The parties obtain the required writing(s) or signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became non-compliant with the requirements of the applicable exception (that is, the date on which the writing(s) or signature(s) were required under the applicable exception but the parties had not yet obtained them).

[85 FR 77656, Dec. 2, 2020, as amended at 86 FR 65667, Nov. 19, 2021]

§411.355 General exceptions to the referral prohibition related to both ownership/investment and compensation.

The prohibition on referrals set forth in §411.353 does not apply to the following types of services:

(a) *Physician services.* (1) Physician services as defined at §410.20(a) of this chapter that are furnished—

(i) Personally by another physician who is a member of the referring physician's group practice or is a physician in the same group practice (as defined at §411.351) as the referring physician; or

(ii) Under the supervision of another physician who is a member of the referring physician's group practice or is a physician in the same group practice (as defined at §411.351) as the referring physician, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the physician services.

(2) For purposes of this paragraph (a), "physician services" include only those "incident to" services (as defined at §411.351) that are physician services under §410.20(a) of this chapter.

(b) *In-office ancillary services.* Services (including certain items of durable

medical equipment (DME), as defined in paragraph (b)(4) of this section, and infusion pumps that are DME (including external ambulatory infusion pumps), but excluding all other DME and parenteral and enteral nutrients, equipment, and supplies (such as infusion pumps used for PEN)), that meet the following conditions:

(1) *Individual who furnishes the service.* They are furnished personally by one of the following individuals:

- (i) The referring physician.
- (ii) A physician who is a member of the same group practice as the referring physician.
- (iii) An individual who is supervised by the referring physician or, if the referring physician is in a group practice, by another physician in the group practice, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the services.

(2) *Location where service is furnished.* They are furnished in one of the following locations:

- (i) The same building (as defined at § 411.351), but not necessarily in the same space or part of the building, in which all of the conditions of paragraph (b)(2)(i)(A), (b)(2)(i)(B), or (b)(2)(i)(C) of this section are satisfied:

(A)(1) The referring physician or his or her group practice (if any) has an office that is normally open to the physician's or group's patients for medical services at least 35 hours per week; and

(2) The referring physician or one or more members of the referring physician's group practice regularly practices medicine and furnishes physician services to patients at least 30 hours per week. The 30 hours must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS; or

(B)(1) The patient receiving the DHS usually receives physician services from the referring physician or members of the referring physician's group practice (if any);

(2) The referring physician or the referring physician's group practice owns or rents an office that is normally open to the physician's or group's patients

for medical services at least 8 hours per week; and

(3) The referring physician regularly practices medicine and furnishes physician services to patients at least 6 hours per week. The 6 hours must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS; or

(C)(1) The referring physician is present and orders the DHS during a patient visit on the premises as set forth in paragraph (b)(2)(i)(C)(2) of this section or the referring physician or a member of the referring physician's group practice (if any) is present while the DHS is furnished during occupancy of the premises as set forth in paragraph (b)(2)(i)(C)(2) of this section;

(2) The referring physician or the referring physician's group practice owns or rents an office that is normally open to the physician's or group's patients for medical services at least 8 hours per week; and

(3) The referring physician or one or more members of the referring physician's group practice regularly practices medicine and furnishes physician services to patients at least 6 hours per week. The 6 hours must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS.

(ii) A centralized building (as defined at § 411.351) that is used by the group practice for the provision of some or all of the group practice's clinical laboratory services.

(iii) A centralized building (as defined at § 411.351) that is used by the group practice for the provision of some or all of the group practice's DHS (other than clinical laboratory services).

(3) *Billing of the service.* They are billed by one of the following:

(i) The physician performing or supervising the service.

(ii) The group practice of which the performing or supervising physician is a member under a billing number assigned to the group practice.

(iii) The group practice if the supervising physician is a “physician in the group practice” (as defined at §411.351) under a billing number assigned to the group practice.

(iv) An entity that is wholly owned by the performing or supervising physician or by that physician’s group practice under the entity’s own billing number or under a billing number assigned to the physician or group practice.

(v) An independent third party billing company acting as an agent of the physician, group practice, or entity specified in paragraphs (b)(3)(i) through (iv) of this section under a billing number assigned to the physician, group practice, or entity, provided that the billing arrangement meets the requirements of §424.80(b)(5) of this chapter. For purposes of this paragraph (b)(3), a group practice may have, and bill under, more than one Medicare billing number, subject to any applicable Medicare program restrictions.

(4) *Durable Medical Equipment.* For purposes of this paragraph (b), DME covered by the in-office ancillary services exception means canes, crutches, walkers and folding manual wheelchairs, and blood glucose monitors, that meet the following conditions:

(i) The item is one that a patient requires for the purpose of ambulating, a patient uses in order to depart from the physician’s office, or is a blood glucose monitor (including one starter set of test strips and lancets, consisting of no more than 100 of each). A blood glucose monitor may be furnished only by a physician or employee of a physician or group practice that also furnishes outpatient diabetes self-management training to the patient.

(ii) The item is furnished in a building that meets the “same building” requirements in the in-office ancillary services exception as part of the treatment for the specific condition for which the patient-physician encounter occurred.

(iii) The item is furnished personally by the physician who ordered the DME, by another physician in the group practice, or by an employee of the physician or the group practice.

(iv) A physician or group practice that furnishes the DME meets all DME

supplier standards set forth in §424.57(c) of this chapter.

(v) [Reserved]

(vi) All other requirements of the in-office ancillary services exception in this paragraph (b) are met.

(5) *Furnishing a service.* A designated health service is “furnished” for purposes of this paragraph (b) in the location where the service is actually performed upon a patient or where an item is dispensed to a patient in a manner that is sufficient to meet the applicable Medicare payment and coverage rules.

(6) *Special rule for home care physicians.* In the case of a referring physician whose principal medical practice consists of treating patients in their private homes, the “same building” requirements of paragraph (b)(2)(i) of this section are met if the referring physician (or a qualified person accompanying the physician, such as a nurse or technician) provides the DHS contemporaneously with a physician service that is not a designated health service provided by the referring physician to the patient in the patient’s private home. For purposes of paragraph (b)(5) of this section only, a private home does not include a nursing, long-term care, or other facility or institution, except that a patient may have a private home in an assisted living or independent living facility.

(7) *Disclosure requirement for certain imaging services.* (i) With respect to magnetic resonance imaging, computed tomography, and positron emission tomography services identified as “radiology and certain other imaging services” on the List of CPT/HCPCS Codes, the referring physician must provide written notice to the patient at the time of the referral that the patient may receive the same services from a person other than one described in paragraph (b)(1) of this section. Except as set forth in paragraph (b)(7)(ii) of this section, the written notice must include a list of at least 5 other suppliers (as defined at §400.202 of this chapter) that provide the services for which the individual is being referred and which are located within a 25-mile radius of the referring physician’s office location at the time of the referral. The notice should be written in a

manner sufficient to be reasonably understood by all patients and should include for each supplier on the list, at a minimum, the supplier's name, address, and telephone number.

(ii) If there are fewer than 5 other suppliers located within a 25-mile radius of the physician's office location at the time of the referral, the physician must list all of the other suppliers of the imaging service that are present within a 25-mile radius of the referring physician's office location. Provision of the written list of alternate suppliers will not be required if no other suppliers provide the services for which the individual is being referred within the 25-mile radius.

(c) *Services furnished by an organization (or its contractors or subcontractors) to enrollees.* Services furnished by an organization (or its contractors or subcontractors) to enrollees of one of the following prepaid health plans (not including services provided to enrollees in any other plan or line of business offered or administered by the same organization):

(1) An HMO or a CMP in accordance with a contract with CMS under section 1876 of the Act and part 417, subparts J through M of this chapter.

(2) A health care prepayment plan in accordance with an agreement with CMS under section 1833(a)(1)(A) of the Act and part 417, subpart U of this chapter.

(3) An organization that is receiving payments on a prepaid basis for Medicare enrollees through a demonstration project under section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1) or under section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b–1 note).

(4) A qualified HMO (within the meaning of section 1310(d) of the Public Health Service Act).

(5) A coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by a Medicare Advantage organization in accordance with a contract with CMS under section 1857 of the Act and part 422 of this chapter.

(6) A MCO contracting with a State under section 1903(m) of the Act.

(7) A prepaid inpatient health plan (PIHP) or prepaid ambulance health

plan (PAHP) contracting with a State under part 438 of this chapter.

(8) A health insuring organization (HIO) contracting with a State under part 438, subpart D of this chapter.

(9) An entity operating under a demonstration project under sections 1115(a), 1915(a), 1915(b), or 1932(a) of the Act.

(d) [Reserved]

(e) *Academic medical centers.* (1) Services provided by an academic medical center if all of the following conditions are met:

(i) The referring physician—

(A) Is a *bona fide* employee of a component of the academic medical center on a full-time or substantial part-time basis. (A “component” of an academic medical center means an affiliated medical school, faculty practice plan, hospital, teaching facility, institution of higher education, departmental professional corporation, or nonprofit support organization whose primary purpose is supporting the teaching mission of the academic medical center.) The components need not be separate legal entities;

(B) Is licensed to practice medicine in the State(s) in which he or she practices medicine;

(C) Has a *bona fide* faculty appointment at the affiliated medical school or at one or more of the educational programs at the accredited academic hospital (as defined at § 411.355(e)(3)); and

(D) Provides either substantial academic services or substantial clinical teaching services (or a combination of academic services and clinical teaching services) for which the faculty member receives compensation as part of his or her employment relationship with the academic medical center. Parties should use a reasonable and consistent method for calculating a physician's academic services and clinical teaching services. A physician will be deemed to meet this requirement if he or she spends at least 20 percent of his or her professional time or 8 hours per week providing academic services or clinical teaching services (or a combination of academic services or clinical teaching services). A physician who does not spend at least 20 percent of his or her professional time or 8 hours per week

providing academic services or clinical teaching services (or a combination of academic services or clinical teaching services) is not precluded from qualifying under this paragraph (e)(1)(i)(D).

(ii) The compensation paid to the referring physician must meet all of the following conditions:

(A) The total compensation paid by each academic medical center component to the referring physician is set in advance.

(B) In the aggregate, the compensation paid by all academic medical center components to the referring physician does not exceed fair market value for the services provided.

(C) The total compensation paid by each academic medical center component is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician within the academic medical center.

(D) If any compensation paid to the referring physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of §411.354(d)(4).

(iii) The academic medical center must meet all of the following conditions:

(A) All transfers of money between components of the academic medical center must directly or indirectly support the missions of teaching, indigent care, research, or community service.

(B) The relationship of the components of the academic medical center must be set forth in one or more written agreements or other written documents that have been adopted by the governing body of each component. If the academic medical center is one legal entity, this requirement will be satisfied if transfers of funds between components of the academic medical center are reflected in the routine financial reports covering the components.

(C) All money paid to a referring physician for research must be used solely to support *bona fide* research or teaching and must be consistent with the terms and conditions of the grant.

(2) The "academic medical center" for purposes of this section consists of—

(i) An accredited medical school (including a university, when appropriate) or an accredited academic hospital (as defined at paragraph (e)(3) of this section);

(ii) One or more faculty practice plans affiliated with the medical school, the affiliated hospital(s), or the accredited academic hospital; and

(iii) One or more affiliated hospitals in which a majority of the physicians on the medical staff consists of physicians who are faculty members and a majority of all hospital admissions is made by physicians who are faculty members. The hospital for purposes of this paragraph (e)(2)(iii) may be the same hospital that satisfies the requirement of paragraph (e)(2)(i) of this section. For purposes of this paragraph (e)(2)(iii), a faculty member is a physician who is either on the faculty of the affiliated medical school or on the faculty of one or more of the educational programs at the accredited academic hospital. In meeting this paragraph (e)(2)(iii), faculty from any affiliated medical school or accredited academic hospital education program may be aggregated, and residents and non-physician professionals need not be counted. Any faculty member may be counted, including courtesy and volunteer faculty. For purposes of determining whether the majority of physicians on the medical staff consists of faculty members, the affiliated hospital must include or exclude all individual physicians with the same class of privileges at the affiliated hospital (for example, physicians holding courtesy privileges).

(3) An accredited academic hospital for purposes of this section means a hospital or a health system that sponsors four or more approved medical education programs.

(f) *Implants furnished by an ASC.* Implants furnished by an ASC, including, but not limited to, cochlear implants, intraocular lenses, and other implanted prosthetics, implanted prosthetic devices, and implanted DME that meet the following conditions:

(1) The implant is implanted by the referring physician or a member of the referring physician's group practice in an ASC that is certified by Medicare under part 416 of this chapter and with

which the referring physician has a financial relationship.

(2) The implant is implanted in the patient during a surgical procedure paid by Medicare to the ASC as an ASC procedure under § 416.65 of this chapter.

(3) [Reserved]

(4) [Reserved]

(5) The exception set forth in this paragraph (f) does not apply to any financial relationships between the referring physician and any entity other than the ASC in which the implant is furnished to, and implanted in, the patient.

(g) *EPO and other dialysis-related drugs.* EPO and other dialysis-related drugs that meet the following conditions:

(1) The EPO and other dialysis-related drugs are furnished in or by an ESRD facility. For purposes of this paragraph (g)(1), “EPO and other dialysis-related drugs” means certain outpatient prescription drugs that are required for the efficacy of dialysis and identified as eligible for this exception on the List of CPT/HCPCS Codes; and “furnished” means that the EPO or dialysis-related drugs are administered to a patient in the ESRD facility or, in the case of EPO or Aranesp (or equivalent drug identified on the List of CPT/HCPCS Codes) only, are dispensed by the ESRD facility for use at home.

(2) [Reserved]

(3) [Reserved]

(4) The exception set forth in this paragraph (g) does not apply to any financial relationship between the referring physician and any entity other than the ESRD facility that furnishes the EPO and other dialysis-related drugs to the patient.

(h) *Preventive screening tests and vaccines.* (1) Preventive screening tests and vaccines that meet the following conditions:

(i) The preventive screening test or vaccine is listed on the List of CPT/HCPCS Codes as a code to which the exception in this paragraph is applicable.

(ii) The preventive screening test or vaccine is covered by Medicare.

(iii) The preventive screening test or vaccine is subject to a CMS-mandated frequency limit.

(2) During such period as the vaccine is not subject to a CMS-mandated frequency limit, paragraph (h)(1)(iii) of this section does not apply to a COVID-19 vaccine identified on the List of CPT/HCPCS Codes as a code to which the exception in this paragraph is applicable.

(i) *Eyeglasses and contact lenses following cataract surgery.* Eyeglasses and contact lenses that are covered by Medicare when furnished to patients following cataract surgery that meet the following conditions:

(1) The eyeglasses or contact lenses are provided in accordance with the coverage and payment provisions set forth in §§ 410.36(a)(2)(ii) and 414.228 of this chapter, respectively.

(2) [Reserved]

(j) *Intra-family rural referrals.* (1) Services provided pursuant to a referral from a referring physician to his or her immediate family member or to an entity furnishing DHS with which the immediate family member has a financial relationship, if all of the following conditions are met:

(i) The patient who is referred resides in a rural area as defined at § 411.351 of this subpart;

(ii) Except as provided in paragraph (j)(1)(iii) of this section, in light of the patient’s condition, no other person or entity is available to furnish the services in a timely manner within 25 miles of or 45 minutes transportation time from the patient’s residence;

(iii) In the case of services furnished to patients where they reside (for example, home health services or DME), no other person or entity is available to furnish the services in a timely manner in light of the patient’s condition; and

(2) The referring physician or the immediate family member must make reasonable inquiries as to the availability of other persons or entities to furnish the DHS. However, neither the referring physician nor the immediate family member has any obligation to inquire as to the availability of persons or entities located farther than 25 miles of or 45 minutes transportation time from (whichever test the referring

physician utilized for purposes of paragraph (j)(1)(ii)) the patient's residence.

[85 FR 77656, Dec. 2, 2020, as amended at 86 FR 65668, Nov. 19 2021]

§411.356 Exceptions to the referral prohibition related to ownership or investment interests.

For purposes of §411.353, the following ownership or investment interests do not constitute a financial relationship:

(a) *Publicly traded securities.* Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) that at the time the DHS referral was made could be purchased on the open market and that meet the requirements of paragraphs (a)(1) and (2) of this section.

(1) They are either—

(i) Listed for trading on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis;

(ii) Traded under an automated inter-dealer quotation system operated by the National Association of Securities Dealers; or

(iii) Listed for trading on an electronic stock market or over-the-counter quotation system in which quotations are published on a daily basis and trades are standardized and publicly transparent.

(2) They are in a corporation that had stockholder equity exceeding \$75 million at the end of the corporation's most recent fiscal year or on average during the previous 3 fiscal years. "Stockholder equity" is the difference in value between a corporation's total assets and total liabilities.

(b) *Mutual funds.* Ownership of shares in a regulated investment company as defined in section 851(a) of the Internal Revenue Code of 1986, if the company had, at the end of its most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding \$75 million.

(c) *Specific providers.* Ownership or investment interest in the following enti-

ties, for purposes of the services specified:

(1) A rural provider, in the case of DHS furnished in a rural area (as defined at §411.351 of this part) by the provider. A "rural provider" is an entity that furnishes substantially all (not less than 75 percent) of the DHS that it furnishes to residents of a rural area and, for the 18-month period beginning on December 8, 2003 (or such other period as Congress may specify), is not a specialty hospital, and in the case where the entity is a hospital, the hospital meets the requirements of §411.362 no later than September 23, 2011.

(2) A hospital that is located in Puerto Rico, in the case of DHS furnished by such a hospital.

(3) A hospital that is located outside of Puerto Rico, in the case of DHS furnished by such a hospital, if—

(i) The referring physician is authorized to perform services at the hospital;

(ii) Effective for the 18-month period beginning on December 8, 2003 (or such other period as Congress may specify), the hospital is not a specialty hospital;

(iii) The ownership or investment interest is in the entire hospital and not merely in a distinct part or department of the hospital; and

(iv) The hospital meets the requirements described in §411.362 not later than September 23, 2011.

[85 FR 77656, Dec. 2, 2020]

§411.357 Exceptions to the referral prohibition related to compensation arrangements.

For purposes of §411.353, the following compensation arrangements do not constitute a financial relationship:

(a) *Rental of office space.* Payments for the use of office space made by a lessee to a lessor if the arrangement meets the following requirements:

(1) The lease arrangement is set out in writing, is signed by the parties, and specifies the premises it covers.

(2) The duration of the lease arrangement is at least 1 year. To meet this requirement, if the lease arrangement is terminated with or without cause, the parties may not enter into a new lease arrangement for the same space

during the first year of the original lease arrangement.

(3) The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor), except that the lessee may make payments for the use of space consisting of common areas if the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas. For purposes of this paragraph (a), exclusive use means that the lessee (and any other lessees of the same office space) uses the office space to the exclusion of the lessor (or any person or entity related to the lessor). The lessor (or any person or entity related to the lessor) may not be an invitee of the lessee to use the office space.

(4) The rental charges over the term of the lease arrangement are set in advance and are consistent with fair market value.

(5) The rental charges over the term of the lease arrangement are not determined—

(i) In any manner that takes into account the volume or value of referrals or other business generated between the parties; or

(ii) Using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(6) The lease arrangement would be commercially reasonable even if no referrals were made between the lessee and the lessor.

(7) If the lease arrangement expires after a term of at least 1 year, a holdover lease arrangement immediately following the expiration of the lease arrangement satisfies the requirements

of paragraph (a) of this section if the following conditions are met:

(i) The lease arrangement met the conditions of paragraphs (a)(1) through (6) of this section when the arrangement expired;

(ii) The holdover lease arrangement is on the same terms and conditions as the immediately preceding arrangement; and

(iii) The holdover lease arrangement continues to satisfy the conditions of paragraphs (a)(1) through (6) of this section.

(b) *Rental of equipment.* Payments made by a lessee to a lessor for the use of equipment under the following conditions:

(1) The lease arrangement is set out in writing, is signed by the parties, and specifies the equipment it covers.

(2) The equipment leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor). For purposes of this paragraph (b), exclusive use means that the lessee (and any other lessees of the same equipment) uses the equipment to the exclusion of the lessor (or any person or entity related to the lessor). The lessor (or any person or entity related to the lessor) may not be an invitee of the lessee to use the equipment.

(3) The duration of the lease arrangement is at least 1 year. To meet this requirement, if the lease arrangement is terminated with or without cause, the parties may not enter into a new lease arrangement for the same equipment during the first year of the original lease arrangement.

(4) The rental charges over the term of the lease arrangement are set in advance, are consistent with fair market value, and are not determined—

(i) In any manner that takes into account the volume or value of referrals or other business generated between the parties; or

(ii) Using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed on or business generated through the use of the equipment; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(5) The lease arrangement would be commercially reasonable even if no referrals were made between the parties.

(6) If the lease arrangement expires after a term of at least 1 year, a holdover lease arrangement immediately following the expiration of the lease arrangement satisfies the requirements of this paragraph (b) if the following conditions are met:

(i) The lease arrangement met the conditions of paragraphs (b)(1) through (5) of this section when the arrangement expired;

(ii) The holdover lease arrangement is on the same terms and conditions as the immediately preceding lease arrangement; and

(iii) The holdover lease arrangement continues to satisfy the conditions of paragraphs (b)(1) through (5) of this section.

(c) *Bona fide employment relationships.* Any amount paid by an employer to a physician (or immediate family member) who has a *bona fide* employment relationship with the employer for the provision of services if the following conditions are met:

(1) The employment is for identifiable services.

(2) The amount of the remuneration under the employment is—

(i) Consistent with the fair market value of the services; and

(ii) Except as provided in paragraph (c)(4) of this section, is not determined in any manner that takes into account the volume or value of referrals by the referring physician.

(3) The remuneration is provided under an arrangement that would be commercially reasonable even if no referrals were made to the employer.

(4) Paragraph (c)(2)(ii) of this section does not prohibit payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or immediate family member of the physician).

(5) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of §411.354(d)(4).

(d) *Personal service arrangements*—(1) *General.* Remuneration from an entity under an arrangement or multiple arrangements to a physician or his or her immediate family member, or to a group practice, including remuneration for specific physician services furnished to a nonprofit blood center, if the following conditions are met:

(i) Each arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.

(ii) Except for services provided under an arrangement that satisfies all of the conditions of paragraph (z) of this section, the arrangement(s) covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity. This requirement is met if all separate arrangements between the entity and the physician and the entity and any family members incorporate each other by reference or if they cross-reference a master list of contracts that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of contracts. A physician or family member may “furnish” services through employees whom they have hired for the purpose of performing the services; through a wholly-owned entity; or through *locum tenens* physicians (as defined at §411.351, except that the regular physician need not be a member of a group practice).

(iii) The aggregate services covered by the arrangement do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement(s).

(iv) The duration of each arrangement is at least 1 year. To meet this requirement, if an arrangement is terminated with or without cause, the parties may not enter into the same or substantially the same arrangement during the first year of the original arrangement.

(v) The compensation to be paid over the term of each arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan (as defined at § 411.351), is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

(vi) The services to be furnished under each arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any Federal or State law.

(vii) If the arrangement expires after a term of at least 1 year, a holdover arrangement immediately following the expiration of the arrangement satisfies the requirements of paragraph (d) of this section if the following conditions are met:

(A) The arrangement met the conditions of paragraphs (d)(1)(i) through (vi) of this section when the arrangement expired;

(B) The holdover arrangement is on the same terms and conditions as the immediately preceding arrangement; and

(C) The holdover arrangement continues to satisfy the conditions of paragraphs (d)(1)(i) through (vi) of this section.

(viii) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of § 411.354(d)(4).

(2) *Physician incentive plan exception.* In the case of a physician incentive plan (as defined at § 411.351) between a physician and an entity (or downstream contractor), the compensation may be determined in any manner (through a withhold, capitation, bonus, or otherwise) that takes into account the volume or value of referrals or other business generated between the parties, if the plan meets the following requirements:

(i) No specific payment is made directly or indirectly under the plan to a physician or a physician group as an inducement to reduce or limit medically necessary services furnished with respect to a specific individual enrolled with the entity.

(ii) Upon request of the Secretary, the entity provides the Secretary with

access to information regarding the plan (including any downstream contractor plans), in order to permit the Secretary to determine whether the plan is in compliance with paragraph (d)(2) of this section.

(iii) In the case of a plan that places a physician or a physician group at substantial financial risk as defined at § 422.208, the entity or any downstream contractor (or both) complies with the requirements concerning physician incentive plans set forth in §§ 422.208 and 422.210 of this chapter.

(iv) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of § 411.354(d)(4).

(e) *Physician recruitment.* (1) Remuneration provided by a hospital to recruit a physician that is paid directly to the physician and that is intended to induce the physician to relocate his or her medical practice to the geographic area served by the hospital in order to become a member of the hospital's medical staff, if all of the following conditions are met:

(i) The arrangement is set out in writing and signed by both parties;

(ii) The arrangement is not conditioned on the physician's referral of patients to the hospital;

(iii) The amount of remuneration under the arrangement is not determined in any manner that takes into account the volume or value of actual or anticipated referrals by the physician or other business generated between the parties; and

(iv) The physician is allowed to establish staff privileges at any other hospital(s) and to refer business to any other entities (except as referrals may be restricted under an employment or services arrangement that complies with § 411.354(d)(4)).

(2)(i) *Geographic area served by the hospital—defined.* The “geographic area served by the hospital” is the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients. The geographic area served by the hospital may include one or more zip codes from which the hospital draws no inpatients, provided that such zip codes are entirely surrounded by zip

codes in the geographic area described above from which the hospital draws at least 75 percent of its inpatients.

(ii) *Noncontiguous zip codes.* With respect to a hospital that draws fewer than 75 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients, the “geographic area served by the hospital” will be deemed to be the area composed of all of the contiguous zip codes from which the hospital draws its inpatients.

(iii) *Special optional rule for rural hospitals.* In the case of a hospital located in a rural area (as defined at §411.351), the “geographic area served by the hospital” may also be the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 90 percent of its inpatients. If the hospital draws fewer than 90 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients, the “geographic area served by the hospital” may include noncontiguous zip codes, beginning with the noncontiguous zip code in which the highest percentage of the hospital’s inpatients resides, and continuing to add noncontiguous zip codes in decreasing order of percentage of inpatients.

(iv) *Relocation of medical practice.* A physician will be considered to have relocated his or her medical practice if the medical practice was located outside the geographic area served by the hospital and—

(A) The physician moves his or her medical practice at least 25 miles and into the geographic area served by the hospital; or

(B) The physician moves his medical practice into the geographic area served by the hospital, and the physician’s new medical practice derives at least 75 percent of its revenues from professional services furnished to patients (including hospital inpatients) not seen or treated by the physician at his or her prior medical practice site during the preceding 3 years, measured on an annual basis (fiscal or calendar year). For the initial “start up” year of the recruited physician’s practice, the 75 percent test in the preceding sentence will be satisfied if there is a reasonable expectation that the recruited physician’s medical practice for the

year will derive at least 75 percent of its revenues from professional services furnished to patients not seen or treated by the physician at his or her prior medical practice site during the preceding 3 years.

(3) The recruited physician will not be subject to the relocation requirement of this paragraph (e), provided that he or she establishes his or her medical practice in the geographic area served by the recruiting hospital, if—

(i) He or she is a resident or physician who has been in practice 1 year or less;

(ii) He or she was employed on a full-time basis for at least 2 years immediately prior to the recruitment arrangement by one of the following (and did not maintain a private practice in addition to such full-time employment):

(A) A Federal or State bureau of prisons (or similar entity operating one or more correctional facilities) to serve a prison population;

(B) The Department of Defense or Department of Veterans Affairs to serve active or veteran military personnel and their families; or

(C) A facility of the Indian Health Service to serve patients who receive medical care exclusively through the Indian Health Service; or

(iii) The Secretary has deemed in an advisory opinion issued under section 1877(g) of the Act that the physician does not have an established medical practice that serves or could serve a significant number of patients who are or could become patients of the recruiting hospital.

(4) In the case of remuneration provided by a hospital to a physician either indirectly through payments made to another physician practice, or directly to a physician who joins a physician practice, the following additional conditions must be met:

(i) The writing in paragraph (e)(1) of this section is also signed by the physician practice if the remuneration is provided indirectly to the physician through payments made to the physician practice and the physician practice does not pass directly through to the physician all of the remuneration from the hospital.

(ii) Except for actual costs incurred by the physician practice in recruiting the new physician, the remuneration is passed directly through to or remains with the recruited physician.

(iii) In the case of an income guarantee of any type made by the hospital to a recruited physician who joins a physician practice, the costs allocated by the physician practice to the recruited physician do not exceed the actual additional incremental costs attributable to the recruited physician. With respect to a physician recruited to join a physician practice located in a rural area or HPSA, if the physician is recruited to replace a physician who, within the previous 12-month period, retired, relocated outside of the geographic area served by the hospital, or died, the costs allocated by the physician practice to the recruited physician do not exceed either—

(A) The actual additional incremental costs attributable to the recruited physician; or

(B) The lower of a *per capita* allocation or 20 percent of the practice's aggregate costs.

(iv) Records of the actual costs and the passed-through amounts are maintained for a period of at least 6 years and made available to the Secretary upon request.

(v) The remuneration from the hospital under the arrangement is not determined in any manner that takes into account the volume or value of actual or anticipated referrals by the recruited physician or the physician practice (or any physician affiliated with the physician practice) receiving the direct payments from the hospital.

(vi) The physician practice may not impose on the recruited physician practice restrictions that unreasonably restrict the recruited physician's ability to practice medicine in the geographic area served by the hospital.

(5) Recruitment of a physician by a hospital located in a rural area (as defined at § 411.351) to an area outside the geographic area served by the hospital is permitted under this exception if the Secretary determines in an advisory opinion issued under section 1877(g) of the Act that the area has a demonstrated need for the recruited physi-

cian and all other requirements of this paragraph (e) are met.

(6)(i) This paragraph (e) applies to remuneration provided by a federally qualified health center, rural health clinic, or rural emergency hospital in the same manner as it applies to remuneration provided by a hospital.

(ii) The "geographic area served" by a federally qualified health center, rural health clinic, or rural emergency hospital is the area composed of the lowest number of contiguous or non-contiguous zip codes from which the federally qualified health center, rural health clinic, or rural emergency hospital draws at least 90 percent of its patients, as determined on an encounter basis. The geographic area served by the federally qualified health center, rural health clinic, or rural emergency hospital may include one or more zip codes from which the federally qualified health center, rural health clinic, or rural emergency hospital draws no patients, provided that such zip codes are entirely surrounded by zip codes in the geographic area described in the preceding sentence from which the federally qualified health center, rural health clinic, or rural emergency hospital draws at least 90 percent of its patients.

(f) *Isolated transactions.* Isolated financial transactions, such as a one-time sale of property or a practice, or a single instance of forgiveness of an amount owed in settlement of a *bona fide* dispute, if all of the following conditions are met:

(1) The amount of remuneration under the isolated financial transaction is—

(i) Consistent with the fair market value of the isolated financial transaction; and

(ii) Not determined in any manner that takes into account the volume or value of referrals by the referring physician or other business generated between the parties.

(2) The remuneration is provided under an arrangement that would be commercially reasonable even if the physician made no referrals to the entity.

(3) There are no additional transactions between the parties for 6 months after the isolated transaction,

except for transactions that are specifically excepted under the other provisions in §§411.355 through 411.357 and except for commercially reasonable post-closing adjustments that do not take into account the volume or value of referrals or other business generated by the referring physician.

(4) An isolated financial transaction that is an instance of forgiveness of an amount owed in settlement of a *bona fide* dispute is not part of the compensation arrangement giving rise to the *bona fide* dispute.

(g) *Certain arrangements with hospitals.* Remuneration provided by a hospital to a physician if the remuneration does not relate, directly or indirectly, to the furnishing of DHS. To qualify as “unrelated,” remuneration must be wholly unrelated to the furnishing of DHS and must not in any way take into account the volume or value of a physician’s referrals. Remuneration relates to the furnishing of DHS if it—

(1) Is an item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid under cost reporting principles;

(2) Is furnished, directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditioned manner to medical staff or other persons in a position to make or influence referrals; or

(3) Otherwise takes into account the volume or value of referrals or other business generated by the referring physician.

(h) *Group practice arrangements with a hospital.* An arrangement between a hospital and a group practice under which DHS are furnished by the group but are billed by the hospital if the following conditions are met:

(1) With respect to services furnished to an inpatient of the hospital, the arrangement is pursuant to the provision of inpatient hospital services under section 1861(b)(3) of the Act.

(2) The arrangement began before, and has continued in effect without interruption since, December 19, 1989.

(3) With respect to the DHS covered under the arrangement, at least 75 percent of these services furnished to patients of the hospital are furnished by the group under the arrangement.

(4) The arrangement is in accordance with a written agreement that specifies the services to be furnished by the parties and the compensation for services furnished under the agreement.

(5) The compensation paid over the term of the agreement is consistent with fair market value, and the compensation per unit of service is fixed in advance and is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

(6) The compensation is provided in accordance with an agreement that would be commercially reasonable even if no referrals were made to the entity.

(7) If remuneration to the physician is conditioned on the physician’s referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of §411.354(d)(4).

(i) *Payments by a physician.* Payments made by a physician (or his or her immediate family member)—

(1) To a laboratory in exchange for the provision of clinical laboratory services; or

(2) To an entity as compensation for any other items or services—

(i) That are furnished at a price that is consistent with fair market value; and

(ii) To which the exceptions in paragraphs (a) through (h) of this section are not applicable.

(3) For purposes of this paragraph (i), “services” means services of any kind (not merely those defined as “services” for purposes of the Medicare program in §400.202 of this chapter).

(j) *Charitable donations by a physician.* *Bona fide* charitable donations made by a physician (or immediate family member) to an entity if all of the following conditions are satisfied:

(1) The charitable donation is made to an organization exempt from taxation under the Internal Revenue Code (or to a supporting organization);

(2) The donation is neither solicited, nor offered, in any manner that takes into account the volume or value of referrals or other business generated between the physician and the entity; and

(k) *Nonmonetary compensation.* (1) Compensation from an entity in the form of items or services (not including

cash or cash equivalents) that does not exceed an aggregate of \$300 per calendar year, as adjusted for inflation in accordance with paragraph (k)(2) of this section, if all of the following conditions are satisfied:

(i) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.

(ii) The compensation may not be solicited by the physician or the physician's practice (including employees and staff members).

(2) The annual aggregate nonmonetary compensation limit in this paragraph (k) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI-U) for the 12-month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI-U for the 12-month period and the new nonmonetary compensation limit on the physician self-referral website at http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Up-dates.asp.

(3) Where an entity has inadvertently provided nonmonetary compensation to a physician in excess of the limit (as set forth in paragraph (k)(1) of this section), such compensation is deemed to be within the limit if—

(i) The value of the excess nonmonetary compensation is no more than 50 percent of the limit; and

(ii) The physician returns to the entity the excess nonmonetary compensation (or an amount equal to the value of the excess nonmonetary compensation) by the end of the calendar year in which the excess nonmonetary compensation was received or within 180 consecutive calendar days following the date the excess nonmonetary compensation was received by the physician, whichever is earlier.

(iii) This paragraph (k)(3) may be used by an entity only once every 3 years with respect to the same referring physician.

(4) In addition to nonmonetary compensation up to the limit described in paragraph (k)(1) of this section, an entity that has a formal medical staff may provide one local medical staff ap-

preciation event per year for the entire medical staff. Any gifts or gratuities provided in connection with the medical staff appreciation event are subject to the limit in paragraph (k)(1).

(1) *Fair market value compensation.* Compensation resulting from an arrangement between an entity and a physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in § 411.352) for the provision of items or services or for the lease of office space or equipment by the physician (or an immediate family member) or group of physicians to the entity, or by the entity to the physician (or an immediate family member) or a group of physicians, if the arrangement meets the following conditions:

(1) The arrangement is in writing, signed by the parties, and covers only identifiable items, services, office space, or equipment. The writing specifies—

(i) The items, services, office space, or equipment covered under the arrangement;

(ii) The compensation that will be provided under the arrangement; and

(iii) The timeframe for the arrangement.

(2) An arrangement may be for any period of time and contain a termination clause. An arrangement may be renewed any number of times if the terms of the arrangement and the compensation for the same items, services, office space, or equipment do not change. Other than an arrangement that satisfies all of the conditions of paragraph (z) of this section, the parties may not enter into more than one arrangement for the same items, services, office space, or equipment during the course of a year.

(3) The compensation must be set in advance, consistent with fair market value, and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician. Compensation for the rental of office space or equipment may not be determined using a formula based on—

(i) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or

(ii) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(4) The arrangement would be commercially reasonable even if no referrals were made between the parties.

(5) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act).

(6) The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a Federal or State law.

(7) The arrangement satisfies the requirements of §411.354(d)(4) in the case of—

(i) Remuneration to the physician that is conditioned on the physician's referrals to a particular provider, practitioner, or supplier; or

(ii) Remuneration paid to the group of physicians that is conditioned on one or more of the group's physicians' referrals to a particular provider, practitioner, or supplier.

(m) *Medical staff incidental benefits.* Compensation in the form of items or services (not including cash or cash equivalents) from a hospital to a member of its medical staff when the item or service is used on the hospital's campus, if all of the following conditions are met:

(1) The compensation is offered to all members of the medical staff practicing in the same specialty (but not necessarily accepted by every member to whom it is offered) and is not offered in any manner that takes into account the volume or value of referrals or other business generated between the parties.

(2) Except with respect to identification of medical staff on a hospital website or in hospital advertising, the compensation is provided only during periods when the medical staff members are making rounds or are engaged

in other services or activities that benefit the hospital or its patients.

(3) The compensation is provided by the hospital and used by the medical staff members only on the hospital's campus. Compensation, including, but not limited to, internet access, pagers, or two-way radios, used away from the campus only to access hospital medical records or information or to access patients or personnel who are on the hospital campus, as well as the identification of the medical staff on a hospital website or in hospital advertising, meets the "on campus" requirement of this paragraph (m).

(4) The compensation is reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services at the hospital.

(5) The compensation is of low value (that is, less than \$25) with respect to each occurrence of the benefit (for example, each meal given to a physician while he or she is serving patients who are hospitalized must be of low value). The \$25 limit in this paragraph (m)(5) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI-I) for the 12 month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI-I for the 12 month period and the new limits on the physician self-referral website at http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp.

(6) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

(7) [Reserved]

(8) Other facilities and health care clinics (including, but not limited to, federally qualified health centers) that have *bona fide* medical staffs may provide compensation under this paragraph (m) on the same terms and conditions applied to hospitals under this paragraph (m).

(n) *Risk-sharing arrangements.* Compensation paid directly or indirectly by a MCO or an IPA to a physician pursuant to a risk-sharing arrangement (including, but not limited to, withholds,

bonuses, and risk pools) for services provided by the physician to enrollees of a health plan. For purposes of this paragraph (n), “health plan” and “enrollees” have the meanings set forth in § 1001.952(l) of this title.

(o) *Compliance training.* Compliance training provided by an entity to a physician (or to the physician’s immediate family member or office staff) who practices in the entity’s local community or service area, provided that the training is held in the local community or service area. For purposes of this paragraph (o), “compliance training” means training regarding the basic elements of a compliance program (for example, establishing policies and procedures, training of staff, internal monitoring, or reporting); specific training regarding the requirements of Federal and State health care programs (for example, billing, coding, reasonable and necessary services, documentation, or unlawful referral arrangements); or training regarding other Federal, State, or local laws, regulations, or rules governing the conduct of the party for whom the training is provided. For purposes of this paragraph, “compliance training” includes programs that offer continuing medical education credit, provided that compliance training is the primary purpose of the program.

(p) *Indirect compensation arrangements.* Indirect compensation arrangements, as defined at § 411.354(c)(2), if all of the following conditions are satisfied:

(1)(i) The compensation received by the referring physician (or immediate family member) described in § 411.354(c)(2)(ii) is fair market value for services and items actually provided and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS.

(ii) Compensation for the rental of office space or equipment may not be determined using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed

on or business generated through the use of the equipment; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(2) The compensation arrangement described in § 411.354(c)(2)(ii) is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a bona fide employment relationship between an employer and an employee, in which case the arrangement need not be set out in writing, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer.

(3) [Reserved]

(4) If remuneration to the physician is conditioned on the physician’s referrals to a particular provider, practitioner, or supplier, the compensation arrangement described in § 411.354(c)(2)(ii) satisfies the conditions of § 411.354(d)(4).

(q) *Referral services.* Remuneration that meets all of the conditions set forth in § 1001.952(f) of this title.

(r) *Obstetrical malpractice insurance subsidies.* Remuneration that meets all of the conditions of paragraph (r)(1) or (2) of this section.

(1) Remuneration that meets all of the conditions set forth in § 1001.952(o) of this title.

(2) A payment from a hospital, federally qualified health center, rural health clinic, or rural emergency hospital that is used to pay for some or all of the costs of malpractice insurance premiums for a physician who engages in obstetrical practice as a routine part of his or her medical practice, if all of the following conditions are met:

(i)(A) The physician’s medical practice is located in a rural area, a primary care HPSA, or an area with demonstrated need for the physician’s obstetrical services as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(B) At least 75 percent of the physician’s obstetrical patients reside in a medically underserved area or are members of a medically underserved population.

(ii) The arrangement is set out in writing, is signed by the physician and the hospital, federally qualified health center, rural health clinic, or rural emergency hospital providing the payment, and specifies the payment to be made by the hospital, federally qualified health center, rural health clinic, or rural emergency hospital and the terms under which the payment is to be provided.

(iii) The arrangement is not conditioned on the physician's referral of patients to the hospital, federally qualified health center, rural health clinic, or rural emergency hospital providing the payment.

(iv) The hospital, federally qualified health center, rural health clinic, or rural emergency hospital does not determine the amount of the payment in any manner that takes into account the volume or value of referrals by the physician or any other business generated between the parties.

(v) The physician is allowed to establish staff privileges at any hospital(s), federally qualified health center(s), rural health clinic(s), or rural emergency hospital(s) and to refer business to any other entities (except as referrals may be restricted under an employment arrangement or services arrangement that complies with §411.354(d)(4)).

(vi) The payment is made to a person or organization (other than the physician) that is providing malpractice insurance (including a self-funded organization).

(vii) The physician treats obstetrical patients who receive medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(viii) The insurance is a *bona fide* malpractice insurance policy or program, and the premium, if any, is calculated based on a *bona fide* assessment of the liability risk covered under the insurance.

(ix)(A) For each coverage period (not to exceed 1 year), at least 75 percent of the physician's obstetrical patients treated under the coverage of the obstetrical malpractice insurance during the prior period (not to exceed 1 year)—

(I) Resided in a rural area, HPSA, medically underserved area, or an area

with a demonstrated need for the physician's obstetrical services as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(2) Were part of a medically underserved population.

(B) For the initial coverage period (not to exceed 1 year), the requirements of paragraph (r)(2)(ix)(A) of this section will be satisfied if the physician certifies that he or she has a reasonable expectation that at least 75 percent of the physician's obstetrical patients treated under the coverage of the malpractice insurance will—

(I) Reside in a rural area, HPSA, medically underserved area, or an area with a demonstrated need for the physician's obstetrical services as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(2) Be part of a medically underserved population.

(3) For purposes of paragraph (r)(2) of this section, *costs of malpractice insurance premiums* means:

(i) For physicians who engage in obstetrical practice on a full-time basis, any costs attributable to malpractice insurance; or

(ii) For physicians who engage in obstetrical practice on a part-time or sporadic basis, the costs attributable exclusively to the obstetrical portion of the physician's malpractice insurance, and related exclusively to obstetrical services provided—

(A) In a rural area, primary care HPSA, or an area with demonstrated need for the physician's obstetrical services, as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(B) In any area, provided that at least 75 percent of the physician's obstetrical patients treated in the coverage period (not to exceed 1 year) resided in a medically underserved area or were part of a medically underserved population.

(s) *Professional courtesy*. Professional courtesy (as defined at §411.351) offered by an entity with a formal medical staff to a physician or a physician's immediate family member or office staff

if all of the following conditions are met:

(1) The professional courtesy is offered to all physicians on the entity's bona fide medical staff or in such entity's local community or service area, and the offer does not take into account the volume or value of referrals or other business generated between the parties;

(2) The health care items and services provided are of a type routinely provided by the entity;

(3) The entity has a professional courtesy policy that is set out in writing and approved in advance by the entity's governing body; and

(4) The professional courtesy is not offered to a physician (or immediate family member) who is a Federal health care program beneficiary, unless there has been a good faith showing of financial need.

(t) *Retention payments in underserved areas*—(1) *Bona fide written offer*. Remuneration provided by a hospital directly to a physician on the hospital's medical staff to retain the physician's medical practice in the geographic area served by the hospital (as defined in paragraph (e)(2) of this section), if all of the following conditions are met:

(i) The physician has a *bona fide* firm, written recruitment offer or offer of employment from a hospital, academic medical center (as defined at § 411.355(e)), or physician organization (as defined at § 411.351) that is not related to the hospital making the payment, and the offer specifies the remuneration being offered and requires the physician to move the location of his or her medical practice at least 25 miles and outside of the geographic area served by the hospital making the retention payment.

(ii) The requirements of paragraphs (e)(1)(i) through (iv) of this section are satisfied.

(iii) Any retention payment is subject to the same obligations and restrictions, if any, on repayment or forgiveness of indebtedness as the written recruitment offer or offer of employment.

(iv) The retention payment does not exceed the lower of—

(A) The amount obtained by subtracting the physician's current in-

come from physician and related services from the income the physician would receive from comparable physician and related services in the written recruitment or employment offer, provided that the respective incomes are determined using a reasonable and consistent methodology, and that they are calculated uniformly over no more than a 24-month period; or

(B) The reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area served by the hospital to join the medical staff of the hospital to replace the retained physician.

(v) The requirements of paragraph (t)(3) of this section are satisfied.

(2) *Written certification from physician*. Remuneration provided by a hospital directly to a physician on the hospital's medical staff to retain the physician's medical practice in the geographic area served by the hospital (as defined in paragraph (e)(2) of this section), if all of the following conditions are met:

(i) The physician furnishes to the hospital before the retention payment is made a written certification that the physician has a *bona fide* opportunity for future employment by a hospital, academic medical center (as defined at § 411.355(e)), or physician organization (as defined at § 411.351) that requires the physician to move the location of his or her medical practice at least 25 miles and outside the geographic area served by the hospital. The certification contains at least the following—

(A) Details regarding the steps taken by the physician to effectuate the employment opportunity;

(B) Details of the physician's employment opportunity, including the identity and location of the physician's future employer or employment location or both, and the anticipated income and benefits (or a range for income and benefits);

(C) A statement that the future employer is not related to the hospital making the payment;

(D) The date on which the physician anticipates relocating his or her medical practice outside of the geographic area served by the hospital; and

(E) Information sufficient for the hospital to verify the information included in the written certification.

(ii) The hospital takes reasonable steps to verify that the physician has a *bona fide* opportunity for future employment that requires the physician to relocate outside the geographic area served by the hospital.

(iii) The requirements of paragraphs (e)(1)(i) through (iv) of this section are satisfied.

(iv) The retention payment does not exceed the lower of—

(A) An amount equal to 25 percent of the physician's current annual income (averaged over the previous 24 months), using a reasonable and consistent methodology that is calculated uniformly; or

(B) The reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area served by the hospital to join the medical staff of the hospital to replace the retained physician.

(v) The requirements of paragraph (t)(3) of this section are satisfied.

(3) *Additional requirements.* Remuneration provided under paragraph (t)(1) or (2) of this section must meet the following additional requirements:

(i)(A) The physician's current medical practice is located in a rural area or HPSA (regardless of the physician's specialty) or is located in an area with demonstrated need for the physician as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(B) At least 75 percent of the physician's patients reside in a medically underserved area or are members of a medically underserved population.

(ii) The hospital does not enter into a retention arrangement with a particular referring physician more frequently than once every 5 years.

(iii) The amount and terms of the retention payment are not altered during the term of the arrangement in any manner that takes into account the volume or value of referrals or other business generated by the physician.

(4) *Waiver of relocation requirement.* The Secretary may waive the relocation requirement of paragraphs (t)(1) and (t)(2) of this section for payments made to physicians practicing in a

HPSA or an area with demonstrated need for the physician through an advisory opinion issued in accordance with section 1877(g)(6) of the Act, if the retention payment arrangement otherwise complies with all of the conditions of this paragraph (t).

(5) *Application to other entities.* This paragraph (t) applies to remuneration provided by a federally qualified health center, rural health clinic, or rural emergency hospital in the same manner as it applies to remuneration provided by a hospital. For purposes of this paragraph (t), the geographic area served by a federally qualified health center, rural health clinic, or rural emergency hospital has the meaning set forth in paragraph (e)(6)(ii) of this section.

(u) *Community-wide health information systems.* Items or services of information technology provided by an entity to a physician that allow access to, and sharing of, electronic health care records and any complementary drug information systems, general health information, medical alerts, and related information for patients served by community providers and practitioners, in order to enhance the community's overall health, provided that—

(1) The items or services are available as necessary to enable the physician to participate in a community-wide health information system, are principally used by the physician as part of the community-wide health information system, and are not provided to the physician in any manner that takes into account the volume or value of referrals or other business generated by the physician;

(2) The community-wide health information systems are available to all providers, practitioners, and residents of the community who desire to participate; and

(v) *Electronic prescribing items and services.* Nonmonetary remuneration (consisting of items and services in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information, if all of the following conditions are met:

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(1) The items and services are provided by a—

(i) Hospital or rural emergency hospital to a physician who is a member of its medical staff;

(ii) Group practice (as defined at § 411.352) to a physician who is a member of the group (as defined at § 411.351); or

(iii) PDP sponsor or MA organization to a prescribing physician.

(2) The items and services are provided as part of, or are used to access, an electronic prescription drug program that meets the applicable standards under Medicare Part D at the time the items and services are provided.

(3) The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use or compatibility of the items or services with other electronic prescribing or electronic health records systems.

(4) For items or services that are of the type that can be used for any patient without regard to payer status, the donor does not restrict, or take any action to limit, the physician's right or ability to use the items or services for any patient.

(5) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

(6) Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, is determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.

(7) The arrangement is set forth in a written agreement that—

(i) Is signed by the parties;

(ii) Specifies the items and services being provided and the donor's cost of the items and services; and

(iii) Covers all of the electronic prescribing items and services to be provided by the donor. This requirement is met if all separate agreements between the donor and the physician (and the donor and any family members of the physician) incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is

available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of agreements.

(8) The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor.

(w) *Electronic health records items and services.* Nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services, including cybersecurity software and services) necessary and used predominantly to create, maintain, transmit, receive, or protect electronic health records, if all of the following conditions are met:

(1) The items and services are provided to a physician by an entity (as defined at § 411.351) that is not a laboratory company.

(2) The software is interoperable (as defined at § 411.351) at the time it is provided to the physician. For purposes of this paragraph (w), software is deemed to be interoperable if, on the date it is provided to the physician, it is certified by a certifying body authorized by the National Coordinator for Health Information Technology to certification criteria identified in the then-applicable version of 45 CFR part 170.

(3) [Reserved]

(4)(i) Before receipt of the initial donation of items and services or the donation of replacement items and services, the physician pays 15 percent of the donor's cost for the items and services.

(ii) Except as provided in paragraph (w)(4)(i) of this section, with respect to items and services received from the donor after the initial donation of items and services or the donation of replacement items and services, the physician pays 15 percent of the donor's cost for the items and services at reasonable intervals.

(iii) The donor (or any party related to the donor) does not finance the physician's payment or loan funds to be used by the physician to pay for the items and services.

(5) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

(6) Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties. For purposes of this paragraph (w), the determination is deemed not to directly take into account the volume or value of referrals or other business generated between the parties if any one of the following conditions is met:

(i) The determination is based on the total number of prescriptions written by the physician (but not the volume or value of prescriptions dispensed or paid by the donor or billed to the program);

(ii) The determination is based on the size of the physician's medical practice (for example, total patients, total patient encounters, or total relative value units);

(iii) The determination is based on the total number of hours that the physician practices medicine;

(iv) The determination is based on the physician's overall use of automated technology in his or her medical practice (without specific reference to the use of technology in connection with referrals made to the donor);

(v) The determination is based on whether the physician is a member of the donor's medical staff, if the donor has a formal medical staff;

(vi) The determination is based on the level of uncompensated care provided by the physician; or

(vii) The determination is made in any reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business generated between the parties.

(7) The arrangement is set forth in a written agreement that—

(i) Is signed by the parties;

(ii) Specifies the items and services being provided, the donor's cost of the items and services, and the amount of the physician's contribution; and

(iii) Covers all of the electronic health records items and services to be provided by the donor. This requirement is met if all separate agreements between the donor and the physician (and the donor and any family members of the physician) incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of agreements.

(8) [Reserved]

(9) For items or services that are of the type that can be used for any patient without regard to payer status, the donor does not restrict, or take any action to limit, the physician's right or ability to use the items or services for any patient.

(10) The items and services do not include staffing of physician offices and are not used primarily to conduct personal business or business unrelated to the physician's medical practice.

(x) *Assistance to compensate a non-physician practitioner.* (1) Remuneration provided by a hospital to a physician to compensate a nonphysician practitioner to provide NPP patient care services, if all of the following conditions are met:

(i) The arrangement—

(A) Is set out in writing and signed by the hospital, the physician, and the nonphysician practitioner; and

(B) Commences before the physician (or the physician organization in whose shoes the physician stands under §411.354(c)) enters into the compensation arrangement described in paragraph (x)(1)(vi)(A) of this section.

(ii) The arrangement is not conditioned on—

(A) The physician's referrals to the hospital; or

(B) The nonphysician practitioner's NPP referrals to the hospital.

(iii) The remuneration from the hospital—

(A) Does not exceed 50 percent of the actual compensation, signing bonus, and benefits paid by the physician to the nonphysician practitioner during a

period not to exceed the first 2 consecutive years of the compensation arrangement between the nonphysician practitioner and the physician (or the physician organization in whose shoes the physician stands); and

(B) Is not determined in any manner that takes into account the volume or value of actual or anticipated referrals by—

(1) Referrals by the physician (or any physician in the physician's practice) or other business generated between the parties; or

(2) NPP referrals by the nonphysician practitioner (or any nonphysician practitioner in the physician's practice) or other business generated between the parties.

(iv) The compensation, signing bonus, and benefits paid to the nonphysician practitioner by the physician does not exceed fair market value for the NPP patient care services furnished by the nonphysician practitioner to patients of the physician's practice.

(v) The nonphysician practitioner has not, within 1 year of the commencement of his or her compensation arrangement with the physician (or the physician organization in whose shoes the physician stands under § 411.354(c))—

(A) Furnished NPP patient care services in the geographic area served by the hospital; or

(B) Been employed or otherwise engaged to provide NPP patient care services by a physician or a physician organization that has a medical practice site located in the geographic area served by the hospital, regardless of whether the nonphysician practitioner furnished NPP patient care services at the medical practice site located in the geographic area served by the hospital.

(vi)(A) The nonphysician practitioner has a compensation arrangement directly with the physician or the physician organization in whose shoes the physician stands under § 411.354(c); and

(B) Substantially all of the NPP patient care services that the nonphysician practitioner furnishes to patients of the physician's practice are primary care services or mental health care services.

(vii) The physician does not impose practice restrictions on the nonphysician practitioner that unreasonably restrict the nonphysician practitioner's ability to provide NPP patient care services in the geographic area served by the hospital.

(2) Records of the actual amount of remuneration provided under paragraph (x)(1) of this section by the hospital to the physician, and by the physician to the nonphysician practitioner, must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(3) For purposes of this paragraph (x), "nonphysician practitioner" means a physician assistant as defined in section 1861(aa)(5) of the Act, a nurse practitioner or clinical nurse specialist as defined in section 1861(aa)(5) of the Act, a certified nurse-midwife as defined in section 1861(gg) of the Act, a clinical social worker as defined in section 1861(hh) of the Act, or a clinical psychologist as defined at § 410.71(d) of this subchapter.

(4) For purposes of this paragraph (x), the following terms have the meanings indicated.

(i) "NPP patient care services" means direct patient care services furnished by a nonphysician practitioner that address the medical needs of specific patients or any task performed by a nonphysician practitioner that promotes the care of patients of the physician or physician organization with which the nonphysician practitioner has a compensation arrangement.

(ii) "NPP referral" means a request by a nonphysician practitioner that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of any plan of care by a nonphysician practitioner that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but does not include any designated health service personally performed or provided by the nonphysician practitioner.

(5) For purposes of paragraph (x)(1) of this section, "geographic area served by the hospital" has the meaning set forth in paragraph (e)(2) of this section.

(6) For purposes of paragraph (x)(1) of this section, a “compensation arrangement” between a physician (or the physician organization in whose shoes the physician stands under §411.354(c)) and a nonphysician practitioner—

(i) Means an employment, contractual, or other arrangement under which remuneration passes between the parties; and

(ii) Does not include a nonphysician practitioner’s ownership or investment interest in a physician organization.

(7)(i) This paragraph (x) may be used by a hospital, federally qualified health center, rural health clinic, or rural emergency hospital only once every 3 years with respect to the same referring physician.

(ii) Paragraph (x)(7)(i) of this section does not apply to remuneration provided by a hospital, federally qualified health center, rural health clinic, or rural emergency hospital to a physician to compensate a nonphysician practitioner to provide NPP patient care services if—

(A) The nonphysician practitioner is replacing a nonphysician practitioner who terminated his or her employment or contractual arrangement to provide NPP patient care services with the physician (or the physician organization in whose shoes the physician stands) within 1 year of the commencement of the employment or contractual arrangement; and

(B) The remuneration provided to the physician is provided during a period that does not exceed 2 consecutive years as measured from the commencement of the compensation arrangement between the nonphysician practitioner who is being replaced and the physician (or the physician organization in whose shoes the physician stands).

(8)(i) This paragraph (x) applies to remuneration provided by a federally qualified health center, rural health clinic, or rural emergency hospital in the same manner as it applies to remuneration provided by a hospital.

(ii) The “geographic area served” by a federally qualified health center, rural health clinic, or rural emergency hospital has the meaning set forth in paragraph (e)(6)(ii) of this section.

(y) *Timeshare arrangements.* Remuneration provided under an arrange-

ment for the use of premises, equipment, personnel, items, supplies, or services if the following conditions are met:

(1) The arrangement is set out in writing, signed by the parties, and specifies the premises, equipment, personnel, items, supplies, and services covered by the arrangement.

(2) The arrangement is between a physician (or the physician organization in whose shoes the physician stands under §411.354(c)) and—

(i) A hospital; or

(ii) Physician organization of which the physician is not an owner, employee, or contractor.

(3) The premises, equipment, personnel, items, supplies, and services covered by the arrangement are used—

(i) Predominantly for the provision of evaluation and management services to patients; and

(ii) On the same schedule.

(4) The equipment covered by the arrangement is—

(i) Located in the same building where the evaluation and management services are furnished;

(ii) Not used to furnish designated health services other than those incidental to the evaluation and management services furnished at the time of the patient’s evaluation and management visit; and

(iii) Not advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests).

(5) The arrangement is not conditioned on the referral of patients by the physician who is a party to the arrangement to the hospital or physician organization of which the physician is not an owner, employee, or contractor.

(6) The compensation over the term of the arrangement is set in advance, consistent with fair market value, and not determined—

(i) In any manner that takes into account the volume or value of referrals or other business generated between the parties; or

(ii) Using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises, equipment, personnel, items, supplies, or services covered by the arrangement; or

(B) Per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises, equipment, personnel, items, supplies, or services covered by the arrangement to the party to which the permission is granted.

(7) The arrangement would be commercially reasonable even if no referrals were made between the parties.

(8) [Reserved]

(9) The arrangement does not convey a possessory leasehold interest in the office space that is the subject of the arrangement.

(10) This paragraph (y) applies to remuneration provided by a rural emergency hospital in the same manner as it applies to remuneration provided by a hospital.

(z) *Limited remuneration to a physician.* (1) Remuneration from an entity to a physician for the provision of items or services provided by the physician to the entity that does not exceed an aggregate of \$5,000 per calendar year, as adjusted for inflation in accordance with paragraph (z)(3) of this section, if all of the following conditions are satisfied:

(i) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician.

(ii) The compensation does not exceed the fair market value of the items or services.

(iii) The arrangement would be commercially reasonable even if no referrals were made between the parties.

(iv) Compensation for the lease of office space or equipment is not determined using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed

on or business generated through the use of the equipment; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(v) Compensation for the use of premises or equipment is not determined using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises or equipment covered by the arrangement; or

(B) Per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises or equipment covered by the arrangement to the party to which the permission is granted.

(vi) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of § 411.354(d)(4).

(2) A physician may provide items or services through employees whom the physician has hired for the purpose of performing the services; through a wholly-owned entity; or through *locum tenens* physicians (as defined at § 411.351, except that the regular physician need not be a member of a group practice).

(3) The annual aggregate remuneration limit in this paragraph (z) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI-U) for the 12-month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI-U for the 12-month period and the new remuneration limit on the physician self-referral website at http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp.

(aa) *Arrangements that facilitate value-based health care delivery and payment—*

(1) *Full financial risk*—Remuneration paid under a value-based arrangement, as defined at § 411.351, if the following conditions are met:

(i) The value-based enterprise is at full financial risk (or is contractually

obligated to be at full financial risk within the 12 months following the commencement of the value-based arrangement) during the entire duration of the value-based arrangement.

(ii) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

(iii) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.

(iv) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

(v) If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement complies with both of the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

(vi) Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(vii) For purposes of this paragraph (aa), "full financial risk" means that the value-based enterprise is financially responsible on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. For purposes of this paragraph (aa), "prospective basis" means that the value-based enterprise has assumed financial responsibility for the cost of all patient care items

and services covered by the applicable payor prior to providing patient care items and services to patients in the target patient population.

(2) *Value-based arrangements with meaningful downside financial risk to the physician*—Remuneration paid under a value-based arrangement, as defined at §411.351, if the following conditions are met:

(i) The physician is at meaningful downside financial risk for failure to achieve the value-based purpose(s) of the value-based enterprise during the entire duration of the value-based arrangement.

(ii) A description of the nature and extent of the physician's downside financial risk is set forth in writing.

(iii) The methodology used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid.

(iv) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

(v) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.

(vi) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

(vii) If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement complies with both of the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

(viii) Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(ix) For purposes of this paragraph (aa), “meaningful downside financial risk” means that the physician is responsible to repay or forgo no less than 10 percent of the total value of the remuneration the physician receives under the value-based arrangement.

(3) *Value-based arrangements.* Remuneration paid under a value-based arrangement, as defined at § 411.351, if the following conditions are met:

(i) The arrangement is set forth in writing and signed by the parties. The writing includes a description of—

(A) The value-based activities to be undertaken under the arrangement;

(B) How the value-based activities are expected to further the value-based purpose(s) of the value-based enterprise;

(C) The target patient population for the arrangement;

(D) The type or nature of the remuneration;

(E) The methodology used to determine the remuneration; and

(F) The outcome measures against which the recipient of the remuneration is assessed, if any.

(ii) The outcome measures against which the recipient of the remuneration is assessed, if any, are objective, measurable, and selected based on clinical evidence or credible medical support.

(iii) Any changes to the outcome measures against which the recipient of the remuneration will be assessed are made prospectively and set forth in writing.

(iv) The methodology used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid.

(v) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

(vi) The arrangement is commercially reasonable.

(vii)(A) No less frequently than annually, or at least once during the term of the arrangement if the arrangement has a duration of less than 1 year, the value-based enterprise or one or more of the parties monitor:

(1) Whether the parties have furnished the value-based activities required under the arrangement;

(2) Whether and how continuation of the value-based activities is expected to further the value-based purpose(s) of the value-based enterprise; and

(3) Progress toward attainment of the outcome measure(s), if any, against which the recipient of the remuneration is assessed.

(B) If the monitoring indicates that a value-based activity is not expected to further the value-based purpose(s) of the value-based enterprise, the parties must terminate the ineffective value-based activity. Following completion of monitoring that identifies an ineffective value-based activity, the value-based activity is deemed to be reasonably designed to achieve at least one value-based purpose of the value-based enterprise—

(1) For 30 consecutive calendar days after completion of the monitoring, if the parties terminate the arrangement; or

(2) For 90 consecutive calendar days after completion of the monitoring, if the parties modify the arrangement to terminate the ineffective value-based activity.

(C) If the monitoring indicates that an outcome measure is unattainable during the remaining term of the arrangement, the parties must terminate or replace the unattainable outcome measure within 90 consecutive calendar days after completion of the monitoring.

(viii) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.

(ix) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

(x) If the remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the

value-based arrangement complies with both of the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

(xi) Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(xii) For purposes of this paragraph (aa)(3), "outcome measure" means a benchmark that quantifies:

(A) Improvements in or maintenance of the quality of patient care; or

(B) Reductions in the costs to or reductions in growth in expenditures of payors while maintaining or improving the quality of patient care.

(bb) *Cybersecurity technology and related services.* (1) Nonmonetary remuneration (consisting of technology and services) necessary and used predominantly to implement, maintain, or re-establish cybersecurity, if all of the following conditions are met:

(i) Neither the eligibility of a physician for the technology or services, nor the amount or nature of the technology or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties.

(ii) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor.

(iii) The arrangement is documented in writing.

(2) For purposes of this paragraph (bb), "technology" means any software

or other types of information technology.

[85 FR 77656, Dec. 2, 2020, as amended at 87 FR 72285, Nov. 23, 2022; 88 FR 59328, Aug. 28, 2023]

§411.361 Reporting requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, all entities furnishing services for which payment may be made under Medicare must submit information to CMS or to the Office of Inspector General (OIG) concerning their reportable financial relationships (as defined in paragraph (d) of this section), in the form, manner, and at the times that CMS or OIG specifies.

(b) *Exception.* The requirements of paragraph (a) of this section do not apply to entities that furnish 20 or fewer Part A and Part B services during a calendar year, or to any Medicare covered services furnished outside the United States.

(c) *Required information.* The information requested by CMS or OIG can include the following:

(1) The name and unique physician identification number (UPIN) or the national provider identifier (NPI) of each physician who has a reportable financial relationship with the entity.

(2) The name and UPIN or NPI of each physician who has an immediate family member (as defined at §411.351) who has a reportable financial relationship with the entity.

(3) The covered services furnished by the entity.

(4) With respect to each physician identified under paragraphs (c)(1) and (c)(2) of this section, the nature of the financial relationship (including the extent or value of the ownership or investment interest or the compensation arrangement) as evidenced in records that the entity knows or should know about in the course of prudently conducting business, including, but not limited to, records that the entity is already required to retain to comply with the rules of the Internal Revenue Service and the Securities and Exchange Commission and other rules of the Medicare and Medicaid programs.

(d) *Reportable financial relationships.* For purposes of this section, a reportable financial relationship is any ownership or investment interest, as defined at § 411.354(b) or any compensation arrangement, as defined at § 411.354(c), except for ownership or investment interests that satisfy the exceptions set forth in § 411.356(a) or § 411.356(b) regarding publicly traded securities and mutual funds.

(e) *Form and timing of reports.* Entities that are subject to the requirements of this section must submit the required information, upon request, within the time period specified by the request. Entities are given at least 30 days from the date of the request to provide the information. Entities must retain the information, and documentation sufficient to verify the information, for the length of time specified by the applicable regulatory requirements for the information, and, upon request, must make that information and documentation available to CMS or OIG.

(f) *Consequences of failure to report.* Any person who is required, but fails, to submit information concerning his or her financial relationships in accordance with this section is subject to a civil money penalty of up to \$10,000 as adjusted annually under 45 CFR part 102 for each day following the deadline established under paragraph (e) of this section until the information is submitted. Assessment of these penalties will comply with the applicable provisions of part 1003 of this title.

(g) *Public disclosure.* Information furnished to CMS or OIG under this section is subject to public disclosure in accordance with the provisions of part 401 of this chapter.

[72 FR 51098, Sept. 5, 2007, as amended at 80 FR 71378, Nov. 16, 2015; 81 FR 61561, Sept. 6, 2016]

§ 411.362 Additional requirements concerning physician ownership and investment in hospitals.

(a) *Definitions.* For purposes of this section—

Ownership or investment interest means for purposes of this section, a direct or indirect ownership or investment interest in a hospital.

(1) A direct ownership or investment interest in a hospital exists if the own-

ership or investment interest in the hospital is held without any intervening persons or entities between the hospital and the owner or investor.

(2) An indirect ownership or investment interest in a hospital exists if—

(i) Between the owner or investor and the hospital there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests; and

(ii) The hospital has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the owner or investor has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the hospital.

(3) An indirect ownership or investment interest in a hospital exists even though the hospital does not know, or acts in reckless disregard or deliberate ignorance of, the precise composition of the unbroken chain or the specific terms of the ownership or investment interests that form the links in the chain.

Physician owner or investor means a physician (or immediate family member of the physician) with a direct or an indirect ownership or investment interest in the hospital.

Procedure room means a room in which catheterizations, angiographies, angiograms, and endoscopies are performed, except such term shall not include an emergency room or department (exclusive of rooms in which catheterizations, angiographies, angiograms, and endoscopies are performed).

Public advertising for the hospital means any public communication paid for by the hospital that is primarily intended to persuade individuals to seek care at the hospital.

(b) *General requirements.* (1) *Physician ownership and provider agreement.* The hospital had physician ownership or investment on December 31, 2010; and a provider agreement under section 1866 of the Act in effect on that date.

(2) *Prohibition on facility expansion.* The hospital may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital is licensed on March 23, 2010 (or, in the case of a hospital that

did not have a provider agreement in effect as of this date, but does have a provider agreement in effect on December 31, 2010, the effective date of such agreement), unless an exception is approved under §411.363.

(3) *Disclosure of conflicts of interest.* (i) At such time and in such manner as specified by CMS, the hospital must submit an annual report to CMS containing a detailed description of the identity of each owner or investor in the hospital and the nature and extent of all ownership and investment interests in the hospital.

(ii) The hospital must—

(A) Require each referring physician owner or investor who is a member of the hospital's medical staff to agree, as a condition of continued medical staff membership or admitting privileges, to provide written disclosure of his or her ownership or investment interest in the hospital (and, if applicable, the ownership or investment interest of any treating physician) to all patients whom the physician refers to the hospital. Disclosure must be required by a time that permits the patient to make a meaningful decision regarding the receipt of care.

(B) Not condition any physician ownership or investment interests either directly or indirectly on the physician owner or investor making or influencing referrals to the hospital or otherwise generating business for the hospital.

(C) Disclose on any public Web site for the hospital and in any public advertising for the hospital that the hospital is owned or invested in by physicians. Any language that would put a reasonable person on notice that the hospital may be physician-owned would be deemed a sufficient statement of physician ownership or investment. For purposes of this section, a public Web site for the hospital does not include, by way of example: social media Web sites; electronic patient payment portals; electronic patient care portals; and electronic health information exchanges.

(4) *Ensuring bona fide investment.* The hospital satisfies the following criteria:

(i) The percentage of the total value of the ownership or investment inter-

ests held in the hospital, or in an entity whose assets include the hospital, by physician owners or investors in the aggregate does not exceed such percentage as of March 23, 2010.

(ii) Any ownership or investment interests that the hospital offers to a physician owner or investor are not offered on more favorable terms than the terms offered to a person who is not a physician owner or investor.

(iii) The hospital (or any owner or investor in the hospital) does not directly or indirectly provide loans or financing for any investment in the hospital by a physician owner or investor.

(iv) The hospital (or any owner or investor in the hospital) does not directly or indirectly guarantee a loan, make a payment toward a loan, or otherwise subsidize a loan, for any individual physician owner or investor or group of physician owners or investors that is related to acquiring any ownership or investment interest in the hospital.

(v) Ownership or investment returns are distributed to each owner or investor in the hospital in an amount that is directly proportional to the ownership or investment interest of such owner or investor in the hospital.

(vi) Physician owners and investors do not receive, directly or indirectly, any guaranteed receipt of or right to purchase other business interests related to the hospital, including the purchase or lease of any property under the control of other owners or investors in the hospital or located near the premises of the hospital.

(vii) The hospital does not offer a physician owner or investor the opportunity to purchase or lease any property under the control of the hospital or any other owner or investor in the hospital on more favorable terms than the terms offered to an individual who is not a physician owner or investor.

(5) *Patient safety.* The hospital satisfies the following criteria:

(i) If the hospital does not have a physician available on the premises to provide services during all hours in which the hospital is providing services to the patient, the hospital must disclose this information to the patient. Before providing services to the patient, the hospital must receive a

signed acknowledgment from the patient stating that the patient understands that a physician may not be present during all hours services are furnished to the patient.

(ii) The hospital must have the capacity to provide assessment and initial treatment for all patients, and the ability to refer and transfer patients to hospitals with the capability to treat the needs of the patient that the hospital is unable to address. For purposes of this paragraph, the hospital inpatient stay or outpatient visit begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission for inpatient care or an outpatient service.

(6) *Prohibition on conversion from an ambulatory surgery center.* The hospital must not have been converted from an ambulatory surgical center to a hospital on or after March 23, 2010.

[75 FR 72260, Nov. 24, 2010, as amended at 76 FR 74581, Nov. 30, 2011; 79 FR 67029, Nov. 10, 2014; 80 FR 71378, Nov. 16, 2015; 85 FR 86299, Dec. 29, 2020; 88 FR 59328, Aug. 28, 2023]

§ 411.363 Process for requesting an exception from the prohibition on facility expansion.

(a) *Definitions.* For purposes of this section—

Baseline number of operating rooms, procedure rooms, and beds means the number of operating rooms, procedure rooms, and beds for which the applicable hospital or high Medicaid facility is licensed as of March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of March 23, 2010, but does have a provider agreement in effect on December 31, 2010, the date of effect of such agreement). For purposes of determining the number of beds in a hospital's baseline number of operating rooms, procedure rooms, and beds, a bed is included if the bed is considered licensed for purposes of State licensure, regardless of the specific number of beds identified on the physical license issued to the hospital by the State.

External data source means a data source that—

- (i) Is generated, maintained, or under the control of a State Medicaid agency;
- (ii) Is reliable and transparent;

(iii) Maintains data that, for purposes of the process described in this section, are readily available and accessible to the requesting hospital, comparison hospitals, and CMS; and

(iv) Maintains or generates data that, for purposes of the process described in this section, are accurate, complete, and objectively verifiable.

Main campus of the hospital means “campus” as defined at § 413.65(a)(2) of this chapter.

Procedure room has the meaning set forth at § 411.362(a).

(b) *CMS consideration of requests for an exception from the prohibition on facility expansion.* (1) CMS will not consider a request for an exception from the prohibition on facility expansion from a hospital that is not eligible to request the exception.

(2) A hospital that meets the criteria for an applicable hospital or a high Medicaid facility is eligible to request an exception from the prohibition on facility expansion for consideration by CMS, provided that—

(i) CMS has not previously approved a request for an exception from the prohibition on facility expansion that would allow the hospital's number of operating rooms, procedure rooms, and beds for which the hospital is licensed to reach 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds if the full expansion is utilized; and

(ii) It has been at least 2 calendar years from the date of the most recent decision by CMS approving or denying the hospital's most recent request for an exception from the prohibition on facility expansion.

(c) *Criteria for an applicable hospital.* An applicable hospital is a hospital that meets the following criteria:

(1) *Population increase.* The hospital is located in a county that has a percentage increase in population that is at least 150 percent of the percentage increase in population of the State in which the hospital is located during the most recent 5-year period for which data are available as of the date that the hospital submits its request. To calculate State and county population growth, a hospital must use Bureau of the Census estimates.

(2) *Medicaid inpatient admissions.* The hospital has an annual percent of total inpatient admissions under Medicaid that is equal to or greater than the average percent with respect to such admissions for all hospitals (including the requesting hospital) that have Medicare participation agreements with CMS and are located in the county in which the hospital is located during the most recent 12-month period for which data are available as of the date that the hospital submits its request. For purposes of this paragraph (c)(2), the most recent 12-month period for which data are available means the most recent 12-month period for which the data source used contains all data from the requesting hospital and each other hospital that has a Medicare participation agreement with CMS and is located in the county in which the requesting hospital is located.

(i) With respect to requests submitted before October 1, 2023, a hospital may use filed Medicare hospital cost report data from the Healthcare Cost Report Information System (HCRIS) or data from an external data source (as defined in paragraph (a) of this section) to estimate its annual percent of total inpatient admissions under Medicaid and the average percent with respect to such admissions for all hospitals (including the requesting hospital) that have Medicare participation agreements with CMS and are located in the county in which the hospital is located.

(ii) With respect to requests submitted on or after October 1, 2023, a hospital may use only filed Medicare hospital cost report data from HCRIS to estimate its annual percent of total inpatient admissions under Medicaid and the average percent with respect to such admissions for all hospitals (including the requesting hospital) that have Medicare participation agreements with CMS and are located in the county in which the hospital is located.

(3) *Nondiscrimination.* The hospital does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

(4) *Average bed capacity.* The hospital is located in a State in which the aver-

age bed capacity in the State is less than the national average bed capacity during the most recent fiscal year for which HCRIS, as of the date that the hospital submits its request, contains data from a sufficient number of hospitals to determine a State's average bed capacity and the national average bed capacity.

(i) CMS will provide on its website State average bed capacities and the national average bed capacity.

(ii) For purposes of this paragraph (c)(4), *sufficient number* means the number of hospitals, as determined by CMS that would ensure that the determination under this paragraph (c)(4) would not materially change after additional hospital data are reported.

(5) *Average bed occupancy.* The hospital has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located during the most recent fiscal year for which HCRIS, as of the date that the hospital submits its request, contains data from a sufficient number of hospitals to determine the requesting hospital's average bed occupancy rate and the relevant State's average bed occupancy rate.

(i) A hospital must use filed hospital cost report data from HCRIS to determine its average bed occupancy rate.

(ii) CMS will provide on its website State average bed occupancy rates. For purposes of this paragraph (c)(5), *sufficient number* means the number of hospitals, as determined by CMS that would ensure that the determination under this paragraph (c)(5) would not materially change after additional hospital data are reported.

(6) *Hospital location.* For purposes of this paragraph (c), a hospital is located in the county and State in which the main campus of the hospital is located.

(d) *Criteria for a high Medicaid facility.* A high Medicaid facility is a hospital that meets all of the following criteria:

(1) *Sole hospital.* The hospital is not the sole hospital in the county in which the hospital is located.

(2) *Medicaid inpatient admissions.* With respect to each of the three most recent 12-month periods for which data are available as of the date the hospital submits its request, the hospital has an

annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for each other hospital that has a Medicare participation agreement with CMS and is located in the county in which the hospital is located. For purposes of this paragraph (d)(2), the most recent 12-month period for which data are available means the most recent 12-month period for which the data source used contains all data from the requesting hospital and each other hospital that has a Medicare participation agreement with CMS and is located in the county in which the requesting hospital is located.

(i) With respect to requests submitted before October 1, 2023, a hospital may use filed Medicare hospital cost report data from HCRIS or data from an external data source (as defined in paragraph (a) of this section) to estimate its annual percentage of total inpatient admissions under Medicaid and the annual percentages of total inpatient admissions under Medicaid for each other hospital that has a Medicare participation agreement with CMS and is located in the county in which the hospital is located.

(ii) With respect to requests submitted on or after October 1, 2023, a hospital may use only filed Medicare hospital cost report data from HCRIS to estimate its annual percentage of total inpatient admissions under Medicaid and the annual percentages of total inpatient admissions under Medicaid for each other hospital that has a Medicare participation agreement with CMS and is located in the county in which the hospital is located.

(3) *Nondiscrimination.* The hospital does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

(4) *Hospital location.* For purposes of this paragraph (d), a hospital is located in the county in which the main campus of the hospital is located.

(e) *Procedure for submitting a request for an exception from the prohibition on facility expansion.* (1) A hospital must submit the request for an exception from the prohibition on facility expansion

and the signed certification set forth in paragraph (e)(3) of this section electronically to CMS according to the instructions specified on the CMS website.

(2) For a hospital's request for an exception from the prohibition on facility expansion to be considered by CMS, the request must include all of the following information:

(i) The name, address, national provider identification number(s) (NPI), tax identification number (TIN), and CMS certification number (CCN) for the hospital.

(ii)(A) The name of the county in which the main campus is located; and

(B) The names of any counties in which the hospital provides inpatient or outpatient hospital services.

(iii) The name, title, daytime telephone number, electronic mail address, and hard copy mail address for the contact person who will be available to discuss the request with CMS on behalf of the hospital.

(iv)(A) A statement identifying the hospital as an applicable hospital or high Medicaid facility; and

(B) A detailed explanation with supporting documentation regarding whether and how the hospital meets each of the criteria for an applicable hospital or high Medicaid facility.

(v) A statement and supporting documentation, if available, explaining how the hospital satisfies the criterion in paragraph (c)(3) or (d)(3) of this section that it does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

(vi) Documentation supporting—

(A) The hospital's calculations of its baseline number of operating rooms, procedure rooms, and beds;

(B) The number of operating rooms, procedure rooms, and beds for which the hospital is licensed as of the date that the hospital submits a request for an exception;

(C) Whether and how the hospital has used any expansion facility capacity approved in a prior request; and

(D) The additional number of operating rooms, procedure rooms, and beds by which the hospital requests to expand.

(3) A hospital may submit other information with respect to the request, including but not limited to information regarding—

(i) Whether the hospital plans to use expansion facility capacity to provide specialty services (for example, maternity, psychiatric services, or substance use disorder care) if the request is approved; and

(ii) The current or future need, if any, for additional operating rooms, procedure rooms, and beds—

(A) For the hospital to serve Medicaid, uninsured, and underserved populations;

(B) In the county in which the main campus of the hospital is located; and

(C) In any county in which the hospital provides inpatient or outpatient hospital services as of the date the hospital submits the request.

(4) A request for an exception from the prohibition on facility expansion must include the following certification signed by an authorized representative of the hospital: “With knowledge of the penalties for false statements provided by 18 U.S.C. 1001, I certify that all of the information provided in the request and all of the documentation provided with the request is true and correct to the best of my knowledge and belief.” An authorized representative is the chief executive officer, chief financial officer, or other individual who is authorized by the hospital to make the request.

(f) *Community input.* (1) Upon submitting a request for an exception from the prohibition on facility expansion and until the hospital receives a CMS decision on the request, the hospital must disclose on any public website for the hospital that it is requesting an exception from the prohibition on facility expansion.

(2) A hospital submitting a request for an exception from the prohibition on facility expansion must provide actual notification that it is requesting an exception, in either electronic or hard copy form, directly to hospitals whose data are part of the comparisons in paragraphs (c)(2) and (d)(2) of this section.

(3)(i) Individuals and entities in the hospital’s community may provide input with respect to the hospital’s re-

quest for an exception from the prohibition on facility expansion, including, but not limited to, input regarding whether the hospital meets the criteria for an applicable hospital or a high Medicaid facility and the factors listed in paragraph (i)(2) of this section that CMS will consider in deciding whether to approve or deny a hospital’s request.

(ii) The hospital’s community includes the geographic area served by the hospital (as defined at §411.357(e)(2)) and all of the following:

(A) The county in which the hospital’s main campus is located.

(B) The counties in which the hospital provides inpatient or outpatient hospital services as of the date the hospital submits the request.

(iii) Community input must be—

(A) In the form of written comments;

(B) Submitted according to the instructions in the FEDERAL REGISTER notice of the hospital’s request; and

(C) Received no later than 60 days after CMS publishes notice of the hospital’s request in the FEDERAL REGISTER.

(iv) If CMS receives written comments from the community, the hospital has 60 days after CMS notifies the hospital of the written comments to submit a rebuttal statement.

(g) *Timing of complete request.* (1) If only filed Medicare hospital cost report data from HCRIS are used in the hospital’s request for an exception from the prohibition on facility expansion, the written comments, and the hospital’s rebuttal statement, a request will be deemed complete no later than 90 days after the end of—

(i) The 60-day comment period if CMS does not receive written comments from the community.

(ii) The 60-day rebuttal period, regardless of whether the hospital submits a rebuttal statement, if CMS receives written comments from the community.

(2) If data from an external data source are used in the hospital’s request for an exception from the prohibition on facility expansion, the written comments, or the hospital’s rebuttal statement, a request will be deemed complete no later than 180 days after the end of—

(i) The 60-day comment period if CMS does not receive written comments from the community.

(ii) The 60-day rebuttal period, regardless of whether the hospital submits a rebuttal statement, if CMS receives written comments from the community.

(h) *Determination that the hospital is an applicable hospital or a high Medicaid facility.* Based on the information described in paragraph (e) of this section and the community input described in paragraph (f) of this section, if any, CMS will first determine whether the hospital meets the criteria for an applicable hospital or a high Medicaid facility.

(i) *CMS decision to approve or deny a request for an exception from the prohibition on facility expansion—*(1) *Data and information for consideration by CMS.* In reviewing a request for an exception from the prohibition on facility expansion, CMS—

(i) Will consider data and information provided by the hospital in its request, included in the community input, if any, and provided by the hospital in its rebuttal statement, if any; and

(ii) May also consider any other data and information relevant to its decision.

(2) *Factors considered by CMS.* Factors that CMS will consider in deciding whether to approve or deny a hospital's request for an exception from the prohibition on facility expansion include but are not limited to the following:

(i) The specialty (for example, maternity, psychiatric, or substance use disorder care) of the hospital or the services furnished by or to be furnished by the hospital if CMS approves the request.

(ii) Program integrity or quality of care concerns related to the hospital.

(iii) Whether the hospital has a need for additional operating rooms, procedure rooms, or beds.

(iv) Whether there is a need for additional operating rooms, procedure rooms, or beds in the county in which the main campus of the hospital is located or in any county in which the hospital provides inpatient or outpatient hospital services as of the date the hospital submits the request.

(j) *Permitted increase in facility capacity.* (1) Except as provided in paragraph (j)(2) of this section, a permitted increase under this section—

(i) May not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed exceeding 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds; and

(ii) May occur only in facilities on the hospital's main campus.

(2) The limitations of paragraph (j)(1) of this section do not apply to an increase in facility capacity approved by CMS with respect to a request for an exception from the prohibition on facility expansion submitted by a high Medicaid facility between January 1, 2021, and September 30, 2023.

(k) *Publication of final determination and decision.* Not later than 60 days after receiving a complete request—

(1) If CMS determines that the hospital does not meet the criteria for an applicable hospital or a high Medicaid facility, CMS will publish in the FEDERAL REGISTER notice of such determination; or

(2) If CMS determines that the hospital meets the criteria for an applicable hospital or a high Medicaid facility, CMS will publish in the FEDERAL REGISTER notice of such determination and its decision regarding the hospital's request for an exception from the prohibition on facility expansion.

(l) *Limitation on review.* There shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the process under this section (including the establishment of such process and any CMS determination or decision under such process).

[88 FR 59328, Aug. 28, 2023]

§ 411.370 Advisory opinions relating to physician referrals.

(a) *Period during which CMS accepts requests.* The provisions of § 411.370 through § 411.389 apply to requests for advisory opinions that are submitted to CMS during any time period in which CMS is required by law to issue the advisory opinions described in this subpart.

(b) *Matters that qualify for advisory opinions and who may request one.* Any

individual or entity may request a written advisory opinion from CMS concerning whether a physician's referral relating to designated health services (other than clinical laboratory services) is prohibited under section 1877 of the Act. In the advisory opinion, CMS will determine whether a business arrangement described by the parties to that arrangement appears to constitute a "financial relationship" (as defined in section 1877(a)(2) of the Act) that could potentially restrict a physician's referrals, and whether the arrangement or the designated health services at issue appear to qualify for any of the exceptions to the referral prohibition described in section 1877 of the Act.

(1) The request must relate to an existing arrangement or one into which the requestor, in good faith, specifically plans to enter. The planned arrangement may be contingent upon the party or parties receiving a favorable advisory opinion. CMS does not consider, for purposes of an advisory opinion, requests that involve the activities of third parties.

(2) The requestor must be a party to the existing or proposed arrangement.

(c) *Matters not subject to advisory opinions.* CMS will not address through an advisory opinion—

(1) Whether the fair market value was, or will be, paid or received for any goods, services, or property; and

(2) Whether an individual is a *bona fide* employee within the requirements of section 3121(d)(2) of the Internal Revenue Code of 1986.

(d) *Facts subject to advisory opinions.* The requestor must include in the advisory opinion request a complete description of the arrangement that the requestor is undertaking, or plans to undertake, as described in §411.372.

(e) *Acceptance of requests.* (1) CMS does not accept an advisory opinion request or issue an advisory opinion if—

(i) The request is not related to a named individual or entity;

(ii) The request does not describe the arrangement at issue with a level of detail sufficient for CMS to issue an opinion, and the requestor does not timely respond to CMS requests for additional information;

(iii) CMS is aware, after consultation with OIG and DOJ, that the same course of action is under investigation, or is or has been the subject of a proceeding involving the Department of Health and Human Services or another governmental agency;

(iv) CMS believes that it cannot make an informed opinion or could only make an informed opinion after extensive investigation, clinical study, testing, or collateral inquiry; or

(v) CMS determines that the arrangement or course of conduct at issue is or would be in violation of applicable State or Federal law or regulation.

(2) CMS may elect not to accept an advisory opinion request if it determines, after consultation with OIG and DOJ:

(i) The course of action described is substantially similar to a course of conduct that is under investigation or the subject of a proceeding involving the Department or other law enforcement agencies; and

(ii) Issuing an advisory opinion could interfere with the investigation or proceeding.

(f) *Effects of an advisory opinion on other Governmental authority.* Nothing in this part limits the investigatory or prosecutorial authority of the OIG, the Department of Justice, or any other agency of the Government. In addition, in connection with any request for an advisory opinion, CMS, the OIG, or the Department of Justice may conduct whatever independent investigation it believes appropriate.

[69 FR 57227, Sept. 24, 2004, as amended at 72 FR 51098, Sept. 5, 2007; 84 FR 63191, Nov. 15, 2019]

§411.372 Procedure for submitting a request.

(a) *Format for a request.* A party or parties must submit a request for an advisory opinion to CMS according to the instructions specified on the CMS Web site.

(b) *Information CMS requires with all submissions.* The request must include the following:

(1) The name, address, telephone number, and Taxpayer Identification Number of the requestor.

(2) The names and addresses, to the extent known, of all other actual and

potential parties to the arrangement that is the subject of the request.

(3) The name, title, address, and daytime telephone number of a contact person who will be available to discuss the request with CMS on behalf of the requestor.

(4) A complete and specific description of all relevant information bearing on the arrangement, including—

(i) A complete description of the arrangement that the requestor is undertaking, or plans to undertake, including:

(A) The purpose of the arrangement; the nature of each party's (including each entity's) contribution to the arrangement; the direct or indirect relationships between the parties, with an emphasis on the relationships between physicians involved in the arrangement (or their immediate family members who are involved); and

(B) Any entities that provide designated health services; the types of services for which a physician wishes to refer, and whether the referrals will involve Medicare or Medicaid patients;

(ii) Complete copies of all relevant documents or relevant portions of documents that affect or could affect the arrangement, such as personal service or employment contracts, leases, deeds, pension or insurance plans, or financial statements (or, if these relevant documents do not yet exist, a complete description, to the best of the requestor's knowledge, of what these documents are likely to contain);

(iii) Detailed statements of all collateral or oral understandings, if any; and

(iv) Descriptions of any other arrangements or relationships that could affect CMS's analysis.

(5) The identity of all entities involved either directly or indirectly in the arrangement, including their names, addresses, legal form, ownership structure, nature of the business (products and services) and, if relevant, their Medicare and Medicaid provider numbers. The requestor must also include a brief description of any other entities that could affect the outcome of the opinion, including those with which the requestor, the other parties, or the immediate family members of involved physicians, have any financial relationships (either direct or indirect,

and as defined in section 1877(a)(2) of the Act and § 411.354), or in which any of the parties holds an ownership or control interest as defined in section 1124(a)(3) of the Act.

(6) At the option of the requestor, a discussion of the specific issues or questions to be addressed by CMS including, if possible, a discussion of why the requestor believes the referral prohibition in section 1877 of the Act might or might not be triggered by the arrangement and which, if any, exceptions the requestor believes might apply. The requestor should attempt to designate which facts are relevant to each issue or question raised in the request and should cite the provisions of law under which each issue or question arises.

(7) An indication of whether the parties involved in the request have also asked for or are planning to ask for an advisory opinion on the arrangement in question from the OIG under section 1128D(b) of the Act (42 U.S.C. 1320a–7d(b)) and whether the arrangement is or is not, to the best of the requestor's knowledge, the subject of an investigation.

(8) The certification(s) described in § 411.373. The certification(s) must be signed by—

(i) The requestor, if the requestor is an individual;

(ii) The chief executive officer, or other authorized officer, of the requestor, if the requestor is a corporation;

(iii) The managing partner of the requestor, if the requestor is a partnership; or

(iv) A managing member, if the requestor is a limited liability company.

(c) *Additional information CMS might require.* If the request does not contain all of the information required by paragraph (b) of this section, or, if either before or after accepting the request, CMS believes it needs more information in order to render an advisory opinion, it may request whatever additional information or documents it deems necessary. Additional information must be provided in writing, signed by the same person who signed the initial request (or by an individual in a comparable position), and be certified as described in § 411.373.

(d) *Requests for expedited review.* Parties may seek expedited review of arrangements under §411.380(c)(1)(i) for a determination as to whether the arrangement or course of conduct is indistinguishable in all material aspects from an arrangement or course of conduct that was the subject of a prior advisory opinion. Parties seeking such expedited review must identify the relevant advisory opinion and provide an explanation of why the subject arrangement is indistinguishable from the arrangement that was the subject of the prior relevant advisory opinion. Requestors should clearly and prominently indicate in their submission to CMS that they are seeking expedited review.

[69 FR 57227, Sept. 24, 2004, as amended at 81 FR 80553, Nov. 15, 2016; 84 FR 63191, Nov. 15, 2019]

§411.373 Certification.

(a) Every request must include the following signed certification: “With knowledge of the penalties for false statements provided by 18 U.S.C. 1001 and with knowledge that this request for an advisory opinion is being submitted to the Department of Health and Human Services, I certify that all of the information provided is true and correct, and constitutes a complete description of the facts regarding which an advisory opinion is sought, to the best of my knowledge and belief.”

(b) If the advisory opinion relates to a proposed arrangement, in addition to the certification required by paragraph (a) of this section, the following certification must be included and signed by the requestor: “The arrangement described in this request for an advisory opinion is one into which [the requestor], in good faith, plans to enter.” This statement may be made contingent on a favorable advisory opinion, in which case the requestor should add one of the following phrases to the certification:

(1) “if CMS issues a favorable advisory opinion.”

(2) “if CMS and the OIG issue favorable advisory opinions.”

[69 FR 57227, Sept. 24, 2004]

§411.375 Fees for the cost of advisory opinions.

(a) *Hourly rate.* CMS will charge an hourly rate of \$220. Parties may request an estimate from CMS after submitting a complete request. Before issuing the advisory opinion, CMS will calculate the final fee for responding to the request.

(b) *Agreement to pay all costs.* (1) By submitting the request for an advisory opinion, the requestor agrees, except as indicated in paragraph (c)(3) of this section, to pay all costs the Department incurs in responding to the request for an advisory opinion.

(2) In its request for an advisory opinion, the requestor may designate a triggering dollar amount. If CMS estimates that the costs of processing the advisory opinion request have reached or are likely to exceed the designated triggering dollar amount, CMS notifies the requestor.

(3) If CMS notifies the requestor that the actual or estimated cost of processing the request has reached or is likely to exceed the triggering dollar amount, CMS stops processing the request until the requestor makes a written request for CMS to continue. If CMS is delayed in processing the request for an advisory opinion because of this procedure, the time within which CMS must issue an advisory opinion is suspended until the requestor asks CMS to continue working on the request.

(4) If the requestor chooses not to pay for CMS to complete an advisory opinion, or withdraws the request, the requestor is still obligated to pay for all costs CMS has identified as costs it incurred in processing the request for an advisory opinion, up to that point.

(5) If the costs CMS has incurred in responding to the request are greater than the amount the requestor has paid, CMS, before issuing the advisory opinion, notifies the requestor of any additional amount that is due. CMS does not issue an advisory opinion until the requestor has paid the full amount that is owed. Once the requestor has paid CMS the total amount due for the costs of processing the request, CMS issues the advisory opinion. The time period CMS has for issuing advisory opinions is suspended from

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the time CMS notifies the requestor of the amount owed until the time CMS receives full payment.

(c) *Fees for outside experts.* (1) In addition to the fees identified in this section, the requestor also must pay any required fees for expert opinions, if any, from outside sources, as described in § 411.377.

(2) The time period for issuing an advisory opinion is suspended from the time that CMS notifies the requestor that it needs an outside expert opinion until the time CMS receives that opinion.

[69 FR 57228, Sept. 24, 2004, as amended at 84 FR 63192, Nov. 15, 2019]

§ 411.377 Expert opinions from outside sources.

(a) CMS may request expert advice from qualified sources if CMS believes that the advice is necessary to respond to a request for an advisory opinion. For example, CMS may require the use of accountants or business experts to assess the structure of a complex business arrangement or to ascertain a physician's or immediate family member's financial relationship with entities that provide designated health services.

(b) If CMS determines that it needs to obtain expert advice in order to issue a requested advisory opinion, CMS notifies the requestor of that fact and provides the identity of the appropriate expert and an estimate of the costs of the expert advice. As indicated in § 411.375(d), the requestor must pay the estimated cost of the expert advice.

(c) Once CMS has received payment for the estimated cost of the expert advice, CMS arranges for the expert to provide a prompt review of the issue or issues in question. CMS considers any additional expenses for the expert advice, beyond the estimated amount, as part of the costs CMS has incurred in responding to the request, and the responsibility of the requestor, as described in § 411.375(c).

[69 FR 57229, Sept. 24, 2004]

§ 411.378 Withdrawing a request.

The party requesting an advisory opinion may withdraw the request before CMS issues a formal advisory opinion.

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ion. This party must submit the withdrawal in writing to the same address as the request, as indicated in § 411.372(a). Even if the party withdraws the request, the party must pay the costs the Department has expended in processing the request, as discussed in § 411.375. CMS reserves the right to keep any request for an advisory opinion and any accompanying documents and information, and to use them for any governmental purposes permitted by law.

[69 FR 57229, Sept. 24, 2004]

§ 411.379 When CMS accepts a request.

(a) Upon receiving a request for an advisory opinion, CMS promptly makes an initial determination of whether the request contains a level of detail sufficient for CMS to process the request.

(b) If CMS determines that the request submitted lacks details necessary for CMS to process the request, CMS will provide notification to the requestor within 15 working days of receiving the request.

(c) If the requestor provides the additional information CMS has requested, or otherwise resubmits the request, CMS processes the resubmission in accordance with paragraphs (a) and (b) of this section as if it were an initial request for an advisory opinion.

(d) CMS formally accepts a request when CMS determines that the request (inclusive of any supplemental submissions) describes the arrangement at issue with sufficient detail and that the grounds for rejection of a request listed at § 411.370(e) do not apply. Upon accepting the request, CMS notifies the requestor by regular U.S. mail of the date that CMS formally accepts the request.

(e) The applicable time period that CMS has to issue an advisory opinion set forth in § 411.380(c) does not begin until CMS formally accepts the request for an advisory opinion.

[69 FR 57229, Sept. 24, 2004, as amended at 84 FR 63192, Nov. 15, 2019]

§ 411.380 When CMS issues a formal advisory opinion.

(a) CMS considers an advisory opinion to be issued once it has received payment and once the opinion has been

dated, numbered, and signed by an authorized CMS official.

(b) An advisory opinion contains a description of the material facts known to CMS that relate to the arrangement that is the subject of the advisory opinion, and states CMS's opinion about the subject matter of the request based on those facts. If necessary, CMS includes in the advisory opinion material facts that could be considered confidential information or trade secrets within the meaning of 18 U.S.C. 1095.

(c)(1) Except as set forth in paragraph (c)(2) of this section, CMS issues an advisory opinion in accordance with the provisions of this part within 60 working days after the date on which it formally accepts the advisory opinion request.

(i) In the case of a request for a determination that an arrangement or course of conduct is indistinguishable in all material aspects from another arrangement or course of conduct that was the subject of a prior opinion, CMS issues an advisory opinion within 30 working days after the date on which it formally accepts the advisory opinion request.

(ii) In the case of a request that CMS determines, in its discretion, involves complex legal issues or highly complicated fact patterns, CMS issues an advisory opinion within a reasonable time period after the date on which it formally accepts the advisory opinion request.

(iii) If the last day of the 60-working day or 30-working day time period falls on a Saturday, Sunday, or Federal holiday, CMS may issue the advisory opinion at the close of business on the first business day following the weekend or holiday.

(2) The applicable time period for issuing an advisory opinion is suspended from the time CMS;

(i) Notifies the requestor that the costs have reached or are likely to exceed the triggering amount as described in §411.375(c)(2) until CMS receives written notice from the requestor to continue processing the request;

(ii) Requests additional information from the requestor until CMS receives the additional information;

(iii) Notifies the requestor of the full amount due until CMS receives payment of this amount; and

(iv) Notifies the requestor of the need for expert advice until CMS receives the expert advice.

(d) After CMS has notified the requestor of the full amount owed and has received full payment of that amount, CMS issues the advisory opinion and promptly mails it to the requestor by regular first class U.S. mail.

[69 FR 57229, Sept. 24, 2004, as amended at 84 FR 63192, Nov. 15, 2019]

§411.382 CMS' right to rescind advisory opinions.

(a)(1) Any advice CMS gives in an advisory opinion does not prejudice its right to reconsider the questions involved in the opinion, and CMS may rescind or revoke the opinion if it determines that there is good cause to rescind or revoke the opinion.

(2) Good cause shall exist where—

(i) There is a material change in the law that affects the conclusions reached in an opinion; or

(ii) A party that has received a negative advisory opinion seeks reconsideration based on new facts or law.

(b) CMS provides advance notice to the requestor and to the public of its decision to rescind or revoke the opinion so that the requestor and other parties may discontinue any course of action they have taken in accordance with, or in good faith reliance on, the advisory opinion.

(c) CMS does not proceed against the requestor with respect to any action the requestor and the involved parties have taken in good faith reliance upon CMS' advice under this part, provided—

(1) The requestor presented to CMS a full, complete and accurate description of all the relevant facts; and

(2) The parties promptly discontinue the action upon receiving notice that CMS had rescinded or revoked its approval, or discontinue the action within a reasonable "wind down" period, as determined by CMS.

[84 FR 63193, Nov. 15, 2019]

§411.384 Disclosing advisory opinions and supporting information.

(a) Advisory opinions that CMS issues and releases in accordance with

§ 411.386

the procedures set forth in this subpart are available to the public.

(b) Promptly after CMS issues an advisory opinion and releases it to the requestor, CMS makes available a copy of the advisory opinion on the CMS Web site.

(c) Any predecisional document, or part of such predecisional document, that is prepared by CMS, the Department of Justice, or any other Department or agency of the United States in connection with an advisory opinion request under the procedures set forth in this part is exempt from disclosure under 5 U.S.C. 552, and will not be made publicly available.

(d) Documents submitted by the requestor to CMS in connection with a request for an advisory opinion are available to the public to the extent they are required to be made available by 5 U.S.C. 552, through procedures set forth in 45 CFR part 5.

(e) Nothing in this section limits CMS's obligation, under applicable laws, to publicly disclose the identity of the requesting party or parties, and the nature of the action CMS has taken in response to the request.

[69 FR 57230, Sept. 24, 2004, as amended at 80 FR 71379, Nov. 16, 2015; 84 FR 63193, Nov. 15, 2019]

§ 411.386 CMS's advisory opinions as exclusive.

The procedures described in this subpart constitute the only method by which any individuals or entities can obtain a binding advisory opinion on the subject of a physician's referrals, as described in § 411.370. CMS has not and does not issue a binding advisory opinion on the subject matter in § 411.370, in either oral or written form, except through written opinions it issues in accordance with this subpart.

[69 FR 57230, Sept. 24, 2004]

§ 411.387 Effect of an advisory opinion.

(a) An advisory opinion is binding on the Secretary, and a favorable advisory opinion shall preclude imposition of sanctions under section 1877(g) of the Act with respect to:

(1) The individuals or entities requesting the opinion; and

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(2) Individuals or entities that are parties to the specific arrangement with respect to which such advisory opinion has been issued.

(b) The Secretary will not pursue sanctions under section 1877(g) of the Act against any party to an arrangement that CMS determines is indistinguishable in all its material aspects from an arrangement with respect to which CMS issued a favorable advisory opinion.

(c) Individuals and entities may rely on an advisory opinion as non-binding guidance that illustrates the application of the physician self-referral law and regulations to the specific facts and circumstances described in the advisory opinion.

[84 FR 63193, Nov. 15, 2019]

§ 411.388 When advisory opinions are not admissible evidence.

The failure of a party to seek or to receive an advisory opinion may not be introduced into evidence to prove that the party either intended or did not intend to violate the provisions of sections 1128, 1128A or 1128B of the Act.

[69 FR 57230, Sept. 24, 2004]

§ 411.389 Range of the advisory opinion.

(a) An advisory opinion states only CMS's opinion regarding the subject matter of the request. If the subject of an advisory opinion is an arrangement that must be approved by or is regulated by any other agency, CMS's advisory opinion cannot be read to indicate CMS's views on the legal or factual issues that may be raised before that agency.

(b) An advisory opinion that CMS issues under this part does not bind or obligate any agency other than the Department. It does not affect the requestor's, or anyone else's, obligations to any other agency, or under any statutory or regulatory provision other than that which is the specific subject matter of the advisory opinion.

[69 FR 57230, Sept. 24, 2004]

Subpart K—Payment for Certain Excluded Services

§ 411.400 Payment for custodial care and services not reasonable and necessary.

(a) *Conditions for payment.* Notwithstanding the exclusions set forth in § 411.15 (g) and (k). Medicare pays for “custodial care” and “services not reasonable and necessary” if the following conditions are met:

(1) The services were furnished by a provider or by a practitioner or supplier that had accepted assignment of benefits for those services.

(2) Neither the beneficiary nor the provider, practitioner, or supplier knew, or could reasonably have been expected to know, that the services were excluded from coverage under § 411.15 (g) or (k).

(b) *Time limits on payment*—(1) *Basic rule.* Except as provided in paragraph (b)(2) of this section, payment may not be made for inpatient hospital care, posthospital SNF care, or home health services furnished after the earlier of the following:

(i) The day on which the beneficiary has been determined, under § 411.404, to have knowledge, actual or imputed, that the services were excluded from coverage by reason of § 411.15(g) or § 411.15(k).

(ii) The day on which the provider has been determined, under § 411.406 to have knowledge, actual or imputed, that the services are excluded from coverage by reason of § 411.15(g) or § 411.15(k).

(2) *Exception.* Payment may be made for services furnished during the first day after the limit established in paragraph (b)(1) of this section, if the QIO or the intermediary determines that the additional period of one day is necessary for planning post-discharge care. If the QIO or the intermediary determines that yet another day is necessary for planning post-discharge care, payment may be made for services furnished during the second day after the limit established in paragraph (b)(1) of this section.

§ 411.402 Indemnification of beneficiary.

(a) *Conditions for indemnification.* If Medicare payment is precluded because the conditions of § 411.400(a)(2) are not met. Medicare indemnifies the beneficiary (and recovers from the provider, practitioner, or supplier), if the following conditions are met:

(1) The beneficiary paid the provider, practitioner, or supplier some or all of the charges for the excluded services.

(2) The beneficiary did not know and could not reasonably have been expected to know that the services were not covered.

(3) The provider, practitioner, or supplier knew, or could reasonably have been expected to know that the services were not covered.

(4) The beneficiary files a proper request for indemnification before the end of the sixth month after whichever of the following is later:

(i) The month in which the beneficiary paid the provider, practitioner, or supplier.

(ii) The month in which the intermediary or carrier notified the beneficiary (or someone on his or her behalf) that the beneficiary would not be liable for the services.

For good cause shown by the beneficiary, the 6-month period may be extended.

(b) *Amount of indemnification.*¹ The amount of indemnification is the total that the beneficiary paid the provider, practitioner, or supplier.

(c) *Effect of indemnification.* The amount of indemnification is considered an overpayment to the provider, practitioner, or supplier, and as such is recoverable under this part or in accordance with other applicable provisions of law.

¹For services furnished before 1988, the indemnification amount was reduced by any deductible or coinsurance amounts that would have been applied if the services had been covered.

§ 411.404 Criteria for determining that a beneficiary knew that services were excluded from coverage as custodial care or as not reasonable and necessary.

(a) *Basic rule.* A beneficiary who receives services that constitute custodial care under § 411.15(g) or that are not reasonable and necessary under § 411.15(k), is considered to have known that the services were not covered if the criteria of paragraphs (b) and (c) of this section are met.

(b) *Written notice.* (1) Written notice is given to the beneficiary, or to someone acting on his or her behalf, that the services were not covered because they did not meet Medicare coverage guidelines.

(2) A notice concerning similar or reasonably comparable services furnished on a previous occasion also meets this criterion.

(3) After a beneficiary is notified that there is no Medicare payment for a service that is not covered by Medicare, he or she is presumed to know that there is no Medicare payment for any form of subsequent treatment for the non-covered condition.

(c) *Source of notice.* The notice was given by one of the following:

(1) The QIO, intermediary, or carrier.
(2) The group or committee responsible for utilization review for the provider that furnished the services.

(3) The provider, practitioner, or supplier that furnished the service.

[54 FR 41734, Oct. 11, 1989, as amended at 69 FR 66423, Nov. 15, 2004]

§ 411.406 Criteria for determining that a provider, practitioner, or supplier knew that services were excluded from coverage as custodial care or as not reasonable and necessary.

(a) *Basic rule.* A provider, practitioner, or supplier that furnished services which constitute custodial care under § 411.15(g) or that are not reasonable and necessary under § 411.15(k) is considered to have known that the services were not covered if any one of the conditions specified in paragraphs (b) through (e) of this section is met.

(b) *Notice from the QIO, intermediary or carrier.* The QIO, intermediary, or carrier had informed the provider, practitioner, or supplier that the serv-

ices furnished were not covered, or that similar or reasonably comparable services were not covered.

(c) *Notice from the utilization review committee or the beneficiary's attending physician.* The utilization review group or committee for the provider or the beneficiary's attending physician had informed the provider that these services were not covered.

(d) *Notice from the provider, practitioner, or supplier to the beneficiary.* Before the services were furnished, the provider, practitioner or supplier informed the beneficiary that—

(1) The services were not covered; or
(2) The beneficiary no longer needed covered services.

(e) *Knowledge based on experience, actual notice, or constructive notice.* It is clear that the provider, practitioner, or supplier could have been expected to have known that the services were excluded from coverage on the basis of the following:

(1) Its receipt of CMS notices, including manual issuances, bulletins, or other written guides or directives from intermediaries, carriers, or QIOs, including notification of QIO screening criteria specific to the condition of the beneficiary for whom the furnished services are at issue and of medical procedures subject to preadmission review by a QIO.

(2) FEDERAL REGISTER publications containing notice of national coverage decisions or of other specifications regarding noncoverage of an item or service.

(3) Its knowledge of what are considered acceptable standards of practice by the local medical community.

[54 FR 41734, Oct. 11, 1989, as amended at 60 FR 48425, Sept. 19, 1995]

§ 411.408 Refunds of amounts collected for physician services not reasonable and necessary, payment not accepted on an assignment-related basis.

(a) *Basic rule.* Except as provided in paragraph (d) of this section, a physician who furnishes a beneficiary services for which the physician does not undertake to claim payment on an assignment-related basis must refund any amounts collected from the beneficiary for services otherwise covered if

Medicare payment is denied because the services are found to be not reasonable and necessary under §411.15(k).

(b) *Time limits for making refunds.* A timely refund of any incorrectly collected amounts of money must be made to the beneficiary to whom the services were furnished. A refund is timely if—

(1) A physician who does not request a review within 30 days after receipt of the denial notice makes the refund within that time period; or

(2) A physician who files a request for review within 30 days after receipt of the denial notice makes the refund within 15 days after receiving notice of an initial adverse review determination, whether or not the physician further appeals the initial adverse review determination.

(c) *Notices and appeals.* If payment is denied for nonassignment-related claims because the services are found to be not reasonable and necessary, a notice of denial will be sent to both the physician and the beneficiary. The physician who does not accept assignment will have the same rights as a physician who submits claims on an assignment-related basis, as detailed in subpart H of part 405 and subpart B of part 473, to appeal the determination, and will be subject to the same time limitations.

(d) *When a refund is not required.* A refund of any amounts collected for services not reasonable and necessary is not required if—

(1) The physician did not know, and could not reasonably have been expected to know, that Medicare would not pay for the service; or

(2) Before the service was provided—

(i) The physician informed the beneficiary, or someone acting on the beneficiary's behalf, in writing that the physician believed Medicare was likely to deny payment for the specific service; and

(ii) The beneficiary (or someone eligible to sign for the beneficiary under §424.36(b) of this chapter) signed a statement agreeing to pay for that service.

(e) *Criteria for determining that a physician knew that services were excluded as not reasonable and necessary.* A physician will be determined to have known that furnished services were excluded

from coverage as not reasonable and necessary if one or more of the conditions in §411.406 of this subpart are met.

(f) *Acceptable evidence of prior notice to a beneficiary that Medicare was likely to deny payment for a particular service.* To qualify for waiver of the refund requirement under paragraph (d)(2) of this section, the physician must inform the beneficiary (or person acting on his or her behalf) that the physician believes Medicare is likely to deny payment.

(1) The notice must—

(i) Be in writing, using approved notice language;

(ii) Cite the particular service or services for which payment is likely to be denied; and

(iii) Cite the physician's reasons for believing Medicare payment will be denied.

(2) The notice is not acceptable evidence if—

(i) The physician routinely gives this notice to all beneficiaries for whom he or she furnishes services; or

(ii) The notice is no more than a statement to the effect that there is a possibility that Medicare may not pay for the service.

(g) *Applicability of sanctions to physicians who fail to make refunds under this section.* A physician who knowingly and willfully fails to make refunds as required by this section may be subject to sanctions as provided for in chapter V, parts 1001, 1002, and 1003 of this title.

[55 FR 24568, June 18, 1990; 55 FR 35142, 35143, Aug. 28, 1990]

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

Subpart A—General Provisions

Sec.

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