

(A) The name, address, telephone number, and health insurance claim number of the beneficiary.

(B) The date the complaint was received; the name of the person receiving the services; and a summary of actions taken to resolve the complaint.

(C) If an investigation was not conducted, the name of the person making the decision and the reason for the decision.

(ii) Paragraph (g)(8)(i) of this section does not apply to IDTFs that only perform services that do not require direct or in-person beneficiary interaction, treatment, or testing.

(9) Openly post these standards for review by patients and the public. (This requirement does not apply to IDTFs that only perform services that do not require direct or in-person beneficiary interaction, treatment, or testing.)

(10) Disclose to the government any person having ownership, financial, or control interest or any other legal interest in the supplier at the time of enrollment or within 30 days of a change.

(11) Have its testing equipment calibrated and maintained per equipment instructions and in compliance with applicable manufacturers suggested maintenance and calibration standards.

(12) Have technical staff on duty with the appropriate credentials to perform tests. The IDTF must be able to produce the applicable Federal or State licenses or certifications of the individuals performing these services.

(13) Have proper medical record storage and be able to retrieve medical records upon request from CMS or its fee-for-service contractor within 2 business days.

(14) Permit CMS, including its agents, or its designated fee-for-service contractors, to conduct unannounced, on-site inspections to confirm the IDTF's compliance with these standards. The IDTF must—

(i) Be accessible during regular business hours to CMS and beneficiaries; and

(ii) Maintain a visible sign posting its normal business hours.

(15) With the exception of hospital-based and mobile IDTFs, a fixed-base IDTF is prohibited from the following:

(i) Sharing a practice location with another Medicare-enrolled individual or organization;

(ii) Leasing or subleasing its operations or its practice location to another Medicare-enrolled individual or organization; or

(iii) Sharing diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization.

(16) Enrolls for any diagnostic testing services that it furnishes to a Medicare beneficiary, regardless of whether the service is furnished in a mobile or fixed base location.

(17) Bills for all mobile diagnostic services that are furnished to a Medicare beneficiary, unless the mobile diagnostic service is part of a service provided under arrangement as described in section 1861(w)(1) of the Act.

(h) *Failure to meet standards.* If an IDTF fails to meet one or more of the standards in paragraph (g) of this section at the time of enrollment, its enrollment will be denied. CMS will revoke a supplier's billing privileges if and IDTF is found not to meet the standards in paragraph (g) or (b)(1) of this section.

(i) *Effective date of billing privileges.* The filing date of the Medicare enrollment application is the date that the Medicare contractor receives a signed provider enrollment application that it is able to process to approval. The effective date of billing privileges for a newly enrolled IDTF is the later of the following:

(1) The filing date of the Medicare enrollment application that was subsequently approved by a Medicare fee-for-service contractor; or

(2) The date the IDTF first started furnishing services at its new practice location.

[62 FR 59099, Oct. 31, 1997, as amended at 64 FR 59440, Nov. 2, 1999; 71 FR 69784, Dec. 1, 2006; 72 FR 18914, Apr. 16, 2007; 72 FR 66398, Nov. 27, 2007; 73 FR 2432, Jan. 15, 2008; 73 FR 69933, Nov. 19, 2008; 73 FR 80304, Dec. 31, 2008; 86 FR 65662, Nov. 19, 2021; 88 FR 79526, Nov. 16, 2023]

#### **§ 410.34 Mammography services: Conditions for and limitations on coverage.**

(a) *Definitions.* As used in this section, the following definitions apply:

(1) *Diagnostic mammography* means a radiologic procedure furnished to a man or woman with signs or symptoms of breast disease, or a personal history of breast cancer, or a personal history of biopsy-proven benign breast disease, and includes a physician's interpretation of the results of the procedure.

(2) *Screening mammography* means a radiologic procedure furnished to a woman without signs or symptoms of breast disease, for the purpose of early detection of breast cancer, and includes a physician's interpretation of the results of the procedure.

(3) *Supplier of diagnostic mammography* means a facility that is certified and responsible for ensuring that all diagnostic mammography services furnished to Medicare beneficiaries meet the conditions for coverage of diagnostic mammography services as specified in paragraph (b) of this section.

(4) *Supplier of screening mammography* means a facility that is certified and responsible for ensuring that all screening mammography services furnished to Medicare beneficiaries meet the conditions and limitations for coverage of screening mammography services as specified in paragraphs (c) and (d) of this section.

(5) *Certificate* means the certificate described in 21 CFR 900.2(b) that may be issued to, or renewed for, a facility that meets the requirements for conducting an examination or procedure involving mammography.

(6) *Provisional certificate* means the provisional certificate described in 21 CFR 900.2(m) that may be issued to a facility to enable the facility to qualify to meet the requirements for conducting an examination or procedure involving mammography.

(7) The term *meets the certification requirements of section 354 of the Public Health Service (PHS) Act* means that in order to qualify for coverage of its services under the Medicare program, a supplier of diagnostic or screening mammography services must meet the following requirements:

(i) Must have a valid provisional certificate, or a valid certificate, that has been issued by FDA indicating that the supplier meets the certification requirements of section 354 of the PHS

Act, as implemented by 21 CFR part 900, subpart B.

(ii) Has not been issued a written notification by FDA that states that the supplier must cease conducting mammography examinations because the supplier is not in compliance with certain critical certification requirements of section 354 of the PHS Act, implemented by 21 CFR part 900, subpart B.

(iii) Must not employ for provision of the professional component of mammography services a physician or physicians for whom the facility has received written notification by FDA that the physician (or physicians) is (or are) in violation of the certification requirements set forth in section 354 of the PHS Act, as implemented by 21 CFR 900.12(a)(1)(i).

(b) *Conditions for coverage of diagnostic mammography services.* Medicare Part B pays for diagnostic mammography services if they meet the following conditions:

(1) They are ordered by a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act).

(2) They are furnished by a supplier of diagnostic mammography services that meets the certification requirements of section 354 of the PHS Act, as implemented by 21 CFR part 900, subpart B.

(c) *Conditions for coverage of screening mammography services.* Medicare Part B pays for screening mammography services if they are furnished by a supplier of screening mammography services that meets the certification requirements of section 354 of the PHS Act, as implemented by 21 CFR part 900, subpart B.

(d) *Limitations on coverage of screening mammography services.* The following limitations apply to coverage of screening mammography services as described in paragraphs (c) and (d) of this section:

(1) The service must be, at a minimum a two-view exposure (that is, a cranio-caudal and a medial lateral oblique view) of each breast.

(2) Payment may not be made for screening mammography performed on a woman under age 35.

(3) Payment may be made for only 1 screening mammography performed on a woman over age 34, but under age 40.

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(4) For an asymptomatic woman over 39 years of age, payment may be made for a screening mammography performed after at least 11 months have passed following the month in which the last screening mammography was performed.

[59 FR 49833, Sept. 30, 1994, as amended at 60 FR 14224, Mar. 16, 1995; 60 FR 63176, Dec. 8, 1995; 62 FR 59100, Oct. 31, 1997; 63 FR 4596, Jan. 30, 1998]

### § 410.35 X-ray therapy and other radiation therapy services: Scope.

Medicare Part B pays for X-ray therapy and other radiation therapy services, including radium therapy and radioactive isotope therapy, and materials and the services of technicians administering the treatment.

[51 FR 41339, Nov. 14, 1986. Redesignated at 55 FR 53522, Dec. 31, 1990]

### § 410.36 Medical supplies, appliances, and devices: Scope.

(a) Medicare Part B pays for the following medical supplies, appliances and devices:

(1) Surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations.

(2) Prosthetic devices, other than dental, that replace all or part of an internal body organ, including colostomy bags and supplies directly related to colostomy care, including—

(i) Replacement of prosthetic devices; and

(ii) One pair of conventional eyeglasses or conventional contact lenses furnished after each cataract surgery during which an intraocular lens is inserted.

(3)(i) Leg, arm, back, and neck braces.

(A) A leg brace may include a shoe if it is an integral part of the brace (necessary for the leg brace to function properly) and its expense is included as part of the cost of the brace.

(ii) Artificial legs, arms, and eyes; and

(iii) Replacements for the devices specified in paragraphs (a)(3)(i) and (ii) if required because of a change in the individual's physical condition.

(4) Lymphedema compression treatment items, including the following:

(i) Standard and custom fitted gradient compression garments.

(ii) Gradient compression wraps with adjustable straps.

(iii) Compression bandaging systems.

(iv) Other items determined to be lymphedema compression treatment items under the process established under § 414.1670.

(v) For the purposes of paragraphs (i) and (ii) of this paragraph, the scope of the benefit for lymphedema compression treatment items includes accessories such as zippers in garments, liners worn under garments or wraps with adjustable straps, and padding or fillers that are necessary for the effective use of a gradient compression garment or wrap with adjustable straps.

(b) The conditions of payment described in § 410.38(d) also apply to medical supplies, appliances, and devices.

[51 FR 41339, Nov. 14, 1986, as amended at 57 FR 36014, Aug. 12, 1992; 57 FR 57688, Dec. 7, 1992; 84 FR 60801, Nov. 8, 2019; 88 FR 77874, Nov. 13, 2023]

### § 410.37 Colorectal cancer screening tests: Conditions for and limitations on coverage.

(a) *Definitions.* As used in this section, the following definitions apply:

(1) *Colorectal cancer screening tests* means any of the following procedures furnished to an individual for the purpose of early detection of colorectal cancer:

(i) Screening fecal-occult blood tests.

(ii) Screening flexible sigmoidoscopies.

(iii) Screening colonoscopies, including anesthesia furnished in conjunction with the service.

(iv) Screening barium enemas.

(v) Other tests or procedures established by a national coverage determination, and modifications to tests under this paragraph, with such frequency and payment limits as CMS determines appropriate, in consultation with appropriate organizations

(2) *Screening fecal-occult blood test* means—

(i) A guaiac-based test for peroxidase activity, testing two samples from each of three consecutive stools, or,

(ii) Other tests as determined by the Secretary through a national coverage determination.