emerging trends, vulnerabilities identified in official agency reports, or other analysis.

(d) *Conditions of Payment.* The requirements described in this paragraph (d) are conditions of payment applicable to DMEPOS items.

(1) *Written Order/Prescription.* All DMEPOS items require a written order/prescription for Medicare payment. Medicare Contractors shall consider the totality of the medical records when reviewing for compliance with standardized written order/prescription elements.

(i) *Elements.* A written order/prescription must include the following elements:

(A) Beneficiary Name or Medicare Beneficiary Identifier (MBI).

(B) General Description of the item.

(C) Quantity to be dispensed, if applicable.

(D) Order Date.

(E) Treating Practitioner Name or National Provider Identifier (NPI).

(F) Treating Practitioner Signature.

(ii) *Timing of the Written Order/Prescription.*

(A) For PMDs and other DMEPOS items selected for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, the written order/prescription must be communicated to the supplier prior to delivery.

(B) For all other DMEPOS, the written order/prescription must be communicated to the supplier prior to claim submission.

(2) *Items Requiring a Face-to-Face Encounter.* For PMDs and other DMEPOS items selected for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, the treating practitioner must document and communicate to the DMEPOS supplier that the treating practitioner has had a face-to-face encounter with the beneficiary within the 6 months preceding the date of the written order/prescription.

(i) The encounter must be used for the purpose of gathering subjective and objective information associated with diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered.

(ii) If it is a telehealth encounter, the requirements of §§ 410.78 and 414.65 of this chapter must be met.

(3) *Documentation:* A supplier must maintain the written order/prescription and the supporting documentation provided by the treating practitioner and make them available to CMS and its agents upon request.

(i) Upon request by CMS or its agents, a supplier must submit additional documentation to CMS or its agents to support and/or substantiate the medical necessity for the DMEPOS item.

(ii) The face-to-face encounter must be documented in the pertinent portion of the medical record (for example, history, physical examination, diagnostic tests, summary of findings, progress notes, treatment plans or other sources of information that may be appropriate). The supporting documentation must include subjective and objective beneficiary specific information used for diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered.

(e) *Suspension of face-to-face encounter and written order prior to delivery requirements.* CMS may suspend face-to-face encounter and written order prior to delivery requirements generally or for a particular item or items at any time and without undertaking rulemaking, except those items for which inclusion on the Master List was statutorily imposed.

[51 FR 41339, Nov. 14, 1986, as amended at 57 FR 57688, Dec. 7, 1992; 58 FR 30668, May 26, 1993; 70 FR 50946, Aug. 26, 2005; 71 FR 17030, Apr. 5, 2006; 77 FR 69362, Nov. 16, 2012; 84 FR 60802, Nov. 8, 2019]

§ 410.39 Prostate cancer screening tests: Conditions for and limitations on coverage.

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

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

(i) A screening digital rectal examination.

(ii) A screening prostate-specific antigen blood test.

(iii) For years beginning after 2002, other procedures CMS finds appropriate for the purpose of early detection of prostate cancer, taking into account changes in technology and standards of medical practice, availability, effectiveness, costs, and other factors CMS considers appropriate.

(2) *A screening digital rectal examination* means a clinical examination of an individual's prostate for nodules or other abnormalities of the prostate.

(3) *A screening prostate-specific antigen blood test* means a test that measures the level of prostate-specific antigen in an individual's blood.

(4) A physician for purposes of this provision means a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act) who is fully knowledgeable about the beneficiary, and who would be responsible for explaining the results of the screening examination or test.

(5) A physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife for purposes of this provision means a physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife (as defined in sections 1861(aa) and 1861(gg) of the Act) who is fully knowledgeable about the beneficiary, and who would be responsible for explaining the results of the screening examination or test.

(b) *Condition for coverage of screening digital rectal examinations.* Medicare Part B pays for a screening digital rectal examination if it is performed by the beneficiary's physician, or by the beneficiary's physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife as defined in paragraphs (a)(4) or (a)(5) of this section who is authorized to perform this service under State law.

(c) *Limitation on coverage of screening digital rectal examinations.* (1) Payment may not be made for a screening digital rectal examination performed for a man age 50 or younger.

(2) For an individual over 50 years of age, payment may be made for a screening digital rectal examination only if the man has not had such an examination paid for by Medicare during the preceding 11 months following the month in which his last Medicare-covered screening digital rectal examination was performed.

(d) *Condition for coverage of screening prostate-specific antigen blood tests.* Medicare Part B pays for a screening prostate-specific antigen blood test if it is ordered by the beneficiary's physician, or by the beneficiary's physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife as defined in paragraphs (a)(4) or (a)(5) of this section who is authorized to order this test under State law.

(e) *Limitation on coverage of screening prostate-specific antigen blood test.* (1) Payment may not be made for a screening prostate-specific antigen blood test performed for a man age 50 or younger.

(2) For an individual over 50 years of age, payment may be made for a screening prostate-specific antigen blood test only if the man has not had such an examination paid for by Medicare during the preceding 11 months following the month in which his last Medicare-covered screening prostate-specific antigen blood test was performed.

[64 FR 59440, Nov. 2, 1999, as amended at 65 FR 19331, Apr. 11, 2000]

§ 410.40 Coverage of ambulance services.

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

Non-physician certification statement means a statement signed and dated by an individual which certifies that the medical necessity provisions of paragraph (e)(1) of this section are met and who meets all of the criteria in paragraphs (i) through (iii) of this definition. The statement need not be a stand-alone document and no specific format or title is required.

(i) Has personal knowledge of the beneficiary's condition at the time the ambulance transport is ordered or the service is furnished;

(ii) Who must be employed:

(A) By the beneficiary's attending physician; or

(B) By the hospital or facility where the beneficiary is being treated and from which the beneficiary is transported;