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*** 79 FR 23414, April 28, 2014 and at 79 FR 24192, April 29, 2014 ***

TITLE 21 -- FOOD AND DRUGS
CHAPTER II -- DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE
PART 1300 -- DEFINITIONS

21 CFR 1300.04

§ 1300.04 Definitions relating to the dispensing of controlled substances by means of the Internet.

(a) Any term not defined in this part or elsewhere in this chapter shall have the definition set forth in sections 102 and 309 of the Act (21 U.S.C. 802, 829).

(b) The term covering practitioner means, with respect to a patient, a practitioner who conducts a medical evaluation (other than an in-person medical evaluation) at the request of a practitioner who:

(1) Has conducted at least one in-person medical evaluation of the patient or an evaluation of the patient through the practice of **telemedicine**, within the previous 24 months; and

(2) Is temporarily unavailable to conduct the evaluation of the patient.

(c) The term deliver, distribute, or dispense by means of the Internet refers, respectively, to any delivery, distribution, or dispensing of a controlled substance that is caused or facilitated by means of the Internet.

(d) The term filling new prescriptions for controlled substances in Schedule III, IV, or V means filling a prescription for an individual for a controlled substance in Schedule III, IV, or V, if:

(1) The pharmacy dispensing that prescription has previously dispensed to the patient a controlled substance other than by means of the Internet and pursuant to the valid prescription of a practitioner that meets the applicable requirements of subsections (b) and (c) of section 309 of the Act (21 U.S.C. 829) and §§ 1306.21 and 1306.22 of this chapter (for purposes of this definition, such a prescription shall be referred to as the "original prescription");

(2) The pharmacy contacts the practitioner who issued the original prescription at the request of that individual to determine whether the practitioner will authorize the issuance of a new prescription for that individual for the controlled substance described in paragraph (d)(1) of this section (i.e., the same controlled substance as described in paragraph (d)(1)); and

(3) The practitioner, acting in the usual course of professional practice, determines there is a legitimate medical purpose for the issuance of the new prescription.

(e) The term homepage means the opening or main page or screen of the Web site of an online pharmacy that is

viewable on the Internet.

(f) The term in-person medical evaluation means a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluationare conducted by other health professionals. Nothing in this paragraph shall be construed to imply that one in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice.

(g) The term Internet means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected worldwide network of networks that employ the Transmission Control Protocol/Internet Protocol, or any predecessor or successor protocol to such protocol, to communicate information of all kinds by wire or radio.

(h) The term online pharmacy means a person, entity, or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet. The term includes, but is not limited to, a pharmacy that has obtained a modification of its registration pursuant to §§ 1301.13 and 1301.19 of this chapter that currently authorizes it to dispense controlled substances by means of the Internet, regardless of whether the pharmacy is currently dispensing controlled substances by means of the Internet. The term does not include:

(1) Manufacturers or distributors registered under subsection (a), (b), (d), or (e) of section 303 of the Act (21 U.S.C. 823(a), (b), (d), or (e)) (§ 1301.13 of this chapter) who do not dispense controlled substances to an unregistered individual or entity;

(2) Nonpharmacy practitioners who are registered under section 303(f) of the Act (21 U.S.C. 823(f)) (§ 1301.13 of this chapter) and whose activities are authorized by that registration;

(3) Any hospital or other medical facility that is operated by an agency of the United States (including the Armed Forces), provided such hospital or other facility is registered under section 303(f) of the Act (21 U.S.C. 823(f)) (§ 1301.13 of this chapter);

(4) A health care facility owned or operated by an Indian tribe or tribal organization, only to the extent such facility is carrying out a contract or compact under the Indian Self-Determination and Education Assistance Act;

(5) Any agent or employee of any hospital or facility referred to in paragraph (h)(3) or (h)(4) of this section, provided such agent or employee is lawfully acting in the usual course of business or employment, and within the scope of the official duties of such agent or employee, with such hospital or facility, and, with respect to agents or employees of health care facilities specified in paragraph (h)(4) of this section, only to the extent such individuals are furnishing services pursuant to the contracts or compacts described in such paragraph;

(6) Mere advertisements that do not attempt to facilitate an actual transaction involving a controlled substance;

(7) A person, entity, or Internet site that is not in the United States and does not facilitate the delivery, distribution, or dispensing of a controlled substance by means of the Internet to any person in the United States;

(8) A pharmacy registered under section 303(f) of the Act (21 U.S.C. 823(f)) (§ 1301.13 of this chapter) whose dispensing of controlled substances via the Internet consists solely of:

(i) Refilling prescriptions for controlled substances in Schedule III, IV, or V, as defined in paragraph (k) of this section; or

(ii) Filling new prescriptions for controlled substances in Schedule III, IV, or V, as defined in paragraph (d) of this section;

(9)(i) Any registered pharmacy whose delivery, distribution, or dispensing of controlled substances by means of the Internet consists solely of filling prescriptions that were electronically prescribed in a manner authorized by this chapter and otherwise in compliance with the Act.

(ii) A registered pharmacy will be deemed to meet this exception if, in view of all of its activities other than those referred to in paragraph (h)(9)(i) of this section, it would fall outside the definition of an online pharmacy; or

(10)(i) Any registered pharmacy whose delivery, distribution, or dispensing of controlled substances by means of the Internet consists solely of the transmission of prescription information between a pharmacy and an automated dispensing system located in a long term care facility when the registration of the automated dispensing system is held by that pharmacy as described in §§ 1301.17 and 1301.27 and the pharmacy is otherwise complying with this chapter.

(ii) A registered pharmacy will be deemed to meet this exception if, in view of all of its activities other than those referred to in paragraph (h)(10)(i) of this section, it would fall outside the definition of an online pharmacy.

(i) Effective January 15, 2010, the term practice of **telemedicine** means the practice of medicine in accordance with applicable Federal and State laws by a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)), which practice falls within a category listed in the following paragraphs (i)(1) through (7):

(1) Treatment in a hospital or clinic. The practice of **telemedicine** is being conducted while the patient is being treated by, and physically located in, a hospital or clinic registered under section 303(f) of the Act (21 U.S.C. 823(f)) by a practitioner acting in the usual course of professional practice, who is acting in accordance with applicable State law, and who is registered under section 303(f) of the Act (21 U.S.C. 823(f)) in the State in which the patient is located, unless the practitioner:

(i) Is exempted from such registration in all States under section 302(d) of the Act (21 U.S.C. 822(d); or

(ii) Is an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract, and registered under section 303(f) of the Act (21 U.S.C. 823(f)) in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f);

(2) Treatment in the physical presence of a practitioner. The practice of **telemedicine** is being conducted while the patient is being treated by, and in the physical presence of, a practitioner acting in the usual course of professional practice, who is acting in accordance with applicable State law, and who is registered under section 303(f) of the Act (21 U.S.C. 823(f)) in the State in which the patient is located, unless the practitioner:

(i) Is exempted from such registration in all States under section 302(d) of the Act (21 U.S.C. 822(d)); or

(ii) Is an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract, and registered under section 303(f) of the Act (21 U.S.C. 823(f)) in any State or is using the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f);

(3) Indian Health Service or tribal organization. The practice of **telemedicine** is being conducted by a practitioner who is an employee or contractor of the Indian Health Service, or is working for an Indian tribe or tribal organization under its contract or compact with the Indian Health Service under the Indian Self-Determination and Education Assistance Act; who is acting within the scope of the employment, contract, or compact; and who is designated as an Internet Eligible Controlled Substances Provider by the Secretary of Health and Human Services under section 311(g)(2) of the Act (21 U.S.C. 831(g)(2));

(4) Public health emergency declared by the Secretary of Health and Human Services. The practice of **telemedicine** is being conducted during a public health emergency declared by the Secretary of Health and Human Services under section 319 of the Public Health Service Act (42 U.S.C. 247d), and involves patients located in such areas, and such controlled substances, as the Secretary of Health and Human Services, with the concurrence of the Administrator, designates, provided that such designation shall not be subject to the procedures prescribed by the Administrative Procedure Act (5 U.S.C. 551-559 and 701-706);

(5) Special registration. The practice of **telemedicine** is being conducted by a practitioner who has obtained from the Administrator a special registration under section 311(h) of the Act (21 U.S.C. 831(h));

(6) Department of Veterans Affairs medical emergency. The practice of **telemedicine** is being conducted:

(i) In a medical emergency situation:

(A) That prevents the patient from being in the physical presence of a practitioner registered under section 303(f) of the Act (21 U.S.C. 823(f)) who is an employee or contractor of the Veterans Health Administration acting in the usual course of business and employment and within the scope of the official duties or contract of that employee or contractor;

(B) That prevents the patient from being physically present at a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f) of the Act (21 U.S.C. 823(f));

(C) During which the primary care practitioner of the patient or a practitioner otherwise practicing **telemedicine** within the meaning of this paragraph is unable to provide care or consultation; and

(D) That requires immediate intervention by a health care practitioner using controlled substances to prevent what the practitioner reasonably believes in good faith will be imminent and serious clinical consequences, such as further injury or death; and

(ii) By a practitioner that:

(A) Is an employee or contractor of the Veterans Health Administration acting within the scope of that employment or contract;

(B) Is registered under section 303(f) of the Act (21 U.S.C. 823(f)) in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f); and

(C) Issues a controlled substance prescription in this emergency context that is limited to a maximum of a five-day supply which may not be extended or refilled; or

(7) Other circumstances specified by regulation. The practice of **telemedicine** is being conducted under any other circumstances that the Administrator and the Secretary of Health and Human Services have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.

(j) Temporary definition of practice of **telemedicine**. Prior to January 15, 2010, or as otherwise specified by regulation prior to that date, instead of the definition in paragraph (i), the term practice of **telemedicine** means the practice of medicine in accordance with applicable Federal and State laws by a practitioner (as that term is defined in section 102 of the Act (21 U.S.C. 802)) (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)), if the practitioner is using an interactive telecommunications system that satisfies the requirements of section 410.78(a)(3) of title 42, Code of Federal Regulations.

(k) The term refilling prescriptions for controlled substances in Schedule III, IV, or V:

(1) Means the dispensing of a controlled substance in Schedule III, IV, or V in accordance with refill instructions issued by a practitioner as part of a valid prescription that meets the requirements of subsections (b) and (c) of section 309 of the Act (21 U.S.C. 829) and §§ 1306.21 and 1306.22 of this chapter, as appropriate; and

(2) Does not include the issuance of a new prescription to an individual for a controlled substance that individual was previously prescribed.

(l)(1) The term valid prescription means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by:

(i) A practitioner who has conducted at least one in-person medical evaluation of the patient; or

(ii) A covering practitioner.

(2) Nothing in this paragraph (l) shall be construed to imply that one in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice.

HISTORY:
[74 FR 15596, 15619, Apr. 6, 2009]

AUTHORITY:
AUTHORITY NOTE APPLICABLE TO ENTIRE PART :
21 U.S.C. 802, 821, 829, 871(b), 951, 958(f).

NOTES:
[EFFECTIVE DATE NOTE: 74 FR 15596, 15619, Apr. 6, 2009, added this section, effective Apr. 6, 2009, which provides: "Section 1300.04(i) (the definition of "practice of **telemedicine**") has an implementation date of January 15, 2010, unless such date is superseded by future regulatory actions as explained in the SUPPLEMENTARY INFORMATION section."]
NOTES APPLICABLE TO ENTIRE TITLE:
Cross References: Food Safety and Inspection Services, Department of Agriculture: See Meat and Poultry Inspection, 9 CFR CHAPTER III.
Federal Trade Commission: See Commercial Practices, 16 CFR chapter I.
U.S. Customs Service, Department of the Treasury: See Customs Duties, 19 CFR chapter I.
Internal Revenue Service, Department of the Treasury: See Internal Revenue, 26 CFR chapter I.
Bureau of Alcohol, Tobacco, and Firearms, Department of the Treasury: See Alcohol, Tobacco Production and Firearms, 27 CFR chapter I.

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*** 79 FR 23414, April 28, 2014 and at 79 FR 24192, April 29, 2014 ***

TITLE 21 -- FOOD AND DRUGS
CHAPTER II -- DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE
PART 1304 -- RECORDS AND REPORTS OF REGISTRANTS
ONLINE PHARMACIES

21 CFR 1304.45

§ 1304.45 Internet Web site disclosure requirements.

(a) Each online pharmacy shall display, at all times and in a visible and clear manner, on its homepage a statement that it complies with the requirements of section 311 of the Act (21 U.S.C. 831) with respect to the delivery or sale or offer for sale of controlled substances. This statement must include the name of the pharmacy as it appears on the DEA Certificate of Registration.

(b) Each online pharmacy shall clearly display the following information on the homepage of each Internet site it operates, or on a page directly linked to the homepage. If the information is displayed on a page directly linked to the homepage, that link on the homepage must be visible and clear. The information must be displayed for each pharmacy that delivers, distributes, or dispenses controlled substances pursuant to orders made on, through, or on behalf of that Web site.

(1) The name and address of the pharmacy as it appears on the pharmacy's DEA Certificate of Registration.

(2) The pharmacy's telephone number and e-mail address.

(3) The name, professional degree, and States of licensure of the pharmacist-in-charge, and a telephone number at which the pharmacist-in-charge can be contacted.

(4) A list of the States in which the pharmacy is licensed to dispense controlled substances.

(5) A certification that the pharmacy is registered under part 1301 of this chapter with a modification of its registration authorizing it to deliver, distribute, or dispense controlled substances by means of the Internet.

(6) The name, address, telephone number, professional degree, and States of licensure with State license number of any practitioner who has a contractual relationship to provide medical evaluations or issue prescriptions for controlled substances, through referrals from the Web site or at the request of the owner or operator of theWeb site, or any employee or agent thereof.

(7) The following statement: "This online pharmacy is obligated to comply fully with the Controlled Substances Act and DEA regulations. As part of this obligation, this online pharmacy has obtained a modified DEA registration authorizing it to operate as an online pharmacy. In addition, this online pharmacy will only dispense

a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation in accordance with section 309 of the Controlled Substances Act (21 U.S.C. 829) or a medical evaluation via **telemedicine** in accordance with section 102(54) of the Controlled Substances Act (21 U.S.C. 802(54))."

HISTORY:
[74 FR 15596, 15623, Apr. 6, 2009]

AUTHORITY:
AUTHORITY NOTE APPLICABLE TO ENTIRE PART:
21 U.S.C. 821, 827, 831, 871(b), 958(e), 965.

NOTES:
[EFFECTIVE DATE NOTE: 74 FR 15596, 15623, Apr. 6, 2009, added this section, effective Apr. 13, 2009.]
NOTES APPLICABLE TO ENTIRE TITLE:
Cross References: Food Safety and Inspection Services, Department of Agriculture: See Meat and Poultry Inspection, 9 CFR CHAPTER III.
Federal Trade Commission: See Commercial Practices, 16 CFR chapter I.
U.S. Customs Service, Department of the Treasury: See Customs Duties, 19 CFR chapter I.
Internal Revenue Service, Department of the Treasury: See Internal Revenue, 26 CFR chapter I.
Bureau of Alcohol, Tobacco, and Firearms, Department of the Treasury: See Alcohol, Tobacco Production and Firearms, 27 CFR chapter I.

CASE NOTES Applicable to entire Part:Part Note

42 CFR 410.38

§ 410.38 Durable medical equipment: Scope and conditions.

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

(a) Medicare Part B pays for t.he rental or purchase of durable medical equipment, including iron lungs, oxygen tents, hospital beds, and wheelchairs, if the equipment is used in the patient's home or in an institution that is used as a home.

(b) An institution that is used as a home may not be a hospital or a CAH or a SNF as defined in sections 1861(e)(1), 1861(mm)(1) and 1819(a)(1) of the Act, respectively.

(c) Power mobility devices (PMDs). (1) Definitions. For the purposes of this paragraph, the following definitions apply:

Physician has the same meaning as in section 1861(r)(1) of the Act.

Power mobility device means a covered item of durable medical equipment that is in a class of wheelchairs that includes a power wheelchair (a four-wheeled motorized vehicle whose steering is operated by an electronic device or a joystick to control direction and turning) or a power-operated vehicle (a three or four-wheeled motorized scooter that is operated by a tiller) that a beneficiary uses in the home.

Prescription means a written order completed by the physician or treating practitioner who performed the face-to-face examination and that includes the beneficiary's name, the date of the face-to-face examination, the diagnoses and conditions that the PMD is expected to modify, a description of the item (for example, a narrative description of the specific type of PMD), the length of need, and the physician or treating practitioner's signature and the date the prescription was written.

Treating practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist as those terms are defined in section 1861(aa)(5) of the Act, who has conducted a face-to-face examination of the beneficiary.

Supplier means an entity with a valid Medicare supplier number, including an entity that furnishes items through the mail.

(2) Conditions of payment. Medicare Part B pays for a power mobility device if the physician or treating practitioner, as defined in paragraph (c)(1) of this section meets the following conditions:

(i) Conducts a face-to-face examination of the beneficiary for the purpose of evaluating and treating the beneficiary for his or her medical condition and determining the medical necessity for the PMD as part of an

appropriate overall treatment plan.

(ii) Writes a prescription, as defined in paragraph (c)(1) of this section that is provided to the beneficiary or supplier, and is received by the supplier within 45 days after the face-to-face examination.

(iii) Provides supporting documentation, including pertinent parts of the beneficiary's medical record (for example, history, physical examination, diagnostic tests, summary of findings, diagnoses, treatment plans and/or other information as may be appropriate) that supports the medical necessity for the power mobility device, which is received by the supplier within 45 days after the face-to-face examination.

(3) Exceptions. (i) Beneficiaries discharged from a hospital do not need to receive a separate face-to-face examination as long as the physician or treating practitioner who performed the face-to-face examination of the beneficiary in the hospital issues a PMD prescription and supporting documentation that is received by the supplier within 45 days after the date of discharge.

(ii) Accessories for PMDs may be ordered by the physician or treating practitioner without conducting a face-to-face examination of the beneficiary.

(4) Dispensing a power mobility device. Suppliers may not dispense a PMD to a beneficiary until the PMD prescription and the supporting documentation have been received from the physician or treating practitioner who performed the face-to-face examination of the beneficiary. These documents must be received within 45 days after the date of the face-to-face examination.

(5) Documentation. (i) A supplier must maintain the prescription and the supporting documentation provided by the physician or treating practitioner and make them available to CMS and its agents upon request.

(ii) 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 power mobility device.

(6) Safety requirements. The PMD must meet any safety requirements specified by CMS.

(d) Medicare Part B pays for medically necessary equipment that is used for treatment of decubitus ulcers if --

(1) The equipment is ordered in writing by the beneficiary's attending physician, or by a specialty physician on referral from the beneficiary's attending physician, and the written order is furnished to the supplier before the delivery of the equipment; and

(2) The prescribing physician has specified in the prescription that he or she will be supervising the use of the equipment in connection with the course of treatment.

(e) Medicare Part B pays for a medically necessary seat-lift if it --

(1) Is ordered in writing by the beneficiary's attending physician, or by a specialty physician on referral from the beneficiary's attending physician, and the written order is furnished to the supplier before the delivery of the seat-lift;

(2) Is for a beneficiary who has a diagnosis designated by CMS as requiring a seat-lift; and

(3) Meets safety requirements specified by CMS.

(f) Medicare Part B pays for transcutaneous electrical nerve stimulator units that are --

(1) Determined to be medically necessary; and

(2) Ordered in writing by the beneficiary's attending physician, or by a specialty physician on referral from the beneficiary's attending physician, and the written order is furnished to the supplier before the delivery of the unit to the beneficiary.

(g)(1) Items requiring a written order. As a condition of payment, Specified Covered Items (as described in paragraph (g)(2) of this section) require a written order that meets the requirements in paragraphs (g)(3) and (4) of this section before delivery of the item.

(2) Specified covered items. (i) Specified Covered Items are items of durable medical equipment that CMS has specified in accordance with section 1834(a)(11)(B)(i) of the Act. A list of these items is updated annually in the Federal Register .

(ii) The list of Specified Covered Items includes the following:

(A) Any item described by a Healthcare Common Procedure Coding System (HCPCS) code for the following types of durable medical equipment:

(1) Transcutaneous electrical nerve stimulation (TENS) unit.

(2) Rollabout chair.

(3) Oxygen and respiratory equipment.

(4) Hospital beds and accessories.

(5) Traction-cervical.

(B) Any item of durable medical equipment that appears on the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Fee Schedule with a price ceiling at or greater than $ 1,000.

(C) Any other item of durable medical equipment that CMS adds to the list of Specified Covered Items through the notice and comment rulemaking process in order to reduce the risk of fraud, waste, and abuse.

(iii) The list of specific covered items excludes the following:

(A) Any item that is no longer covered by Medicare.

(B) Any HCPCS code that is discontinued.

(3) Face-to-face encounter requirements. (i) For orders issued in accordance with paragraphs (g)(1) and (2) of this section, as a condition of payment for the Specified Covered Item, all of the following must occur:

(A) The physician must document and communicate to the DME supplier that the physician or a physician assistant, a nurse practitioner, or a clinical nurse specialist has had a face-to-face encounter with the beneficiary on the date of the written order up to 6 months before the date of the written order.

(B) During the face-to-face encounter the physician, a physician assistant, a nurse practitioner, or a clinical nurse specialist must conduct a needs assessment, evaluate, and/or treat the beneficiary for the medical condition that supports the need for each covered item of DME ordered.

(C) 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, diagnoses, treatment plans or other information as it may be appropriate). Physician must sign or cosign the pertinent portion of the medical record indicating the occurrence of a face-to-face encounter for the beneficiary for the date of the face-to-face encounter when performed by a physician assistant, a nurse practitioner, or a clinical nurse specialist. For purposes of this paragraph (g), a face-to-face encounter does not include DME items and services furnished from an "incident to" service.

(ii) For purposes of this paragraph (g), a face-to-face encounter may occur via **telehealth** in accordance with all of the following:

(A) Section 1834(m) of the Act.

(B)(1) Medicare **telehealth** regulations in § 410.78 and § 414.65 of this chapter; and

(2) Subject to the list of payable Medicare **telehealth** services established by the applicable PFS.

(4) Written order issuance requirements. Written orders issued in accordance with paragraphs (g)(1) and (2) of this section must include all of the following:

(i) Beneficiary's name.

(ii) Item of DME ordered.

(iii) Signature of the prescribing practitioner.

(iv) Prescribing practitioner NPI.

(v) The date of the order.

(5) Supplier's order and documentation requirements. (i) A supplier must maintain the written order and the supporting documentation provided by the physician, physician assistant, nurse practitioner, or clinical nurse specialist and make them available to CMS upon request for 7 years from the date of service consistent with § 424.516(f) of this chapter.

(ii) Upon request by CMS or its agents, a supplier must submit additional documentation to CMS or its agents to support and substantiate that a face-to-face encounter has occurred.

HISTORY:
[51 FR 41339, Nov. 14, 1986, as amended at 57 FR 57688, Dec. 7, 1992; 58 FR 30668, May 26, 1993; 62 FR 45966, 46037, Aug. 29, 1997; 70 FR 50940, 50946, Aug. 26, 2005, as confirmed and amended at 71 FR 17021, 17029, 17030, Apr. 5, 2006; 77 FR 68892, 69362, Nov. 16, 2012]

AUTHORITY:
AUTHORITY NOTE APPLICABLE TO ENTIRE PART:
Secs. 1102, 1834, 1871, 1881, and 1893 of the Social Security Act (42 U.S.C. 1302. 1395m, 1395hh, and 1395ddd.

NOTES:
[EFFECTIVE DATE NOTE: 77 FR 68892, 69362, Nov. 16, 2012, revised paragraph (g), effective July 1, 2013.]

NOTES APPLICABLE TO ENTIRE CHAPTER:
[PUBLISHER'S NOTE: Nomenclature changes affecting Chapter IV appear at 45 FR 53806, Aug. 13, 1980; 50 FR 12741, Mar. 29, 1985; 50 FR 33034, Aug. 16, 1985; 51 FR 41338, Nov. 14, 1986; 53 FR 6634, Mar. 2, 1988; 53 FR 47201, Nov. 22, 1988; 56 FR 8852, Mar. 1, 1991; 66 FR 39450, 39452, July 31, 2001; 67 FR 36539, 36540, May 24, 2002; 77 FR 29002, 29028, May 16, 2012.]

NOTES APPLICABLE TO ENTIRE PART:
[PUBLISHER'S NOTE: For Federal Register citation concerning Part 410 Physician Fee Schedule, see 68 FR 9567, Feb. 28, 2003; 68 FR 63398, Nov. 7, 2003, as corrected at 68 FR 75442, Dec. 31, 2003.]

CASE NOTES Applicable to entire Part:Part Note

TITLE 42 -- PUBLIC HEALTH
CHAPTER IV -- CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER B -- MEDICARE PROGRAM
PART 410 -- SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS
SUBPART B -- MEDICAL AND OTHER HEALTH SERVICES

42 CFR 410.78

§ 410.78 **Telehealth** services.

(a) Definitions. For the purposes of this section the following definitions apply:

(1) Asynchronous store and forward technologies means the transmission of a patient's medical information from an originating site to the physician or practitioner at the distant site. The physician or practitioner at the distant site can review the medical case without the patient being present. An asynchronous telecommunications system in single media format does not include telephone calls, images transmitted via facsimile machines and text messages without visualization of the patient (electronic mail). Photographs visualized by a telecommunications system must be specific to the patient's medical condition and adequate for furnishing or confirming a diagnosis and or treatment plan. Dermatological photographs, for example, a photograph of a skin lesion, may be considered to meet the requirement of a single media format under this provision.

(2) Distant site means the site at which the physician or practitioner delivering the service is located at the time the service is provided via a telecommunications system.

(3) Interactive telecommunications system means multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. Telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system.

(4) Originating site means the location of an eligible Medicare beneficiary at the time the service being furnished via a telecommunications system occurs. For asynchronous store and forward telecommunications technologies, the only originating sites are Federal **telemedicine** demonstration programs conducted in Alaska or Hawaii.

(b) General rule. Medicare Part B pays for office or other outpatient visits, subsequent hospital care services (with the limitation of one **telehealth** visit every three days by the patient's admitting physician or practitioner), subsequent nursing facility care services (not including the Federally-mandated periodic visits under § 483.40(c) of this chapter and with the limitation of one **telehealth** visit every 30 days by the patient's admitting

physician or nonphysician practitioner), professional consultations, psychiatric diagnostic interview examination, neurobehavioral status exam, individual psychotherapy, pharmacologic management, end-stage renal disease-related services included in the monthly capitation payment (except for one "hands on" visit per month to examine the access site), individual and group medical nutrition therapy services, individual and group kidney disease education services, individual and group diabetes self-management training services (except for one hour of "hands on" services to be furnished in the initial year training period to ensure effective injection training), individual and group health and behavior assessment and intervention services, smoking cessation services, alcohol and/or substance abuse and brief intervention services, screening and behavioral counseling interventions in primary care to reduce alcohol misuse, screening for depression in adults, screening for sexually transmitted infections (STIs) and high intensity behavioral counseling (HIBC) to prevent STIs, intensive behavioral therapy for cardiovascular disease, behavioral counseling for obesity, and transitional care management services furnished by an interactive telecommunications system if the following conditions are met:

(1) The physician or practitioner at the distant site must be licensed to furnish the service under State law. The physician or practitioner at the distant site who is licensed under State law to furnish a covered **telehealth** service described in this section may bill, and receive payment for, the service when it is delivered via a telecommunications system.

(2) The practitioner at the distant site is one of the following:

(i) A physician as described in § 410.20.

(ii) A physician assistant as described § 410.74.

(iii) A nurse practitioner as described in § 410.75.

(iv) A clinical nurse specialist as described in § 410.76.

(v) A nurse-midwife as described in § 410.77.

(vi) A clinical psychologist as described in § 410.71.

(vii) A clinical social worker as described in § 410.73.

(viii) A registered dietitian or nutrition professional as described in § 410.134.

(3) The services are furnished to a beneficiary at an originating site, which is one of the following:

(i) The office of a physician or practitioner.

(ii) A critical access hospital (as described in section 1861(mm)(1) of the Act).

(iii) A rural health clinic (as described in section 1861(aa)(2) of the Act).

(iv) A Federally qualified health center (as defined in section 1861(aa)(4) of the Act).

(v) A hospital (as defined in section 1861(e) of the Act).

(vi) A hospital-based or critical access hospital-based renal dialysis center (including satellites).

(vii) A skilled nursing facility (as defined in section 1819(a) of the Act).

(viii) A community mental health center (as defined in section 1861(ff)(3)(B) of the Act).

(4) Originating sites must be:

(i) Located in a health professional shortage area (as defined under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A)) that is either outside of a Metropolitan Statistical Area (MSA) as of December 31st of the preceding calendar year or within a rural census tract of an MSA as determined by the Office of Rural Health Policy of the Health Resources and Services Administration as of December 31st of the preceding calendar year, or

(ii) Located in a county that is not included in a Metropolitan Statistical Area as defined in section 1886(d)(2)(D) of the Act as of December 31st of the preceding year, or

(iii) An entity participating in a Federal **telemedicine** demonstration project that has been approved by, or receive funding from, the Secretary as of December 31, 2000, regardless of its geographic location.

(5) The medical examination of the patient is under the control of the physician or practitioner at the distant site.

(c) Telepresenter not required. A telepresenter is not required as a condition of payment unless a telepresenter is medically necessary as determined by the physician or practitioner at the distant site.

(d) Exception to the interactive telecommunications system requirement. For Federal **telemedicine** demonstration programs conducted in Alaska or Hawaii only, Medicare payment is permitted for **telehealth** when asynchronous store and forward technologies, in single or multimedia formats, are used as a substitute for an interactive telecommunications system.

(e) Limitations. (1) A clinical psychologist and a clinical social worker may bill and receive payment for individual psychotherapy via a telecommunications system, but may not seek payment for medical evaluation and management services.

(2) The physician visits required under § 483.40(c) of this title may not be furnished as **telehealth** services.

(f) Process for adding or deleting services. Changes to the list of Medicare **telehealth** services are made through the annual physician fee schedule rulemaking process.

HISTORY:
[63 FR 58814, 58909, Nov. 2, 1998; 66 FR 55246, 55330, Nov. 1, 2001; 67 FR 79966, 80041, Dec. 31, 2002; 69 FR 66236, 66423, Nov. 15, 2004; 70 FR 70116, 70330, Nov. 21, 2005; 72 FR 66222, 66399, Nov. 27, 2007; 73 FR 69726, 69934, Nov. 19, 2008; 74 FR 61738, 62005, Nov. 25, 2009; 75 FR 73170, 73615, Nov. 29, 2010; 76 FR 73026, 73470, Nov. 28, 2011; 77 FR 68892, 69363, Nov. 16, 2012; 78 FR 74230, 74811, Dec. 10, 2013]

AUTHORITY:
AUTHORITY NOTE APPLICABLE TO ENTIRE PART:
Secs. 1102, 1834, 1871, 1881, and 1893 of the Social Security Act (42 U.S.C. 1302. 1395m, 1395hh, and 1395ddd.

NOTES:
[EFFECTIVE DATE NOTE: 78 FR 74230, 74811, Dec. 10, 2013, revised paragraph (b) introductory text and paragraph (b)(4), effective Jan. 1, 2014.]

NOTES APPLICABLE TO ENTIRE CHAPTER:
[PUBLISHER'S NOTE: Nomenclature changes affecting Chapter IV appear at 45 FR 53806, Aug. 13, 1980; 50 FR 12741, Mar. 29, 1985; 50 FR 33034, Aug. 16, 1985; 51 FR 41338, Nov. 14, 1986; 53 FR 6634, Mar. 2, 1988; 53 FR 47201, Nov. 22, 1988; 56 FR 8852, Mar. 1, 1991; 66 FR 39450, 39452, July 31, 2001; 67 FR 36539, 36540, May 24, 2002; 77 FR 29002, 29028, May 16, 2012.]

NOTES APPLICABLE TO ENTIRE PART:
[PUBLISHER'S NOTE: For Federal Register citation concerning Part 410 Physician Fee Schedule, see 68 FR 9567, Feb. 28, 2003; 68 FR 63398, Nov. 7, 2003, as corrected at 68 FR 75442, Dec. 31, 2003.]

*** This document is current through the May 1, 2014 ***
*** issue of the Federal Register, except for the amendments appearing at ***
*** 79 FR 23414, April 28, 2014 and at 79 FR 24192, April 29, 2014 ***

TITLE 42 -- PUBLIC HEALTH
CHAPTER IV -- CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER B -- MEDICARE PROGRAM
PART 414 -- PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES
SUBPART A -- GENERAL PROVISIONS

42 CFR 414.1

§ 414.1 Basis and scope.

This part implements the following provisions of the Act:

1802 -- Rules for private contracts by Medicare beneficiaries.

1833 -- Rules for payment for most Part B services.

1834(a) and (h) -- Amounts and frequency of payments for durable medical equipment and for prosthetic devices and orthotics and prosthetics.

1834(l) -- Establishment of a fee schedule for ambulance services.

1834(m) -- Rules for Medicare reimbursement for **telehealth** services.

1842(o) -- Rules for payment of certain drugs and biologicals.

1847(a) and (b) -- Competitive bidding for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

1848 -- Fee schedule for physician services.

1881(b) -- Rules for payment for services to ESRD beneficiaries.

1887 -- Payment of charges for physician services to patients in providers.

HISTORY:
[56 FR 59624, Nov. 25, 1991; 60 FR 50439, 50442, Sept. 29, 1995; 63 FR 58814, 58910, Nov. 2, 1998; 67 FR 9100, 9132, Feb. 27, 2002; 69 FR 1084, 1116, Jan. 7, 2004; 71 FR 48354, 48409, Aug. 18, 2006]

AUTHORITY:

AUTHORITY NOTE APPLICABLE TO ENTIRE PART:
Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

NOTES:
[EFFECTIVE DATE NOTE: 71 FR 48354, 48409, Aug. 18, 2006, added the entry for "1847 (a) and (b)" to the list of statutory sections, effective Aug. 31, 2006, and provides: "The regulatory changes to part 412 of 42 CFR are effective October 1, 2006. The regulatory changes to part 414 of 42 CFR, other than § 414.406(e), are effective August 31, 2006. The regulatory changes to part 424 of 42 CFR are effective October 2, 2006. The updated IRF prospective payment rates are effective October 1, 2006, for discharges occurring on or after October 1, 2006 and on or before September 30, 2007 (that is, during FY 2007)."]

NOTES APPLICABLE TO ENTIRE CHAPTER:
[PUBLISHER'S NOTE: Nomenclature changes affecting Chapter IV appear at 45 FR 53806, Aug. 13, 1980; 50 FR 12741, Mar. 29, 1985; 50 FR 33034, Aug. 16, 1985; 51 FR 41338, Nov. 14, 1986; 53 FR 6634, Mar. 2, 1988; 53 FR 47201, Nov. 22, 1988; 56 FR 8852, Mar. 1, 1991; 66 FR 39450, 39452, July 31, 2001; 67 FR 36539, 36540, May 24, 2002; 77 FR 29002, 29028, May 16, 2012.]

NOTES APPLICABLE TO ENTIRE PART:
EDITORIAL NOTE: Nomenclature changes affecting this part appear at 60 FR 50442, Sept. 29, 1995, and 60 Fr 53877, Oct. 18, 1995.
[PUBLISHER'S NOTE: For Federal Register citation concerning Part 414 Physician Fee Schedule, see 68 FR 9567, Feb. 28, 2003.]

CASE NOTES Applicable to entire Part:Part Note

*** This document is current through the May 1, 2014 ***
*** issue of the Federal Register, except for the amendments appearing at ***
*** 79 FR 23414, April 28, 2014 and at 79 FR 24192, April 29, 2014 ***

TITLE 42 -- PUBLIC HEALTH
CHAPTER IV -- CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER B -- MEDICARE PROGRAM
PART 414 -- PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES
SUBPART B -- PHYSICIANS AND OTHER PRACTITIONERS

42 CFR 414.65

§ 414.65 Payment for **telehealth** services.

(a) Professional service. Medicare payment for the professional service via an interactive telecommunications system is made according to the following limitations:

(1) The Medicare payment amount for office or other outpatient visits, subsequent hospital care services (with the limitation of one **telehealth** visit every 3 days by the patient's admitting physician or practitioner), subsequent nursing facility care services (with the limitation of one **telehealth** visit every 30 days by the patient's admitting physician or nonphysician practitioner), professional consultations, psychiatric diagnostic interview examination, neurobehavioral status exam, individual psychotherapy, pharmacologic management, end-stage renal disease-related services included in the monthly capitation payment (except for one "hands on" visit per month to examine the access site), individual and group medical nutrition therapy services, individual and group kidney disease education services, individual and group diabetes self-management training services (except for one hour of "hands on" services to be furnished in the initial year training period to ensure effective injection training), individual and group health and behavior assessment and intervention, smoking cessation services, alcohol and/or substance abuse and brief intervention services, screening and behavioral counseling interventions in primary care to reduce alcohol misuse, screening for depression in adults, screening for sexually transmitted infections (STIs) and high intensity behavioral counseling (HIBC) to prevent STIs, intensive behavioral therapy for cardiovascular disease, behavioral counseling for obesity, and transitional care management services furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable for the service of the physician or practitioner.

(i) Emergency department or initial inpatient **telehealth** consultations. The Medicare payment amount for emergency department or initial inpatient **telehealth** consultations furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable to initial hospital care provided by a physician or practitioner.

(ii) Follow-up inpatient **telehealth** consultations. The Medicare payment amount for follow-up inpatient **telehealth** consultations furnished via an interactive telecommunications system is equal to the current fee

schedule amount applicable to subsequent hospital care provided by a physician or practitioner.

(2) Only the physician or practitioner at the distant site may bill and receive payment for the professional service via an interactive telecommunications system.

(3) Payments made to the physician or practitioner at the distant site, including deductible and coinsurance, for the professional service may not be shared with the referring practitioner or telepresenter.

(b) Originating site facility fee. For **telehealth** services furnished on or after October 1, 2001:

(1) For services furnished on or after October 1, 2001 through December 31, 2002, the payment amount to the originating site is the lesser of the actual charge or the originating site facility fee of $ 20. For services furnished on or after January 1 of each subsequent year, the facility fee for the originating site will be updated by the Medicare Economic Index (MEI) as defined in section 1842(i)(3) of the Act.

(2) Only the originating site may bill for the originating site facility fee and only on an assignment-related basis. The distant site physician or practitioner may not bill for or receive payment for facility fees associated with the professional service furnished via an interactive telecommunications system.

(c) Deductible and coinsurance apply. The payment for the professional service and originating site facility fee is subject to the coinsurance and deductible requirements of sections 1833(a)(1) and (b) of the Act.

(d) Assignment required for physicians, practitioners, and originating sites. Payment to physicians, practitioners, and originating sites is made only on an assignment-related basis.

(e) Sanctions. A distant site practitioner or originating site facility may be subject to the applicable sanctions provided for in chapter IV, part 402 and chapter V, parts 1001, 1002, and 1003 of this title if he or she does any of the following:

(1) Knowingly and willfully bills or collects for services in violation of the limitation of this section.

(2) Fails to timely correct excess charges by reducing the actual charge billed for the service in an amount that does not exceed the limiting charge for the service or fails to timely refund excess collections.

(3) Fails to submit a claim on a standard form for services provided for which payment is made on a fee schedule basis.

(4) Imposes a charge for completing and submitting the standard claims form.

HISTORY:
[63 FR 58814, 58911, Nov. 2, 1998; 66 FR 55246, 55332, Nov. 1, 2001; 67 FR 79966, 80041, Dec. 31, 2002; 69 FR 66236, 66424, Nov. 15, 2004; 70 FR 70116, 70332, Nov. 21, 2005; 72 FR 66222, 66401, Nov. 27, 2007; 73 FR 69726, 69936, Nov. 19, 2008; 74 FR 61738, 62006, Nov. 25, 2009; 75 FR 73170, 73617, Nov. 29, 2010; 76 FR 73026, 73471, Nov. 28, 2011; 77 FR 68892, 69363, Nov. 16, 2012; 78 FR 74230, 74812, Dec. 10, 2013]

AUTHORITY:
AUTHORITY NOTE APPLICABLE TO ENTIRE PART:
Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

NOTES:
[EFFECTIVE DATE NOTE: 77 FR 68892, 69363, Nov. 16, 2012, revised paragraph (a)(1), effective Jan. 1, 2013; 78 FR 74230, 74812, Dec. 10, 2013, revised paragraph (a)(1), effective Jan. 1, 2014.]

[EFFECTIVE DATE NOTE: 78 FR 74230, 74812, Dec. 10, 2013, revised paragraphs (o)(1) and (2), effective Jan. 1, 2015.]

NOTES APPLICABLE TO ENTIRE CHAPTER:
[PUBLISHER'S NOTE: Nomenclature changes affecting Chapter IV appear at 45 FR 53806, Aug. 13, 1980; 50 FR 12741, Mar. 29, 1985; 50 FR 33034, Aug. 16, 1985; 51 FR 41338, Nov. 14, 1986; 53 FR 6634, Mar. 2, 1988; 53 FR 47201, Nov. 22, 1988; 56 FR 8852, Mar. 1, 1991; 66 FR 39450, 39452, July 31, 2001; 67 FR 36539, 36540, May 24, 2002; 77 FR 29002, 29028, May 16, 2012.]

NOTES APPLICABLE TO ENTIRE PART:
EDITORIAL NOTE: Nomenclature changes affecting this part appear at 60 FR 50442, Sept. 29, 1995, and 60 Fr 53877, Oct. 18, 1995.
[PUBLISHER'S NOTE: For Federal Register citation concerning Part 414 Physician Fee Schedule, see 68 FR 9567, Feb. 28, 2003.]

TITLE 42 -- PUBLIC HEALTH
CHAPTER IV -- CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER B -- MEDICARE PROGRAM
PART 424 -- CONDITIONS FOR MEDICARE PAYMENT
SUBPART B -- CERTIFICATION AND PLAN REQUIREMENTS

42 CFR 424.22

§ 424.22 Requirements for home health services.

Medicare Part A or Part B pays for home health services only if a physician certifies and recertifies the content specified in paragraphs (a)(1) and (b)(2) of this section, as appropriate.

(a) Certification -- (1) Content of certification. As a condition for payment of home health services under Medicare Part A or Medicare Part B, a physician must certify as follows:

(i) The individual needs or needed intermittent skilled nursing care, or physical or speech therapy, or (for the period from July through November 30, 1981) occupational therapy. If a patient's underlying condition or complication requires a registered nurse to ensure that essential non-skilled care is achieving its purpose, and necessitates a registered nurse be involved in the development, management, and evaluation of a patient's care plan, the physician will include a brief narrative describing the clinical justification of this need. If the narrative is part of the certification or recertification form, then the narrative must be located immediately prior to the physician's signature. If the narrative exists as an addendum to the certification or recertification form, in addition to the physician's signature on the certification or recertification form, the physician must sign immediately following the narrative in the addendum.

(ii) Home health services were required because the individual was confined to the home except when receiving outpatient services.

(iii) A plan for furnishing the services has been established and is periodically reviewed by a physician who is a doctor of medicine, osteopathy, or podiatric medicine, and who is not precluded from performing this function under paragraph (d) of this section. (A doctor of podiatric medicine may perform only plan of treatment functions that are consistent with the functions he or she is authorized to perform under State law.)

(iv) The services were furnished while the individual was under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine. n1

n1 As a condition of Medicare Part A payment for home health services furnished before July 1981, the

physician was also required to certify that the services were needed for a condition for which the individual had received inpatient hospital or SNF services.

(v) The physician responsible for performing the initial certification must document that the face-to-face patient encounter, which is related to the primary reason the patient requires home health services, has occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care by including the date of the encounter, and including an explanation of why the clinical findings of such encounter support that the patient is homebound and in need of either intermittent skilled nursing services or therapy services as defined in § 409.42(a) and (c) of this chapter, respectively.

(A) The face-to-face encounter must be performed by one of the following:

(1) The certifying physician himself or herself.

(2) A physician, with privileges, who cared for the patient in an acute or post-acute care facility from which the patient was directly admitted to home health.

(3) A nurse practitioner or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5) of the Act) who is working in accordance with State law and in collaboration with the certifying physician or in collaboration with an acute or post-acute care physician with privileges who cared for the patient in the acute or post-acute care facility from which the patient was directly admitted to home health.

(4) A certified nurse midwife (as defined in section 1861(gg)of the Act) as authorized by State law, under the supervision of the certifying physician or under the supervision of an acute or post-acute care physician with privileges who cared for the patient in the acute or post-acute care facility from which the patient was directly admitted to home health.

(5) A physician assistant (as defined in section 1861(aa)(5) of the Act) under the supervision of the certifying physician or under the supervision of an acute or post-acute care physician with privileges who cared for the patient in the acute or post-acute care facility from which the patient was directly admitted to home health.

(B) The documentation of the face-to-face patient encounter must be a separate and distinct section of, or an addendum to, the certification, and must be clearly titled and dated and the certification must be signed by the certifying physician.

(C) In cases where the face-to-face encounter is performed by a physician who cared for the patient in an acute or post-acute care facility or by a nonphysician practitioner in collaboration with or under the supervision of such an acute or post-acute care physician and that nonphysician practitioner is not directly communicating to the certifying physician the clinical findings (that is, the patient's homebound status and need for intermittent skilled nursing services or therapy services as defined in § 409.42(a) and (c) of this chapter), the acute or post-acute care physician must communicate the clinical findings of that face-to-face encounter to the certifying physician. In all other cases where a nonphysician practitioner performs the face-to-face encounter, the nonphysician practitioner must communicate the clinical findings of that face-to-face patient encounter to the certifying physician.

(D) If a face-to-face patient encounter occurred within 90 days of the start of care but is not related to the primary reason the patient requires home health services, or the patient has not seen the certifying physician or allowed nonphysician practitioner within the 90 days prior to the start of the home health episode, the certifying physician or nonphysician practitioner must have a face to face encounter with the patient within 30 days of the start of the home health care.

(E) The face-to-face patient encounter may occur through **telehealth,** in compliance with Section 1834(m) of

the Act and subject to the list of payable Medicare **telehealth** services established by the applicable physician fee schedule regulation.

(F) The physician responsible for certifying the patient for home care must document the face-to-face encounter on the certification itself, or as an addendum to the certification (as described in paragraph (a)(1)(v) of this section), that the condition for which the patient was being treated in the face-to-face patient encounter is related to the primary reason the patient requires home health services, and why the clinical findings of such encounter support that the patient is homebound and in need of either intermittent skilled nursing services or therapy services as defined in § 409.42(a) and (c) respectively. The documentation must be clearly titled and dated and the documentation must be signed by the certifying physician.

(2) Timing and signature. The certification of need for home health services must be obtained at the time the plan of care is established or as soon thereafter as possible and must be signed and dated by the physician who establishes the plan.

(b) Recertification. (1) Timing and signature of recertification. Recertification is required at least every 60 days, preferably at the time the plan is reviewed, and must be signed and dated by the physician who reviews the plan of care. The recertification is required at least every 60 days when there is a--

(i) Beneficiary elected transfer; or

(ii) Discharge and return to the same HHA during the 60-day episode.

(2) Content and basis of recertification. The recertification statement must indicate the continuing need for services and estimate how much longer the services will be required. Need for occupational therapy may be the basis for continuing services that were initiated because the individual needed skilled nursing care or physical therapy or speech therapy. If a patient's underlying condition or complication requires a registered nurse to ensure that essential non-skilled care is achieving its purpose, and necessitates a registered nurse be involved in the development, management, and evaluation of a patient's care plan, the physician will include a brief narrative describing the clinical justification of this need. If the narrative is part of the certification or recertification form, then the narrative must be located immediately prior to the physician's signature. If the narrative exists as an addendum to the certification or recertification form, in addition to the physician's signature on the certification or recertification form, the physician must sign immediately following the narrative in the addendum.

(c) [Reserved]

(d) Limitation of the performance of physician certification and plan of care functions. The need for home health services to be provided by an HHA may not be certified or recertified, and a plan of care may not be established and reviewed, by any physician who has a financial relationship as defined in § 411.354 of this chapter, with that HHA, unless the physician's relationship meets one of the exceptions in section 1877 of the Act, which sets forth general exceptions to the referral prohibition related to both ownership/investment and compensation; exceptions to the referral prohibition related to ownership or investment interests; and exceptions to the referral prohibition related to compensation arrangements.

(1) If a physician has a financial relationship as defined in § 411.354 of this chapter, with an HHA, the physician may not certify or recertify need for home health services provided by that HHA, establish or review a plan of treatment for such services, or conduct the face-to-face encounter required under sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act unless the financial relationship meets one of the exceptions set forth in § 411.355 through § 411.357 of this chapter.

(2) A Nonphysician practitioner may not perform the face-to-face encounter required under sections

1814(a)(2)(C) and 1835(a)(2)(A) of the Act if such encounter would be prohibited under paragraph (d)(i) if the nonphysician practitioner were a physician.

HISTORY:
[53 FR 6638, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988; 56 FR 8845, Mar. 1, 1991; 65 FR 41128, 41211, July 3, 2000; 66 FR 856, 962, Jan. 4, 2001, as corrected and amended at 66 FR 8771, Feb. 2, 2001; 69 FR 16054, 16143, Mar. 26, 2004; 70 FR 70116, 70334, Nov. 21, 2005; 72 FR 51012, 51098, Sept. 5, 2007; 74 FR 58078, 58133, Nov. 10, 2009; 75 FR 70372, 70463, Nov. 17, 2010; 76 FR 9502, 9503, Feb. 18, 2011; 76 FR 68526, 68606, Nov. 4, 2011; 77 FR 67068, 67163, Nov. 8, 2012]

AUTHORITY:
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Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

NOTES:
[EFFECTIVE DATE NOTE: 75 FR 70372, 70463, Nov. 17, 2010, amended this section, effective Jan. 1, 2011; 76 FR 9502, 9503, Feb. 18, 2011, added paragraphs (b)(1)(i) and (b)(1)(ii), effective Feb. 18, 2011; 76 FR 68526, 68606, Nov. 4, 2011, amended paragraph (a)(1)(v), effective Jan. 1, 2012; 77 FR 67068, 67163, Nov. 8, 2012, amended paragraph (a)(1)(v), effective Jan. 1, 2013.]

NOTES APPLICABLE TO ENTIRE CHAPTER:
[PUBLISHER'S NOTE: Nomenclature changes affecting Chapter IV appear at 45 FR 53806, Aug. 13, 1980; 50 FR 12741, Mar. 29, 1985; 50 FR 33034, Aug. 16, 1985; 51 FR 41338, Nov. 14, 1986; 53 FR 6634, Mar. 2, 1988; 53 FR 47201, Nov. 22, 1988; 56 FR 8852, Mar. 1, 1991; 66 FR 39450, 39452, July 31, 2001; 67 FR 36539, 36540, May 24, 2002; 77 FR 29002, 29028, May 16, 2012.]

NOTES APPLICABLE TO ENTIRE PART:
[PUBLISHER'S NOTE: 72 FR 13710, Mar. 23, 2007, provides "This notice extends the timeline for publication of the Phase III final rule through March 26, 2008. In accordance with section 1871(a)(3)(C) of the Act, the March 26, 2004 interim final rule [69 FR 16054] shall remain in effect through March 26, 2008 (unless Phase III is published and becomes effective before March 26, 2008)."]
[PUBLISHER'S NOTE: For Federal Register citations concerning Part 424 Rulings, see: 78 FR 16614, Mar. 18, 2013.]
[PUBLISHER'S NOTE: For Federal Register citations concerning Part 424 Extension and establishment of temporary moratoria, see: 79 FR 6475, Feb. 4, 2014.]

LexisNexis (R) Notes:

CASE NOTES

CASE NOTES Applicable to entire Part:Part Note
Governments > Federal Government > Claims By & Against
Healthcare Law > Antitrust Actions > Facilities
Healthcare Law > Managed Healthcare > Home Health Agencies
Public Health & Welfare Law > Social Security > Medicare > Coverage > General Overview
Public Health & Welfare Law > Social Security > Medicare > Providers > General Overview

Governments > Federal Government > Claims By & Against
Ebeid v. Lungwitz, 616 F.3d 993, 2010 U.S. App. LEXIS 16438 (9th Cir Aug. 9, 2010), writ of certiorari denied by 131 S. Ct. 801, 178 L. Ed. 2d 546, 2010 U.S. LEXIS 9456, 79 U.S.L.W. 3343 (U.S. 2010).

Overview: *In an False Claims Act qui tam action under a theory of implied false certification for the unlawful corporate practice of medicine and referrals among health care businesses, which allegedly made fraudulent providers' claims for Medicare reimbursement, a physician failed to plead fraud with sufficient particularity to satisfy Fed. R. Civ. P. 9(b).*

- Like the Stark Act, 42 C.F.R. § 424.22(d) may serve as the basis for an implied false certification because it provides a condition of payment, not participation. Go To Headnote

Healthcare Law > Antitrust Actions > Facilities
Ebeid v. Lungwitz, 616 F.3d 993, 2010 U.S. App. LEXIS 16438 (9th Cir Aug. 9, 2010), writ of certiorari denied by 131 S. Ct. 801, 178 L. Ed. 2d 546, 2010 U.S. LEXIS 9456, 79 U.S.L.W. 3343 (U.S. 2010).

Overview: *In an False Claims Act qui tam action under a theory of implied false certification for the unlawful corporate practice of medicine and referrals among health care businesses, which allegedly made fraudulent providers' claims for Medicare reimbursement, a physician failed to plead fraud with sufficient particularity to satisfy Fed. R. Civ. P. 9(b).*

- Like the Stark Act, 42 C.F.R. § 424.22(d) may serve as the basis for an implied false certification because it provides a condition of payment, not participation. Go To Headnote
- Certification of compliance with the ban on financial relationships prohibited under 42 C.F.R. § 424.22(d) may be inferred by the submission of a related Medicare claim for home health care services. Go To Headnote

Healthcare Law > Managed Healthcare > Home Health Agencies
United States Ex Rel. Roberts v. Aging Care Home Health, Inc., 474 F. Supp. 2d 810, 2007 U.S. Dist. LEXIS 11242 (WD LA Feb. 16, 2007).

Overview: *A home health care provider that fraudulently billed Medicare for physicians' services prior to 2001 was liable under the Stark Act, 42 U.S.C.S. § 1395nn; a magistrate judge erred in concluding that 42 C.F.R. § 424.22(d) was the only substantive regulation governing prohibited physician referrals before final regulations were published in 2001.*

- 42 C.F.R. § 424.22(d) (1982) restricts the financial relationship between a physician who certifies the need for home health services or establishes and reviews a plan of treatment and a home health services provider (HHA). Under § 424.22(d)(3), a HHA cannot bill the Medicare program if certifying physicians receive more than $25,000 or 5 percent of a HHA's operating expenses for the year, whichever is less. Go To Headnote
- In 2001, final regulations for the Stark Act (Stark II), 42 U.S.C.S. § 1395nn, were published. 66 Fed. Reg. 856 (Jan. 4, 2001). The $25,000 limit in 42 C.F.R. § 424.22(d) (1982) no longer exists. 42 C.F.R. § 424.22(d) (2001) contains the same limits on financial relationships as Stark II. Go To Headnote
- While the Stark Act, 42 U.S.C.S. § 1395nn, and 42 C.F.R. § 424.22(d) (1982) overlap, they are not mutually exclusive. Go To Headnote

Public Health & Welfare Law > Social Security > Medicare > Coverage > General Overview
Ebeid v. Lungwitz, 616 F.3d 993, 2010 U.S. App. LEXIS 16438 (9th Cir Aug. 9, 2010), writ of certiorari denied by 131 S. Ct. 801, 178 L. Ed. 2d 546, 2010 U.S. LEXIS 9456, 79 U.S.L.W. 3343 (U.S. 2010).

Overview: *In an False Claims Act qui tam action under a theory of implied false certification for the unlawful corporate practice of medicine and referrals among health care businesses, which allegedly made fraudulent providers' claims for Medicare reimbursement, a physician failed to plead fraud with sufficient particularity to satisfy Fed. R. Civ. P. 9(b).*

- Medicare pays for home health services only if a physician certifies and recertifies the need for home health care services. 42 C.F.R. § 424.22. Go To Headnote

Public Health & Welfare Law > Social Security > Medicare > Providers > General Overview
Ebeid v. Lungwitz, 616 F.3d 993, 2010 U.S. App. LEXIS 16438 (9th Cir Aug. 9, 2010), writ of certiorari denied by 131 S. Ct. 801, 178 L. Ed. 2d 546, 2010 U.S. LEXIS 9456, 79 U.S.L.W. 3343 (U.S. 2010).

Overview: *In an False Claims Act qui tam action under a theory of implied false certification for the unlawful corporate practice of medicine and referrals among health care businesses, which allegedly made fraudulent providers' claims for Medicare reimbursement, a physician failed to plead fraud with sufficient particularity to satisfy Fed. R. Civ. P. 9(b).*

- Like the Stark Act, 42 C.F.R. § 424.22(d) may serve as the basis for an implied false certification because it provides a condition of payment, not participation. Go To Headnote
- Medicare pays for home health services only if a physician certifies and recertifies the need for home health care services. 42 C.F.R. § 424.22. Go To Headnote
- Certification of compliance with the ban on financial relationships prohibited under 42 C.F.R. § 424.22(d) may be inferred by the submission of a related Medicare claim for home health care services. Go To Headnote

*** This document is current through the May 1, 2014 ***
*** issue of the Federal Register, except for the amendments appearing at ***
*** 79 FR 23414, April 28, 2014 and at 79 FR 24192, April 29, 2014 ***

TITLE 42 -- PUBLIC HEALTH
CHAPTER IV -- CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER C -- MEDICAL ASSISTANCE PROGRAMS
PART 441 -- SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES
SUBPART K--HOME AND COMMUNITY-BASED ATTENDANT SERVICES AND SUPPORTS STATE PLAN OPTION (COMMUNITY FIRST CHOICE)

42 CFR 441.535

§ 441.535 Assessment of functional need.

States must conduct a face-to-face assessment of the individual's needs, strengths, preferences, and goals for the services and supports provided under Community First Choice in accordance with the following:

(a) States may use one or more processes and techniques to obtain information, including **telemedicine**, or other information technology medium, in lieu of a face-to-face assessment if the following conditions apply:

(1) The health care professional(s) performing the assessment meet the provider qualifications defined by the State, including any additional qualifications or training requirements for the operation of required information technology;

(2) The individual receives appropriate support during the assessment, including the use of any necessary on-site support-staff; and

(3) The individual is provided the opportunity for an in-person assessment in lieu of one performed via **telemedicine**.

(b) Assessment information supports the determination that an individual requires Community First Choice and also supports the development of the person-centered service plan and, if applicable, service budget.

(c) The assessment of functional need must be conducted at least every 12 months, as needed when the individual's support needs or circumstances change significantly necessitating revisions to the person-centered service plan, and at the request of the individual.

(d) Other requirements as determined by the Secretary.

HISTORY:
[77 FR 26828, 26898, May 7, 2012]

AUTHORITY:
AUTHORITY NOTE APPLICABLE TO ENTIRE PART:
Secs. 1102, 1902, and 1928 of the Social Security Act (42 U.S.C. 1302).

NOTES:
[EFFECTIVE DATE NOTE: 77 FR 26828, 26898, May 7, 2012, added Subpart K, effective July 6, 2012.]

NOTES APPLICABLE TO ENTIRE CHAPTER:
[PUBLISHER'S NOTE: Nomenclature changes affecting Chapter IV appear at 45 FR 53806, Aug. 13, 1980; 50 FR 12741, Mar. 29, 1985; 50 FR 33034, Aug. 16, 1985; 51 FR 41338, Nov. 14, 1986; 53 FR 6634, Mar. 2, 1988; 53 FR 47201, Nov. 22, 1988; 56 FR 8852, Mar. 1, 1991; 66 FR 39450, 39452, July 31, 2001; 67 FR 36539, 36540, May 24, 2002; 77 FR 29002, 29028, May 16, 2012.]

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TITLE 42 -- PUBLIC HEALTH
CHAPTER IV -- CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER C -- MEDICAL ASSISTANCE PROGRAMS
SUBPART M--STATE PLAN HOME AND COMMUNITY-BASED SERVICES FOR ELDERLY AND DISABLED INDIVIDUALS

42 CFR 441.720

§ 441.720 Independent assessment.

(a) Requirements. For each individual determined to be eligible for the State plan HCBS benefit, the State must provide for an independent assessment of needs, which may include the results of a standardized functional needs assessment, in order to establish a service plan. In applying the requirements of section 1915(i)(1)(F) of the Act, the State must:

(1) Perform a face-to-face assessment of the individual by an agent who is independent and qualified as defined in § 441.730, and with a person-centered process that meets the requirements of § 441.725(a) and is guided by best practice and research on effective strategies that result in improved health and quality of life outcomes.

(i) For the purposes of this section, a face-to-face assessment may include assessments performed by **telemedicine,** or other information technology medium, if the following conditions are met:

(A) The agent performing the assessment is independent and qualified as defined in § 441.730 and meets the provider qualifications defined by the State, including any additional qualifications or training requirements for the operation of required information technology.

(B) The individual receives appropriate support during the assessment, including the use of any necessary on-site support-staff.

(C) The individual provides informed consent for this type of assessment.

(ii) [Reserved]

(2) Conduct the assessment in consultation with the individual, and if applicable, the individual's authorized representative, and include the opportunity for the individual to identify other persons to be consulted, such as, but not limited to, the individual's spouse, family, guardian, and treating and consulting health and support professionals responsible for the individual's care.

(3) Examine the individual's relevant history including the findings from the independent evaluation of eligibility, medical records, an objective evaluation of functional ability, and any other records or information needed to develop the person-centered service plan as required in § 441.725.

(4) Include in the assessment the individual's physical, cognitive, and behavioral health care and support needs, strengths and preferences, available service and housing options, and if unpaid caregivers will be relied upon to implement any elements of the person-centered service plan, a caregiver assessment.

(5) For each service, apply the State's additional needs-based criteria (if any) that the individual may require. Individuals are considered enrolled in the State plan HCBS benefit only if they meet the eligibility and needs-based criteria for the benefit, and are also assessed to require and receive at least one home and community-based service offered under the State plan for medical assistance.

(6) Include in the assessment, if the State offers individuals the option to self-direct a State plan home and community-based service or services, any information needed for the self-directed portion of the service plan, as required in § 441.740(b), including the ability of the individual (with and without supports) to exercise budget or employer authority.

(7) Include in the assessment, for individuals receiving habilitation services, documentation that no Medicaid services are provided which would otherwise be available to the individual, specifically including but not limited to services available to the individual through a program funded under section 110 of the Rehabilitation Act of 1973, or the Individuals with Disabilities Education Improvement Act of 2004.

(8) Include in the assessment and subsequent service plan, for individuals receiving Secretary approved services under the authority of § 440.182 of this chapter, documentation that no State plan HCBS are provided which would otherwise be available to the individual through other Medicaid services or other Federally funded programs.

(9) Include in the assessment and subsequent service plan, for individuals receiving HCBS through a waiver approved under § 441.300, documentation that HCBS provided through the State plan and waiver are not duplicative.

(10) Coordinate the assessment and subsequent service plan with any other assessment or service plan required for services through a waiver authorized under section 1115 or section 1915 of the Social Security Act.

(b) Reassessments. The independent assessment of need must be conducted at least every 12 months and as needed when the individual's support needs or circumstances change significantly, in order to revise the service plan.

HISTORY:
[79 FR 2948, 3033, Jan. 16, 2014]

NOTES:
[EFFECTIVE DATE NOTE: 79 FR 2948, 3033, Jan. 16, 2014, added Subpart M, effective Mar. 17, 2014.]

NOTES APPLICABLE TO ENTIRE CHAPTER:
[PUBLISHER'S NOTE: Nomenclature changes affecting Chapter IV appear at 45 FR 53806, Aug. 13, 1980; 50 FR 12741, Mar. 29, 1985; 50 FR 33034, Aug. 16, 1985; 51 FR 41338, Nov. 14, 1986; 53 FR 6634, Mar. 2, 1988; 53 FR 47201, Nov. 22, 1988; 56 FR 8852, Mar. 1, 1991; 66 FR 39450, 39452, July 31, 2001; 67 FR 36539, 36540, May 24, 2002; 77 FR 29002, 29028, May 16, 2012.]