

South St. Louis Orthopedic Group, Inc. Pursuant to a written contract, defendant Hardy received an annual salary of \$55,000 and 50-60% of the monthly billed revenue over \$12,000.

4. Defendant Hardy provided services to patients at the offices of South St. Louis Orthopedic Group, Inc., at several nursing homes, and at senior service centers at St. Alexius Hospital and St. Anthony's Medical Center.

**Relevant Medicare and Medicaid
Regulatory and Administrative Provisions**

General Medicare Provisions

5. Medicare is a federal health insurance program for individuals age 65 and older and for certain categories of disabled people. Medicare was authorized in 1965 by Title XVIII of the Social Security Act and is the nation's largest health insurance program. Persons eligible for Medicare-reimbursed services are occasionally referred to as "beneficiaries" or "Medicare beneficiaries."

6. The Centers for Medicare and Medicaid Services (CMS) of the United States Department of Health and Human Services (HHS) administers the Medicare Program.

7. The Secretary of HHS has broad statutory authority to "prescribe such regulations as may be necessary to carry out the administration of the [Medicare] insurance programs..." 42 U.S.C. §1395hh(a)(1).

8. In addition to promulgating regulations, the Secretary has the power to formulate rules for the administration of the Medicare Program, through the issuance of manual instructions, interpretative rules, statements of policy, and guidelines of general applicability. 42 U.S.C. §1395hh(c)(1). Under this power the Secretary of HHS formulated the Medicare Carrier's

Manual. HHS requires that providers comply with the Medicare Carrier's Manual, as well as Medicare statutes and regulations, when submitting reimbursement claims for services.

9. CMS selects and contracts with private insurance companies to act as its agents in administering the Medicare Program and these insurance companies are responsible for receiving, reviewing, and paying claims for services provided to Medicare beneficiaries. These private insurance companies are called carriers or intermediaries. At all times relevant to this indictment, Arkansas Blue Cross Blue Shield (now known as Pinnacle Business Solutions, Inc.) was the Medicare carrier for the state of Missouri (referred to hereafter as Medicare Carrier).

10. A person or entity rendering a medical service to Medicare beneficiaries must enter into a written "provider agreement" with Medicare. Providers agree that they will comply with all applicable Medicare statutes, regulations and guidelines. To obtain reimbursement for services rendered, the provider must submit a claim form and certify that the information on the Medicare claim form is accurate, including the identity of the patient, the provider number, the service provided, and the medical necessity for the service rendered.

11. Because of the large number of claims received by Medicare carriers, carriers generally rely on and pay claims based on the information on the Medicare claim forms and the providers' certifications. However, Medicare providers are required to document services rendered to Medicare beneficiaries and if requested, must produce the documents reflecting the patients' conditions, diagnoses, and treatments.

General Medicaid Provisions

12. Title XIX of the Social Security Act, 42 U.S.C. §§1396, et seq., established the Grants to States for Medical Assistance Programs, popularly known as the Medicaid Program.

The Medicaid Program is a federal and state-funded health insurance program administered by the various states. The State of Missouri administers its Medicaid Program through the Department of Social Services, Division of Medical Services (“Missouri Medicaid”). Missouri Medicaid provides health insurance for the indigent population of the state.

13. In order to be reimbursed by Medicaid, a person or entity rendering a medical service to Medicaid beneficiaries must enter into a “provider agreement” with Missouri Medicaid. Providers agree that they will comply with all applicable Medicaid statutes, regulations and guidelines.

14. When a provider renders services to a person who is both a Medicare beneficiary and a Medicaid beneficiary, the provider submits the claim to Medicare only. If the claim is acceptable to Medicare, Medicare pays 80% of the allowable charge and sends the claim to Medicaid for payment of 20% of the allowable charge. This latter payment is sometimes called a crossover claim or payment. Missouri Medicaid relies on the review by Medicare of the claim and generally does not independently review the claim prior to payment.

Medicare Coverage for Debridement of Nails

15. In general, Medicare will only pay for items or services which are reasonable and necessary to diagnose or treat an illness or injury.

16. Under Medicare regulations, routine foot care is generally a non-covered service. “Medicare Local Coverage Determination AC - 03-003.” Services that are normally considered routine and not covered by Medicare include the trimming, clipping, or debriding of nails. However, in very limited circumstances, Medicare reimburses for routine foot care, including toenail debridement, which is defined as the: “significant reduction in the thickness and length

of the nail to the tolerance of the patient with the aim of allowing the patient to ambulate without pain.” Medicare LCD AC - 03-003. Simple trimming of the end of the toenails by cutting or grinding is not considered debridement.

Documented Systemic Conditions

17. Certain foot care procedures, that are otherwise considered routine by Medicare, may be covered by Medicare if the patient has a systemic condition that causes severe circulatory problems or areas of diminished sensation in the legs or feet. Under such circumstances, the patient may require foot care by a professional because foot care performed by a non-professional could be hazardous to the patient.

18. Debridement of toenails may be covered by Medicare for patients who are diagnosed with peripheral vascular disease (PVD), which is the narrowing or blocking of blood vessels resulting in ischemia. Ischemia is defined as poor blood circulation or an inadequate blood flow to the tissues of the body, often in arteries leading to the legs and feet. Medicare covers toenail debridement for patients with PVD, only if the patient has intermittent claudication, that is, pain on walking that causes the patient to limp or stop. Medicare Part B Local Coverage Determination Policy AC-02 043.

19. However, the presence of a systemic condition such as PVD is not sufficient, without more, to obtain Medicare reimbursement. Additionally, the patient must have specific symptoms or findings documented in the medical record and identified on the claim form by one of the following modifiers:

- Q7 modifier, which indicates that the patient has had a non-traumatic amputation of the foot or integral skeletal portion thereof, referred to as a Class A finding;

- Q8 modifier, which indicates that the patient has two Class B findings:
 - no posterior tibia pulse;
 - no dorsalis pedis pulse;
 - advanced trophic changes (three of which are equal to one Class B finding): no or decreased hair growth; nail changes with thickening; pigment changes with discoloration; thin and shiny skin texture; skin color with rubor or redness; or
- Q9 modifier, which indicates that the patient has one Class B and two Class C findings, which include: claudication (pain in the calf); temperature changes (e.g., cold feet); edema; paresthesias (abnormal spontaneous sensations in the feet); or burning.

20. In summary, Medicare will cover debridement of the toenails if the patient has a documented systemic condition and class findings, and also has certain toenail conditions, including nail fungus (ICD-9 code 110.1), ingrown nails with infection (ICD-9 code 703.0), other specified diseases (ICD-9 code 703.8), and anomalies of the nail (ICD-9 code 757.5).

Documented Onychomycosis of the Nails

21. If the patient does not have a systemic condition, Medicare may nonetheless reimburse for toenail debridement if the patient has onychomycosis of the nails and certain other symptoms also exist. Onychomycosis is sometimes referred to as mycosis, mycotic nails, or simply toenail fungus.

22. Medicare will reimburse for the treatment of mycotic nails only if the physician attending the patient's mycotic condition documents that

- there is clinical evidence of mycosis of the toenail and
- an ambulatory patient has marked limitation of ambulation, pain, or a secondary infection resulting from the thickening and dystrophy of the infected toenail plate
or
- a non-ambulatory patients suffers from pain or secondary infection resulting from the thickening and dystrophy of the infected toenail plate.

CPT Codes and ICD-9 Codes

23. Health care providers utilize numerical codes, called CPT codes and ICD-9 codes, on their claim forms to identify the services provided to the patient and the medical diagnoses justifying the services.

24. CPT codes or “Current Procedural Terminology” codes are a uniform way of accurately describing medical, surgical, and diagnostic services provided to patients. The CPT code consists of a number and descriptive terms. Physicians are required to include the appropriate CPT codes when billing for services provided to Medicare beneficiaries.

25. ICD-9 codes (International Classification of Diseases) are uniform codes that health care providers use to reflect their diagnoses of patients. The ICD-9 code consists of a number and descriptive terms. Physicians are required to include the appropriate ICD-9 codes when billing for services provided to Medicare beneficiaries.

26. CPT code I1720 describes the debridement of one to five nails and CPT code 11721 describes the debridement of six or more nails.

27. ICD code 443.9 is used when a patient is diagnosed with peripheral vascular disease. Medicare Part B Local Coverage Determination Policy AC-02-043 limits the use of ICD-9 code

443.9 to patients with peripheral vascular disease, with intermittent claudication, that is pain on walking that causes the patient to limp or stop.

28. ICD-9 code 110.1 is used when a patient is diagnosed with dermatophytosis, which is defined as a superficial infection of the nail caused by a parasitic fungus.

29. ICD code 703.0 is used when a patient is diagnosed with an ingrowing nail with infection.

Defendant's Fraudulent Billing Practices

30. Prior to September 30, 2003, defendant Hardy and defendant South St. Louis Orthopedic Group, Inc. generally billed Medicare for the debridement of toenails (CPT code 11721) and diagnosed the patients as having mycotic nails, that is, diseased nails due to a fungus (ICD-9 diagnosis code 110.1).

31. In a letter dated September 30, 2003, Medicare informed defendant Hardy that from January 2003 through June 2003, she billed for the debridement of six or more toenails (CPT code 11721) more frequently than any other podiatrist (Medicare specialty 48) in Missouri (not including podiatrists in the Kansas City). During the same period, CPT code 11721 represented 84.02% of defendant Hardy's billings to Medicare and 72.2% of allowed dollars paid by Medicare to defendant Hardy. In the September 2003 letter, Medicare referred defendant Hardy to Medicare Local Coverage Determination AC - 03-003, which specifies when Medicare will reimburse for the debridement of toenails. Defendant Hardy has admitted that she received and read the letter.

32. Almost immediately after receiving the letter, defendant Hardy and defendant South St. Louis Orthopedic Group, Inc. stopped using ICD-9 diagnosis code 110.1 (disease of the nails)

as the primary diagnosis on the claim forms for her debridement patients, although in many cases she had diagnosed the patients as having this disease for years. For these same debridement patients, defendant Hardy now began using ICD-9 diagnosis code 443.9 (peripheral vascular disease) as the primary diagnosis on the claim forms.

False Statements and Claims concerning Fungus of Toenails

33. It was part of the scheme and artifice to defraud that prior to September 2003 defendant Hardy falsely stated in her treatment notes and on claim forms that almost all of her debridement patients had diseased nails due to a fungus, when she knew that most of the patients did not have the disease. Defendant Hardy's treatment notes do not reflect any treatment, other than debridement, for the diseased nails. Although fungus of the nails is a communicable disease, defendant Hardy never informed the nursing home staff that any of the residents had fungus of the nails.

False Statements concerning Pain on Ambulation

34. The word "ambulate" is defined as the act of walking from place to place or traveling by foot. The word "ambulatory" is defined as capable of walking and not bed-ridden.

35. It was further part of the scheme and artifice to defraud that defendant Hardy falsely indicated in her treatment notes that the patients had pain on ambulation (POA) that restricted activities or the patient could not ambulate without pain. Some of the patients for whom defendant Hardy described pain on ambulation were paralyzed, bed-ridden, or confined to a wheelchair or geri-chair.

36. As an example, it was further part of the scheme and artifice to defraud that defendant Hardy falsely stated in her treatment notes that South County Nursing Center patient

D.A., who is paralyzed from the neck down and bed-ridden, had “pain on ambulation that restricts activities . . . [and] patient cannot ambulate without pain.”

37. As another example, defendant Hardy falsely stated in her treatment notes that Northview Village Nursing Home patient D.S., who is paralyzed from the waist down, had “pain on ambulation that restricts activities . . . [and] cannot ambulate without pain.”

38. As another example, defendant Hardy falsely stated in her treatment notes that South County patient V. M., who is bed-ridden, had “pain on ambulation that restricts activities . . . and patient cannot ambulate without pain.”

False Statements and Claims concerning Peripheral Vascular Disease

39. It was further part of the scheme and artifice to defraud that defendant Hardy falsely indicated in her treatment notes that almost all of her debridement patients lacked a pulse or had severely compromised circulation in their feet. Defendant Hardy never informed the nursing home staff that the residents suffered from compromised circulation.

40. It was further part of the scheme and artifice to defraud that Defendant Hardy falsely stated on the claim forms that patients had PVD and used CPT code 443.9 although she knew that the patients did not have claudication, that is pain when walking. Medicare Local Coverage Determination AC-02-043 states that ICD-9 code 443.9 is used when there is peripheral vascular disease, with intermittent claudication.

41. It was further part of the scheme and artifice to defraud that defendant Hardy falsely stated in her treatment notes and claim forms that the following residents had peripheral vascular disease. No medical professional, other than defendant Hardy, had diagnosed PVD in these patients at the time defendant Hardy was purportedly providing treatment.

- M.A.
- M.B.
- F.C.
- A.C.
- P.C.
- R.D.
- H.F.
- R.J.
- E.J.
- A.K.
- R.M.
- S.M.
- L.P.
- A.P.
- E.T.

Billing for Non-Rendered Services

42. It was further part of the scheme and artifice to defraud that defendant Hardy and defendant South St. Louis Orthopedic Group, Inc. submitted, or caused to be submitted, claims to Medicare for debridement when she knew she had not provided a debridement.

43. It was further part of the scheme and artifice to defraud that defendant Hardy and defendant South St. Louis Orthopedic Group, Inc. submitted, or caused to be submitted, claims to Medicare that falsely indicated that she had provided toenail debridements (CPT code 11721) to 85 patients on a single day-- January 7, 2001, when she knew that she had not provided all these services.

44. It was further part of the scheme and artifice to defraud that defendant Hardy and defendant South St. Louis Orthopedic Group, Inc. submitted, or caused to be submitted, claims to Medicare, that falsely indicated that she had provided toenail debridements (CPT code 11721) to 96 patients on a single day-- February 17, 2001, when she knew that she had not provided all these services.

On or about November 29, 2004, in the Eastern District of Missouri,

**DENISE HARDY, and
SOUTH ST. LOUIS ORTHOPEDIC GROUP, INC.,**

the defendants herein, knowingly and willfully executed and attempted to execute, the above described scheme or artifice to defraud Medicare and Missouri Medicaid, which are health care benefit programs, in connection with the delivery and payment for health care benefits, items, and services, that is, defendant Hardy made entries, that she knew to be false, in the medical records of Patient D.A. concerning his medical diagnoses, conditions, and symptoms and submitted a claim, that she knew contained false information, in order to obtain reimbursement for services that she purportedly rendered to Patient D.A.

All in violation of Title 18, United States Code, Sections 1347 and 2.

COUNTS 2-20

**FALSE STATEMENTS CONCERNING
HEALTH CARE BENEFIT PROGRAM
18 USC 1035(a)(2)**

The Grand Jury further charges that:

45. Paragraphs 1 through 43 are incorporated as if fully set forth herein.
46. On or about the dates indicated below, in the Eastern District of Missouri,

**DENISE HARDY, and
SOUTH ST. LOUIS ORTHOPEDIC GROUP, INC.,**

the defendants herein, in a matter involving a health care benefit program, knowingly and willfully made and used, and caused to be made and used, materially false writings and documents knowing the same to contain materially false, fictitious, and fraudulent statements and entries in connection with the delivery of or payment for health care benefits, items, and services,

that is, defendant Hardy stated and represented in her treatment notes (which are part of the patients' medical records) that patients had pain on ambulation, when defendant Hardy then and there well knew said statements and representations were false.

<u>COUNT</u>	<u>BENEFICIARY</u>	<u>DATE OF SERVICE</u>
2	D.A.	November 29, 2004
3	D.C.	November 29, 2004
4	D.E.	February 7, 2005
5	D.E.	April 14, 2005
6	B.F.	July 5, 2004
7	B.F.	February 11, 2005
8	R.J.	November 17, 2004
9	E.J.	December 14, 2004
10	E.J.	March 5, 2005
11	R.M.	November 22, 2004
12	V.M.	October 27, 2004
13	V.M.	March 23, 2005
14	A.P.	October 27, 2004
15	A.P.	March 23, 2005
16	D.S.	May 26, 2004
17	D.S.	February 19, 2005
18	D.S.	May 5, 2005
19	V.T.	March 10, 2005

20 V.T. July 9, 2005

All in violation of Title 18, United States Code, Sections 1035(a)(2) and 2.

COUNTS 21 -30

**FALSE STATEMENTS CONCERNING
HEALTH CARE BENEFIT PROGRAM
18 USC 1035(a)(2)**

The Grand Jury further charges that:

47. Paragraphs 1 through 43 are incorporated as if fully set forth herein.

48. On or about the dates indicated below, in the Eastern District of Missouri,

**DENISE HARDY, and
SOUTH ST. LOUIS ORTHOPEDIC GROUP, INC.,**

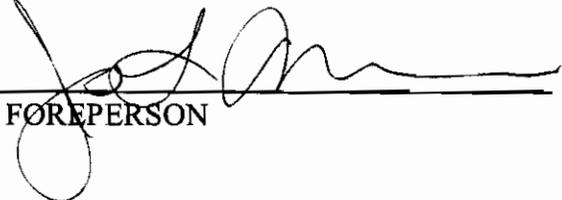
the defendants herein, in a matter involving a health care benefit program, knowingly and willfully made and used, and caused to be made and used, materially false writings and documents knowing the same to contain materially false, fictitious, and fraudulent statements and entries in connection with the delivery of or payment for health care benefits, items, and services, in that Defendant Hardy stated and represented on claim forms that patients had peripheral vascular disease with claudication, when she knew that such statements were false.

<u>COUNT</u>	<u>BENEFICIARY</u>	<u>DATE OF SERVICE</u>
21	M.A.	January 26, 2005
22	M.B.	August 18, 2004
23	F.C.	December 31, 2004
24	P.C.	January 26, 2005
25	R.D.	October 13, 2005

26	E.J.	March 5, 2005
27	A.K.	November 17, 2004
28	R.M.	June 8, 2004
29	A.P.	October 27, 2004
30	E.T.	July 6, 2004

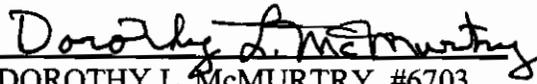
All in violation of Title 18, United States Code, Sections 1035(a)(2) and 2.

A TRUE BILL.



FOREPERSON

CATHERINE L. HANAWAY
United States Attorney



DOROTHY L. McMURTRY, #6703
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