DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General
Office of Audit Services

REGION IV
61 Forsyth Street, S.W., Suite 3T41
Atlanta, Georgia 30303

JUN 28 2007

Report Number: A-04-05-03005

Dr. Ira A. Zucker, President
Florida Urology Physicians, P.A.
7451 Gladiolus Drive, Suite A
Fort Myers, Florida 33908

Dear Dr. Zucker:

Enclosed are two copies of the Department of Health and Human Services, Office of Inspector General (OIG) final report entitled "Audit of Pathology Laboratory Services Claimed by Florida Urology Physicians, P.A. for the Period September Through December 2004." The objectives of this review were to determine whether the Practice claimed reimbursement for pathology laboratory services in accordance with Medicare Part B medical necessity and documentation requirements from September through December 2004 and to analyze the Practice's utilization patterns for pathology services.

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If you have any questions or comments about this report, please do not hesitate to call John Drake, Audit Manager, at (404) 562-7755. Please refer to report number A-04-05-03005 in all correspondence.

Sincerely,

Peter J. Barbera

Peter J. Barbera
Regional Inspector General
for Audit Services, Region IV

Enclosures

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

AUDIT OF PATHOLOGY LABORATORY SERVICES CLAIMED BY FLORIDA UROLOGY PHYSICIANS, P.A. FOR THE PERIOD SEPTEMBER THROUGH DECEMBER 2004

Daniel R. Levinson
Inspector General

June 2007
A-04-05-03005

Office of Inspector General

http://oig.hhs.gov

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In accordance with the principles of the Freedom of Information Act (5 U.S.C. 552, as amended by Public Law 104-231), Office of Inspector General, Office of Audit Services reports are made available to members of the public to the extent the information is not subject to exemptions in the act. (See 45 CFR Part 5.)

OAS FINDINGS AND OPINIONS

The designation of financial or management practices as questionable or a recommendation for the disallowance of costs incurred or claimed, as well as other conclusions and recommendations in this report, represent the findings and opinions of the HHS/OIG/OAS. Authorized officials of the HHS divisions will make final determination on these matters.

EXECUTIVE SUMMARY

BACKGROUND

Congress established Medicare under Title XVIII of the Social Security Act to provide health insurance coverage to people age 65 and over, the disabled, and people with end-stage renal disease. The Medicare program pays for expenses incurred for items or services that are reasonable and necessary for the diagnosis or treatment of illness or injury.

Sections 1833 and 1861 of the Social Security Act provide for payment of clinical diagnostic laboratory services, including pathology services, under Medicare Part B. The services must be ordered either by a physician or a qualified non-physician practitioner and may be furnished by certain entities including hospitals, skilled nursing facilities, and laboratories. A laboratory performing tests on human specimens must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988.

The Medicare program reimburses Medicare entities for pathology services based on the number of biopsies examined. Biopsies are excised tissue packaged and sent to a pathologist for a microscopic examination. Each tissue examination is billed as one unit of service, and each is reimbursed equally within the same Current Procedural Terminology (CPT) code. The majority of pathology services reviewed in this audit were billed under CPT code 88305, "Level IV – Surgical pathology, gross and microscopic examination, Prostate, Needle Biopsy."

Florida Urology Physicians, P.A. (the Practice) is a physicians' group practice located in Fort Myers, Florida, that provides urology services to its patients. Prior to 2004, the Practice ordered pathology services from independent laboratories. In September 2004, the Practice began operating its own laboratory by contracting with a pathologist to provide pathology services and with a management company to oversee the daily operations of the laboratory, with responsibilities that included securing rental space, hiring non-physician personnel, purchasing laboratory supplies, and assisting in ordering furniture and equipment. The Practice's laboratory was one of 15 laboratories operated by the management company within the same office building. The Practice's laboratory contained its own equipment and was in a separate room within this office building.

Through its contractual arrangements, the Practice received Medicare reimbursement totaling $33,587 from September through December of 2004 for pathology services performed at its laboratory in Sarasota, Florida. We contracted with a Medicare Program Safeguard Contractor (PSC) to review the Practice's medical records for 51 paid claims during this period to determine whether pathology services provided were reasonable, medically necessary, and supported by adequate documentation.

OBJECTIVES

Our audit objectives were:

- to determine whether the Practice claimed reimbursement for pathology laboratory services in accordance with Medicare Part B medical necessity and documentation requirements from September through December 2004 and

- to analyze the Practice's utilization patterns for pathology services.

RESULTS OF REVIEW

During our audit period, the Medicare program had not created any national or local coverage determinations or standards for the number of tissue samples that should be examined for urology patients with primarily prostate-related diagnoses. In the absence of these standards, the PSC medical reviewer determined that the Practice's claims for pathology laboratory services generally complied with Medicare Part B medical necessity and documentation requirements. The reviewer stated that the medical necessity for a biopsy procedure could be established, within the realm of professional judgment, for each of the 51 claims reviewed. The reviewer also stated that sufficient documentation existed for each of the claims to indicate that the services billed to Medicare were actually provided.

We noted an increase in the number of pathology services requested and performed after the Practice opened its own laboratory. Prior to the Practice opening its own laboratory in September 2004, the Practice's physicians requested pathology services from independent laboratories on an average of one tissue examination per claim. After establishing its own laboratory, the Practice's physicians requested pathology services on an average of nine tissue examinations per claim. In addition, the Medicare carrier, First Coast Service Options, Inc. (FCSO), reimbursed the Practice for more units of service of CPT 88305, on average, than other providers who were reimbursed by FCSO.

The Practice acknowledged that its utilization increased and explained the increase by noting that industry standards were evolving. The Practice stated that it had increased the number of tissue examination requests from earlier years in an attempt to more fully meet the needs of its patients.

This report contains no recommendations.

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INTRODUCTION

BACKGROUND

Medicare Overview

Congress established Medicare under Title XVIII of the Social Security Act to provide health insurance coverage to people age 65 and over, the disabled, and people with end-stage renal disease. The Medicare program pays for expenses incurred for items or services that are reasonable and necessary for the diagnosis or treatment of illness or injury. Medicare Part B reimburses for physician services, outpatient hospital services, medical equipment, supplies and clinical laboratory services. Within the Department of Health and Human Services, the Centers for Medicare & Medicaid Services (CMS) administers the Medicare program.

Anatomical Pathology Laboratory Services

Sections 1833 and 1861 of the Social Security Act provide for payment of clinical diagnostic laboratory services, including pathology services, under Medicare Part B. The services must be ordered either by a physician, as described in 42 CFR § 410.32(a), or by a qualified non-physician practitioner, as described in 42 CFR § 410.32(a)(3), and may be furnished by any of the entities identified in 42 CFR § 410.32(d)(1), including hospitals, skilled nursing facilities, and laboratories. A laboratory seeking Medicare reimbursement for performing tests on human specimens must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988, as set forth at 42 CFR part 493.

The Medicare program reimburses for pathology services based on the number of biopsies examined. Biopsies are excised tissue packaged and sent to a pathologist for a microscopic examination. Each tissue examination is billed as one unit of service, and each is reimbursed equally within the same Current Procedural Terminology (CPT) code. The majority of pathology services reviewed in this audit were billed under CPT code 88305, "Level IV – Surgical pathology, gross and microscopic examination, Prostate, Needle Biopsy".

Florida Urology Physicians, P.A.

Florida Urology Physicians, P.A. (the Practice) is a physicians' group practice licensed in the State of Florida. As of December 31, 2004, the Practice employed five physicians. Two of the five physicians owned the Practice while the other three physicians were employees of the group. The Practice has been in existence since 2001 and has offices where patients are seen in Cape Coral, Bonita Springs, and Lehigh Acres, Florida, in addition to the main office in Fort Myers, Florida.

In 2004 the Practice started providing pathology laboratory services on behalf of both Medicare and non-Medicare patients through an in-office laboratory. A management company oversaw the daily operations of the laboratory, with responsibilities that included securing rental space, hiring non-physician personnel, purchasing laboratory supplies, and assisting in ordering furniture and equipment. The Practice's laboratory was one of 15 laboratories operated by the

management company within the same office building. The Practice's laboratory contained its own equipment and was in a separate room within this office building. The laboratory is located in Sarasota, Florida, approximately 83 miles from the Practice's main office. The Practice contracted with a physician to serve as the laboratory's pathologist and director. The State of Florida issued a Clinical Laboratory certificate for the Practice's laboratory, effective September 3, 2004, for the performance of tests related to cytology and histopathology.

The Practice received $33,587 in Medicare reimbursement for 51 claims for pathology services performed from September through December 2004 through the contractual arrangements at its Sarasota laboratory. Prior to the contractual arrangements and establishing its laboratory, the Practice ordered these services from independent laboratories. First Coast Service Options, Inc. (FCSO) processed the Medicare claims for the Practice.

OBJECTIVES, SCOPE, AND METHODOLOGY

Objectives

Our audit objectives were:

- to determine whether the Practice claimed reimbursement for pathology laboratory services in accordance with Medicare Part B medical necessity and documentation requirements from September through December 2004 and

- to analyze the Practice's utilization patterns for pathology services.

Scope

We reviewed the 51 Medicare claims totaling $33,587 that FSCO paid during the 4-month period September through December 2004 and provided the associated medical records to the Program Safeguard Contractor (PSC) for medical review to determine whether the pathology services billed for were reasonable, necessary, and in accordance with Medicare Part B requirements.

Our review of internal controls was limited to understanding the Practice's patient biopsy process, labeling and recording of biopsy tissue for shipment to their Sarasota laboratory, receipting and recording of tissue samples at the Sarasota laboratory, laboratory processing, bill processing, and receipting of Medicare payments.

We conducted our fieldwork at the Practice's office in Fort Myers and its laboratory in Sarasota, Florida.

Methodology

To accomplish our objectives, we:

- reviewed applicable provisions of the Social Security Act, Code of Federal Regulations, and the Provider Reimbursement Manual;

- interviewed staff at the Practice's office and laboratory and gained an understanding of the procedures the Practice used at its office and laboratory;

- reviewed various contractual documentation regarding arrangements for laboratory services, including the employment of the contracted pathologist, rental of space, and management operations;

- identified and reviewed the universe of 51 claims that FCSO paid for the Practice's pathology services during the period September through December 2004, to verify compliance with Medicare regulations, and calculated the average number of tissue samples per claim of CPT 88305 that the Practice examined;

- contracted with a PSC to review the Practice's medical records for the 51 claims to determine if pathology services were medically necessary, adequately documented, and performed at the level indicated on the claim;

- identified the units of CPT 88305 per claim for which FSCO paid to independent laboratories that the Practice used during the period September through December 2003;

- identified the units of CPT 88305 per claim that FCSO reimbursed to all other providers during calendar year (CY) 2004; and

- compared[1] the Practice's average units of CPT 88305 per claim before and after it opened its own laboratory and compared the Practice's average units of CPT 88305 after it opened its own laboratory to the average units of CPT 88305 FCSO paid to all other providers.

We performed our review in accordance with generally accepted government auditing standards.

RESULTS OF REVIEW

During our audit period, the Medicare program had not created any national or local coverage determinations or standards for the number of tissue samples that should be examined for urology patients with primarily prostate-related diagnoses. In the absence of these standards, the PSC medical reviewer determined that the Practice's claims for pathology laboratory services

[1]We limited the claims that were compared to those that contained a diagnosis code the practice billed during CY 2004 and with a place of service code of 11 or 81 ("in-office" or "independent laboratory," respectively).

generally complied with Medicare Part B medical necessity and documentation requirements. The reviewer stated that the medical necessity for a biopsy procedure could be established, within the realm of professional judgment, for each of the 51 claims reviewed. The reviewer also stated that sufficient documentation existed for each of the claims to indicate that the services billed to Medicare were actually provided.

We noted an increase in the number of pathology services requested and performed after the Practice opened its own laboratory. In addition, as shown below, the Practice was reimbursed by FCSO for more units of CPT 88305, on average, than other providers who also received reimbursement from FCSO.

Average units of CPT 88305 requested *before* opening its own laboratory and claiming reimbursement for services	1.09
Average units of CPT 88305 requested *after* opening its own laboratory and claiming reimbursement for services	8.71
Average units of CPT 88305 FCSO paid to all other providers	5.50

The Practice acknowledged that its utilization increased and explained the increase by noting that industry standards were evolving. The Practice stated that it had increased the number of tissue examination requests from earlier years in an attempt to more fully meet the needs of its patients. The Practice provided some industry literature in support of its contention that an increased number of tissue examinations may improve patient outcomes.

This report contains no recommendations.