DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF AUDIT SERVICES
233 NORTH MICHIGAN AVENUE
CHICAGO, ILLINOIS 60601

REGION V
OFFICE OF
INSPECTOR GENERAL

June 28, 2007

Report Number: A-05-05-00037

Ms. Carol Lusk
Administrator
Urology Tyler, P.A.
700 Olympic Plaza, Suite 700
Tyler, TX 75701

Dear Ms. Lusk:

Enclosed are two copies of the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG) final report entitled "Review of Pathology Services Claimed by Urology Tyler, Tyler, Texas, From May Through December 2004." Should you have any questions or comments concerning the matters commented on in this report, please direct them to the HHS official named below.

In accordance with the principles of the Freedom of Information Act (5 U.S.C. § 552, as amended by Public Law 104-231), OIG reports issued to the Department's grantees and contractors are made available to the public to the extent information is not subject to exemptions in the Act (see 45 CFR Part 5).

Please refer to report number A-05-05-00037 in all correspondence.

Sincerely,

Marc Gustafson
Regional Inspector General
for Audit Services

Enclosures

Direct Reply to HHS Action Official:

Ms. Jackie Garner
Regional Administrator
Centers for Medicare & Medicaid Services, Region V
233 North Michigan Avenue
Suite 600
Chicago, Illinois 60601

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF PATHOLOGY SERVICES CLAIMED BY UROLOGY TYLER, P.A. TYLER, TEXAS FROM MAY THROUGH DECEMBER 2004

Daniel R. Levinson
Inspector General

June 2007
A-05-05-00037

Office of Inspector General

http://oig.hhs.gov

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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."

Urology Tyler, P.A. (the Practice) is a physicians' group practice located in Tyler, Texas, that provides urology services to its patients. Prior to May 2004, the Practice ordered pathology services from independent laboratories. In May 2004, the Practice began operating its own laboratory by contracting with a pathologist to provide prostate-related pathology services and 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 $257,632 from May through December 2004 for prostate-related pathology services performed at its laboratory in San Antonio, Texas. We contracted with a Medicare Program Safeguard Contractor (PSC) to review the Practice's medical records for a random sample of 100 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 May 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 prostate-related diagnoses. The PSC medical reviewer stated that medical necessity for biopsies cannot be determined in the absence of national or local coverage determinations by Medicare. However, in the absence of these standards, but within the realm of his professional judgment, the PSC medical reviewer was satisfied that the Practice's claims for pathology laboratory services generally complied with Medicare Part B medical necessity and documentation requirements for 99 of 100 reviewed claims. The one exception was improperly billed and paid due to a clerical error, which was corrected during our audit.

We noted an increase in the number of prostate-related pathology services requested and performed after the Practice opened its own laboratory. Prior to the Practice opening its own laboratory in May 2004, the Practice's physicians requested pathology services from independent laboratories on an average of four tissue examinations per claim. After establishing its own laboratory, the Practice's physicians requested pathology services on an average of 12 tissue examinations per claim. In addition, the Medicare carrier, TrailBlazer Health Enterprises, LLC, reimbursed the Practice for more units of service of CPT 88305, on average, than it reimbursed to other providers for CPT 88305.

The Practice's staff stated that research at the time that they established the laboratory indicated that 12 tissue examinations were the industry standard. The Practice's staff stated that they increased the number of tissue examinations requested to be comparable to the standard industry practice.

This report contains no recommendations.

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INTRODUCTION

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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."

Urology Tyler, P.A.

Urology Tyler, P.A. (the Practice) is a group practice of physicians who are licensed in the State of Texas. As of December 31, 2004, the Practice employed 9 physicians, consisting of 8 partners and 1 employed physician. The Practice has been in existence since 1994 and its office is located in Tyler, Texas where urology services are provided to its patients.

In May 2004, the Practice started providing prostate-related pathology 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 the management company operated 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 San Antonio, Texas, approximately 365 miles from its group practice office. The Practice contracted with a physician to serve as the laboratory's pathologist and director. The State of Texas issued a Clinical Laboratory certificate for the Practice's laboratory, effective May 2004.

The Practice received $257,632 in Medicare reimbursement for 296 claims for prostate-related pathology services performed from May through December of 2004 through the contractual arrangements at its San Antonio laboratory. Prior to the contractual arrangements and establishing its laboratory, the Practice ordered these services from independent laboratories. TrailBlazer Health Enterprises, LLC (TrailBlazer) 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 May through December 2004 and

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

Scope

We selected and reviewed a random sample of 100 Medicare claims totaling $86,197 that TrailBlazer paid during the eight-month period May through December 2004. We 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 its San Antonio laboratory, receipting and recording of tissue samples at the San Antonio laboratory, laboratory processing, bill processing, and receipting of Medicare payments.

We conducted our fieldwork at the Practice's office in Tyler and its laboratory in San Antonio, Texas.

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 arrangement for laboratory services, including the employment of the contracted pathologist, rental of space, and management operations;

- identified and reviewed a random sample of 100 claims that TrailBlazer paid for the Practice's prostate-related pathology services during the period May through December 2004, to verify compliance with Medicare regulations, and calculated the average number of tissue samples per claim of CPT 88305 the Practice examined;

- contracted with a PSC to review the Practice's medical records for the 100 sampled claims to determine if pathology services were medically necessary, adequately documented, and performed at the level indicated on the claim;

- identified claims containing units of CPT 88305 for which TrailBlazer paid to independent laboratories that the Practice used during the period September 2003 through April 2004;

- identified claims containing units of CPT 88305 that TrailBlazer reimbursed to all other providers during the period May through December 2004; and

- compared[1] the Practice's average units per claim of CPT 88305 claimed before and after it opened its own laboratory and compared the Practice's average units per claim of CPT 88305 after it opened its own laboratory to the average units per claim of CPT 88305 TrailBlazer 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 prostate-related diagnoses. The PSC medical reviewer stated that medical necessity for biopsies cannot be determined in the absence of national or local coverage determinations by Medicare. However, in the absence of these standards, but within the realm of his professional judgment, the PSC medical reviewer was satisfied that the Practice's claims for pathology laboratory services generally complied with Medicare Part B medical necessity and

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

documentation requirements for 99 of 100 reviewed claims. The one exception was improperly billed and paid due to a clerical error, which was corrected during our audit.

We noted an increase in the number of prostate-related pathology services requested and performed after the Practice opened its own laboratory. In addition, as shown below, TrailBlazer reimbursed the Practice for more units per claim of CPT 88305, on average, than it reimbursed other providers for CPT 88305.

Average units of CPT 88305 requested *before* opening its own laboratory (September 2003 through April 2004)	3.57
Average units of CPT 88305 requested *after* opening its own laboratory and claiming reimbursement for services (May through December 2004)	11.79
Average units of CPT 88305 TrailBlazer paid to all other providers (May through December 2004)	5.26

The Practice acknowledged that its utilization increased and stated that research at the time it established the laboratory indicated that 12 tissue examinations were the industry standard. The Practice's staff stated that they increased the number of tissue examinations requested to be comparable with industry standards. The Practice provided some industry literature to support the theory that taking more biopsies improves cancer detection.

This report contains no recommendations.