

Sleaze, Graft and Corruption in Surgical Pathology Version 3.0

- Introduction and Overview
 - Robert E. Petras, M.D., AmeriPath Inc.
- How to Compete When Everyone Seems to be Cheating
 - Jane Pine Wood, Esq., McDonald Hopkins Co.
- ASCP to the Rescue
 - Jeff Jacobs, ASCP

AmeriPath GI Product Line

Jan. 3, 2002 – AmeriPath announces agreement with Robert E. Petras, M.D.

“...Dr. Petras’ experience and expertise in GI disease management...will provide unparalleled excellence in GI pathology. We are excited about Dr. Petras joining the...team to provide leadership and expertise and to help...our growth in this ...market”

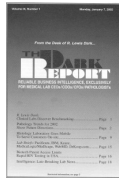
Brian Carr, President AmeriPath Inc.



The Dark Report

Reports R. E. Petras affiliation with AmeriPath

- Example of “national branding”
- Example of how national pathology centers of excellence will develop



“Dr. Petras’ arrival at AmeriPath will enhance the company’s credibility in this subspecialty”

The Dark Report, Jan. 7, 2002, p.18.



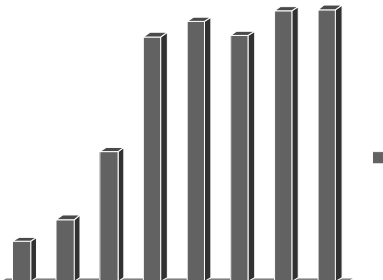
The Dark Report

- Pathology Branding
 - “Marquee” pathologists
 - Predicts that more will be recruited to pathology companies
 - Recognized clinical expertise draws case referrals

The Dark Report, Jan. 7, 2002, p.18.



AmeriPath GI Institute Patient Accessions



AmeriPath GI Institute What Happened?

- Discounted client billing
- TC/PC splits, condominium/“in house” laboratories and sham group practices
 - Loophole in the Stark Law
- Gifting, kickbacks, inducements
- Insurance exclusions

Why Did It Happen? Gastroenterologist Income Squeeze

- **Regular decline in income**
 - Drives endoscopy center and ASC development to capture facility fees
- **Gastroenterologists learn from the ASCs about profit from support services including pathology**
- **Pressure to financially benefit from pathology referrals continues and is increasing**

Client Billing

- **A.K.A. - Discounted account billing with markup, account billing**
- **Example:**
 - Laboratory bills gastroenterologist or ASC for professional and technical services for biopsy at a discount
 - Gastroenterologist or endoscopy center bills patient and/or insurance full price and pockets the difference

Client Billing Current Uses

- **Used by laboratory to enter new market in which it has no insurance footprint**
- **Used by some laboratories as form of inducement to gain market share**
 - Make money on Medicare referrals
- **Used by clinician groups as form of revenue enhancement**

Client Bill

- **Gastroenterologist/endoscopy center entitled to fair compensation for:**
 - Billing services
 - Access to insurance contracts
 - Acceptance of risk
 - Bad debt
 - Pathology CPT codes may be seen as "out of network"

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Client Billing The PEC Experience

- **Competitor contracted with PEC for \$45/CPT 88305**
- **PEC bills patient and/or insurance full price and on average receives \$130/CPT 88305**
- **PEC profits \$85/CPT 88305 for doing nothing but rebilling**

Client Billing Issues

- Excessive and unnecessary testing
- Patient care
- AMA ethical guidelines; prohibition on fee splitting
- Medicare and Medicaid Anti-kickback Law
- The Stark Law
- Medicare Usual Charge
- State prohibitions

Client Billing Legislative Restrictions

- Require direct billing for pathology
 - Arizona, California, Iowa, Kansas, Louisiana, Maryland, Massachusetts, Montana, Nevada, New Jersey, New York, Ohio, Rhode Island, South Carolina, Utah
- Prohibit excessive markups
 - Florida, Michigan, Oregon
- Billing physician must disclose actual price
 - Connecticut, Maine, North Carolina, Pennsylvania, Tennessee, Texas, Vermont

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TC/PC Split

- Hospital model – hospital owns laboratory and bills TC; pathologist bills PC
- TC/PC split to gastroenterologists
 - Independent laboratory will perform and bill TC and send slides to gastroenterologists
 - Gastroenterology group retains a pathologist to provide PC
 - Must comply with new Stark phase III regulations as of December 2007
 - Potential for revenue enhancement limited

Arrangements Allowed Under “In-house” Ancillary Services Exception to Stark Law

- Condominium (POD) laboratory model – Off site laboratory owned by gastroenterologist
 - TC ± PC billed by practice
- In-office variations – Gastroenterologist builds a laboratory on site
 - Practice performs and bills TC
 - PC done and billed in a variety of ways

Pathology Services by Non- Pathologist Practices

- Exploit loophole in Stark prohibition against self referral
 - In-house ancillary services exception available to “group practices”
 - Must be either in same building or off site with exclusive use (i.e., no shared facility)

Condominium Laboratory

- Single building with up to 12 (or more) fully equipped pathology laboratories, each in a separate room
- Each condominium owned by a different medical group
- Histotechnologist and pathologist move from room to room to perform work
- 2001 – 2004: 47 separate labs in 6 condo complexes in Florida and Texas
- Growth limited after OIG Advisory Opinion No. 04-17 but set to explode

Arrangements Allowed Under “In-house” Ancillary Services Exception to Stark Law

- Condominium (POD) laboratory model – Off site laboratory owned by gastroenterologist
 - TC ± PC billed by practice
 - Made economically non-viable by 2008 Medicare physician fee schedule
 - May have inadvertently become possible again as a result of 2009 Medicare physician fee schedule

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Gastroenterologists and Pathology Laboratories

- Up to five gastroenterologists – TC/PC arrangement is best
- Six or more gastroenterologists – In-house laboratory or Condo with or without pathology professional services
- Will approach local pathologist first

Pathology Services by Non-Pathologist Practices In House Laboratory

- Financial expenditure
 - Equipment, personnel, supplies, education, training, licensure, certification, malpractice liability
- Stark Law compliance
- Fraud and abuse compliance
- Payor issues
 - Payors may not reimburse for pathology codes
 - National payors with exclusive contracts
 - Changes of policy
 - Errors in claim submission

Pathology Services by Non-Pathologist Practices In House Laboratory

- Financial expenditure – Equipment
 - Processor \$40,000
 - Embedding center 9,000
 - Microtome 13,000
 - Other 6,000
- Small equipment, consumables, chemicals, space, labor

Pathology Services by Non-Pathologist Practices

- My experience with providing PC for gastroenterology groups under TC/PC split:
 - Logistics (couriers, accessioning, storage, gross description, LIS, transcription) are problematic
 - Consultants and CLIA exemption
 - Reduced control and compromises on slide and stain quality

Client Billing, TC/PC Splits, In House Labs

- AMA ethical guidelines prohibit fee splitting
 - 6.02 - Payment for referrals is fee splitting
 - 6.03 - Entities that compensate for referrals engage in fee splitting
 - 6.10 – No physician should bill for services not performed; Physician should not profit on services rendered by others
 - 8.03 - Physicians may not place their financial interests above the welfare of patients
 - 8.09 - Physicians who disregard quality as the primary criterion and choose a laboratory based on profit are not acting in the best interest of the patient
- Medical license requires compliance with AMA ethical guidelines

AmeriPath GI Institute What Happened?

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- Insurance exclusions

Gifting

- Asked for donations to various charities
- Asked to cover cost of staff meetings, office luncheons and holiday parties
- Approached to reimburse a practice \$22 per specimen as a handling fee
- Lost clients because of donations of office computer systems
 - Protected by safe harbor for donation of electronic health records (EHR) as of August 2006

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Insurance Exclusions

- April 1, 2005 – received letter from IBC (Philadelphia) informing that they will no longer pay for outpatient AP services
 - Immediate loss of \$1.5M annual revenue (pull through)
- Threatened loss of UHC in 2009
 - Makes up 20% of practice

**Professional Pathology Services by
Non-Pathologist Practices
Lobbying Strategies**

- **Educate the payors**
 - Potential for over-utilization
 - Lower quality providers
- **Educate malpractice providers**
 - Additional risks
 - “Cutting corners” to increase profits
- **Legislative initiatives**
 - CMS to restrict Stark exception
 - States to prohibit discounted client billing

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NEW CMS ANTI-MARKUP RULE

Jane Pine Wood, Esq.
McDonald Hopkins LLC
956 Main Street
Dennis, MA 02638
508/385-5227 (direct dial)
508/385-4355 (facsimile)
jwood@mcdonaldhopkins.com

On October 30, 2008, the Centers for Medicare and Medicaid Services (“CMS”) released the 2009 Medicare Physician Fee Schedule final rule, which was published in the Federal Register on November 19, 2008. The final rule includes revisions to the Medicare anti-markup restriction, which became effective January 1, 2009 for most diagnostic tests (not only anatomic pathology services) billed by the ordering physician or other Part B supplier.

To apply the new Medicare anti-markup rule to a particular situation, it is best to assume that the anti-markup rule applies where an ordering physician bills for the professional and/or technical component of a diagnostic service, unless one of the two “sharing a practice” exceptions is met. For example, the anti-markup restriction applies to the professional component of a diagnostic test billed by the ordering physician unless the physician who performs the professional component shares a practice with the ordering physician. There are two ways in which the performing physician can share a practice with the ordering physician. The first test can be met if the performing physician furnishes at least 75% of his or her professional services through the same medical practice as the ordering physician.

The second way in which the performing physician can share a practice with the ordering physician is if the performing physician is an owner, employee, or independent contractor of the ordering physician and the professional component is performed in medical office space in which the ordering physician regularly furnishes patient care. If the ordering physician is part of a group practice, this means space in which the ordering physician (the physician who actually orders the service) provides substantially the full range of patient care services that the ordering physician generally provides to patients.

With respect to TC/PC arrangements, if the interpreting pathologist provides at least 75% of his or her professional pathology services through the practice of the ordering physician, the anti-markup rule will not apply. If this first “sharing a practice” test cannot be met, but if the interpreting pathologist performs his or her interpretations in the same medical space in which the ordering physician regularly furnishes patient care (thereby meeting the second “sharing a practice” test), then the ordering physician will also escape the application of the anti-markup rule.

The new rules will cause some problems for multi-location practices that engage in TC/PC arrangements. For example, if a urology practice has five locations, and the pathologist provides professional interpretations in only one location, and if the pathologist does not meet the first “sharing a practice” test (the 75% test), then the anti-markup rule will apply

with respect to any interpretations performed by the pathologist that were ordered by urologists who do not practice in the building in which the pathologist is providing his or her professional interpretations. If the urologists do not rotate through the office where the pathologist performs his or her professional interpretations, then the professional interpretations ordered by the urologists in the other four offices will be subject to the anti-markup rule. A second alternative is for the pathologist to move from building-to-building, interpreting in each location only specimens ordered by the physicians who practice in that location.

With respect to the technical component of a diagnostic service, the “sharing a practice” test is measured by looking at the physician who supervises the performance of the technical component. If a urology practice has its own in-house histology laboratory, the physician who supervises the performance of the technical component must meet either the first 75% test or the second onsite in the office of the ordering physician test.

The “problem” with the new rule is that CMS has indicated that supervision of histology processing need not be performed by a pathologist, but could be performed by any physician within the medical practice. This is because CLIA certification (and therefore pathologist supervision) is not required for histology processing. Therefore, if a urology practice has an in-house laboratory, any urologist within that practice could be designated as the supervising physician for purposes of the anti-markup rule. Assuming the urologist provides at least 75% of his or her services through the urology practice, the urology practice will avoid the application of the anti-markup rule with respect to all of its technical component histology processing services. Pathologist supervision is required, however, for services that are regulated by CLIA.

Under the 75% test, the supervision need not be provided onsite in the technical laboratory nor must it be provided in a location where the ordering physician provides services. Therefore, the door presumably has reopened for pod laboratories, because a urologist could be designated as the supervising physician, and his or her supervision need not be onsite supervision (although pod laboratories still implicate the Medicare and Medicaid anti-kickback law). Furthermore, some lawyers have questioned whether the new anti-markup rule even applies to histology processing at all, because the preamble to the rule suggests that the anti-markup restriction does not apply if the services do not require supervision under Medicare regulations. Assuming no supervision is required for histology processing, then perhaps the anti-markup restriction is inapplicable.

This appears to be an inadvertent drafting error by CMS, presumably because CMS did not realize that CLIA certification does not apply to histology processing, so there is no specific pathologist supervision requirement for technical processing. This is one of the aspects of the new rule which is being questioned by the national pathology and laboratory societies.

ACCOUNT BILLING ISSUES

Jane Pine Wood, Esq.
McDonald Hopkins LLC
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Dennis, MA 02638
508/385-5227 (direct dial)
508/385-4355 (facsimile)
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A. Medicare and Medicaid Anti-kickback Law

The Medicare and Medicaid anti-kickback law prohibits the payment, receipt, offering or solicitation of remuneration in exchange for the referral of services or items covered by the Medicare or Medicaid programs. Because a physician who contracts with a pathology provider is a source of Medicare and Medicaid referrals to the pathology provider, the Medicare and Medicaid anti-kickback law must be considered when negotiating the compensation arrangement between the physician and the pathology provider.

As a general matter, if the prices paid by the physician for the pathology services are less than fair market value, an allegation could be made that the physician has received a kickback from the pathology provider (in the form of below market prices) in exchange for the physician's continued referrals to the pathology provider. Therefore, it is critical that pathology providers charge, and physicians pay, reasonable amounts for the pathology services. It is significant that fair market pricing is an important theme throughout the Office of the Inspector General's ("OIG") model compliance guidance for both physician practices and pathology providers.

OIG Advisory Opinion 99-13 provides insight into the parameters for discounted billing for pathology services. This Advisory Opinion explains that pathology providers and the physicians who purchase pathology services risk violating the Medicare and Medicaid anti-kickback law if they have deeply discounted pricing arrangements. The OIG wrote that suspect discounts include, but are not limited to discounted prices that are below the pathology provider's cost. In determining whether a discount is below cost, the OIG explained that it will consider the total of all costs (including labor, overhead, equipment, etc.) divided by the total number of tests.

B. The Stark Law

The Stark law also is implicated by discounted account billing. The Stark law prohibits a physician from making a referral for certain designated health services, including pathology services, which are covered by the Medicare or Medicaid programs if the physician has a financial relationship with the provider of the services. Some government officials have raised concerns regarding discounted account billing to physicians, and have expressed the opinion that excessive discounts to physicians could violate the Stark law. However, to date, there have not been any public investigations or prosecutions of account billing arrangements based upon a violation of the Stark law.

C. State Prohibitions

Many states have statutory restrictions on account billing and/or markup, although some of the prohibitions relate only to clinical laboratory or cytology services. Ohio does not yet have a state restriction that is applicable to private payors, but such a restriction could be adopted in the future. More and more states adopt such restrictions every year. The current prohibitions include the following:

Direct Billing: *Arizona*, Rev. Stat. 32-3210, *California*, Bus. & Prof. Code Sec. 655.6 and 655.7; *Iowa*, Iowa Code Sec. 147.105; *Kansas*, K.S.A. 65-2837; *Louisiana*, Rev. Stat. Sec. 1742; *Maryland*, Ann. Code of Maryland 1-301; *Massachusetts*, Mass. Gen. Laws Sec. 118G (29), *Montana*, Montana Code Sec. 37-2; *Nevada*, Rev. Stat. Sec. 652.195 (cytology); *New Jersey*, Stat. Sec. 45:9-42.41A; *New York*, Pub. Health Law Sec. 586; *Rhode Island*, Gen. Laws Sec. 23-16.2-5.1; *South Carolina*, South Carolina Code Sec. 44-132-10 – 40; *Utah*, Utah Code Ann. 58-1-501.

Anti-Markup: *California*, Bus. & Prof. Code Sec. 655.5; *Florida*, Admin. Code, Rule 59A-7.037; *Michigan*, Comp. Laws Ann. Sec. 445.161; *Oregon*, Rev. Stat. Sec. 676.310.

Disclosure (markup allowed so long as physicians disclose the price they paid for the testing to patients and non-federal third-party payers): *Arizona*, Rev. Stat. Sec. 36-472; *Connecticut*, Gen. Stat. Ann. Sec. 1769; *Louisiana*, Rev. Stat. Ann. Sec. 37:1741; *Maine*, Rev. Stat. Ann. Sec. 2033; *Maryland*, Health Occ. Code Ann. Sec. 14-404; *North Carolina*, Gen. Stat. 90-681, *Pennsylvania*, Admin. Code Sec. 5.48; *Tennessee*, Tenn. Code. Ann. Sec. 63-6-214(b)(22); *Texas*, Health & Safety Code Sec. 161.061; *Vermont*, 26 Vt. Stat. Ann. Sec. 1354.

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**Advocate to Succeed –
Together we Can Win**



March 8, 2009



Jeff Jacobs, MA
*ASCP Vice President, Public Policy and
Government Relations*
American Society for Clinical Pathology

It was a very good year.



Why?

- Pod Labs: Stopped**
- Competitive Bidding: Stopped**
- Clinical Laboratory Fee Schedule: Increased**
- Sustainable Growth Rate: Temporary Respite**

How?

- Understanding politics.**
- Making the right argument, with the power of numbers.**

Pod Labs Stopped



Anti-Mark-Up Regulations Promulgated in January 2008

**Lawsuit to prevent CMS from enforcing the rule on
anatomic pathology services dismissed**

**Continued vigilance against weakening anti-markup
regulations**

Formation of New Pathology Coalition – IOAS

What ASCP Did: Capitol Hill



**Multiple Visits to Congressional Offices
(legislative component to regulatory campaign)**



What ASCP Did: CMS



Multiple Targeted HHS Visits



**CMS Rule: Anti-markup
2008 Original Construct**



*The anti-markup provisions promulgated in
2008 stopped pod labs from bilking Medicare.*

Sec. 414.50, as revised at 72 FR 66222, except with respect to the technical component of a purchased diagnostic test and with respect to any anatomic pathology diagnostic testing services furnished in space that is utilized by a physician group practice as a "centralized building" (as defined at Sec. 411.351 of this chapter) for purposes of complying with the physician self-referral rules; and does not qualify as a "same building" under Sec. 411.355(b)(2)(i) of this chapter. DATES: The provisions of this final rule are effective January 1, 2008.

CMS Rule: Anti-Markup 2009 Revisions Undermine Success



Excluded Diagnostic Tests that are Not Subject to Physician Supervision (Medicare/CLIA)

May Undermine 2008 Anti-Mark-Up Rule for Anatomic Pathology
Original Rule focused on Anatomic Pathology
Exemption on Supervision *appears* to exempt Anatomic because neither CLIA nor Medicare Requires Supervision (Histology)

Additional Concerns:

HHS Leadership
CMS Staff Turnover
Are Further Revisions Necessary?
Are We at End of Regulatory Road?

Medicare Improvement Act



Competitive Bidding



Clinical Laboratory Fee Schedule

Sustainable Growth Rate: Medicare Physician Fee Schedule

Repeal of Competitive Bidding



HHS proposed Competitive Bidding Demonstration Project for Laboratory Services

ASCP representative placed on project advisory group
ASCP contributed financially to the Scripps lawsuit to enjoin demonstration project

Lawsuit successful

Legislation in both House and Senate

Multiple Action Alerts (15,000+ contacts with lawmakers)

ASCP direct meetings with Baucus & Grassley staff

Repeal of project included in Medicare package

Passage ensured the project is finally dead!



Clinical Laboratory Fee Schedule (CLFS)



CLFS Update: 4.5% increase for 2009 (*First update in 15 years*)

CLFS Updates to be reduced by 0.5% over 2009 to 2013

The money saved between 2008-2013 is \$600 million. Labs will receive the full CPI update beginning in 2014.

The savings to Medicare over the 10-year period are projected to be \$2.0 billion because the baseline on which our CPI is calculated will be lower in 2014-2018 than it otherwise would have been under current law.

Sustainable Growth Rate (SGR)



18-month Medicare physician payment fix:

- stops 10.6% cut scheduled for July 2008;
- stops an additional cut of 5% projected for January 2009;
- continues existing 0.5% increase through December 2008;
- and provides an additional 1.1% update for 2009.

Congressional Budget Office has estimated a 1% update for 2009 could lead to a 21% cut in January 2010.

Law establishes Medicare Improvement Fund to be used to avert the 2010 physician payment cut.

BUT: Action only postpones real solution.

The Future Battle: Within the "House of Medicine"



Revisiting Stark Self-Referral Laws

Specialty organizations are very well organized

American Medical Association will side with specialists



State Medical Societies may side with specialists



Stark-Related Advocacy: | ASCP Goals


Advocacy with CMS:
Exclude anatomic pathology from Stark in-office ancillary services exception
Do not dilute anti-mark-up rule
CMS should address use of in-house pathologists/technologists


Advocacy with US Congress:
Explore revisiting Stark self-referral laws

Formation of New Coalition: | In-Office Ancillary Services (IOAS)






American Clinical Laboratory Association



The Power of Grassroots: | ASCP e-Advocacy Center

GOAL: 130,000 Member Organization + Principled Arguments + Savvy Government Relations = Effectiveness in Washington




To Date: Since 2004 over 12,000 individuals have sent over 50,000 messages on legislative and regulatory issues to key decision makers.

Key Issues: Stop Pod Labs Now; Thaw the [CLFS] Freeze; Repeal Competitive Bidding; Fix the SCG; Address the Workforce Shortage; Direct Billing at State Level; PEPFAR Reauthorization

Future Plan: Maximize power of Center; Connect with grassroots operation; Incorporate into communication plan and achieve Goal


ASCP e-Advocacy Center |

Very simple:
Select issue;
Enter zip code;
Modify, add message;
Hit send.
Very successful.



Crisis or Opportunity? |

We have been rudely awakened.
We did respond - and won this round.
What else should we be doing as a Professional Society, as a Profession, and as Individuals?



What can we all do? |

- Engage in the large issues affecting health care.**
- Build bridges with those institutions that can influence our future.**
- Collaborate in improving patient care and patient outcomes.**
- Advocate to ensure our Patients have access to quality pathology services**

Pathology is not a commodity; it is a service.