

Specialist Docs Want AP \$s: Signs of Deeper Change to the Pathology Profession

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My Three Objectives!

- **One:** Explore how specialist physician interest in capturing AP revenues represents a visible sign of deeper change.
- **Two:** Identify market changes now altering long-standing business practices in anatomic pathology.
- **Three:** Predict how markets may evolve in anatomic pathology.

AP Lab Condo Lab Characteristics

- In a single building, up to 12 fully-equipped pathology laboratories, each in a separate room.
- Each pathology laboratory is owned by a different medical group.
- A histotechnologist and a pathologist will move from room to room to perform the work.

Quick History of the AP Lab Condo

- Evidence points to a urology group in Ocala, Florida. It built its first in-house anatomic pathology laboratory in 1996.
- Around 2001, the Ocala urologists formalized a business to sell this "ancillary services opportunity" to other urology groups and specialist physician groups.

Quick History of the AP Lab Condo...cont.

- By 2002, a urology group on Florida's East Coast establishes its own management company, builds its own AP laboratory condominium complex, and was actively promoting this business to other urology groups.
- During 2002, urology groups in Texas acquire AP lab condos in Florida.

Quick History of the AP Lab Condo...cont.

- Texas groups take ownership in a new company intended to develop AP laboratory condominiums to be sold to other specialist physician groups. This company would also manage the AP lab condos per agreement with physician group-owners.
- In 2003, lab condo promoters heavily market this business model within the urology, gastroenterology, and dermatology professions.

Quick History of the AP Lab Condo...cont.

- By the summer of 2004, THE DARK REPORT had firm evidence to indicate that as many as 47 separate laboratory condominiums, in as many as six different condo complexes, were in operation.
- AP lab condos are located in Florida and Texas primarily because that is where the organizers conducted business.
- Specialist medical groups located in other states purchased and operate their AP lab condos in the Florida and Texas lab condominium complexes.

Quick History of TC/PC

- TC = Technical component.
- PC = Professional Component.
- TC/PC is a term to describe an arrangement where different parties will bill for TC and PC on the same case.
- Long tradition of TC/PC in anatomic pathology where hospital-owned histology labs billed TC and private practice pathologists billed PC.

TC/PC Becomes Sales Tool

- To compete against IMPATH, US LABS began to offer TC/PC services to local community-hospital based pathologists.
- IMPATH wanted both TC/PC. US Labs would provide TC services, send images to referring pathologist.
- Referring pathologist would read the case, issue the report, and bill for PC.

TC/PC Hits Doc's Offices

- Evidence points to US Labs first taking TC/PC arrangements to office-based specialist-physicians in Maryland area.
- Quickly spread to New Jersey, New York, Pennsylvania, other mid-Atlantic areas.
- Lab does PC, sends processed slide to referring physician group.
- Physician group retains pathologist to read the processed slides.

TC/PC Educates Specialists

- Lab bills for TC and does TC/PC for all Medicare cases.
- Specialist-physicians bill for PC.
- Inside urology and gastroenterology, docs learned about money to be made from anatomic pathology.
- Presentations on this topic at meetings.
- Stories in trade magazines.

Why Sudden Interest in In-house AP?

- No coincidence that specialist physicians have strong interest in capturing AP revenues from their patient referrals.
- Three major factors created this situation.
 - ◆ One: healthcare consolidation
 - ◆ Two: AP failed to "sell" its value
 - ◆ Three: Ongoing income squeeze to specialist physician incomes.

Major Factor #1

Healthcare Consolidation

- During the 1988-1999 period, managed care contracting practices triggered widespread consolidation of laboratories, hospitals, physician groups.
- Specialist physicians responded by creating regional “super-practices” to gain negotiating leverage with managed care companies.
- Often, these physicians remained in their existing offices, but the “super-practice” would encompass five to 20 locations.

Healthcare Consolidation...cont.

- During 1988-1999, relatively few pathology groups opted to consolidate with other groups in their local area.
- Consequently, even as specialist docs consolidated in a market, pathologists continued to practice in small-group settings.
- Fast-forward to 2005: specialist “super-practices” have specimen volume to justify some type of technical lab/AP professional arrangement.

Healthcare Consolidation...cont.

- Now, when they approach their existing AP provider, if those pathologists aren't interested in a collaborative arrangement...
- ...specialist docs will often go to cross-town pathology rivals (who don't have this AP work) and negotiate a joint venture.
- Because pathologists remain unconsolidated in most communities, it allows them to be “shopped” against each other.

Major Factor #2

Anatomic Path Failed to Sell its Value

- Through the decades of the 1980s and 1990s, the anatomic pathology profession failed to establish its value proposition with the American healthcare system.
- For better or worse, both anatomic path and clinical path are “background” clinical services—essential but under-appreciated.
- Health insurers, Medicare/Medicaid, physicians, patients, employers and elected officials don't know much about pathology and don't appreciate its role.

AP Failed to Sell its Value...cont.

- Lacking recognition of AP and CP value, both payers and referring physicians can discount the need to pay for quality.
- This reinforces the desire of specialist physicians to consider anatomic path to opt for AP arrangements that allow them to share in revenues from their patient referrals, despite obvious issues of quality and sub-specialty expertise.

Major Factor #3

Income Squeeze on Specialist Docs

- It was the healthcare evolution of the '80s and the 90's that set the stage for this decade.
- Many urologists had a unique revenue set-back in recent years, when their Lupron® “Gold Mine” was shut by the feds.
- That motivated urologists to replace lost revenue by capturing revenues from their anatomic path referrals.

Specialist Docs' Income Squeeze...cont.

- Gastroenterologists, seeing regular declines in their income, decided to capture facility fees related to their professional procedures.
- Ambulatory surgery centers and endoscopy centers taught them how much profit could be harvested from support services.
- Armed with this knowledge, GIs became interested in opportunities to financially-benefit from their anatomic path referrals.

National Labs' Contribution

- National labs like UroCor and DIANON were selling urologists and GIs to refer specimens to out-of-state laboratories.
- In so doing, national labs were breaking the loyalty bonds between specialist docs and their local anatomic pathology group.
- Between 1995 and 2005, most local pathology groups did not respond to this market development.

Today's Established Trends

- Sub-specialization in anatomic pathology.
- Continued growth in both the number of national AP lab companies and the market share they hold.
- Ongoing reductions in both AP and CP reimbursement, which has a much greater impact on smaller AP groups than on regional pathology super-practices.
- Major increases in both the cost and technical complexity of acquiring new AP technology.

Specialty Physicians Create In-House AP Laboratories

- When interest cooled off in AP laboratory condominiums, specialist docs turned began to build their own in-house pathology laboratories.
- This trend expanded during 2005 and 2006.
- A group with 6-8 physicians can make money with in-house histology and AP professional services.

TC/PC Arrangements

- Specialist groups with less than five physicians often look for a TC/PC arrangement.
- Quite often, specialist groups first approach their local AP group to discuss and explore a collaboration.
- Many AP groups refuse to discuss a TC/PC arrangement, so the specialist docs end up taking all their AP business elsewhere.

Where Goes Pathology Next?

- Specialist physicians will face sustained financial pressure, giving them continued motivation to explore AP revenue opportunities.
- Measuring clinical outcomes will encourage physicians to increase the clinical integration within their group practice setting.
- This reinforces the need for faster turnaround times for anatomic pathology services. Will closer be better?

Where Goes Pathology Next?...cont.

- The anatomic pathology profession's demonstrated lack of both strategic vision and effective "public relations" during the 1980s and the 1990s, will continue to negatively impact pathology in coming years.
- On the other hand, the arrival of molecular diagnostics carries the potential to make pathology indispensable to all sectors of healthcare.

Anatomic Pathology at a Crossroads

- Physicians' interest to share in AP revenues and physicians' lack of support for CP reimbursement is a product of two decades of educational neglect by the pathology profession.
- Without pro-active and concerted effort by the pathology profession's leadership, further erosion of pathology independence will occur.
- Smallest pathology groups will be impacted first. They lack economic scale to compete.

Anatomic Path at a Crossroads...cont

- Pathology's winners will be those regional groups which consolidate and provide the only viable local option for high-quality pathology services in their community.
- In largest urban areas, expect to see a growing number of highly-specialized esoteric pathology laboratories.
- This is a visible sign that "general purpose" pathology will be subsumed by developing business models, causing sub-specialist pathologists to opt to practice in specialty laboratory settings.

Imperfect Crystal Ball

- Today's pathology threats and problems can be traced back to passive responses to healthcare changes by the profession between 1983 and the present.
- Inaction is not a winning strategy for any pathology group. Yet, by default, that is how many pathology groups continue to manage their business.
- Pathology is at the threshold of what can be its "Golden Age." But its existing institutions may be incapable of guiding the profession to achieve that goal.

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HOW TO COMPETE WHEN EVERYONE SEEMS TO BE CHEATING

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DISCOUNTED ACCOUNT BILLING AND MARKUPS

"Account billing" or "client billing" occurs when physicians such as urologists and gastroenterologists purchase anatomic pathology services at a discount and then re-bill the pathology services to private payers and patients with a significant markup in price. Not only are the purchased technical component pathology services being marked up, but the purchased professional pathology services are being marked up as well. This practice would be analogous to the purchase by a primary care physician of the professional services of a cardiologist or a surgeon and the rebilling of the cardiologist's or surgeon's professional services by the primary care physician.

As explained in more detail below, the practice of discounted account billing and markups often results in excessive ordering of pathology services, medically unnecessary biopsies, and inferior patient care. Purchasing physicians have a strong incentive to make referrals for pathology services based upon the lowest price (and thus the greatest profit margin) rather than quality.

Furthermore, by accepting deep discounts on price and marking up the pathology services, the purchasing physicians not only may be acting in violation of their professional codes of ethics, but also state fee splitting prohibitions, thereby placing their medical licenses at risk. Significant discounts are in violation of both the Medicare and Medicaid anti-kickback law and the Stark law, thereby placing all parties involved at risk for the substantial criminal and civil penalties of these federal laws. In addition, this type of discount places the pathology provider at risk for violation of another federal statute, the Medicare "usual charge" requirement.

A. Excessive and Medically Unnecessary Services

Account billing arrangements permit physicians such as urologists and gastroenterologists to profit substantially on the ordering of anatomic pathology services for their patients. For example, a urologist may purchase the professional and technical pathology services for a prostate biopsy for \$25, and then re-bill the services to patients and payors for \$85. The urologist makes a profit of \$60, with no investment of time or effort other than the re-billing of the services.

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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 OIG's 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.

In addition, in June of 2004, a federal grand jury in Oklahoma City indicted several former UroCor officials for alleged violations of the anti-kickback law by offering extremely discounted prices on non-Medicare and non-Medicaid pathology testing in exchange for the referral of Medicare and Medicaid services from the urologists. The alleged discounts were very low, at times approaching 10% of the Medicare allowable for the same service. At the time of the preparation of this outline (early June 2006), the case is scheduled to go to trial in June 2006.

The problem with many account billing arrangements is that the referring physicians wish to maximize their profits by paying the lowest possible price for the purchased pathology services. The prices paid by many physicians for purchased pathology services appear significantly below fair market value, thereby implicating the Medicare and Medicaid anti-kickback law. This is a difficult abuse to detect, however, because the claims submitted by the purchasing physicians to payors and patients do not indicate that the services were purchased, but rather portray the billed services as performed by the referring physician's practice.

E. 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. Government officials, including the OIG, have raised concerns regarding discounted account billing to physicians, and have expressed the opinion that excessive discounts to physicians could violate the Stark law.

F. Medicare Usual Charge

Another discounted billing issue is compliance with the Medicare "usual charge" statute. 42 U.S.C. 1320a-7(b)(6)(A) states that the Secretary of Health and Human Services may

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Pathologists around the country report significant increases in the number of biopsies being performed by physicians who engage in account billing, often with no corresponding medical indicators for the increases. It appears as though these physicians are excising additional specimens from their patients and performing medical unnecessary biopsies. The physicians then refer the specimens for pathological processing and interpretation, purchase the pathology services at a discount, and re-bill the pathology services at marked-up prices. Obviously, these reported increases in the ordering of pathology services are cause for alarm, not only because the patients may be subjected to medically unnecessary procedures (with the potential for adverse medical consequences), but also because the resulting health care expenditures associated with the services burden an already strained health care system.

Unfortunately, when the dangers posed by discounted account billing are brought to the attention of some state medical boards, these medical boards often decline to take decisive action. It appears that some state medical board members are concerned about alienating physicians who take advantage of account billing. In addition, it is likely that some of the board members themselves have participated or continue to participate in account billing arrangements. Until the public becomes more aware of the abuses of account billing, it is unlikely that state medical boards will take action against these abusive practices and ensure patient welfare.

B. Patient Care Issues

The account billing practice raises the specter of significant patient harm. A patient could suffer harm if pathology services are sent to the "lowest cost" provider, rather than to the "best quality" provider so that the referring physician could pocket the profit. For example, assume a gastroenterologist sends a biopsy to the pathology provider who has the lowest account billing price, without regard to (or in deliberate disregard of) the credentials and quality of the pathology provider. The gastroenterologist marks up the price and pockets the profit. The biopsy is misdiagnosed and the patient suffers additional harm or dies. As long as account billing is legally permissible, human nature will cause some referring physicians to consider discounted prices (and profit margin) over quality. As noted above, many state medical boards appear unwilling to confront this potential for grave harm to patients as a result of discount account billing arrangements, and fail to take action to curb the abuses and protect patient welfare.

In addition, some low cost pathology providers utilize physicians out of state who are not licensed in the state where the patient resides. Many state laws prohibit a physician who resides in another state from performing services for a patient unless the physician is licensed in the state in which the patient resides. (Exceptions sometime exist for irregular, occasional consultation services.) Again, it appears as though many state medical boards are "looking the other way" and permitting unlicensed physicians to provide services.

Finally, to answer the claim from some purchasing physicians that account billing arrangements benefit the patients because the patients receive a single bill, the physicians do not purchase the pathology services for their Medicare patients, but only purchase the pathology services for the private patients. This is because Medicare regulations restrict account billing. If the physicians only purchase the services from which they can profit through a markup (the non-Medicare services), and their elderly (and more vulnerable) Medicare patients are left with

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exclude from the Medicare program any provider who bills Medicare or Medicaid for charges that are "substantially in excess of such [provider's] usual charge."

In September 2003, the OIG proposed a new regulation that defines "substantially in excess" as "any charge or cost submitted for a furnished item or service that is more than 120 percent of the individual's or entity's usual charge or cost for that item or service...". Many discounted account billing arrangements contain prices that 50 percent or even less of the Medicare charges for the same services. Clearly, these discounted prices would raise significant issues under the OIG's proposal.

Prior to the September 2003 proposed regulation, the OIG explained that charges in excess of a provider's usual charges are permissible where they are "due to unusual circumstances or medical complications requiring additional time, effort, expense, or other good cause." In Advisory Opinion 98-8, the OIG offered that a useful benchmark for determining whether a higher Medicare charge would meet the "good cause" exception is to compare the profit margin on the Medicare sale. If the profit margin on the Medicare sale is equal to or less than the profit margin on the "cash and carry" sale, the OIG probably would consider the "good cause" exception to be met. A pathology provider likely could not justify discounts significantly below the Medicare allowable fee under this standard. In fact, the OIG's legal counsel has stated that the OIG does not believe that such significant discounts can be justified under the Medicare "usual charge" statute.

G. Fee Splitting Prohibition

Most state medical practice acts also prohibit fee splitting, which involves the division of professional fees in exchange for a referral. When a pathology provider significantly discounts its fee to the referrer of the pathology services, so that the referrer can re-bill the pathology services with a substantial markup, both parties are splitting the professional fee in exchange for the referral. Furthermore, many state medical boards endorse the AMA's ethical prohibition against fee splitting, and include fee splitting as grounds for disciplinary action.

However, as noted above, state medical boards have declined to take disciplinary action against physicians who engage in fee splitting through discounted account billing arrangements. In Mississippi, for example, although the Mississippi Health Care Fraud Task Force issued a report in 2000 that criticizes discounted account billing as fee splitting, no medical board action has been taken against violators.

H. State Prohibitions

Several states have statutory restrictions on account billing and/or markup, although some of the prohibitions relate only to clinical laboratory or cytology services. These prohibitions include the following:

Direct Billing: *California*, Bus. & Prof. Code Sec. 655.6 (cytology); *Iowa*, Iowa Code Sec. 147.105; *Louisiana*, Rev. Stat. Sec. 1742; *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;

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multiple bills, the claim that the physicians are engaging in account billing to benefit their patients is rather hollow.

C. AMA Ethical Guidelines

Several opinions of the Council on Ethical and Judicial Affairs of the American Medical Association (the "Council") address fee splitting. For example, Opinion 6.02 states that "payment by or to a physician solely for the referral of a patient is fee splitting and is unethical." Opinion 6.03 states that "clinics, laboratories, hospitals or other health care facilities that compensate physicians for referral of patients are engaged in fee splitting, which is unethical."

Opinion 8.03 states that "under no circumstances may physicians place their own financial interests above the welfare of their patients... For a physician to unnecessarily ... conduct diagnostic tests for the physician's financial benefit is unethical."

Opinion 8.09 explains that "the physician who disregards quality as the primary criterion or who chooses a laboratory solely because it provides low-cost laboratory services on which the patient is charged a profit, is not acting in the best interests of the patient... A physician should not charge a markup, commission, or profit on the services rendered by others. A markup is an excessive charge that exploits patients if it is nothing more than a tacked on amount for a service already provided and accounted for by the laboratory. A physician may make an acquisition charge or processing charge. The patient should be notified of any such charge in advance." In a letter dated July 27, 2001, the Council addressed the issue of the markup of purchased anatomic pathology services. The Council explained that if anatomic pathology services are provided by pathologists at a discount, the purchasing physicians should not charge a markup. The Council considered such a markup to be an excessive charge added to the service provided by the pathologist and would "exploit patients".

The Council's position also has direct bearing upon many state medical practice acts. Many states condition a physician's medical license upon compliance with professional codes of ethics. If a pathology practice's physician clients are marking up discounted anatomic pathology services, then these physicians risk violating the AMA's ethical guidelines, and consequently risk sanction by their state medical boards, including revocation of their medical licenses.

Despite the ability of state medical boards to discipline physicians for violation of the AMA's code of ethics by engaging in discounted account billing, there has not been a history of enforcement by state medical boards.

D. 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 patients for 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.

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Rhode Island, Gen. Laws Sec. 23-16.2-5.1; *South Carolina*, South Carolina Code Sec. 44-132-10 -40.

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 test) 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*, General Statutes 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.

The Louisiana law states that "No person licensed in the state to practice medicine, dentistry, optometry, podiatry or chiropractic shall charge, bill, or otherwise solicit payment for outpatient anatomic pathology services unless the services were rendered personally by the licensed practitioner or under the licensed practitioner's direct supervision."

The Montana law explains that "A physician or other practitioner of the healing arts ... may not directly or indirectly bill or charge for or solicit payment for anatomic pathology services unless those services were provided personally by the physician or other practitioner or under the direct supervision of [the] physician...."

The Tennessee law states that "No person licensed in this state to practice medicine shall agree or contract with any clinical, bio-analytical or hospital laboratory, wherever located, to pay such laboratory for anatomic pathology services or cytology services and thereafter include such costs in the bill or statement submitted to the patient or any entity or person for payment, unless the practitioner discloses on the bill or statement, or in writing by a separate disclosure statement in a minimum print size of ten (10) font, the name and address of the laboratory and the net amount or amounts paid or to be paid to the laboratory for the anatomic pathology services or cytology services."

The South Carolina direct billing law states that "No person licensed to practice in this State as a physician, surgeon, or osteopath, a dentist or dental surgeon, a nurse practitioner, or a physician's assistant shall charge, bill, or otherwise solicit payment for outpatient anatomic pathology services unless the services were rendered personally by the licensed practitioner or under the licensed practitioner's supervision."

The Iowa direct billing law states that "a clinical laboratory or a physician providing anatomic pathology services to patients in this state shall not, directly or indirectly, charge, bill, or otherwise solicit payment for such services unless the services were personally rendered by the physician or under the direct supervision of the physician...."

The California law states that "It is unlawful for any person licensed under this division ... to charge, bill, or otherwise solicit payment from any patient, client, customer, or

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third-party payor for cytologic services relating to the examination of gynecologic slides if those services were not actually rendered by that person or under his or her direct supervision."

Similarly, the Nevada law provides that "It is unlawful for a physician to charge, bill, or otherwise solicit payment from a person for cytologic services ... [unless the] cytologic services were rendered by the physician himself or in a laboratory operated solely in connection with the diagnosis or treatment of his own patients."

The Vermont law states that it is unprofessional conduct (subject to disciplinary action) for a physician to agree "with clinical or bio-analytical laboratories to make payments to such laboratories. unless the physician discloses on the bills to patients or third-party payors the name of such laboratory, the amount or amounts to such laboratory. and the amount of his or her processing charge or procurement, if any, for each specimen taken." Delaware and Maryland have an almost identical statute.

The Connecticut law prohibits "any system of billing or accepting payment for laboratory services that does not accurately identify the laboratory, the requester, the patient or recipient and the cost of such laboratory services."

The Oregon law states that "... a practitioner shall not mark up or charge a commission or make a profit on services rendered by an independent person or laboratory. ... Any services rendered to the patient that were performed by persons other than those in direct employ of the practitioner and the charges therefore shall be indicated on the patient's bill."

The North Carolina provides that "It shall be illegal [for a licensed practitioner]... to bill a patient, entity or person for anatomic pathology services in an amount in excess of the amount charged by the clinical laboratory for performing the service unless the licensed practitioner discloses conspicuously ... (1) the amounts charged by the laboratory for the anatomic pathology services; any other charge that has been included in the bill; and (3) the name of the licensed practitioner performing or supervising the anatomic pathology service."

PROFESSIONAL PATHOLOGY SERVICES BY UROLOGY AND GASTROENTEROLOGY PRACTICES

Currently, the most popular "new" arrangement for non-pathology specialists such as urologists and gastroenterologists to get a piece of the pathology pie is for the non-pathology specialists to employ or contract with a pathologist or pathology practice for the provision of the professional interpretation services. In this arrangement, the professional pathology component will be performed and billed by urology or gastroenterology practice, and the technical pathology component will be performed and billed by an independent, off-site pathology laboratory.

A. Stark Law Compliance

The Stark Law prohibits referrals of certain designated health services by physicians to entities with which they or an immediate family member have a financial relationship, unless there is an exception. In this context, the most valuable exception is the

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assistance and the like, must reflect fair market value as well as the other elements of the Anti-Kickback safe harbor for personal services contracts.

It also is important to note that the Office of the Inspector General ("OIG") warned in a December 2004 Advisory Opinion that, even if the relationship between a urology or gastroenterology practice and the pathology provider is protected by a safe harbor, the safe harbor protection does not extend to the profit recognized by the urology or gastroenterology practice from the pathologist's professional services. In addition, this type of arrangement was specifically targeted for review by the OIG in its 2005 Work Plan, and reappears in the OIG's 2006 Work Plan.

C. Malpractice Issues

There may also be additional malpractice insurance expense as the urology or gastroenterology practice expands the scope of its practice to include pathology. It is also important to keep in mind that, as the provider of professional pathology services, the urology or gastroenterology practice will also bear the related liability.

D. Payor Issues

It is important to structure the arrangement between the urology or gastroenterology practice and the pathology provider so that it complies with Medicare reassignment rules. Medicare prohibits physicians from assigning Medicare benefits to anyone but the physician who rendered the services. There are a number of exceptions, most notably that an employed physician may assign benefits to its employer and an independent contractor physician may assign benefits to a medical group for services provided on the group's premises as long as there is a contractual arrangement allowing the group to bill and collect for the physician's services. Accordingly, each pathology provider for whom the urology or gastroenterology practice is billing must render services on-site at the urology or gastroenterology practice's office and must be individually enrolled and credentialed as a member of the urology or gastroenterology practice. It is important to note that the Medicare program will hold the individual pathologist jointly and severally liable, with the urology or gastroenterology practice, for any erroneous billings submitted by the urology or gastroenterology practice for the physician's professional pathology services.

Commercial payors may have completely different guidelines for the provision of pathology services by the urology or gastroenterology practice. Some payors limit the scope of a practice's credentials to a specific specialty area, or require a separate credentialing process in order to add a service such as pathology. There may also be laboratory carve-outs or preferred provider arrangements in place that prevent the group from rendering pathology services to its patients. Increasingly, commercial payors are expressing concerns regarding over-utilization of pathology services by Urology or gastroenterology practices that profit from the pathology services, and these payors are looking at ways to restrict payment and curb overutilization. It is important to assess payor requirements prior to implementing a pathology program to be sure that the services will be reimbursed.

E. Audit Risks

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in-office ancillary services exception, which is available only to organizations that satisfy all of the requirements of the Stark Law definition of "group practice", including the following:

1. two or more physicians who are owners or employees, organized as a single legal entity. A physician who is an owner or employee is a "member of the group"; independent contractors are "physicians in the group";
2. each member of the group must provide the full range of services which the physician normally provides through the group;
3. at least 75 percent of the total patient care services of the members of the group must be provided through the group;
4. members of the group must personally conduct at least 75 percent of the physician-patient encounters of the group;
5. the group must be a unified business with centralized decision making, consolidated billing, accounting and financial reporting, and centralized utilization review;
6. members of the group and physicians in the group may be paid productivity bonuses based on services personally performed or supervised, but may not be compensated in a manner that is directly related to volume or value of referrals.

In order to consider whether the urology or gastroenterology practice may render professional pathology services, the threshold determination of the urology or gastroenterology practice's group practice status must be made. The urology or gastroenterology practice may then look to the specific provisions of the in-office ancillary services exception, the first of which requires that designated health services be furnished personally by:

1. the referring physician; or
2. a physician who is a member of the group; or
3. individuals supervised by a member of the group or a physician in the group, under the level of supervision required by Medicare and Medicaid.

A strict application of this provision in the context of professional pathology services by a urology or gastroenterology practice would require that the pathology provider be a "member of the group", i.e., either an employee or an owner of urology or gastroenterology practice, because he or she will neither be the referring physician nor a supervised individual. This may impact urology or gastroenterology practice's ability to meet the group practice definition, particularly with respect to the 75 percent tests. There are a number of conflicting references in Stark Law commentary, which may lead to a broader interpretation that pathology services could be personally performed by a "physician in the group", or an independent contractor. However, employment is preferred, as the employed pathologist would be a member

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The potential for overutilization of pathology services when a urology or gastroenterology practice profits from its referrals can send up multiple "red flags" that could invite an audit from a government or commercial payor. First, billing utilization patterns that exceed the established norm can trigger an audit, and result in an overpayment demand from the payor. It is important to remember that the Medicare program specifically holds the pathology provider joint and severally liable, on an individual basis, with the urology or gastroenterology practice, for any assessed overpayments. Commercial payors could adopt the same policy. Furthermore, if the payor believes billing fraud is involved, the payors could include the pathology provider in its charges.

Another audit "red flag" involves improper billing of purchased technical component pathology services. If the urology or gastroenterology practice purchases technical component services from another laboratory, and the services are for Medicare patients, the urology or gastroenterology practice must abide by the Medicare purchased service regulations and cannot mark up the cost of the purchased technical component services. Many Medicaid programs and some commercial payors have comparable requirements. If the urology or gastroenterology practice bills globally, and not in compliance with such purchased service requirements, the billing violation could trigger an audit.

ESTABLISHMENT OF "IN-HOUSE" HISTOLOGY LABORATORY

In the technical component laboratory scenario, the urology or gastroenterology practice establishes its own anatomic pathology laboratory for the processing of specimens. The pathologist provides the professional anatomic pathology services for specimens that are processed in the urology or gastroenterology practice's laboratory.

A. Financial Expenditures

Obviously, there are significant financial expenditures involved in the establishment and operation of a histology laboratory. Not only must the urology or gastroenterology practice make space available for the laboratory, but it also must invest in equipment, personnel, and supplies. In order to provide quality services, the urology or gastroenterology practice must continue to invest in new equipment and in education and training for laboratory staff. The failure to do so not only can have an adverse impact upon patient care, but also can increase the urology or gastroenterology practice's malpractice risk from the histology services that it provides.

B. Licensure and Certification

The urology or gastroenterology practice must ensure that its histology laboratory is in full compliance with all applicable federal and state licensure and certification requirements, including but not limited to CLIA certification, state laboratory licenses, etc. This requires not only time and effort, but also financial expenditures. The failure to maintain proper licenses and certifications places the urology or gastroenterology practice at risk for administrative penalties, the disallowance of payment for the pathology services, and increased malpractice liability.

C. Malpractice Liability

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of the group and there is an additional Stark Law exception for *bona fide* employment relationships.

If the pathology provider is an independent contractor, the pathologist will be a Stark Law "physician in the group" and the compensation arrangement must meet the Stark Law exception for personal services arrangements or fair market value compensation. In both cases, there must be a written agreement that specifies the covered services, and payment to the pathology provider must reflect fair market value, and may not be determined in a manner that reflects the volume or value of referrals or other business generated between the parties.

Another significant component of the in-office ancillary services exception is that the pathology services must be rendered either in the same building in which the referring physician or another physician who is a member of the group furnishes services unrelated to the furnishing of designated health services, or in a centralized building which is utilized exclusively by the group practice. The Stark Law provides several examples that comply with the same building requirement, but, essentially, the pathology provider must perform the professional interpretations on-site at the urology or gastroenterology practice, or in an off-site location that is leased exclusively by and used exclusively by the Urology or gastroenterology practice, on a 24/7 basis. No shared facility or space is permitted.

B. The Anti-Kickback Statute

The Anti-Kickback Statute, which prohibits the payment or receipt of any remuneration in exchange for a referral for services covered by Medicare or Medicaid, must also be considered. There are a number of safe harbors under this statute that provide guidance. Unlike the Stark Law, which requires strict compliance, an arrangement which falls outside an anti-kickback safe harbor is not an automatic violation, but is reviewed based on facts and circumstances.

If the urology or gastroenterology practice employs the pathology provider, amounts paid by an employer to a bona fide employee for employment in the provision of Medicare/Medicaid reimbursable services are safe-harbored. If the urology or gastroenterology practice engages the pathology provider as an independent contractor, there is a safe harbor that addresses personal services contracts. There must be a written agreement, for specified services, for a term of not less than one year, with aggregate compensation set in advance, consistent with fair market value, and without regard to volume or value of referrals or other business generated. Accordingly, it is important to structure the arrangement between urology or gastroenterology practice and the pathology provider so that it reflects fair market value. This is of particular concern because these arrangements often involve the provision of services by the pathology provider to the urology or gastroenterology practice at a discount from prevailing third party payor rates, and the billing by the urology or gastroenterology practice to third party payors at prevailing rates. Fair market value analysis requires assessment of factors such as reduced billing and other overhead expenses of the pathology provider as well as time spent at the urology or gastroenterology practice. Likewise, the arrangement between the urology or gastroenterology practice and the laboratory requires careful scrutiny. The provision of goods and services by the pathology provider, such as software, equipment, reporting, reimbursement

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Malpractice liability is a significant issue involved in the establishment of a histology laboratory. Because the urology or gastroenterology practice will be the actual provider of the technical component pathology services, it will have full legal liability for the services. In the event of a malpractice action, the urology or gastroenterology practice will be held to the standard of care of a hospital or pathology laboratory, which is a high standard of care.

Furthermore, the individual physicians in the urology or gastroenterology practice who are responsible for the supervision of the pathology services will bear legal liability for their supervisory services. In a malpractice action, the plaintiff's legal counsel may argue that the applicable liability standard is the quality of supervision provided by a board certified pathologist, and any supervising the urology or gastroenterology practice physician must be prepared to fulfill this standard of care.

The urology or gastroenterology practice also should confirm that its malpractice insurance covers not only the provision of the pathology services, but also the supervision of the laboratory personnel. This could entail additional insurance premiums and/or an endorsement or supplement to the policy.

D. Fraud and Abuse Compliance

In order to refer specimens of its Medicare and Medicaid patients to its own anatomic laboratory, the urology or gastroenterology practice must comply fully with the in-office ancillary services exception of the Stark Law. An important requirement of this exception is that the revenues from the urology or gastroenterology practice's technical component services cannot be allocated among the urology or gastroenterology practice physicians based upon referral volume.

If the urology or gastroenterology practice wishes to establish its laboratory in an off-site location and comply with the in-office ancillary services exception, the urology or gastroenterology practice must lease or own the office space on a continuous (24/7) and exclusive basis. No shared laboratory location is permissible. Also, the applicable Stark Law exception requires that the technical component services be provided by or under the supervision of one of the urology or gastroenterology practice's physicians, or an independent contractor of the urology or gastroenterology practice. In light of both the location and the supervisor requirements of the Stark Law prohibition, the most reasonable location for the laboratory is in the urology or gastroenterology practice's offices (i.e., where the urology or gastroenterology practice's physicians see patients). If the urology or gastroenterology practice has more than one office location, it is acceptable for the laboratory to be housed in one of the office locations.

It is permissible for the urology or gastroenterology practice to contract with the pathology provider to provide consulting services with respect to the establishment and management of the ongoing operations of the urology or gastroenterology practice's laboratory, provided that (a) the consulting and management arrangements comply with the Stark Law exception for personal services contracts or the Stark Law exception for fair market value compensation, (b) the arrangements comply with the safe harbor under the Medicare and Medicaid anti-kickback law for personal services contracts, and (c) the urology or

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gastroenterology practice remains responsible for its supervision obligations under the in office ancillary service exception. It also is possible for the urology or gastroenterology practice to contract with the pathology provider as an independent contractor to provide the required supervision of the performance of the technical component services by the urology or gastroenterology practice's technical personnel. Both Stark Law exceptions and the anti-kickback safe harbor require that the compensation paid to the pathology provider for the consulting and management services, as well as the supervision services, reflect fair market value, and the compensation paid to Pathology cannot vary based upon the value or volume of referrals between the parties.

E. Payor Issues

If the urology or gastroenterology practice's operations comply with the Stark Law in-office ancillary services exception, then the urology or gastroenterology practice can submit claims for its technical component of anatomic pathology services to the Medicare and Medicaid programs as well as non-government payors (assuming the payors do not require designated laboratories to provide these services). The urology or gastroenterology practice also should confirm that its major payors will reimburse the urology or gastroenterology practice for the pathology services. Increasingly, payors are refusing to reimburse for diagnostic services provided by a referring physician practice. Instead, such payors will only reimburse for diagnostic services provided by a hospital or an independent freestanding diagnostic provider. Many national payors contract exclusively with selected laboratories for all pathology services.

Even if the urology or gastroenterology practice's major payors currently reimburse for pathology services provided in its histology laboratory, the urology or gastroenterology practice should be prepared for a change in the payors' policies, and the potential loss of the urology or gastroenterology practice's investment in the histology laboratory.

Another payor issue that should not be overlooked is the increased billing risk for submitting claims for pathology services, particularly with respect to claims submitted to the Medicare and Medicaid programs. Most urology or gastroenterology practices (and their billing agents) do not have experience in billing for pathology services. Errors in claims submission for these services could increase the overpayment exposure of the urology or gastroenterology practice.

OFF-SITE "CONDO" LABORATORY

The offsite "condo" laboratory scenario is one in which the urology or gastroenterology practice provides technical and professional component anatomic pathology services at a location that is separate from its physician offices. This scenario has been widely promoted by consultants, who explain that an offsite anatomic pathology laboratory can be set up, often in a small unit in a "strip mall" location. The concept is that several offsite laboratory operations will be established in the strip mall, each in its own unit. While each laboratory operation will have its own physical space and equipment, the same technical personnel and pathologists will be employed or contracted, on a part time basis, by each of the laboratories. The technical personnel and pathologists will move between units to provide their services for each of the laboratories.

If the urology or gastroenterology practice wishes to bill for the technical and professional component services for all payors (including the Medicare and Medicaid programs), it must establish a technical processing laboratory and employ or contract with one or more pathologists, all as previously described. All of the issues discussed previously are applicable to the offsite location scenario.

A. Stark Law Compliance

In particular, the urology or gastroenterology practice must be careful to comply fully with the Stark Law exception for in-office ancillary services. Because the laboratory will not be in an office where the urology or gastroenterology practice's physicians provide services to patients, the Stark Law requires that Urology or gastroenterology practice lease the physical space for the laboratory operation on a continuous (24/7) and exclusive basis. No shared laboratory arrangement is permissible. This is the reason that the "condo" or "strip mall" model requires that each laboratory operation have its own physical unit.

In day-to-day operations, it is possible that compliance with the Stark Law in-office ancillary services criteria could slip, particularly if the offsite laboratory is in a "strip mall" arrangement that is susceptible to prohibited shared utilization by other offsite laboratory operations. It is conceivable that, for convenience's sake, a technician or a pathologist may decide to carry slides from several laboratories to a central location for processing or interpretation. Such an action would be in violation of the in-office ancillary service exception. In a December 2004 Advisory Opinion (discussed below), the OIG notes that the actual operation of the laboratory is critical to Stark Law compliance.

B. Medicare and Medicaid Anti-kickback Law

The offsite laboratory arrangement also raises issues under the Medicare and Medicaid anti-kickback law. On December 10, 2004, the OIG issued Advisory Opinion No. 04-17, which examines a condo laboratory arrangement. Under the arrangement considered by the OIG, a pathology company proposed entering into a series of contracts with physician groups specializing in urology, gastroenterology, or dermatology, pursuant to which each physician group practice would establish its own pathology laboratory in an off-site location.

The OIG concluded that it was "unable to exclude the possibility that the parties' contractual relationship is designed to permit the [pathology company] to do indirectly what it cannot do directly: that is, pay the physician groups a share of the profits from their laboratory referrals. In other words, the [pathology company] may be offering the physician groups impermissible remuneration by giving them the opportunity to obtain the difference between the reimbursement received by the physician groups from the federal health care programs and the fees paid by the physician groups to the [pathology company] (i.e., the profit from pathology services ordered by the physician groups)."

In light of the substantial criminal and civil penalties that can be imposed for a violation of the Medicare and Medicaid anti-kickback law, the guidance provided in Advisory Opinion 04-17 should be considered carefully by the urology or gastroenterology practice.

C. Out of State Issues

If the offsite laboratory is in another state, then the urology or gastroenterology practice must ensure that it complies with all of the legal requirements of its home state as well as the state in which the laboratory is located. The employed/contracted pathologists should hold medical licenses in both states. In addition, the urology or gastroenterology practice should confirm that its malpractice insurance covers services provided out of state.

The urology or gastroenterology practice also should confirm that its payor agreements will cover the provision of the out-of-state services.

ASCP American Society for Clinical Pathology

ASCP Companion Meeting: USCAP March 25, 2007

Organized Pathology to the Rescue:
The ASCP Approach

John S. J. Brooks, MD
ASCP President

ASCP American Society for Clinical Pathology

Overview: Pathology in America = Local

- Our current system of laboratories
 - Local: many hospital labs, independent labs associated with hospitals, clinics
 - Developed over 50-75 years
 - Logical: Relationship to Clinicians & Patients
 - Does it serve patients well? YES
 - PRESERVES RELATIONSHIPS
 - RELATIONSHIPS AT CORE OF LAB SERVICE
 - CONTINUITY OF CARE

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Continuity of Care: Pathology

- Single place for key patient data
 - Lab Medicine test results: TRENDS
 - Very important, especially when multiple physicians involved in care - common in our aging population
- Single place for anatomic path tissue analysis
 - Cytology or FNA (leads to-)
 - Biopsy (leads to -)
 - Major surgical resections: ability to correlate and compare
 - Issues of disease status (improving or not)
 - Issues of multiple cancer primaries (vs recurrence)
- Sendouts for 2nd opinion always an option

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Hospital Laboratories (i.e., Local)

- Pay for themselves
- Not Cost-Centers
- Efficient, more so than at any time before
- Offer Quality & Service
- Importantly, offer close **relationships** between clinician, patient and lab personnel

Relationships: the connection to service - a reality now

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Current System of Local Labs: Service Reality

- Others think of lab as number game
 - Idea of service and relationships invisible
- We know local labs provide service
 - quality improvement work
 - suggestions for additional testing
 - personal attendance at patient focused conferences
 - call backs to clinicians with critical values
 - responding to calls on any topic
 - personal interactions on microbial sensitivity testing
 - many other examples

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Major Threats to Pathology - 2007

- Digital Revolution:
 - Images diagnosed overseas
- Molecular Revolution:
 - No need for Surgical Pathology
- Government (outsourcing):
 - Competitive bidding: lab tests as a commodity, ignoring our service linked to our results - formation of regional labs
- Business Arrangements, (outsourcing):
 - Subspecialty biopsies sent out
 - Importance of groups, colleagues

Competitive Bidding

- Major issue facing us
- One Lab for a State/Region
 - Implications for our nation-wide system of labs, hospital and independent
 - Currently, connectivity & interaction between Path/LM personnel and patient's doctors
 - Will sever these relationships
- Will we be left with inpatient testing?
- ASCP will marshal all our forces including natural allies

POD Labs Issue

- Pod labs: clinician-owned facilities with small lab
 - Allow clinician billing for lab services = profit
 - Provide limited services: subspecialty biopsies
 - Pricing often below fair market value
- **Loophole:** In 2005, CMS relaxed rules for independent contractor physicians to reassign Medicare billing rights to health care entities
- Clearly many labs, subspecialty labs, operate above board, bill for own services; **the issue is clinician activity, not pathologists.**

Pod Labs: Information

- Financial incentive to do more biopsies
- In some, pathologists exploited, paid less
- GI, GU outpatient biopsies now
- This financial model may spread to all other clinical specialties performing outpatient biopsies - (GYN, Heme, Breast,...)
- **"Balkanization"** of OP biopsies
 - Where are we then?

Balkanization of Biopsy Pathology

- Need to address larger issue at stake
 - Pod labs, but also others
- Now: GI, GU; Dermopath
- Future: GYN, Breast, Lung, Hemepath?
- What's left: less profitable inpatient work
- Will this movement cause reorganization of Pathology as currently structured?
- What happens to pathology labs as we know them now- Large group practices, whether community or academic? Our whole system of LOCAL labs?
- Clinical subspecialty absorption of corresponding pathologist subspecialist? -- in the future?

Fragmentation of Patient Care: Pathology

- Sources of Fragmentation
 - Health plan contracts to commercial labs
 - Medicare Competitive bidding = regionalization
 - Other individual relationships, some local
 - Legal, ethical specialty biopsy labs (many non-local)
 - Pod, Condo lab situation
- Lack of biopsy comparisons, correlations
- Lack of ability to trend diagnostic testing
- Can/Should everything be done in a vacuum? With no knowledge of patient info, no relationship to clinician or patient?

Fast Forward to a New World

- Lab Medicine results in near & far computers
 - EMR, electronic medical record may correct; national version is long time coming
- AP results in many places
 - Happens now to a degree, manageable
 - Future: cyto, biopsy, resection results all in different locations, dependent only on business arrangements
 - Saving money here NOT in patient's best interest
- Service and Relationships are severed (and we are lost)

ASCP Task Force 2005-2006

- 6 Major trends identified - including
- Globalization (regionalization)
 - National labs contracting with health systems (**competitive bidding issue**)
 - **Condominium labs**
- **Problems with our Image:** Roles in the Health System
 - Perception of laboratory as commodity, not a service
 - Stereotype as APART from patient care

WHO is ASCP

- **Entire Laboratory TEAM (Inclusiveness)**
 - Anatomic Pathologists
 - Clinical (Lab Medicine) Pathologists
 - Residents
 - Laboratory Professionals
 - Managers, Supervisors
 - Medical Technicians, Technologists
 - Histo- & Cyto-technologists
 - Cytogenetic technologists
 - Pathology Assistants
 - Every Corner of the Lab!

**Working together
- Every Day
- Also in Wash. DC**

WHAT ASCP Does

- 5 Commissions (Committees, Councils)

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graph TD
    Education[Education]
    Membership[Membership]
    SelfAssessment[Self Assessment]
    Publications[Publications]
    Advocacy[Advocacy Public Policy]
    Education --> Advocacy
    Membership --> Advocacy
  
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ASCP & Advocacy

- ASCP has had a Washington DC Office since 1990
- Very Active on Every Issue in Pathology & Laboratory Medicine
- Collaborative with Other Lab and Path Organizations
 - Ability to work with Lab Coalition, but also Hospital organizations, other health care groups
- Real Power in Washington: Numbers count
 - 140,000 members; 35,000 messages to Congress via eAdvocacy system (ascp.org/Advocacy/eAdvocacyCenter.aspx)

Pod Lab Issue: Response

- Organized Medicine has difficulty dealing with this
- Interspecialty discussions
- Approach CMS to correct regulations

POD Campaign Elements

- Grass Roots Action, E-Advocacy Center
- Capitol Hill Meetings
- Meetings with CMS
- Collaboration with Pathology Organizations
- USCAP meeting ASCP program
- Letters, Editorial

stoppodlabsnow@ascp.org



Messages to Capitol Hill on Pod Labs

Thousands of messages have been sent to Congress.

- ASCP Member from Aurora Texas:
 - “Please be active in stopping these pod labs. Or at the very least **help institute the same regulations and ethics requirements that all other clinical labs are required to follow.** One or the other needs to occur to protect our patients, your constituents. If these practices are allowed to continue billions of federal tax dollars will be wasted. Please take a minute and consider what this means and help.”*

Messages to Capitol Hill on Pod Labs

- Pathologist from Dallas:
 - “These condo or pod laboratories **distort the normal referral of medical consultation based on quality and service in favor of profiting from this referral.** Further, since the more biopsies you do, the more you make, utilization, and hence total charges, increase when the referring doctor has **perverse incentives** in this way.”*

Messages to Capitol Hill on Pod Labs


- Pathologist from Maryland:
 - I have recently traveled to several states in the country while interviewing for jobs. **I declined offers in states where pod labs are prominent,** as I believe that they are such a detriment to the field and to good patient care. I have no doubt that other physicians will also make similar decisions and that this will cause regional variances in the quality of healthcare; not just because of the inherent faults of the pod labs themselves, but because the best trained pathologists will refuse to work in communities alongside them.”*

ASCP: Work with CAP Leaders

Drs. Jared Schwartz and Thomas Sodeman


Pod Lab Issue: What can you do?

- Support our campaign
 - Use E-Advocacy Center (on ascp web site)
 - This is there for you to use on any issue, not just this one
 - Locally oppose these practices
 - Discourage colleagues from joining
- Discuss with clinical colleagues who are thinking about entering these arrangements
 - Tell them efforts underway with CMS to close this loophole in the law
- Work with your State Pathology Societies and legislators

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What Else is ASCP Doing?

- 2007 Goals, Plans: Communications Plan to enhance Image of Pathologists, Lab Professionals; Labs in general
 - **Emphasis on Services** we provide; counteract concept of lab tests as a “commodity” (anyone can do it anywhere)
 - **Relationship** between pathology and clinician, patient
 - We need to win on this point
 - **Address public, patient advocacy groups, Health Care Execs**

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Message to Health Care Execs: Need Better Understanding of Lab

- Understanding how pathologists & lab professionals provide **SERVICES** and are **ACTIVE** in Patient Care
- Understand the **bond** between clinician and the local laboratory - **VITAL** for the patient
- Understand how LISs are making us Information Managers with new services, crucial for EMR
- Understand how important we are in Patient Care Initiatives - like Patient Safety
- Avoid thinking of lab tests as commodities to be sold to highest bidder (Competitive Bidding)
- Align with ASCP & Lab Orgs in Advocacy

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Message to Public

- What you need to know about your local laboratory
- Myths and Reality: tests not just numbers, neither are you!
- Myth: Anyone Can Do It, Anywhere
 - Have highly trained individuals
 - Great attention to detail
 - Communication skills - to your doctor
 - Not Walmart!
- About Relationship between you, your doctor, and the local laboratory
- Pathologists and Laboratory Professionals

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Importance of Local Lab

- Your doctor is familiar with people in lab
 - Familiar with test menu, significance of results
 - Asks questions- pathologists, lab professionals
- Lab provides interpretative services
 - NOT just numbers, not a commodity to be sold
 - All lab tests are not the same: results depend on “platform” and specific method
 - Suggests additional testing to your doctor
 - Lab knows you! We care for our patients

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ASCP Strategies: Summary

- Campaign against POD lab loophole
- Discussing concepts of continuity (fragmentation) of health care (including Balkanization of biopsy Pathology)
- Stressing Local Service and Relationships as key to patient care
- Educating public and health care executives on our key role in patient care

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2007 ASCP Annual Meeting

- Please join us at our Annual Meeting!
- October 18-21, 2007
- New Orleans, LA
- Rebirth of City and always a great venue

