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College of American Pathologists

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Advancing Excellence

TO: Intersociety Pathology Council

FROM: Mary E. Kass, MD, FCAP
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DATE: January 28, 2004

RE: College of American Pathologists - Report

STATE and FEDERAL ADVOCACY

In 2004 and 2005, the College, with the help of grassroots pathologists around the country has committed its resources to advocate for the following issues on the federal level:

Part A Payment for Hospital-Based Physicians

Strong College advocacy has led to a final hospital compliance guidance that strengthens warnings against no or token payment to pathologists for Medicare Part A services and signals increased federal scrutiny of payment arrangements.

The final Supplemental Compliance Program Guidance for Hospitals issued in late January by the Department of Health and Human Services Office of Inspector General (OIG), adopts some of the strongest language to date on Part A payment to pathologists and other hospital-based physicians.

The final Guidance states "Arrangements that require physicians to provide Medicare Part A supervision and management services for token or no payment in exchange for the ability to provide physician-billable Medicare Part B services at the hospital potentially violate the anti-kickback statute and should be closely scrutinized."

The document lists "a hospital compensating physicians less than the fair market value for goods or services provided to the hospital by the physicians" as one possible form of "illegal kickbacks between hospitals and hospital-based physicians."

An earlier draft of the compliance document included language that would have weakened a 1991 HHS Office of the Inspector General (OIG) statement that agreements requiring pathologists to accept less than fair market value for management and

supervision services could be construed as payments intended to induce referrals. At the urging of the College, key members of Congress sent a letter to the OIG, requesting clarification to ensure that the OIG did not retreat from the 1991 position. Instead, the College urged that the OIG state unequivocally that token or no payment for Medicare Part A supervision and management services in exchange for the ability to bill Part B services violates anti-kickback laws.

The OIG heeded the College's warnings about weakening the language, and in the final document reaffirmed the stronger language from the original compliance document. The OIG also more narrowly focused its language on activities for which no or token payment might not necessarily violate anti-kickback statutes. The examples the OIG uses—service on a tumor board, for example—echo those in CAP comments and are mentioned only in the context of an exclusive contract.

The College has long advocated that hospitals must pay pathologists fair market value for their oversight of the clinical laboratory.

Contractual Joint Ventures

The College opposes certain contractual joint ventures (CJVs) that allow a physician group—typically a large dermatology, gastroenterology or urology practice—to impermissibly share in the revenue generated by pathology services for the group's patients. These arrangements present clear ethical conflicts and jeopardize patient care by focusing on profit margin rather than test quality. The College is working with key members of Congress and the OIG, to respond to the proliferation of questionable CJVs and guard against harm to traditional pathology practices. CAP advocacy has resulted in the OIG including in its 2005 work plan two reviews of contractual joint ventures by the OIG Office of Audit Services (OAS). The College met with OIG officials in December 2004 to begin a dialog about the issue and met with the Centers for Medicare and Medicaid Office of Director of Technical Payment Policy, which has primary responsibility for the enforcement and monitoring of the Stark Law.

On December 10, the OIG issued an advisory opinion suggesting that a CJV in anatomic pathology services may violate Federal anti-kickback statutes. In addition, the final Supplemental Compliance Program Guidance for Hospitals issued in late January includes considerable language devoted to detailing risk areas, including previously published indicia of suspect joint ventures. Of particular interest to pathologists is the document's warning to hospitals that, "Contractual ventures with existing clinical laboratories and outpatient therapy providers, among others, are also potentially problematic, particularly if the venture is functionally a turnkey operation that enables a hospital to use its captive referrals to expand into a new line of business with little or no contribution of resources or assumption of real risk."

While the statement is delivered in the context of hospital arrangements, it dovetails with earlier statements by the OIG and concerns raised by the College and others about "pod" laboratories and other forms of suspect contractual joint ventures that threaten traditional pathology practices.

Medicare Physician Fee Schedule

Congress must act now to fix Medicare's flawed sustainable growth rate (SGR) formula for calculating annual physician fee updates. The SGR lowers physician payment rates when beneficiaries' use of services exceeds the growth in the gross domestic product. But this link fails to recognize that beneficiaries' medical needs do not lessen when the economy slows. The SGR formula also fails to account for regulatory changes in coverage and new federal health initiatives that increase utilization, and does not adequately account for increasing physician practice costs.

Competitive Bidding for Clinical Laboratory Services

The College opposes competitive bidding for laboratory services. Competitive bidding would jeopardize quality by treating laboratory services as commodities rather than essential components of health care. It would increase turnaround time for test results and break important links between treating physicians and local laboratories and pathologists. With its focus on price, competitive bidding has no place in the delivery of a service in which quality can mean the difference between life and death. The College asks that hospital-based and regional independent laboratories be excluded from a statutorily mandated Medicare competitive bidding demonstration on which the Centers for Medicare and Medicaid Services must report to Congress by the end of 2005.

Medical Liability Reform

The College, in partnership with the American Medical Association, strongly advocates for a \$250,000 limit on non-economic damages in medical malpractice cases and other liability reforms as contained in the Help Efficient, Accessible, Low-Cost, Timely Healthcare (HEALTH) Act.

In 2004, the House passed the liability reform bill but the measure failed in the Senate. The legislation will again be a top priority for President Bush, with the benefit of increased Republican majorities in both Houses.

Coding and Payment Advocacy

In 2004, the CAP advocated for new coding and payment levels for three new and revised in situ hybridization (ISH) and two immunohistochemistry (IHC) codes through participation in AMA's CPT and Relative Value Update Committee. Payment for the new codes was accepted by CMS in the 2005 physician fee schedule. The new coding and payment levels resulted in a 29% - 52% increase for ISH and a 26% - 29% increase for IHC.

Also in 2004, CAP advocacy avoided deeper cuts in new tiered flow cytometry codes initiated by CME.

Private Payor Issues

Since November 2003, the College has been working with Aetna to address a nationwide policy change for professional component billing for laboratory services. The new policy limits billing options for pathologists to billing patients, making arrangements with the hospital, or forfeiting CP-PC altogether. This policy has been implemented in several

States and is slated for a national roll-out. The College and Aetna are still discussing working together to develop a CPT-based system as a long term solution. However, this is contingent on Aetna's agreeing to some short term payment mechanism as a prerequisite to a longer term collaborative effort.

A similar policy regarding CP-PC has been promulgated by United Healthcare. The College is working to address this matter and engage UHC. A meeting with key decision-makers of UHC was held in the Washington office on January 14 with follow-up discussions scheduled at the end of the month.

The CAP has also embarked on a pilot project with the Illinois Society of Pathologists to help Illinois Pathologists collect useful practice data to assist in their negotiations with insurance companies who have adopted similarly CP-PC policies. To collect the relevant data, the College is providing its Path Focus product to the ISP free of charge.

In addition, the College participates in the National Specialty Society Insurance Coalition (NSSIC), a group of about 20 like-minded medical associations which meets regularly to discuss private payor problems of common interest. It also meets collectively with medical directors and staffs of over a dozen large, private health insurance companies at least semi-annually to discuss new technology issues, claims processing problems, quality measures, and most recently the industry's interest in developing "pay for performance" metrics.

As part of the College's comprehensive commitment to exercising greater influence at the state level in coordination with state pathology societies, we will continue to assist state pathology societies with a number of legislative priorities in 2005 including:

Direct Billing

The College will assist state pathology societies seeking state legislation to require direct billing for pathology services. College policy states that "payment for anatomic and clinical pathology services should be made only to the person or entity that performed or supervised the service", with an exception for referrals between laboratories that are independent of a physician's office.

In January, the CAP and the South Carolina Pathology Society achieved an extraordinary victory for pathologists in that state by garnering enough support to override a gubernatorial veto direct billing legislation.

Currently, seven states (SC, CA, NY, NJ, LA RI, NV) have laws requiring direct billing for certain pathology services. In addition, direct billing for laboratory/pathology services is required under state Medicaid laws and federal Medicare law. Opposition to direct billing legislation has come from OBGYNs, gastroenterologists, and dermatologists.

Opposition to Personnel Licensure Regulation

The other major state issue for the CAP this year is our opposition to requiring licensure of clinical laboratory personnel. We do not believe that licensure of laboratory personnel is in the best interests of patient care. We believe it is an impediment to recruitment and assignment of laboratory personnel. Acute shortages of laboratory personnel can be partially attributed to licensure requirements. In addition, we believe that licensure limits the authority of the laboratory director to direct the activities of the clinical laboratory. In 2004, the College worked to defeat licensure legislation in Massachusetts and in Illinois.

LABORATORY IMPROVEMENT PROGRAMS

Laboratory Accreditation Program

The College of American Pathologists' (CAP) Laboratory Accreditation Program (LAP) is constantly improving. The CAP recognizes that laboratory medicine is an evolving profession and the accreditation process must be continually enhanced to meet changing needs. The CAP's most recent changes focus on enhanced communication, whistleblower protections, and incorporation of best practices for continuous quality improvement. The following improvements to the CAP Laboratory Accreditation Program have been implemented during 2004:

- Developed and implemented a policy that provides for the revocation of CAP accreditation if complainants are harassed.
- The CAP has increased its scrutiny of laboratories with quality assurance deficiencies. The CAP now requires that these laboratories institute verifiable quality assurance measures that result in sustained compliance with our standards and with CLIA. To assure compliance, the CAP now looks even more critically at each situation and, if appropriate, conducts a second on-site focused re-inspection prior to granting accreditation.
- Established toll-free telephone numbers for laboratory employees to use to confidentially contact the College regarding patient or employee safety issues that are not being resolved in their labs.
- Require all CAP accredited laboratories to post a sign encouraging employees to contact the CAP with any unresolved quality issues.
- The CAP is addressing its responsibilities as an accrediting body by continuing to strengthen its communications with the directors of its accredited labs, with laboratory employees, and with the other accrediting and regulatory bodies.
- Require that labs develop a policy for the appropriate investigation of all complaints.

- Through a Checklist question, ensure that all lab employees are aware of their organization's policy and complaint procedure, including how to contact the CAP if problems are not fully and quickly resolved.
- Continue to work with regulatory bodies such as JCAHO, State agencies and CMS to establish formal communication mechanisms, including the timely release of information. Implement expanded notification to external regulatory agencies (JCAHO, State agencies, DOD/VA and CMS) for all non-routine complaint inspections and substantiated complaints.

Further enhancements will be announced in the coming year.

Gynecologic Cytology Proficiency Testing

In November, the College learned that the Centers for Medicare and Medicaid Services (CMS) had granted approval to the Midwest Institute for Medical Education (MIME) National GYN Proficiency Test beginning in 2005. Subsequently, CAP representatives met with CMS to present the CAP's concerns about the grading nomenclature required under CLIA because we believe it to be outdated. As a result of that meeting, we are pleased to report that CMS has indicated a willingness to discuss our concerns and to work toward a smooth implementation for laboratories.

*CLIA '08
regarding a
problem may occur*

The College has advocated on behalf of its members to clarify enrollment and testing date requirements for gynecologic cytology PT and have informed our members about the CMS implementation plan as details have been made available. The College is committed to supporting its members in successfully meeting this CLIA requirement and will continue to alert its members as new details become available.

In addition, the College has submitted an application to CMS for approval of the CAP PAP program as a national PT program. The CMS and CDC have preliminarily reviewed the CAP's submission of a PAP-PT program and will work with the CAP to resolve any outstanding issues. When the CAP PAP-PT program receives CMS approval, we will enroll individuals for the 2006 compliance year.

e-LAB Solutions

In December the CAP launched e-Lab Solutions™, a new state of the art online proficiency testing program. The new online features simplify and enhance proficiency testing by providing for :

- Online data submission with "smart" result forms that have pre-populated method, reagent and instrument codes, along with drop down boxes for easier completion of new codes;
- Highlighting of invalid responses to help ensure accurate submission of data;
- Online Kit instructions for quick reference;

- Interactive evaluations and online summary reports that can be sorted by performance, allowing the user to focus quickly on areas that need improvement, and;
- Customizable security levels to reflect each laboratories specific structure.

To date, more than 4200 laboratories are using e-Lab Solutions.

In 2005, the Cap will introduce 50 new products for our Surveys, Excel, and Quality Management Programs – more than ever before. CAP customers may continue to earn free Continuing Medical Education (CME) or Continuing Education (CE) credits/hours for participating in Surveys/EXCEL education activities. In the Surveys program, education activities are available in all major disciplines in 2005: Chemistry, Coagulation, Hematology, Immunology, Microbiology, Therapeutic Drug Monitoring/Endocrinology, and Transfusion Medicine. Each mailing of EXCEL contains an education activity. These education activities combine the unique perspective of contributing pathologists, clinicians, and medical technologists.

CAP '05 – THE PATHOLOGISTS MEETING

CAP '04 - The Pathologists' Meeting was huge success – the largest gathering of pathologists ever hosted by the College with attendance exceeding our target goal!

CAP '05 – The Pathologists' Meeting will take place September 11-14, 2005 in Chicago. A variety of classes will be offered in a wide range of formats including: plenary sessions, half-day courses, short sessions, round table discussions, video microscopy tutorials, industry workshops, and two full-day courses.

We will offer several education sessions in collaboration with other pathology organizations such as the American Association for Clinical Chemistry, the Arthur Purdy Stout Society, the Association for Pathology Informatics, and the American Pathology Foundation.

MEDIA AND PUBLIC RELATIONS

In addition to advocating in the legislative and regulatory arena, the College presents the faces and voices of pathologists to our patients and the public through the media.

Over the past five years, the public audience reached by College public affairs radio interviews has increased 858% from 54.4 million people in 2000 to 511 million in 2004. In addition, since 2000, the audience reached through CAP print media has increased 435% from 84.8 million to 445 million. Each year more pathologists conduct media interviews as a result of CAP efforts. The goal of these efforts is to help people understand that pathologists are integral to the quality health care they receive.

In November 2004, the CAP successfully trained 28 new members of its Spokespersons Network. Each of the members participated in a two-and-a-half day intensive program,

which included presentation training and media training, as well as actually taping both a video news release (VNR) interview and a radio interview. There are now 156 trained CAP spokespersons, who participate in the Network.

EDUCATION

A CAP educational track is planned for the 2005 CLMA/ASCP Meeting and Exhibition, scheduled for March 5-8, 2005, in Chicago, Illinois. The track is designed to highlight and support the CAP Laboratory Improvement Programs. Topics include Laboratory Inspection Preparation (2 sessions), ISO 15189, Key Quality Indicators, Building Relationships with Nurses, and Bridging the Laboratory Operations Management Chasm. This is the sixth consecutive year that the College has sponsored an educational track at this meeting, and past evaluations indicate our programs are very well received by attendees.

Problems in Pathologic Staging of Select Cancers is the topic of the CAP Companion Society meeting education program at the 2005 USCAP Conference in San Antonio, Texas. The program will be presented Saturday evening, February 26, 2005, and will address staging issues of colon, breast, lung, and prostate cancers.

In 2004, the CAP completed the development of 45 new or retooled education programs, in addition to the more than 100 programs at CAP '04. Many of these programs are in support of the College's products and publications, such as LAP, Surveys, EXCEL, Quality Management Programs, and *Archives*. Our work on these and other new programs will continue in 2005; at this time there are more than 50 education programs, in addition to CAP '05, planned for development and delivery.

PUBLICATIONS

In 2005, the College will introduce its 12th edition of our best-selling title, "So You're going to College a Blood Specimen: An Introduction to Phlebotomy". The College will also publish a 2nd edition of "An Introduction to Autopsy Technique," and a new publication entitled, "Quality Management in Anatomic Pathology: Promoting Patient Safety Through Systems Improvement and Error Reduction."

Philip T. Cagle, MD, has been appointed as the new editor-in-chief of the *Archives of Pathology and Laboratory Medicine*.

SNOMED

The 2005 SNOMED International Authority (SIA) was restructured to comprise a total of nine members, down from 15 (including two consultants). The 2005 SIA includes three CAP Board members, three CAP members, two National Health Services (NHS) representatives, and one SNOMED staff member.

SNOMED CT® July 2004 Release was successfully delivered on time for both the United States and United Kingdom editions. The July release includes over 360,000 concepts and includes updates for gastroenterology submitted by the National Health Service Information Authority (NHSIA) in conjunction with the British Society of Gastroenterology, public health expansion in collaboration with the Centers for Disease

Control (CDC), new context attributes, new nursing mappings, and additional concepts to support cancer reporting.

The ad hoc TermInfo group is proposing a new Health Level 7 (HL7)-SNOMED Special Interest Group (SIG). This is a major breakthrough for SNOMED and HL7. The group will develop a formal memorandum of understanding between HL7 and SNOMED/CAP as two standards organizations collaborating. Specific marketing or content projects have not yet been proposed. HL7 recently developed relationships with the American Society for Testing and Materials (ASTM) for the Continuity of Care Record (CCR) and the National Council for Prescription Drug Programs (NCPDP) and see part of their role as coordinating with other standards efforts. This should help propel acceptance of SNOMED as an international standard and support our goal of widespread adoption. HL7 has 26 international affiliates plus the United States. The group anticipates meeting at the next HL7 meeting on January 28, 2005. The January release will be ready at the end of the month.

CAP FOUNDATION

The purpose of the CAP Foundation is to conduct activities that advance the science and practice of pathology. Each year, the Foundation's grant-making programs fund approximately 50 research, education, and humanitarian grant projects for residents and pathologists who do innovative research, training in advanced molecular techniques, and assist patients in receiving needed pathology and other medical services. In 2005, the Foundation would like to increase gifts and donors by 10% over 2004.