



TO: Intersociety Pathology Council

FROM: Stephen N. Bauer, MD, FCAP
President, College of American Pathologists

DATE: February 17, 2011

RE: College of American Pathologists – Report

THE TRANSFORMATION OF THE SPECIALTY OF PATHOLOGY

The CAP's multiyear campaign to transform the pathology specialty continues to gain momentum. Transformation refers to collective efforts currently underway at the CAP to foster new and enhanced roles for the pathologist, and greater recognition of the pathologist as a physician and a critical member of the patient care team.

The transformation of the specialty will have an enormous impact on the way pathologists practice, how clinical colleagues, patients, and others in the medical community perceive them, and how reimbursement for pathologist services is structured.

The CAP's "Case for Change" transformation agenda is predicated on direction from our membership regarding priorities. It is a multi-year strategy, developed in response to the unprecedented health care costs, emerging technological developments, market force changes, and emerging health care delivery models that are redefining the physician's role around patient outcomes.

The CAP presented a transformation plenary session at our annual meeting last September, a program designed to provide members with a greater understanding of the foundational roots and future direction of the Case for Change strategy. The session also highlighted the unique value that pathologists provide in health care delivery, and explored the CAP's vision for the pathologist's evolving role in the future.

The College launched the Case for Change in 2010. Four major research modules have been designed to define new and expanded roles for pathologists, identify gaps, business models, and success stories, and to map pathways to the future:

1. Pathology and Related Workforce Supply and Demand
2. Pathologist Value Proposition: Roles and Value Created
3. Pathology Practice and Service Models: Evolution and Economics
4. Timing and Impact of New and Emerging Technologies

Over the next two years, these research modules will provide the Transformation with a firm data-driven foundation, and define, in detail, the pathologist's role as a key physician member of the clinical care team.

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A wide variety of services and programs are currently in development to support the needs of pathologists in their changing roles, including practice guideline development, benchmarking research, advocacy and education programs, diagnostic/practice management tools, and mentoring programs.

Key transformation initiatives now underway at the CAP include:

The Center

The CAP Pathology & Laboratory Quality Center is a forum for developing guidelines & protocols related to the practice of pathology. Specifically, the Center:

- Ensures quality in diagnostic medicine, its linkage with patient outcomes, and the role of the pathologist in improving quality and contributing to patient care.
- Focuses on areas that are directly involved in the practice of pathology, pathologists and their role in lab medicine.
- Uses a multidisciplinary approach to assure broad acceptance of guidelines.
- Conducts the medical literature research necessary to support development of practice guidelines and protocols.
- Identifies and collaborates with other organizations on protocol development needs for supporting research (e.g. HER2 tissue fixation).
- Facilitates the coordination of consensus activities in the absence of evidence-based practice guidelines.

Guidelines and whitepapers currently available through the Center:

- Asbestosis
- CAP Cancer Protocols
- ER/PgR
- HER2
- KRAS

Guidelines and whitepapers slated for 2011 development through the Center:

- Lung cancer (partnering with International Association for the Study of Lung Cancer IASLC)
- HPV terminology
- Validation principles for digital pathology
- Effective Communication of Significant and Unexpected Findings in Anatomic Pathology
- Immunohistochemistry (IHC) Assay Validation
- Algorithm for Acute Leukemia Work-up

The Center is focused on helping pathologists transform and move to the center of patient care, and helps to strengthen alliances and collaboration with other medical specialties and patient advocacy organizations.

The Institute

The CAP Institute is an incubator for forward-thinking ideas designed to help fuel transformation of the specialty. With a focus on small, short-term pilot projects, the Institute will help deepen our understanding of the market viability and the value of new and expanded roles for pathologists. It will also help to define realistic pathways – from skill-building training programs to visibility and advocacy initiatives – that are necessary to help pathologists succeed in a changing healthcare landscape.

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CAP Policy Roundtable

The CAP Policy Roundtable will develop proactive public policy focused on the implementation of health care reform. We envision it as a forward-looking service to health care policymakers that shows what we do and how we can contribute in our evolving health system.

The policies we develop will be data driven and underscore credibility. They will keep patient safety and well-being front and center. Over time, CAP public policy papers will establish the College as a go-to source of solid research and sound policy direction.

The CAP Center for Informatics

The focus for the Informatics center will be to support wider use of decision support tools and the field of informatics, and to promote the growth of the most viable practice models, while offering consultative support.

Through these and other transformation initiatives, the CAP will enable pathologists to change fundamental aspects of how and what they practice in the future, strengthening the distinctive contributions pathologists can make to patients and healthcare colleagues.

Throughout 2011 and beyond, College leaders will be heavily focused on taking our transformation message out to pathology colleagues around the country to build collaboration and offer support to pathologists in their evolving roles.

To learn more, please visit the transformation website, www.cap.org/transformation.

FEDERAL AND STATE ADVOCACY

CAP is pathology's strongest advocate in Washington, D.C.. With an office in our nation's capitol since 1970, our dedicated staff of more than 25 individuals ensures that legislators hear the voice of pathology.

The College's advocacy efforts are focused on a "Now and Future" agenda—one that strives to mitigate against pending policy actions that negatively impact CAP members, while at the same time begins to establish a future role for pathologists in the coordinated care model. The College will also advance other important issues as long they don't impede progress on the pathology "Now and Future" agenda.

Health Care Reform

It has been nearly one year since President Obama signed comprehensive health care reform legislation, H.R. 3590, the *Patient Protection and Affordable Care Act (PPACA)*, into law. It was President Obama's signature legislative achievement in his first term of office and changed the health care reform landscape for years to come.

Implementation of the health care reform continues with the Department of Health and Human Services (HHS) issuing many regulations in the past year. CAP is actively analyzing and monitoring these various regulations, especially a forthcoming rule implementing Accountable Care Organizations (ACO) before January 1, 2012. Under the ACO program, a group of medical care providers accept responsibility for providing and arranging all care for a group of patients under a payment arrangement that allows them to profit from reducing costs and improving quality. The Office of Management and

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Budget (OMB) is in the final stages of reviewing the ACO regulation and CAP anticipates the proposed rule's release in the very near future.

Politically, PPACA's passage had a major impact on the 2010 mid-term elections and undoubtedly contributed to Republicans reclaiming control of the House of Representatives and making substantial gains in the Senate. In response to the outcome of the 2010 elections, new Members of the House of Representatives passed legislation to repeal H.R. 3590, however, a similar effort has, thus far, failed in the Senate. In addition to repealing the bill, the new Republican House Majority has vowed to overhaul major portions of the legislation. Also, multiple states have filed lawsuits challenging the constitutionality of PPACA, specifically provisions mandating all Americans obtain health insurance. CAP continues to closely monitor all aspects of the health care reform law.

Physician Payment

The 2011 Physician Fee Schedule (PFS) final rule, published in November by the Centers for Medicare & Medicaid Services (CMS), addressed a number of physician payment issues affecting pathologists. Notably, CMS rebased and revised the Medical Economic Index (MEI), which resulted in a decrease to physician work from 52.5 to 48.3 percent, and an increase in practice expense (PE), including professional liability (PL) expense from 47.5 to 51.7 percent. To reflect these changes CMS increased the PE RVUs by a factor of 1.8, the malpractice RVUs by an adjustment of 1.358, and so as not to distort the physician work RVUs, adjusted the conversion factor by -8.2 percent.

SGR/ Technical Component (TC) Grandfather

In December of 2010, Congress passed legislation that delayed the impending cuts to the SGR for an additional year. This should give Congress ample opportunity to work on true reform to the SGR. The cost of replacing the SGR may prove difficult for Members of Congress to support. Currently, the cost to replace the SGR is estimated at \$310 Billion. The College will continue to urge Congress to act to avoid these cuts in Medicare payments to physicians.

In December of 2010, Congress extended the TC "Grandfather" for an additional year. The CAP will be working to introduce legislation to permanently extend the TC "Grandfather" in the 112th Congress. The College will be advocating that the TC Grandfather needs to be extended so that independent laboratories can continue to be paid directly by Medicare to cover the technical component's cost.

On February 18th, CMS rescinded a previously announced change to its current technical component (TC) Grandfather payment policies that were set to take effect April 1st. Since the transmittal was initially announced in October of 2010, the College has been in constant contact with CMS to reconsider the change. In addition, the College has met with Congressional leaders to educate them on this issue, as well as urging them to contact CMS to rescind the transmittal.

Direct Billing

Direct billing laws remain a state legislative priority for the College. Sixteen state laws now require direct billing for certain pathology services, six state laws prohibit markups, and 16 require disclosure.

Signature Requirement on Laboratory Requisitions

With regard to the 2011 Physician Fee Schedule, CMS finalized a policy requiring a physician or qualified, non-physician practitioner's (NPP) signature on all laboratory requisitions for clinical diagnostic laboratory tests paid through the Clinical Laboratory Fee Schedule (CLFS). Although this policy was

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specific to tests paid on the CLFS, language in the rule implied that a signature requirement already exists for pathology services paid on the PFS, which CMS later clarified that a signature requirement did not already exist for these services. CAP, joined by the AMA, CLC and others expressed concerns with the policy change, and this month CMS announced that it would review the issue and rescind the physician signature requirement on laboratory requisitions.

RVUs for High Volume Codes Hold Steady in '11 Fee Schedule

The physician work relative value units (RVUs) for many high volume anatomic pathology codes will remain stable next year, despite increased pressure from CMS to reevaluate certain codes that the agency identified as potentially misvalued. CMS detailed their response to recommendations submitted by the AMA/Specialty Society Relative Value Scale Update Committee (RUC) in the recently released [2011 Medicare Physician Fee Schedule](#) (PFS). In the PFS, CMS accepted the RUC's recommendations, which consisted of values developed by CAP for the physician work RVUs of anatomic pathology codes 88300-88309.

Two years ago, CMS instructed the RUC to identify potentially misvalued code families by reviewing high volume codes that met specific criteria, which identified as the 88300-88309 code family, along with services performed by other medical specialties. During this period, the College's Economic Affairs Committee (EAC) worked closely with CMS and the RUC to determine appropriate values for these codes. The CAP developed recommendations for RUC review based on surveying, historical review, and data analysis to validate the current work RVUs for these codes.

EDUCATION

The CAP is the leading resource for information and education in the practice and science of pathology and laboratory medicine. Leading medical and scientific experts develop the education content on standards, best practices, and innovation in test selection, disease diagnosis, and patient therapies. The curriculum of more than 300 courses offers pathologists and laboratory professionals with the "take home and use" tools and resources to:

- Continually improve their scientific and practice skills
- Meet licensure and re-certification requirements
- Prepare for new and enhanced roles

Over the past few years, the College has launched several new programs that build and maintain the competencies of pathologists and laboratory professionals. The CAP Advanced Practical Pathology Program, part of the CAP Institute allows pathologists to demonstrate special knowledge and skill in select practice areas. The College also offers an expanding menu of challenging self-assessment modules to help ABP diplomates meet Maintenance of Certification requirements. The Competency Assessment Program presents opportunities for laboratory professionals to test their knowledge in 11 different laboratory disciplines and helps the laboratory satisfy CLIA requirements.

Here is an overview of CAP's key educational offerings and initiatives:

Maintenance of Certification

As an ABP-approved provider, the CAP is committed to helping pathologists meet the lifelong learning requirements of Maintenance of Certification and is working to ensure that its CME and SAM programs address learning needs across the six competency categories as defined by the ABMS and endorsed by the ABP. The College offers programs that meet MOC Part IV requirements through its Laboratory

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Improvement Programs. Visit the ABP's web site www.abpath.org for a list of approved programs.

The CAP rolled out a service called **MyMOC.com**, which provides CAP members with a single resource offering clear answers about MOC requirements and how those requirements affect individual pathologists. The service alerts members to any changes in MOC requirements and reminds individual members of upcoming MOC deadlines for compliance and reporting. It is provided at no cost to CAP members. All CAP members who pass their boards after 2006 are automatically enrolled in the program.

Self-Assessment Modules (SAMs)

The CAP SAM Committee continues to focus on increasing the volume of SAMs available across topic areas. Forty-six SAM activities (92 CME/SAM credits) released in 2010. The library is expected to expand to fifty-eight SAMs (159 CME/SAM credits) in 2011. CAP SAMs are offered with select CAP Annual Meeting courses, in conjunction with the *Archives of Pathology* journal, as part of the Advanced Practical Pathology Programs and Laboratory Accreditation Program education, and as individual online activities.

Virtual Management College (VMC)

The VMC program offers valuable practice management topics to residents, pathologists in fellowships and those who are new in practice. The interactive Webinar format features polling, chat and scenario-based cases to provide a richer, more interesting learning experience.

Virtual Informatics College (VIC)

The VIC is a series of online courses focusing on pathology informatics. Seven courses are available that address medical coding, digital cameras and imaging, LIS fundamentals, interfaces and middleware), telepathology and whole slide imaging, the electronic medical record, and meaningful use of EHR.

Advanced Practical Pathology Programs

The programs provide practical learning on existing and emerging pathology practice and technologies, and allow pathologists to demonstrate special knowledge and skills in select practice areas. Programs included:

- Breast Predictive Factors Testing (BPFT)
- Multidisciplinary Breast Pathology
- Laboratory Medical Director
- Pharmacogenomics
- Pulmonary
- Renal Pathology
- Ultrasound Guided Fine Needle Aspiration (USFNA)

USCAP Cooperating Society

The College has sponsored an education symposium at the USCAP Annual Meeting since 2000. This year's program—*Whole Slide Imaging (WSI): The Here and Now*—is scheduled on Saturday, February 26 from 7:00–10:00 PM. Dr. Laura Collins and Dr. Terence Colgan will moderate the symposium. Topics covered in the symposium include regulation and validation; use of WSI for remote frozen sections;

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pathology service coverage; tumor boards; presentations; routine pathological diagnosis and teleconsultations; and efficiencies and cost.

CAP'11

The CAP'11 education program is final. Nearly one-hundred courses across a broad menu of Anatomic and Clinical Pathology and Practice Management topics will be offered and will feature scientific tracks in hematopathology and dermatopathology. The program begins Sunday morning with a scientific plenary on sentinel lymph node dissection for melanoma. CAP'11 is scheduled September 11-14 at the Gaylord Texan Resort and Convention Center in Grapevine, Texas.

Laboratory Accreditation Program Curriculum

The Laboratory Accreditation Program curriculum supports pathologists and laboratory professionals in preparing to inspect other's laboratories and in maintaining continuous compliance within their own facilities. It is an internationally recognized program based on the CAP Laboratory Accreditation Standards.

Designed to go well beyond regulatory compliance, the program provides a solid foundation for quality practices and helps laboratories achieve the highest standards of excellence to positively impact patient care:

- **Inspector Training**
Inspector training includes online team leader and team member initial training and update/review courses.
- **LAP Continuous Compliance Series**
The 2011 LAP Audio and Web conference series includes ten events. Discipline-specific as well as general topics help pathologists and laboratory professionals stay current with laboratory accreditation requirements and enhance everyday laboratory operations.
- **International Workshops**
International LAP sessions emphasize the benefits of laboratory accreditation and provide basic guidelines for complying with accreditation requirements. A workshop was presented at the Arab Health 2011 meeting in Dubai earlier this year.
- **Specialty Workshops**
The College offers workshops in conjunction with other organizations' events that provide overall information on the inspection process and/or focus on the unique inspection needs of discipline-specific sections of the laboratory. Workshops at the Clinical Laboratory Management Association, American Society for Reproductive Medicine, American Association of Blood Banks, and Association for Molecular Pathology are planned in 2011.
- **CAP 15189**
In 2008, the College of American Pathologists (CAP) launched a laboratory accreditation program based on the International Organizations for Standardization (ISO) 15189 standard for medical laboratories. This voluntary, non-regulated accreditation does not replace CAP's CLIA-based Laboratory Accreditation Program, but rather complements CAP accreditation and other quality systems. CAP 15189 focuses on optimizing processes to:
 - Improve patient care
 - Strengthen the deployment of quality standards

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- Reduce errors and risk, control costs

A series of seven education modules designed for laboratories interested in education and training tools in quality management systems and ISO is underway. The new series is CAP market branded as **QMed™** Online Educational Courses. On-line learning modules **15189 Walkthrough, QMS Implementation Roadmap Root Cause Analysis and Internal Auditing** were released recently, and have received excellent ratings.

CAP 15189 currently has twenty five laboratory clients in the accreditation program, with some providing opportunities for multiple sites. Currently there are 11 accredited laboratories to ISO15189:2007. Among influential key clientele, CAP is emerging as a global leader in ISO15189 and quality management systems.

While strong interest for the program continues, adoption rate of customers in a domestic based program has proven to be longer and more sales intensive than original projections. To adjust to current market the CAP15189 was redesigned in August 2010 to a niche program cliental and heightened focus on QMS education and new middle market services ex: standalone on-site mini QMS assessments.

These actions combined with the delivery of QMed education is beginning to yield increased traction in clientele, of particular note large influential laboratories (those with international affiliation, clinical trials and genetics orientation). The program is currently tracking an additional 51 prospective laboratories, with potential closure between 12 and 36 months out.

QUALITY MANAGEMENT TOOLS

The CAP's comprehensive collection of Quality Management Tools strengthens a laboratory's knowledge of key laboratory processes, identifies quality improvement opportunities, and provides the information needed for effective laboratory management. The Quality Management Tools help laboratories:

- Deliver quality patient care
- Satisfy accreditation requirements and JCAHO National Patient Safety Goals
- Establish realistic benchmarks for each laboratory

PROFICIENCY TESTING

With more than 580 products, the CAP's Surveys and Anatomic Pathology Education Program is the largest laboratory peer comparison program in the world. The program allows laboratories to regularly evaluate their performance and improve the accuracy of the patient results they provide. Through these programs, the CAP provides individual laboratories with unknown specimens for testing. The participants analyze the specimens and return the results to the CAP for evaluation. In turn, each participating laboratory receives a report of their performance as well as a report summarizing the results of all participating laboratories.

PUBLICATIONS

CAP TODAY, the College's monthly news magazine, claims the highest readership among all laboratory publications. Each issue reports medical, industry, and business news to more than 50,000 laboratory professionals. **Archives of Pathology & Laboratory Medicine** is the College's peer-reviewed, scientific journal giving editorial focus to the introduction and evaluation of new knowledge and technology. **STATLINE** is a biweekly electronic newsletter designed to keep members informed of new legislative and

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regulatory developments as they happen, serving as the first word on the public policy issues facing our members. **CAP@YourService** is a monthly news service for members, offering the latest College news, as well as the CAP member benefits, education opportunities, Spokespersons activities, and issues affecting practice management.

CAP STS

The CAP's STS division (SNOMED Terminology Solutions™) is an expert in health standards and IT implementation. CAP STS' Professional Services, leading the pursuit of semantic interoperability for electronic health records (EHRs), specializes in customized, best-practice health information solutions, from strategy and planning, to implementation and maintenance. CAP STS' DIHIT (Diagnostic Intelligence and Health Information Technology) team is committed to improving and/or developing health IT standards, practices, tools, and standardized reporting. The CAP eCC (electronic Cancer Checklists) and the CAP Diagnostic Work Station are two examples of such initiatives.

CAP is the original creator of SNOMED Clinical Terms® (SNOMED CT®)—a globally recognized controlled medical vocabulary—and has fostered its development for more than 40 years. CAP STS continues to develop and maintain SNOMED CT on behalf of the International Health Terminology Standards Development Organization (IHTSDO®). CAP STS works with clients worldwide to implement standards and health IT solutions; these clients include provider organizations, health IT vendors, health exchange initiatives, universities, research centers, and government agencies.

For more information, please visit www.capsts.org and www.cap.org/DIHIT.

CAP FOUNDATION

Founded in 1963, the *CAP Foundation* serves the pathology community by committing resources to publications and special conferences. It is the leading philanthropic organization for pathologists and has distributed millions of dollars to support education, research and humanitarian programs related to pathology. The Foundation has supported the development of critically needed technology innovations for pathologists by instituting new technology fellowships for residents to study disciplines that are not available at their own institutions and bring back that technology for their own benefit and that of their departments. The Foundation is also responsible for the *CAP Scholars Program*, which annually gives a \$25,000 award to three pathologists who are engaged in research that will enable the transfer of new technology to the general practice of pathology.

Since 2007, the Foundation's Futurescape of Pathology Conference Series has brought together leading thinkers and practitioners to exchange views on the most pressing issues facing pathologists and the specialty of pathology. This strategically focused program offers a variety of interactive formats; and the intimate scale makes the Conference the premier forum for leading pathology specialists and executives. For more information about how to make a contribution or apply for a grant or award, call 800-323-4040 ext. 7324 or e-mail CAPFdn@cap.org.

PUBLIC AFFAIRS

The CAP continues to produce nationally recognized patient and physician education information on topics which include managed care, Pap testing, breast cancer, diabetes, and cholesterol testing. The College's Public Affairs area pursues media opportunities for CAP members to educate the public on the role of the pathologist as physicians who are integral members of the patient care team. Through these proactive efforts, more than 2 billion readers, listeners, and viewers in 2010 saw and heard news about the live-saving contribution of pathologists to patient care.

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In addition, the CAP offers two websites for patients-- one website offers patient information on cancer diagnosis and another focuses on preventive care. Re-launched in 2010, **MyBiopsy.org** provides accurate and credible information on more than 42 of the most common cancers and cancer-related conditions, including breast, colon, lung, and skin. The site includes answers to questions about cancer, lists of available treatment options, a glossary of key terms, and pictures of normal and diseased tissues. In addition, visitors to the site will find tips on how to read a pathology report, survivor stories, and recent cancer news.

The CAP also offers a free, e-mail reminder website, **MyHealthTestReminder.org**, to help individuals remember to schedule important cancer screening tests.

Spokespersons Program

Since 2001, the College has offered media and presentation training to more than 320 CAP members through the CAP Spokespersons Training program. These members are available to speak with the media on a variety of pathology-related, health and wellness topics, including novel H1N1, HPV, SARS, bioterrorism, Pap testing, antibiotic-resistant bacteria, cholesterol, and blood banking, among others.

FUTURE MEETINGS—SAVE THE DATES!!

CAP '12 September 9-12 –Manchester Grand Hyatt, San Diego, California