



COLLEGE OF AMERICAN PATHOLOGISTS UPDATE

CAP President Gene N. Herbek, MD, FCAP



The College of American Pathologists (CAP), the leading organization of board-certified pathologists, serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

LABORATORY IMPROVEMENT PROGRAMS

The CAP Laboratory Improvement Programs provide a comprehensive view of the laboratory quality process with insight, knowledge, and peer-based educational coaching. Backed by the scientific expertise and commitment of the world's largest board-certified pathologist organization, the CAP partnership fosters collaboration and builds confidence that laboratories deliver the most reliable test results to ensure accurate patient diagnoses. Its cornerstones are accreditation and proficiency testing (PT).

CAP Accreditation

Worldwide the CAP accredits more than 7,600 laboratories, including hospitals and commercial laboratories, contract research organizations, and biorepositories, with growth outside of the United States accelerating. The goal of the CAP Laboratory Accreditation Program is to improve patient safety by advancing the quality of pathology and laboratory services through education and rigorous standards to ensure laboratories meet or exceed regulatory requirements. The program incorporates stringent requirements while also providing laboratories the roadmap and tools to achieve these requirements, bringing value to patients, physicians, and providers.

The CAP's Laboratory Accreditation Program is more than 50 years old and has diversified over the years to include:

- Biorepositories
- Forensic drug testing
- Reproductive laboratories (in partnership with the American Society for Reproductive Medicine)
- International Organizations for Standardization (ISO) 15189SM

Proficiency Testing (PT)

The CAP's Surveys and Anatomic Pathology Education Programs (Surveys) is the largest laboratory peer comparison program in the world. There are 58 new Surveys PT programs in 2014, including more options for cytopathology education featuring the DigitalScope® technology platform.

The CAP Surveys program includes more continuing education (CE) credit offerings and self-reported educational opportunities than any other PT provider in the industry. Many Surveys programs also include continuing medical education (CME) and Maintenance of Certification (MOC) educational credits for participants. The Surveys program is backed by the scientific expertise and commitment of CAP members.

The CAP partnership fosters collaboration and builds confidence for laboratories to help them deliver the most reliable test results to ensure accurate patient diagnoses.

INTERNATIONAL MARKET EXPANSION

International laboratories pursue CAP accreditation to be globally recognized and regionally differentiated—and most importantly, to improve the quality of results they provide to the ordering physician/care givers and the care they provide to their patients. The CAP accredits more than 360 international laboratories (excluding the US Department of Defense) in more than 50 countries. More than 2,900 laboratories in more than 90 countries participate in the CAP's PT/external quality assurance programs.

Relevant and comprehensive inspections facilitate a culture of continuous quality improvement and commitment to accurate and reliable patient results. The CAP is the laboratory's partner in quality and an expert resource for those laboratories seeking a ranking among the best—both from an institution level as well as individuals who are leading quality in their communities.

In July 2013, the CAP and BD Diagnostics—Preanalytical Systems announced the launch of a new strategic alliance that will provide solutions to advance laboratory quality for improved patient outcomes in China and India. In China, there are more than 20 CAP-accredited laboratories and nearly 100 laboratories participating in PT. In India, of the more than 80 laboratories participating in CAP PT, more than 40 have achieved CAP accreditation. Market launch of this initiative began in China and India in August 2013 with PT distribution initiated in January 2014.

CAP LEARNING

The CAP is the leading resource for information and education in the practice and science of pathology and laboratory medicine. Leading experts develop education activities focused on all six MOC competency categories, including emerging scientific and technical knowledge and laboratory and practice management. The curriculum of more than 300 courses offers pathologists and laboratory professionals with practical tools and resources to:

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

The CAP's Advanced Practical Pathology Programs (AP³s) include comprehensive CME and cognitive and practical assessment components. These programs offer pathologists

the opportunity to develop, demonstrate, and earn recognition for knowledge and skills in areas not currently addressed by the American Board of Pathology (ABP). The CAP currently offers the following AP³ courses:

- Laboratory Medical Director
- Multidisciplinary Breast Pathology
- Ultrasound-Guided Fine-Needle Aspiration
- Prostate Pathology

The CAP is committed to providing education to help pathologists meet the lifelong learning and performance in practice requirements of the ABP MOC program. The CAP offers programs that meet MOC Parts II and IV requirements, including Self-Assessment Modules (SAMs). The CAP currently offers more than 113 online SAMs in 32 different specialty areas; SAMs are available with select CAP annual meeting courses as well. CAP SAMs offer highly interactive formats and outcomes-based learning.

Education courses are available in a variety of engaging and interactive formats, including live workshops, online courses, Web conferences, and journal-based programs. CAP Learning also develops and coordinates the education program at the College's annual meeting.

The College's annual meeting, CAP '14 – THE Pathologists' Meeting™, will be held on September 7–10, 2014, at the Hyatt Regency in Chicago, Illinois. This year's scientific theme is "Molecular Medicine Meets Morphology." The CAP Abstracts Program kicked off on January 13, 2014.

Now in its eighth year, the online Competency Assessment Program helps laboratories meet CLIA and laboratory accreditation program requirements for competency assessment and training of laboratory professionals through convenient online courses and checklists. The program is comprehensive allowing laboratories to choose from dozens of CE courses in 11 disciplines. The program provides training in more than 130 instrument-specific observation checklists. Individual laboratories can tailor the courses and checklists to fit their laboratory as well as use the tools provided in the program to create their own courses and checklists from scratch. The Safety & Compliance Courses package is available for an additional fee and includes seven courses on safety and OSHA standards for annual laboratory compliance training.

ADVOCACY

The CAP remains committed to our goals to advocate on behalf of the specialty. Our short- and long-term advocacy goals are to:

- Mitigate payment cuts to pathologists and help them adapt to new payment models
- Level the playing field for pathology
- Enhance pathologists' role in coordinated care
- Maximize pathologists' role in test selection and diagnosis

As health care reform continues to shift Medicare from a fee-for-service to a value-based program, the CAP's advocacy objective is to ensure public policy recognizes pathologists as critical members of the patient care and coordinated care team, and help pathologists adapt to new payment models and reporting requirements.

Through the CAP's advocacy efforts, the following accomplishments have resulted in 2013 and 2014:

SGR Reform: Representing a significant victory for pathology in the effort to repeal the sustainable growth rate (SGR) and reform Medicare physician payments, Congress reached a policy agreement, HR 4015/S 2000, that includes a provision providing more flexibility for pathologists to meet requirements under Medicare's Physician Quality Reporting System (PQRS), Electronic Health Record (EHR) Incentive Program, and the Value-Based Modifier (VBM).

Blocked the Centers for Medicare & Medicaid Services (CMS) proposal to link pathology technical component (TC) payments to the hospital ambulatory payment classification (APC) rate: The CAP planned and executed a "textbook" lobbying and grassroots campaign that blocked CMS

from implementing its proposal to link pathology payments to the Hospital Outpatient APC rates. The CAP mobilized more than 3,000 CAP member contacts to Congress and thousands of contacts to CMS. Capitol Hill responded, sending letters with more than 100 signatures in the House and 40 signatures in the Senate.

88305TC: The College defended the 88305TC from additional cuts.

EHR Donations: CMS and the Office of Inspector General (OIG) extended the antikickback safe harbor and Stark exception, but removed laboratories as protected donors of EHRs. The CAP engineered favorable attorney general

actions in nine states over the last two years, including four in 2013. Those state actions helped lay the groundwork for the federal action, which cited the actions in the states as evidence for their favorable action on our behalf.

Physician Quality Reporting System (PQRS): As a result of CAP lobbying, CMS conceded in the 2014 Final Rule that physicians with fewer than the required nine measures will not face penalties in either 2015 or 2016. The net effect is that CAP members will be able to avoid penalties by reporting the existing five measures secured by the CAP, if they apply; members with no measures will face no penalties.

Self-Referral: The CAP influenced a successful report from the Government Accountability Office (GAO) that confirmed the findings of the Mitchell study from 2012; influenced the proposal by the Obama Administration of a ban on self-referral included the President's 2014 budget; secured a Congressional Budget Office (CBO) estimate of the savings from a ban on self-referral; influenced the introduction of legislation in the House to ban self-referral; and positioned self-referral to be considered as a "pay-for" for the SGR reform legislation.

Next-Generation Sequencing (NGS): The CAP developed a consensus CPT coding proposal on NGS in collaboration with the Association of Molecular Pathology (AMP) and other players for submission to the CPT Editorial Panel.

Episodes of Care: CMS asked the CAP to create "episodes of care" that could be used to measure pathologists' performance in the VBM, which combines cost and quality measures. While several hospital-based specialties were asked to make recommendations, the CAP is the only society that brought a proposal to CMS by the July 15 deadline.

Graduate Medical Education (GME): CAP leaders worked to significantly increase the CAP's presence and visibility in GME policy circles, beginning to make pathology's case with key policy stakeholders and influential, such as Health Resources and Services Administration (HRSA) and the Association of American Medical Colleges (AAMC). The CAP also mobilized the national pathology societies behind joint communications to the Council on Graduate Medical Education (COGME).

Pathologists can stay informed and engaged by:

- Reviewing the wealth of resources at cap.org/advocacy
- Subscribing to *STATLINE* (available to CAP members)

- Reviewing the Policy toolkit and issue briefs on cap.org/advocacy
- Registering for one or more of the issue specific webinars
- Attending the 2014 Policy Meeting (May 5-7 in Washington, DC)
- Participating in PathPAC
- Following social media @pathologists and [Facebook.com/capathologists](https://www.facebook.com/capathologists)

STATE AFFAIRS

On the state level, the CAP represents the interests of pathologists by actively working with state pathology societies. Over the last several years, the CAP has undertaken substantial legislative and regulatory advocacy in more than three dozen states, helping craft laws and regulations that help protect the profession against economic and practice challenges. Indeed, the CAP, partnering with state pathology societies, has been successful in advocating enactment of direct billing requirements in 14 states since 2003.

2013 State Affairs Accomplishments

Legislative

- Amended Washington State legislation and law upholding Attorney General Opinion on application of antikickback law, including EHR ban, to clinical laboratories. Negotiated legislative agreement with Washington State Hospital Association and Washington State Medical Association.
- Amended Indiana direct billing law to clarify applicability to technical component and hospital billings. It clarified that physicians who perform anatomic pathology services on a patient sample can bill a patient or payer a global bill that includes the cost of histologic processing (technical component), provided that they do not add a fee to the cost of the histologic processing. In addition, the legislation clarifies that the direct billing law does not regulate hospital billings for in-patients or out-patients of their facilities.
- Amended Pennsylvania legislation, enacted into law, to ensure application of fee-splitting and antikickback provisions to specimen referrals and out-of-state laboratories, including accreditation recognition.
- Introduced in three states (California, Illinois, and New Jersey) the CAP Model Accountable Care Organization (ACO) legislation to promote pathologists' role. If enacted, at least one physician clinical laboratory medical director serving the ACO would be required to participate in newly created clinical laboratory testing advisory boards and recommend protocols for appropriateness of pathology and laboratory testing. The advisory boards would aim to ensure that patients have access to all medically necessary testing.
- Enacted North Carolina law that defers to the CAP professional standards for release of pathologic materials.
- Repealed provision of law in New Jersey allowing Genetic Counselors to interpret genetic tests and also provided an explicit genetic counselor licensing exemption for physicians.

Regulatory

- Secured state opinions banning or limiting EHR donations by clinical laboratories in Tennessee and Massachusetts.
- Secured a formal administrative ruling in Connecticut that supports the CAP's position on EHR donations. The ruling is in response to a petition request submitted by the Connecticut Society of Pathologists (CSP) and supported by the CAP.
- Secured changes to Colorado Correct Coding initiative to ensure coding methodology conforms to state direct billing law for anatomic pathology services. Colorado officials stated that a "final rule will include a statement instructing that the professional component for AP and subcellular/molecular pathology can only be billed by the qualified healthcare professional who performs the interpretation."
- Secured California Department of Managed Health Care commitment to create, by March 2014, new regulatory methodology to determine appropriate access to pathology services in health plans under the Knox Keene Act.

PathPAC and PathNET

PathPAC, the CAP's political action committee, pools voluntary contributions of pathologists across the country to support candidates for elected office who demonstrate their responsiveness to the concerns of our profession. The Pathology Advocacy Network (PathNET), the College's

grassroots program for members, facilitates the building of personal relationships between pathologists and Congress.

The College's Advocacy office—by making the voices of members and the profession heard—continues to build new relationships and strengthen existing partnerships in the public and private sectors, on both the state and national level, with the key decision makers to shape the present and future of pathology.

CAP POLICY MEETING

The CAP's annual policy meeting and national lobby day in the spring has become a premier event for CAP members to actively participate in grassroots advocacy efforts and speak directly with top policymakers, including their Congressional representatives. The **2014 CAP Policy Meeting** will be held **May 5–7, 2014**, in **Washington, DC**.

SPECIALTY ADVANCEMENT

The CAP is committed to pathologists' success today and tomorrow. In response to the challenges and opportunities facing pathology, the CAP has designed a strategy to advance the specialty and to empower pathologists to take control of their professional and economic destinies, reshaping the role of pathology and laboratory services. The strategy has three elements:

1. Make pathologists known
2. Ensure pathologists can deliver
3. Enable pathology's sustainable advantage

The CAP continues to develop services and programs to advance the specialty. These offerings include, but are not limited to, new learning options, evidence-based guidelines, and practice tools. The offerings enable CAP members to enhance their skills, provide cutting-edge services to patients, partner more closely with other clinicians, and demonstrate their value to policymakers and health care system executives.

Promising Practice Pathways™ Report

The CAP commissioned G2 Intelligence to support a focused analysis of emerging pathology practice models. The focused analysis resulted into a report known as the "Promising Practice Pathways." The Pathways report describes new pathologist-driven services and programs that add clinical value outside the laboratory by improving

downstream clinical quality and outcomes and generating downstream clinical cost savings.

The four pathways are:

1. High-Performance Pathology for High-Value Oncology
2. High-Performance Diagnostic Services
3. Coordinated Population Care Services
4. Patient Diagnostic Services Centers

Pathologists may download the report at yourpathyourchoice.org.

New Paths ... New Choices: Pathology in an Era of Advancing Science and Disruptive Health Economics (ebook)

In 2013, the CAP published an ebook, *New Paths ... New Choices: Pathology in an Era of Advancing Science and Disruptive Health Economics*. The ebook illustrates how pathologists are responding to the scientific, economic, and technological changes facing health care today.

Through member case examples, testimonials, and video, the ebook offers an analysis of how pathologists can adapt to the changing value-based medical landscape and approaches pathologists can take to create value, including acquiring new skills, applying new technologies, partnering with other clinical specialists, offering face-to-face patient contact, and participating in ACOs. Pathologists and others may download a complimentary copy at yourpathyourchoice.org/ebook.

THE CAP PATHOLOGY & LABORATORY QUALITY CENTER (THE CENTER)

The Center is a forum for developing evidence-based guidelines and provisional practice guidance to standardize laboratory practice. The Center develops these tools from the CAP and also partners with other organizations. The Center published the following recommendations in 2013:

- Recommendations for HER2 Testing in Breast Cancer: ASCO/CAP Clinical Practice Guideline Update
- Validating Whole Slide Imaging for Diagnostic Purposes in Pathology
- Molecular Testing Guideline for Selection of Lung Cancer Patients for EGFR and ALK Tyrosine Kinase Inhibitors: Guideline from the CAP, the International Association for the Study of Lung Cancer, and AMP

Nine additional guidelines are currently in development, including Principles of Analytic Validation for IHC Assays scheduled to be released in Q1 2014. Pathologists can take the lead by integrating these guidelines into their practices.

MEMBERSHIP AND PRACTICE MANAGEMENT

The CAP serves more than 18,000 board-certified pathologist members. Recent offerings include:

Value-Based Business Center

In 2013, the CAP unveiled the Value-Based Business Center, the first business management solution designed to help pathology practices as health care transitions to a new value-based payment system. Easy-to-use guides, surveys, and workbooks are available to leverage internal data and market research to plan for and implement this shift. The toolkit is divided into three sections:

- 1) Gather Data
- 2) Make Decisions
- 3) Pursue Opportunities

Practices that adapt early will reap the greatest rewards. All of the toolkits in the Value-Based Business Center are available free of charge to all CAP members at cap.org/practice-management.

Engaged Leaders Academy

On December 7–9, 2013, the CAP brought 40 pathologists from around the country to Chicago for the Engaged Leadership Academy. The intensive two-and-a-half-day training program focused on enhancing the ability of pathologists to communicate their value to multiple audiences—clinicians, patients, hospital administrators, regulators, and legislators. The training was centered on how to become effective communicators and leaders in their communities and within their institutions and practices.

As the structure of health care delivery changes from fee-for-service to a value-based model, pathologists are going to need the skills to demonstrate and articulate their value in order to be active members and leaders in the decision-making process. The CAP will offer the program on December 6–8, 2014, in Chicago.

CAP FOUNDATION

As the philanthropic arm of the College, the CAP Foundation champions patient-centered and humanitarian roles for pathologists, striving to connect people, especially those in need, to the specialized, life-saving skills of pathologists.

The CAP Foundation's signature program, See, Test, & Treat[®], is the only pathologist-led program that offers free cervical and breast cancer screening to underserved women throughout the US.

Backed with a CAP Foundation grant, CAP members volunteer and lead multidisciplinary clinical teams in their community. Together these volunteers deliver culturally sensitive preventive care that connects patients in need to community clinics, hospitals, and other health care resources. In a single-day program, women receive a free pelvic and breast exam, a Pap test with same-day results, and a mammogram with same-day or timely results. Clinicians personally share test results and recommendations for follow-up with each patient.

See, Test & Treat serves vulnerable women known to encounter linguistic, social, cultural, and financial barriers to health care. Most are without health insurance, have little health education, lack access to routine disease screenings, have weak support systems, and do not have a medical home. See, Test & Treat helps women overcome these barriers by also offering additional services. Interpreters and multilingual patient education materials help overcome language barriers. Pathology residents offer education to explain how Pap tests and mammograms help detect cancer early, when it is most treatable. Additional materials educate participants on simple lifestyle habits they can adopt to help prevent disease.

In 2013, the CAP Foundation supported the volunteer efforts of 23 pathologists and 15 residents to deliver six See, Test & Treat Programs throughout the US. The Herbek Humanitarian Award was presented to Si Van Nguyen, MD, FCAP, in a special ceremony during the College's 2013 annual meeting. Furthermore, the CAP Foundation continues its commitment to provide notable grants and awards to residents to help advance the specialty of pathology and the delivery of next-generation care.

CAP OFFICIAL PUBLICATIONS

CAP TODAY, the College's monthly news magazine, enjoys 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 award-winning, 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 regulatory developments as they happen, serving as the first word on the public policy issues facing CAP members.

CAPconnect

CAPconnect is the College's members-only, online social network that serves as a source for connecting and sharing knowledge with peers. The community offers unique opportunities for discussion and collaboration on topics such as advocacy, clinical challenges, practice management issues, emerging technologies, and health care trends. By joining the discussion, members can stay informed on professional issues using real-time tools, including online groups, blogs, and discussion forums. In addition, CAPconnect provides members an opportunity to network and get feedback on difficult cases or professional challenges. The CAP encourages participants to share and contribute their point of view in this safe environment by joining at community.cap.org.

FUTURE MEETINGS—SAVE THE DATE

- CAP Policy Meeting: May 5–7, 2014, Fairmont Hotel, Washington, DC
- CAP '14 – THE Pathologists' Meeting™: September 7–10, 2014, Hyatt Regency, Chicago, Illinois
- CAP Engaged Leaders Academy: December 6–8, 2014, Omni Hotel, Chicago, Illinois