Welcome

Patrick Godbey, MD, FCAP
President

• Welcome
• Today’s webinar will focus on the CAP’s response to COVID-19.
CAP’s COVID-19 Updates

• COVID-19-Related Guidance and Updates on cap.org
• Online Education and Lecture Series Available to Members at No Cost in April
Advocacy Update on COVID-19

Jonathan L. Myles, MD, FCAP
Chair, Council on Government and Professional Affairs (CGPA)

CAP’s Advocacy Agenda for COVID-19

• CAP Secures Remote Work Waiver for Pathologists
• Congress Acts on Providing Coverage, Payment, and Assistance to Physicians and Hospitals
• Securing More Regulatory Relief for Pathologists
• State Emergency Actions
CAP Secures Remote Work Waiver for Pathologists

- An organized CAP Advocacy campaign persuaded the federal government to allow pathologists to work remotely on March 26.
- We supported a waiver from CLIA rules mandating pathologists to be onsite to review and diagnose their cases.
- CAP grassroots advocacy had encouraged all CAP members to message HHS and their elected officials to seek relief.
- In addition, the CAP directly lobbied members of Congress.
- CAP worked with Reps. Buddy Carter (R-GA) and Bobby Rush (D-IL) to gain 37 total signatures on a letter to HHS supporting our effort.
Congress Acts on Coverage, Payment, Assistance

• Families First Coronavirus Response Act:
  o Require public and private health plans to cover COVID-19 diagnostic testing.
  o $1 billion to pay for tests provided to patients without health insurance.

• Coronavirus Aid, Relief, and Economic Security (CARES) Act:
  o Clarified insurance plans should also cover tests that have yet to obtain an EUA from the FDA.
  o Insurers must pay a contracted rate or, if there is no contract, the cash price posted.
  o Temporarily lifts budget sequester, which reduces payments by 2%, on Medicare.
  o Add-on payment of 20% to Medicare’s hospital inpatient system for COVID-19 patients
  o Pauses scheduled Medicare cuts to clinical laboratory services in 2021.
  o Directs $130 billion to hospitals to cope with surge capacity.
  o Sets $300 billion to provide relief for small businesses.
Securing More Regulatory Relief

• Following the national emergency declaration on March 13, the CAP urged HHS and CMS to suspend mandatory CLIA inspections.
  o We applauded this action and remain engaged with the CMS to potentially extend the suspension.

• CMS pushed the deadline to submit 2019 MIPS data back 30 days to April 30.
  o Further, if pathologists are unable to submit their 2019 data by April 30, they will be held harmless and apply a neutral pay adjustment.
  o 1,000+ pathologists using the Pathologists Quality Registry have successfully submitted their data for 2019.
  o All Pathologist Quality Registry users are projected to have a positive pay adjustment!
State Emergency Actions

- 34 states have received Section 1135 federal waivers allowing program flexibility in the administration of Medicare, Medicaid, and CHIP.
- Most states have issued emergency declarations allowing for interstate physicians and other professionals to practice.
- FDA has empowered states to determine whether a laboratory-developed test for COVID-19 administered at a high-complexity lab would meet emergency use authorization (EUA) criteria.
  - States may authorize testing without prior FDA approval for the duration of the emergency.
Remote Sign-out for Pathologists

Eric F. Glassy, MD, FCAP
Chair, Information Technology Leadership Committee

- Overview of CMS Ruling on Remote Sign-out
- FAQs Available on CAP Website
- Sample of FAQ Questions
Overview of CMS Ruling on Remote Sign-out

• On March 26, 2020, CMS temporarily waived requirement for remote locations to have separate CLIA licenses provided that designated primary site or home base has a CLIA certificate.
• Remote sign out of pathology cases using digital pathology or glass slide review is now permitted.
• FAQs are available on the CAP website and will be updated as new questions come in.
• An FAQ webinar will be scheduled soon.

Find FAQs at https://www.cap.org/covid-19/remote-sign-out-faqs
FAQs Available on CAP Website

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Sample of FAQ Questions

• What is “remote sign-out”?  
• If I sign a case out from home, do I need to put my home address into the report?  
• Are there any HIPAA issues with remote sign-out?  
• Do I need an FDA-cleared scanner to sign-out cases remotely?  
• Will I have malpractice insurance if I report cases remotely by digital pathology?  
• What constitutes a primary diagnosis in digital pathology?  
• Can I sign out intraoperative consultations (frozen sections) remotely?  
• What basic elements should be present in remote sign-out standing operating procedures (SOP)?
Accreditation Update

Richard M. Scanlan, MD, FCAP
Chair, Council on Accreditation (COA)

• Laboratory Compliance
• Inspections
• Operational Communications/Correspondence
Accreditation Update: Laboratory Compliance

• New COVID-19 tests must either be:
  o Verified if using a validated EUA, or
  o Validated if using an LDT

• External quality control must be run no less frequently than the manufacturer’s instructions.

• Follow IQCP guidance for COVID-19 testing.

• Laboratories should add any new COVID-19 testing to their CAP Activity Menu.
Accreditation Update: Laboratory Compliance

See CAP website for updates on other COVID-19 topics:

- Test method performance specifications for EUAs
- Requirements for collection of COVID-19 specimens
- Necessary PPE for the collection and testing of COVID-19 specimens
- Best practices for grossing of COVID-19 specimens
- Remote sign-out for data and slide review
- Training and competency testing
- How to handle temporary discontinuation of testing
Accreditation Update: Inspections

Inspections Delayed
• Domestically, all inspections* suspended until April 10, 2020.
• Internationally, the CAP has postponed all scheduled and requested laboratory inspections until at least June 1, 2020.
• Impacted laboratories remain CAP accredited.
• Laboratories should continue use of proficiency testing (PT) and CAP checklist requirements.
• This will be evaluated on an ongoing basis and could potentially be extended depending on how the situation evolves.

* Except for “critical” inspections, eg, some complaint investigations or immediate jeopardy
Accreditation Update: Operational Communications/Correspondence

All CAP-accredited laboratories—
• “Guidance for COVID-19 Testing” emailed and posted on cap.org
• Correspondence regarding possible need to delay CAP inspections beyond anniversary dates

Inspection teams—
• We are rescheduling, reassigning, and communicating all we know.

For CAP-Accredited Laboratories

The College of American Pathologists is advocating for pathologists and laboratories in the wake of the outbreak of respiratory disease caused by a novel (new) coronavirus that was first detected in China. The virus has been named “SARS-CoV-2” and the disease it causes has been named “coronavirus disease 2019” (abbreviated “COVID-19”).

The CAP is providing the following guidance for CAP-Accredited Laboratories to ensure availability of reliable testing for rapid detection of the agent that causes COVID-19. Also, please review this from the FDA on March 16: Coronavirus
Scientific Affairs Update

Raouf E. Nakhleh, MD, FCAP
Chair, Council on Scientific Affairs (CSA)

Proficiency Testing (PT)
- Communication to Domestic and International Customers
- Shipments
- COVID-19 PT

Send PT and accreditation questions to accred@cap.org
Scientific Affairs Update: PT Communication

- Notifying all PT customers of routine updates on cap.org “COVID-19 Information” page and in eblasts
Scientific Affairs Update: PT shipments

Domestic Shipments
• To accommodate laboratories during the COVID-19 pandemic, the CAP is delaying some shipments and extending due dates when possible.
• Laboratories encouraged to perform testing as soon as possible.

International Shipments
• Similar to domestic laboratories, most PT shipments will be delayed due to challenges shipping into most countries.
Scientific Affairs Update: COVID-19 PT

COVID-19 PT

• In partnership with our scientific committees, next week we are piloting a material and anticipate having a PT product available shortly.
• We believe piloting is an important step before releasing broadly.
• The PT program would be domestic only—the CAP is unable to ship internationally, due to nature of material being shipped.
• CAP Marketing is making plans for the launch in anticipation of a successful pilot.
Thank you for joining us today

Questions and Answers