COLLEGE of AMERICAN PATHOLOGISTS

CAP Update on COVID-19

A Webinar for the CAP's House of Delegates

Patrick Godbey, MD, FCAP
CAP President

April 3, 2020

Welcome

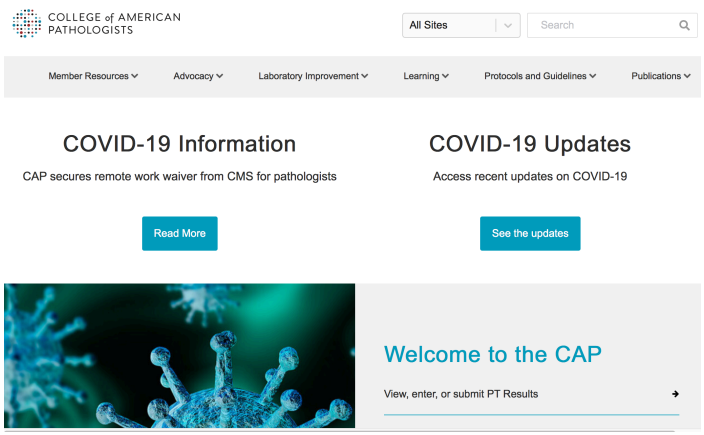
Patrick Godbey, MD, FCAP

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:**
  - Require public and private health plans to cover COVID-19 diagnostic testing.
  - $1 billion to pay for tests provided to patients without health insurance.
- **Coronavirus Aid, Relief, and Economic Security (CARES) Act:**
  - Clarified insurance plans should also cover tests that have yet to obtain an EUA from the FDA.
  - Insurers must pay a contracted rate or, if there is no contract, the cash price posted.
  - Temporarily lifts budget sequester, which reduces payments by 2%, on Medicare.
  - Add-on payment of 20% to Medicare's hospital inpatient system for COVID-19 patients
  - Pauses scheduled Medicare cuts to clinical laboratory services in 2021.
  - Directs $130 billion to hospitals to cope with surge capacity.
  - 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.**
  - **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.**
  - **Further, if pathologists are unable to submit their 2019 data by April 30, they will be held harmless and apply a neutral pay adjustment.**
  - **1,000+ pathologists using the Pathologists Quality Registry have successfully submitted their data for 2019.**
  - **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

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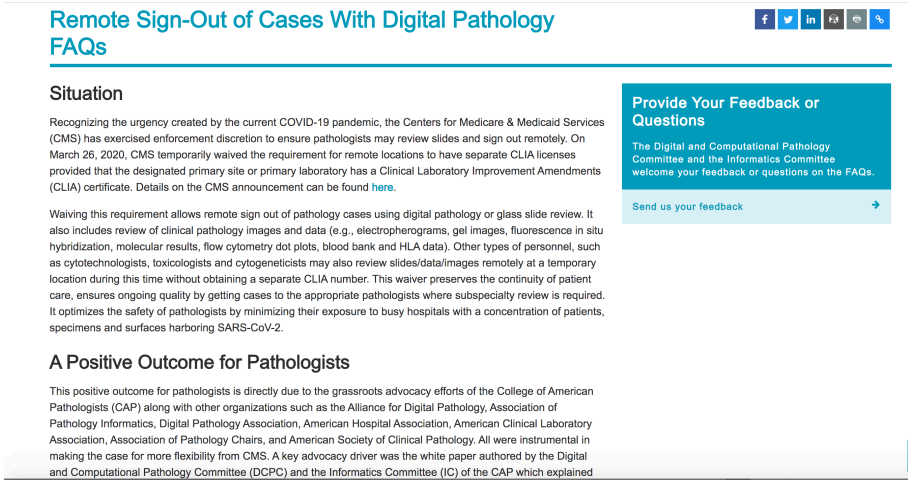


Remote Sign-Out of Cases With Digital Pathology FAQs

Situation

Recognizing the urgency created by the current COVID-19 pandemic, the Centers for Medicare & Medicaid Services (CMS) has exercised enforcement discretion to ensure pathologists may review slides and sign out remotely. On March 26, 2020, CMS temporarily waived the requirement for remote locations to have separate CLIA licenses provided that the designated primary site or primary laboratory has a Clinical Laboratory Improvement Amendments (CLIA) certificate. Details on the CMS announcement can be found here.

Waiving this requirement allows remote sign out of pathology cases using digital pathology or glass slide review. It also includes review of clinical pathology images and data (e.g., electropherograms, gel images, fluorescence in situ hybridization, molecular results, flow cytometry dot plots, blood bank and HLA data). Other types of personnel, such as cytotechnologists, toxicologists and cytogeneticists may also review slides/data/images remotely at a temporary location during this time without obtaining a separate CLIA number. This waiver preserves the continuity of patient care, ensures ongoing quality by getting cases to the appropriate pathologists where subspecialty review is required. It optimizes the safety of pathologists by minimizing their exposure to busy hospitals with a concentration of patients, specimens and surfaces harboring SARS-CoV-2.

A Positive Outcome for Pathologists

This positive outcome for pathologists is directly due to the grassroots advocacy efforts of the College of American Pathologists (CAP) along with other organizations such as the Alliance for Digital Pathology, Association of Pathology Informatics, Digital Pathology Association, American Hospital Association, American Clinical Laboratory Association, Association of Pathology Chairs, and American Society of Clinical Pathology. All were instrumental in making the case for more flexibility from CMS. A key advocacy driver was the white paper authored by the Digital and Computational Pathology Committee (DCPC) and the Informatics Committee (IC) of the CAP which explained

Provide Your Feedback or Questions

The Digital and Computational Pathology Committee and the Informatics Committee welcome your feedback or questions on the FAQs.

Send us your feedback

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:
  - Verified if using a validated EUA, or
  - 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)

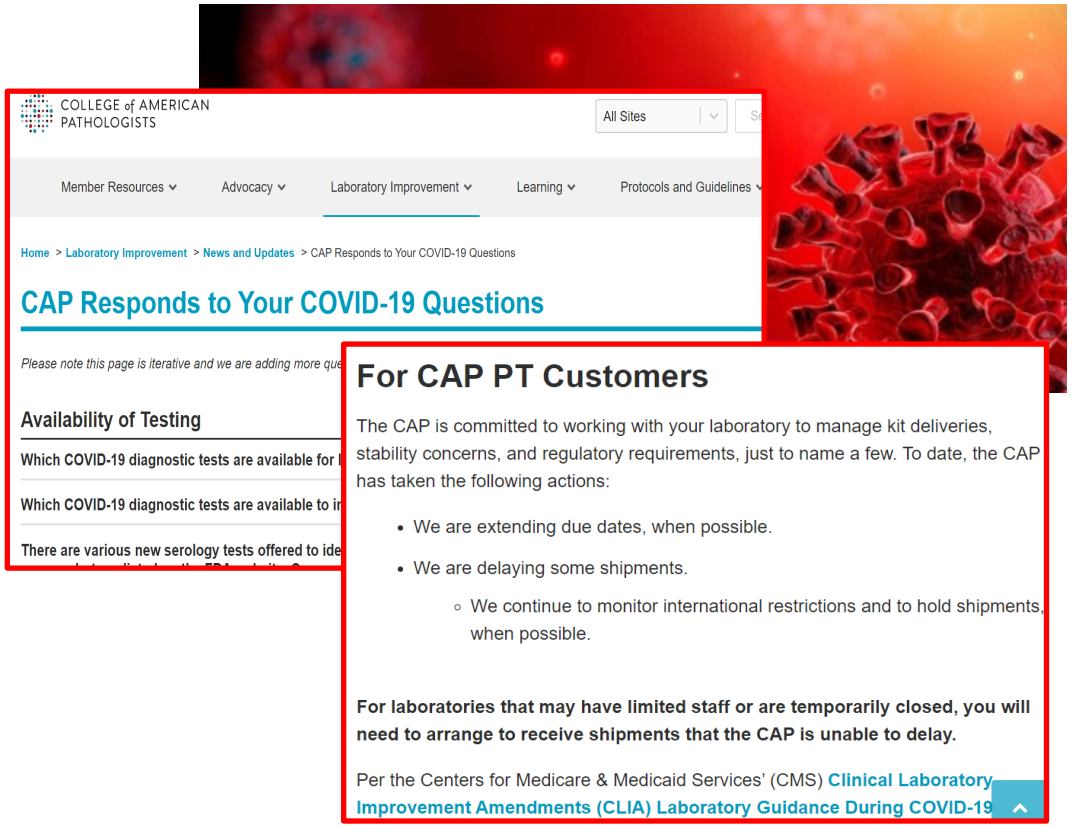
Proficiency Testing (PT)

- **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

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