



COLLEGE of AMERICAN  
PATHOLOGISTS

# CAP Update on COVID-19

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**A Webinar for Council/Committee Chairs, Vice  
Chairs, and Members**

Patrick Godbey, MD, FCAP  
CAP President

April 1, 2020

# Welcome

**Patrick Godbey, MD, FCAP**  
President

- **Welcome**
- **Today's webinar will focus on the CAP's response to COVID-19.**



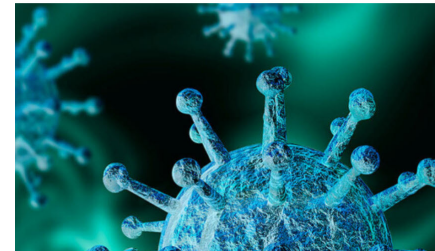
# CAP's COVID-19 Updates

- **COVID-19-Related Guidance and Updates on cap.org**
- **Councils and Committees to Hold Virtual Meetings**
- **Online Education Courses Available to Members at No Cost in April**

## Latest on Novel Coronavirus (COVID-19)

CAP Advocacy lobbies for remote work flexibility

[Read More](#)



## Welcome to the CAP

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# 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.
- **The 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 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**
- **FAQ Sample 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.
- An FAQ document will be available this week on the CAP website. Shortly after it will be converted to webpages and updated as new questions come in.
- An FAQ webinar will be scheduled soon.
- If you have any questions, email [digpath@cap.org](mailto:digpath@cap.org).

# FAQ Sample 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
- **Positive and negative controls must be run daily.**
- **No IQCP allowed for EUA tests at this time; awaiting guidance from CMS.**
- **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 pathologists
- Update on PT requirements for accredited laboratories
- 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 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 Exploration**



# Scientific Affairs Update: PT Communication

- Notifying all PT customers of routine updates on cap.org “Latest on Novel Coronavirus (COVID-19)” page and in eblasts



## For CAP PT Customers

For all CAP PT customers, domestic and international, due dates have been extended and some PT shipments have been delayed. For due date extensions, see [My PT Shipping Calendar](#) in e-LAB Solutions Suite. See the [current list of shipment delays](#) or the [Expected 2020 Shipping Dates](#) spreadsheet on the Catalog and Ordering Information page. We continue to monitor international restrictions and to hold shipments when possible.

# 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 Exploration

- We are working with our scientific committees to identify a PT product specifically for COVID-19.
- We are working to identify suppliers and determining logistics of how and when we could launch.
- The PT program would be domestic only—the CAP is unable to ship internationally, due to nature of material being shipped.

# Thank you for joining us today

## Questions and Comments



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