



COLLEGE of AMERICAN  
PATHOLOGISTS

# State Pathology Society (SPS) Presidents Webinar

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**CAP Response to COVID-19**

Patrick Godbey, MD, FCAP  
CAP President

March 26, 2020

# Welcome

**Patrick Godbey, MD, FCAP**

President

- **Today's webinar will focus on the CAP's response to COVID-19.**
- **We also want to learn what we can do to support our state societies during the COVID-19 crisis.**



# CAP's COVID-19 Updates

- COVID-19-Related Guidance and Updates on cap.org
- State Pathology Society Meeting Cancellations
- Pathologists Leadership Summit Cancellation

## Latest on Novel Coronavirus (COVID-19)

CAP Advocacy lobbies for remote work flexibility

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## Welcome to the CAP

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# State Pathology Society Meeting Cancellations

- April 3-4 Pennsylvania
- April 13 Illinois/Chicago
- April 18 Arizona
- April 18 Oklahoma
- April 24-25 North Carolina
- April 24-25 Wisconsin
- Apr 25 Indiana
- April 25 New York (Rescheduled for 10/24)
- May 2 Ohio
- May 2-3 Tri-State (LA, AL, MS)
- May 9 Michigan
- May 14 New Jersey

# Pathologists Leadership Summit Cancellation

- **Spring House of Delegates and Pathologists Leadership Summit canceled**
- **Cancellation details: [PathologistsLeadershipSummit.org](https://PathologistsLeadershipSummit.org)**
- **Exploring possible options to offer some sessions virtually to all CAP members**
- **Save the Date—2021 Pathologists Leadership Summit,  
May 1-4, 2021, Washington Grand Hyatt**

# 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**

- **Urging CMS to Fix Remote Work Rules**
- **Securing Temporary Suspension of Inspections**
- **Securing Fair Coverage and Funding for COVID-19 Tests**
- **New Economic Stimulus Package on COVID-19**
- **Obtaining MIPS Regulatory Relief for Pathologists**
- **Opposing New Legislation on Laboratory-Developed Tests (LDTs)**
- **State Emergency Actions**



# Urging CMS to Fix Remote Work Rules

- **CAP has urged the CMS to allow pathologists and laboratory personnel to work remotely during the pandemic.**
- **We support a waiver from CLIA rules mandating pathologists to be onsite to review and diagnose their cases.**
- **CAP grassroots advocacy has encouraged all CAP members to message HHS and their elected officials to seek relief.**
- **In addition, the CAP is directly lobbying members of Congress to pressure CMS to make this rule change.**

# CAP “Ask” to CMS on Remote Read-Out

- Temporary suspension of CLIA restrictions.
- Remote sign-out for pathology would include the following:
  - Reviewing glass slides at home with a microscope.
  - Reviewing whole slide images using validated digital platforms.
  - Interpretation of electrophoretic gels, flow cytometry, molecular diagnostics, and related activities using secure remote access to laboratory systems.
  - Reviewing clinical data radiologic images, immunohistochemistry, molecular diagnostics, cancer cytogenetics, etc.
  - Review and signing of laboratory operational documents and procedures using email in lieu of physical signatures.
- **Just yesterday, in response to CAP advocacy, 37 members of the House collectively wrote to Secretary Azar and urged him to grant the CAP’s request.**



# Securing Temporary Suspension of Inspections

- **Following the national emergency declaration on March 13, the CAP urged HHS and CMS to suspend mandatory CLIA inspections.**
- **Beginning March 17, the CMS agreed to suspend routine inspections for three weeks.**
- **We applauded this action and remain engaged with the CMS to potentially extend the suspension.**

# Securing Fair Coverage and Funding for Tests

- **President Trump signed the Families First Coronavirus Response Act into law on March 19.**
- **Key provisions in the bill supported by the CAP:**
  - Require public and private health plans to cover COVID-19 diagnostic testing.
  - \$1 billion to pay for tests provided to patients without health insurance.
- **However, the new law leaves out coverage for tests that have yet to receive FDA emergency use authorization.**
- **Language supported by the CAP in a new legislative package will resolve this issue and mandate coverage for all COVID-19 tests.**

# New Economic Stimulus Package on COVID-19

## ~\$2 Trillion Stimulus Package

- Clarifies coverage requirements for tests in compliance with FDA
- Sets private pay for COVID-19 test at negotiated rate or publicly posted price
- \$130 billion for hospitals for surge capacity
- Pauses 2021 Medicare cuts to clinical laboratory services under PAMA
- Addresses shortages of essential medical devices, including those for tests
- Further boosts funding for COVID-19 response, including diagnostics:
  - \$2 billion to the CDC for surveillance, testing, and local level prevention
  - \$800 million to the NIH to expand research for vaccines and diagnostics
  - More than \$3 billion for the Biomedical Advanced Research and Development Authority

# Obtaining MIPS Regulatory Relief for Pathologists

- **The CAP urged the CMS to give pathologists additional flexibility by extending its data submission deadline for MIPS.**
- **The CMS agreed and 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 payment adjustment.**

# Opposing New Legislation on LDTs

- **The Verified Innovative Testing in American Laboratories Act of 2020 was introduced by Sen. Rand Paul on March 18.**
- **The legislation would redefine laboratory-developed tests at a time when we're focused on streamlining processes to ensure access to COVID-19 tests.**
- **The CAP opposes the bill and issued a statement against it.**

# State Emergency Actions

- **13 states have received Section 1135 federal waivers allowing program flexibility in the administration of Medicare, Medicaid, and CHIP.**
  - Those states are Alabama, Arizona, California, Florida, Illinois, Louisiana, Mississippi, New Hampshire, New Jersey, New Mexico, North Carolina, Virginia, and Washington.
- **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.

# Accreditation Update

**Richard M. Scanlan, MD, FCAP**

Chair, Council on Accreditation (COA)

- **Laboratory Compliance**
- **Domestic CAP 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.**
- **Laboratories must continue PT and other CAP checklist requirements.**
- **Laboratories should add any new COVID-19 testing to their CAP Activity Menu.**



# Accreditation Update: Domestic Inspections

## Domestic CAP Inspections Delayed

- All inspections\* suspended for at least the next three weeks, effective March 17, 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**

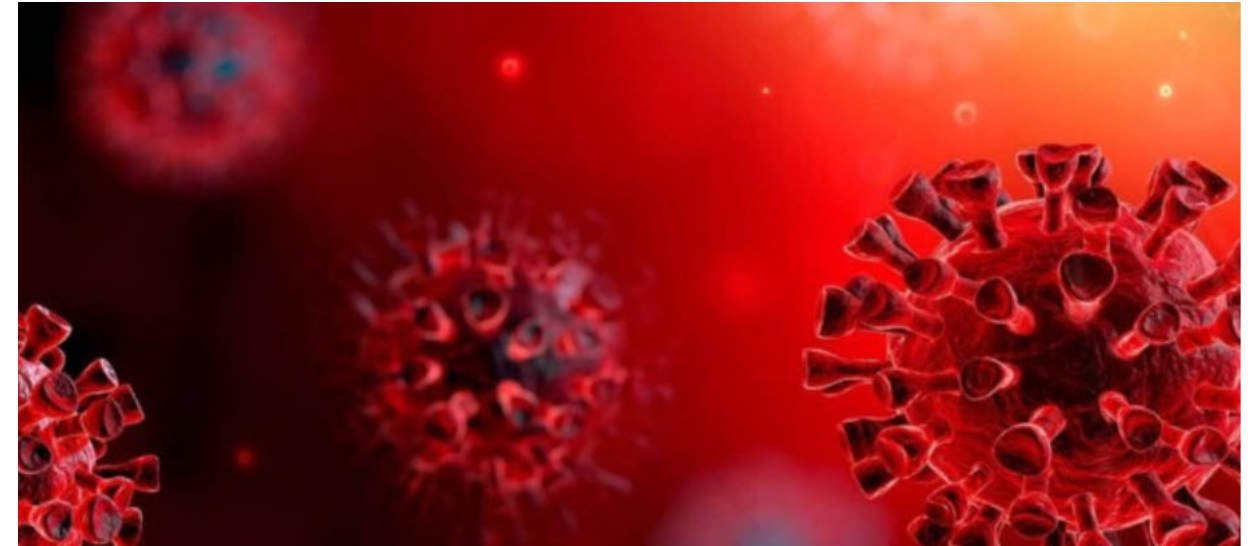
Chair, Council on Scientific Affairs (CSA)

- **Proficiency Testing (PT)**
  - Domestic
  - COVID-19 PT Exploration
- **COVID-19 Media Efforts**



# Scientific Affairs Update: PT Updates

- Notified all PT customers of routine updates on cap.org: “Latest on Novel Coronavirus (COVID-19)”



## For CAP PT Customers

In the US, there are no changes, other than due date extensions, planned for PT shipments. Internationally, we have suspended all PT shipments for a minimum of two weeks, effective March 19, 2020, and extended due dates. We will contact domestic and international PT customers with any updates. For due date extensions, see [My PT Shipping Calendar](#) in e-LAB Solutions Suite.

# Scientific Affairs Update: Domestic PT

## Domestic Shipments

- To accommodate laboratories during the COVID-19 pandemic, the CAP is extending due dates when possible.
- Laboratories encouraged to perform testing as soon as possible.

# Scientific Affairs Update: PT

## COVID-19 PT Exploration

- We are in the early stages of looking to provide PT 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—CAP unable to ship internationally, due to nature of material being shipped.

# Scientific Affairs Update: COVID-19 Media Efforts

- Shared effort with CAP officers, COA, and CGPA
- Members quoted in various media outlets

# Thank you for joining us today

## Questions, Comments, and Discussion