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Update from CAP State Society Presidents Meeting

Hello VSP Members,

As the COVID-19 Pandemic continues, the VSP Board of Directors will make all attempts to keep our members informed on any developments on national and statewide responses by the College of American Pathologists (CAP) and the Virginia Society for Pathology (VSP). Recently, I participated on a teleconference organized by CAP and wanted to provide a summary of key takeaways from that conversation to you as a member of the VSP.

2020 CAP Leadership Summit

The CAP has decided to reschedule its 2020 Leadership Summit and the associated House of Delegates Meeting to May 1 - 4, 2021 due to the COVID-19 pandemic. Some content from this may be provided virtually, however that remains to be decided. Unfortunately many other state pathology societies have had to cancel their meetings due to the pandemic, though the VSP Annual Meeting does not take place until the late fall we will continue to monitor the situation over the coming months.

CAP Requests Temporary Restriction of CLIA Restriction on Remote Sign Out

CAP had requested a temporary restriction of the CLIA restriction on remote sign out, which includes the following:

- Reviewing glass slides at home with a microscope.
- Reviewing whole slide images using a validated digital platform.
- Interpretation of electrophoretic gels, flow cytometry, molecular diagnostics.
- Reviewing clinical data, radiologic images, IHC, molecular diagnostics, cancer cytogenetics, etc.
- Review and signing of laboratory operational documents and procedures using email in lieu of physical signatures.

This request is supported by 37 members of the House of Representatives, and they have sent a collective letter to Secretary of Health and Human Services Alex Azar.

CAP Efforts to Secure Fair Coverage and Funding for Tests

The Families First Coronavirus Response Act was signed on March 19th. It contained several key provisions supported by CAP including:

- Requiring private and public health plans to cover COVID-19 diagnostic testing.
- \$1 billion to pay for tests provided to patients without health insurance.

The new law leaves out coverage for tests that have not yet received FDA approval. CAP supports a new legislative package that will resolve this issue and mandate coverage for all COVID-19 tests.



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Relevant Details from the New Economic Stimulus Package

There are several items from the new economic stimulus package that are relevant to pathologists, including:

- Clarifies coverage requirements for tests in compliance with FDA.
- Sets private pay for COVID-19 test at a 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 testing.
- 20% increase in DRG for inpatient hospitalizations related to COVID-19.
- Small business relief is in discussion.
- Boosts funding for COVID-19 response including;
 - \$2 billion to the CDC.
 - \$800 million to the NIH.
 - More than \$3 billion to the Biomedical Advanced Research and Development Authority.

MIPS Regulatory Relief

The deadline to submit MIPS data has been pushed back 30 days to April 30. If pathologists are unable to submit their 2019 data by April 30, they will be held harmless and apply a neutral payment adjustment.

CAP Opposing new legislation on LDTs

The Verified Innovative Testing in American Laboratories Act of 2020 was introduced by Sen. Rand Paul on March 18th. This legislation would redefine LDTs at a time when we are focused on streamlining processes to ensure access to COVID-19 tests. The CAP opposes this bill and has 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. Most states have issued emergency declarations allowing for interstate physicians and other professionals to practice. The FDA has empowered states to determine whether a LDT 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

New COVID-19 tests must either be verified if using a validated EUA or validated if using an LDT. Positive and negative controls run daily. No IQCP is required at this time. You must continue PT and other CAP checklist requirements. The Lab activity menu has been updated to include COVID-19.



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Domestic inspections

All inspections (except for critical inspections including complaint investigations and immediate jeopardy) are suspended for the next 3 weeks, effective March 17, 2020. Impacted labs remain CAP accredited. There is potential for delay past inspection date for some labs. Extended due dates for PT is secondary to delayed shipping of PT materials. CAP is exploring COVID-19 PT. Shipments will be domestic only (no international shipping of COVID PT samples).

Additional Information

There is no official position from CAP on Autopsy practices, this is being left to local decisions for now. Several state society Presidents urged CAP to expedite a formal position statement. Regarding Medical Director furloughs, hospitals must maintain a LMD to maintain accreditation. Guidance is forthcoming from CAP on digital pathology at home on a non-FDA approved device.

As the COVID-19 pandemic continues, the VSP will strive to keep our members up to date on recent developments. We appreciate all the work our members are doing for our communities at this time and are proud to serve as your state pathology society.

Warm Regards,

Marigny B. Roberts, MD
President
Virginia Society for Pathology