# CAP Review and Forecast: Advocacy 2024/2025

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**Robert Johnson:**

Medicare payment, the FDA rule on LDTs, and working with a new White House and Congress. These are the issues leading the advocacy agenda at the College of American Pathologists. This is your CAP Review and Forecast focused on advocacy in 2024 and 2025.

Thank you for joining us for this special conversation about CP advocacy, accomplishments and priorities with Dr. Joe Saad, chair of the CAP's Council on Government and Professional Affairs. Dr. Saad, we appreciate you making time to talk with us today about CAP advocacy. Let's get right into it with a topic important to everyone listening and that would be Medicare payment. The CAP lobbied throughout the year to stop Medicare payment cuts to pathologists in the new year, but they were finalized by CMS in November. What's the latest?

**Dr. Joe Saad:**

As you mentioned, Robert, the 2025 Medicare Final Physician's fee schedule was released on November 1st, 2024, and it will result in a 2.83% decrease in payment to physicians beginning on January 1st, 2025. This is the result of CMS implementing the evaluation management code, the G2211 and the expiration of congressional relief from the Consolidated Appropriation Act of 2023 and additional relief that was passed earlier this year of 1.68%. For pathology, we can expect a 2.5% cut a little bit less than other physicians, and this is a result of CAP advocacy that actually increased the clinical labor rate for cytotechnologists and histotechnologists and adds back an additional $12 million for pathologists and pathology annually. Congress just passed and President Biden signed the American Relief Act or HR 10545. This is a continuing resolution that will keep government funded through March the 14th of 2025. Although it does extend several health care provisions including telehealth for Medicare flexibilities, it excludes a patch that had been previously agreed upon to mitigate the cut by 2.5% to Medicare and it removed an extension of a bonus payment to the advanced alternative payment model set for another year.

The CAP is actually extremely disappointed with Congress's failure to address declining reimbursement for Medicare. This is the fifth consecutive year of cuts. Actually, Medicare rates have fallen by about 33% over the past two decades when adjusted for inflation. This hurts pathologists, it hurts physicians, it hurts patients. The CAP is committed to working to reverse this trend and the cuts as soon as possible and we'll work with the AMA and other physician organizations. This past year in 2024, it took Congress until March to enact the pay fix for the year. We'll work tirelessly until March 14th, 2025 to enact relief and make it retroactive if possible. We'll also redouble our efforts to permanently fix the declining reimbursement by urging Congress to pass legislation, which will apply an annual inflationary update to the Medicare fee schedule and fix budget neutrality and the Medicare fee schedule. We have our work cut out for us and we'll rise to the challenge with the support of the CAP and our members.

**Robert Johnson:**

Another issue that's taken a lot of time and effort is the FDA rule regarding laboratory-developed tests or LDTs. It's causing, as we might've guessed, a lot of concern among members of the college. What can you tell us about work being done to stop the rule?

**Dr. Joe Saad:**

So CAP has been working tirelessly to prevent the final rule from growing into effect when their proposed rule was circulated a little over a year ago, CAP opposed a proposed rule and in March our president, Dr. Karcher, testified during a House Health subcommittee meeting and he reiterated the CAP's opposition to the LDT regulation in the proposed rule. We also met with the Office of Management and budget of the White House and urge them not to finalize the rule. However, the rule was finalized with a few CAP suggested modifications, but the rule was finalized in May of this year, 2024. The CAP remains opposed to the final rule and we are doing everything we can to block it from being implemented. The CAP is working on multiple fronts. We're working with Congress, we're working with the new administration and we're working through the courts to block implementation of the rule.

In July, Dr. Karcher and I held a briefing on Capitol Hill and encourage legislators to take up legislation for LDT Oversight. CAP members and staff have had numerous meetings with members of Congress over the past year. Our grassroots messages have hit thousands with many CAP members participating for the very first time in the courts. We have filed an amicus brief in support of the lawsuit against the FDA by the American Clinical Laboratory Association and the Association for Molecular Pathology. We are urging the court to vacate the final rule. It is arbitrary and capricious. It will hurt patients, it will hurt access to timely and important tests and it will stifle innovation. We are doing everything we can to ensure that this final rule is vacated and does not take effect

**Robert Johnson:**

And we're hoping to see a resolution in 2025, correct?

**Dr. Joe Saad:**

That is correct. There's an anticipation that the court could rule as early as February and we're hopeful that it will because stage one of the final rule goes into effect on May 6th, 2025. Now there's a chance it could take a little bit longer and it could be midyear before we get a court ruling, so in the meantime we're not resting. We continue to work all angles including Congress and the new administration to either implement legislation or otherwise block this final rule.

**Robert Johnson:**

As we all know, voters in November elected a new president and Congress. They get to work in January. How will the College engage with the new federal leadership in 2025?

**Dr. Joe Saad:**

We have been actively engaged with the new Trump administration and the next Congress. The CAP has outlined our priorities such as calling on the Trump Administration to rescind the LDT final regulation. Now this will have to be done through a notice of proposed rulemaking with a comment period and then a new final rule. However, short of that, the administration could potentially ask the FDA to not enforce the final rule or otherwise delay its implementation. At the same time, we continue to work with Congress to enact legislation for appropriate LDT oversight, which would first and foremost ensure patient safety. That's our main concern, but also allow for innovation and allow patients to have access to these very important tests. We plan a strategy for the first 100 days of the new Trump administration. This includes advocating for fair reimbursement for medicine, including pathology and laboratory services for strengthening the physician workforce, including the workforce and pathology for increased competition and enforcement around health care regulation. The health care industry has become highly consolidated and that is hindering patient's ability to get affordable care and we continue to work for protections on the surprise billing legislation that was passed in No Surprises Act a couple of years ago and price transparency and we are advocating for appropriate regulation of artificial intelligence. Those are just the few of our priorities that we're working on with the new administration.

**Robert Johnson:**

You also helped lead the development and release of a report about insurance companies and the way they interfere with pathology and laboratory services. Can you explain some of the policy solutions the CAP supports to address this problem?

**Dr. Joe Saad:**

As I mentioned, the insurance industry has become highly consolidated and they have an enormous amount of power to do essentially whatever they want. The No Surprises Act has further emboldened them, and they have essentially challenged physicians including pathologists to go out of network because they believe they have the upper hand if this happens and they can pay whatever they want. They know they have deeper pockets than we do, and they know they can outlast us, so they challenge us to go to arbitration if we so desire to. What we need is for there to be adequate networks of hospital-based physicians, and this is a state by state issue. Network adequacy insurance is regulated at a state by state level, and so we need to go state by state and we have been successful in several states. We need them to restrict in network steering and tiering.

If you're in-network, you should be allowed to participate in the care of that patient within your health system. Currently, much of it is being referred to labs that are far away. This fragments care. There's no coordination and care and it's not good ultimately for patient outcomes. We support high quality care and lower costs by keeping physicians as the leader in the health care system, including the physician as a laboratory medical director and head of the laboratory medical team. The departments of insurance need to include regular monitoring and meaningful enforcement of insurance regulations and not allow these insurance companies to get away with what they be getting away with, with network steering and tiering. We also need increased antitrust scrutiny. We need to reverse this trend of consolidation and health care, both horizontal consolidation and vertical consolidation. This is bad for competition. Ultimately, it's bad for patients and bad for everyone in the health care system.

**Robert Johnson:**

Thinking about states, we are very active with state pathology societies. What successes have we achieved working with these groups and what can we expect in the year ahead?

**Dr. Joe Saad:**

Many of the battles are federal battles, but as I mentioned and as you mentioned, there are a lot of state issues that are equally important to what's happening at the federal level, and one of 'em is a regulation of the insurance industry. The health insurance industry that's regulated as state level network adequacy has been a big thing, especially since the passage of the No Surprises Act. This past year in 2024, we worked with the Illinois Society of Pathologists to enact the Network Adequacy Law. We also worked with the Michigan Society of Pathologists to reinstate a network adequacy law standard with the state's insurance department. There were several other accomplishments in states such as in Tennessee, where we worked with the Tennessee Society of Pathologists to amend an information blocking legislation that better reflects the CAP's position in California. We worked with the California Society of Pathologists to enable pathologists in California to utilize the same waiver for remote signout under CLIA as other states do.

California had restricted the ability of their California pathologists to do this. We were successful there. Having said that, it is critically important for us to work with all the states and all the members of CAP and state pathology societies because you are the eyes and ears on the ground and you are our first warning of anything that's happening there that could affect pathology and effect medicine. So if you hear of anything, please bring it to the attention of our advocacy group in Washington DC and we'll follow up on it. Our best asset is our grassroots and our network of pathologists that go state to state.

**Robert Johnson:**

That's a great call to action in what promises to be yet another busy year on the advocacy front.

**Dr. Joe Saad:**

Undoubtedly, we are here. We are ready. We need your help, but we look forward to tackling these challenges together.

**Robert Johnson:**

Dr. Joe Saad, chair of the CAP Council on Government and Professional Affairs, thank you for the update and happy holidays.

**Dr. Joe Saad:**

You're very welcome. Thank you very much and happy holidays to you and all the listeners.

**Robert Johnson:**

You can read more in the episode notes. That's where you'll find links to many of the documents mentioned today. This has been your CAP Review and Forecast focused on advocacy in 2024 and 2025. In January, we'll visit with other CAP Council Chairs about their work and what's ahead for the College of American Pathologists. This is Robert Johnson. Have a great day.