# January 2023 Advocacy Recap

February 5, 2023

**Alec Bose:**

Hello and welcome to the CAP Advocacy Recap, a monthly podcast dedicated to catching you up on the top news for pathologists. I'm Alec Bose here with your January 2023 recap. This month we'll cover the updates from the FDA in regards to breakpoint, as well as some of the latest COVID news. Later we'll sit down with Dr. Joe Saad to discuss federal policy changes pathologists need to know about in 2023. The CAP and three other infectious disease organizations asked the FDA to update the antimicrobial susceptibility interpretive criteria called breakpoints. They have expressed concern that the updated breakpoints aren't being recognized by the FDA promptly putting patients at risk and compromising diagnosis and treatment of infections. In a letter, the coalition of organizations outlined how more than 2.8 million antibiotic resistant infections occur in the United States each year and more than 35,000 people die, as a result. They note it's critical to determine how to speed updating breakpoints, in cooperation with the FDA. In the absence of an FDA recognized breakpoint, laboratories are forced to either apply off-label testing or use grandfather tests, which in many cases are obsolete.

The 21st Century Cures Act allowed the FDA to codify the recognition of breakpoints from the Recognized Standards Development Organization. However, since its enactment, the Center for Drug Evaluation and Research has been slow to accept current updated breakpoints, which puts patients at high risk and increases the likelihood of disease transmission and proliferation of antibiotic resistant infections. A meeting with the FDA has been requested to discuss this critical matter further. We will keep you updated as the situation progresses. We turn now to COVID News. After the HHS extended the COVID-19 Public Health Emergency through April, President Biden announced that the Public Health Emergency declaration will end on May 11th. By extending the emergency states and Medicaid services will continue with affiliated waivers for various sectors of the US healthcare system. For more information on what the end of the COVID Public Health Emergency entails, please visit our website.

In related COVID news, the FDA recently announced that the COVID-19 Emergency Use Authorization or EUA policies would remain in effect after the COVID-19 Public Health Emergency declaration ends in May. The director of the FDA Office of In Vitro Diagnostics and Radiological Health, Timothy Stencil announced that the FDA has an independent authority to end EUAs under the Public Health Emergency. And we end the day with Federal news you need to know. There were three very important policy changes that happened at the end of last year that all pathologists should know about. We spoke to the vice chair of the CAP's Council on Government and Professional Affairs, Dr. Joe Saad to better understand what these changes were and how they could impact you.

Okay, Dr. Saad, thank you so much for joining us today. We really appreciate you being here with us.

**Dr. Joe Saad:**

A pleasure. Glad to be with you.

**Alec Bose:**

So Dr. Saad, tell us a bit about the new digital pathology codes and how the CAP was involved in getting them implemented.

**Dr. Joe Saad:**

This is really very exciting news. For 2023, we do have 13 brand new digital pathology codes, which are very important for securing our future in the digital pathology realm. Just very briefly, the good news first, as of January 1st, these 13 new codes go into effect. They're Category III codes, but they're still very important that we use them. So if you're doing digital pathology for primary diagnosis, it's important that you use these codes going forward throughout the year. These are tracking codes which we need to demonstrate widespread use. Once we have demonstrated that, we can go back and get them transitioned to Category I codes and they'll be valued and then put on the physician fee schedule. So the backstory... now for the backstory of how we got here. This is the result of hard work by the Economic Affairs Committee of the CAP.

In particular, the CPT RUC Subcommittee of [inaudible 00:05:00] worked for many, many months to prepare to submit these codes to the AMA CPT Editorial Board for approval. Once they were submitted, our representatives on the Editorial Board had to do a lot of work to convince our colleagues in order to put them on the schedule to be published in July of last year to take effective this year. It was a result of advocacy and hard work by CAP members and CAP staff, and it's no small feat to get these through and to take them to the entire house of medicine through the AMA, which owns CPT to get them published in the CPT book.

So a lot of hard work, many, many months of preparation, and now we're here, 2023, we need to use these codes. Once we start using them and as I said, demonstrate widespread use, we can try to migrate them to Category I codes and those will be valued by the AMA RUC committee and then hopefully put on a physician fee schedule for payment. But we're not there yet. We still have a year or two or maybe three years to demonstrate the use of these codes, but we're on the right path.

**Alec Bose:**

Great, and I agree Dr. Saad, that is very exciting and I'm sure there will be more to say about these codes in the future. Moving right on to Medicare cuts, can you talk a little bit about how the CAP helped mitigate Medicare cuts for this year?

**Dr. Joe Saad:**

Sure. Yeah. So we need to go back a year. In 2022, we were facing 7.6% cut to the Physician Fee Schedule for our codes, and 4% of that was due to PAYGO or pay as you go. This was the result of the American Rescue Plan in which there was no appropriations for the funds to pay for it, and so there was a 4% across the board cut that was to be implemented, and that's across all of medicine, includes hospitals, includes physicians, includes nursing homes, et cetera. A 4% cut was to be implemented in 2023, so we're successful in mitigating that 4% cut for 2023 and 2024. So we have a two-year reprieve on the 4% cut. In addition, pathology was facing an additional 3.6% cut to our fees because of the revaluation of the E and M codes, the Evaluation and Management codes, which are used primarily by primary care docs when they see patients in their offices and bill these codes. Pathology and other specialists tend not to bill these codes, although there are very small instances in which we could potentially bill them, in general, we don't bill them.

And so as a result of the revaluation, remember Medicare is one pie, and so if one group of physicians gets more, another group of physicians gets less. So medicine overall was facing... The specialists overall, were facing a 4.6% cut. In pathology specifically, we were facing a 3.6% cut and our cut was less because of advocacy done by the CAP, again, the Economic Affairs Committee, the Council of Government Professional Affairs, to get our codes revalued as far as the technical component for histology, histopathology, histotechs, they were undervalued and we had them revalued, so we did better than the rest of medicine facing only 3.6% versus their 4.6% cut. Well, what happened was at the end of 2023, the Consolidated Appropriations Act of 2023 was passed and Congress mitigated the cuts by 2.5% for 2023 and 1.25% for 2024.

As a result of this mitigation, pathology is now facing a 1.1, 1.2% cut instead of the 3.6% cut. So good news, overall, we did much better than would've been expected had it not been for the advocacy of the CAP for other physicians, for the AMA as a result of our Hill Day ask, as a result of a fly-in in October, virtual fly-in in October, and as a result of our members responding to the STAT alerts to contact Congress to avert these cuts. We still, as I said, face an additional 1.25% cut in 2024 that was part of the bill that was passed. They mitigated it by 2.5% for this year, but we still face an additional 1.25% cut in 2024, and we will work to continue to avert that cut. In addition, I need to add that we're facing a potential cut of 3% based on G codes. These are government codes, not CPT codes, government codes that are to go into effect in 2024.

CMS decided they wanted to give an additional increase in fees to primary care, and so they created these new codes. For the past three years, Congress has basically because of COVID and other circumstances, our advocacy, others' advocacy, et cetera, put these codes on a moratorium, but the moratorium expires in 2024, so we're potentially facing a 3% cut as a result of that. Now, we do not object to our colleagues in primary care getting a 3% increase, but we do object to it coming out of the rest of us. We think that Congress should actually put more money in and not make the rest of us pay for the additional 3% that primary care is going to get.

**Alec Bose:**

Well, it sounds like the CAP'S done a lot of work, but it does sound like there's still a lot of work left to do right?

**Dr. Joe Saad:**

Absolutely. It never ends. Advocacy never ends.

**Alec Bose:**

I agree. And so the last thing or the last Federal change I think our listeners should know about is the latest action from the CMS on Good Faith Estimate requirements. What was this latest action and what does it mean to patients and pathologists?

**Dr. Joe Saad:**

So in order to understand the Good Faith Estimate, we need to go back to the No Surprises Act. This was passed and went into effect in January of 2022. As part of the No Surprises Act, there were two main components that affect pathology. The first one was an independent dispute resolution, which has been discussed before and could be a topic for another discussion. That's the subject of litigation. Several lawsuits have been filed, it's in total disarray right now. There's a backlog, the rules around batching have been all messed up, et cetera. The second part of that that affects pathology and a lot of medicine in general, is the Good Faith Estimate. There's a requirement in the No Surprises Act that if a patient is uninsured or self-paying, that the convening facility or physician provide an estimate of the charges that the patient can expect to pay out of pocket.

And so the effects for the convening provider and convening facility went into effect on January 1st, 2022. There's also a requirement that the co-providers provide estimates of their charges, and a co-provider would include pathology. If a patient's going to have a procedure in a hospital in which pathology is expected to be performed, a Co-provider would include pathology. This also went into effect, however, the agency decided to exercise enforcement discretion for a year until January 1st, 2023 while they figured out how to implement this. Now, pathology has a particular problem with this because we do not know upfront what our charges are going to be. We have no idea if a specimen is going to be submitted, and if it is, what kind of specimen? Is it going to be one, is it going to be multiple and what kind of workup we need to do until we actually look at it.

So providing an estimate upfront is particularly problematic to pathology. We made this argument with CMS on multiple occasions, through conversations and through letters, and they essentially said, "We hear you, we understand your problem, but we're sorry, you just have to do the best that you can". And so throughout the year, they heard comments from our organization and from other organizations. As a last minute action, they decided that they were going to delay enforcement until further notice because there were so many questions and so much confusion about how to implement this. So, instead of going to effect on January 1st, 2023, the agency is continuing to exercise enforcement discretion until further notice. They said they will give us plenty of warning when they decide to start implementing the rule, but for now, we have a reprieve and we will continue to make our arguments and express our concerns over pathology, specifically, having to give a good faith estimate when we have no real good idea upfront what specimens we're going to get and what workup we need to do.

**Alec Bose:**

Well, I think that's a fantastic note to leave on. Dr. Saad, thank you so much again for being with us. We really appreciate your time.

**Dr. Joe Saad:**

Thank you very much. It's been my pleasure.

**Alec Bose:**

That's all for this edition of the Advocacy Recap. Thank you so much for listening. For more information on any of the stories you heard today, be sure to subscribe to our weekly advocacy newsletter and follow us on Twitter at CAP Advocacy. Once again for CAP Advocacy Communications, I'm Alec Bose, and we'll see you next month.