Healthcare Regulatory Roundup #86 Webinar Transcript

The American Relief Act, 2025

Presented January 15, 2025

https://www.pyapc.com/insights/webinar-hcrr-86-the-american-relief-act-2025/

Please note, this transcript was generated automatically. PYA cannot guarantee its accuracy or completeness.

SPEAKERS

Martie Ross, Kathy Reep, PYA Moderator

SUMMARY KEYWORDS

American Relief Act 2025, ARA, Medicare telehealth coverage, physician fee schedule, HIPAA security rule, Consumer Financial Protection Board, Medicare Advantage, price transparency legislation, drug pricing negotiations, 340B program, opioid epidemic, AI debate, rural emergency hospital program, No Surprises Act

WEBINAR SUMMARY

The American Relief Act 2025, a slimmed-down version of the initial Consolidated Appropriations package, extends healthcare provisions until March 31, 2025. Key provisions include a 3% add-on payment for rural ambulance services, a 1% floor for rural hospital payments, and a $2 billion reduction in Medicaid disproportionate share payments. The Act also extends Medicare telehealth waivers and adjusts the physician fee schedule reduction. The new HIPAA Security Rule, effective 180 days after finalization, mandates stringent cybersecurity measures. The Consumer Financial Protection Bureau's rule on medical debt's impact on credit scores is under legal challenge. Upcoming webinars will delve into these topics and more.

The webinar focused on 9 key topics:

1. Introduction and overview of the American Relief Act 2025
2. Healthcare expenditure and industry segmentation
3. Healthcare provisions in the American Relief Act 2025
4. Medicare telehealth coverage waivers
5. Impact of the American Relief Act 2025 on telehealth services
6. Proposed changes to the Physician Fee Schedule
7. Medicare Advantage proposed rules and advanced notice
8. HIPAA Security Rule proposed changes
9. Consumer Financial Protection Board final rule on medical debt

ACTION ITEMS

- ☐ Monitor the extension of healthcare programs and telehealth coverage beyond March 31.
- ☐ Attend the upcoming webinar on the HIPAA security rule updates.
- ☐ Stay informed on the potential changes to regulations and policies under the new administration.

TRANSCRIPT

PYA Moderator **00:08**

Thank you for joining us. The webinar will begin shortly.

Good morning, everyone. Welcome to the latest episode of PYA is Healthcare Regulatory Roundup webinar series. Today's topic is *American Relief Act 2025*. PYA is happy to present today's webinar on this important topic.

You may submit questions during the webinar by typing a message into the questions pane of the control panel. Also immediately following the end of the webinar, you'll be asked to complete a short survey and submit any additional questions. We'll respond to questions posed after the webinar via email. We've posted in the handouts pane of the control panel a PDF copy of the slides for your reference. Also, you'll receive an email later today with a copy of the slides and a recording of the webinar.

With that, I'd like to introduce our presenters, Martie Ross and Kathy Reep.

Martie Ross **01:30**

Thank you, Jennifer. Good morning, everyone. Thank you for joining us for the first Healthcare Regulatory Roundup webinar of 2025.

Well, what a topic we have ahead of us. Today, I'm going to take you back to early December 2024. Kathy and I were discussing the webinar scheduled for January, and we knew that the first webinar would need to address the Consolidated Appropriations Package that Congress was expected to pass at the end of the year. We knew that we had an absolute December 20 deadline, as that was when the government would shut down, absent appropriations action by Congress. And so, we set this date.

Kathy Reep **02:13**

That's all we knew!

Martie Ross **02:19**

That’s all we knew at that point. So, like, okay, we'll talk about something on January 15. So, we get to the week before Christmas, December 18, and we have an announcement that a budget compromise has been reached. There's a piece of legislation moving forward, and that several of the topics of interest to healthcare providers were addressed in that compromise package; and favorably, we saw a number of one-year extensions of programs, just what we've become used to and sometimes the best we can hope. And that bill seemed to be on a fast track towards passage and signature by the President.

And then Elon Musk jumped on X and said, I don't like this bill. It spends too much, and I think that Congress needs to go back to work and start over. And soon thereafter, you had President-elect Trump join that chorus. And so, a bill that was ready to go was off the table. And in very, very short order, literally a number of hours, we came up with a new piece of legislation. A, to say a skinny version is making skinny sound fat, this is so thin. And that is the American Relief Act 2025, which passed early in the morning, I believe, on the 20th, the 21st. So, actually, we had a few seconds shut down and then was signed into law.

Just for comparison's sake, last year Consolidated Appropriations Act 2024 which actually came to us in two parts, two bills passed in March of 2024, the first section of that bill was 466 pages, followed by another 401 pages. By comparison, the print of the American Relief Act 2025 is a whopping 51 pages long, of which seven pages cover the entirety of the healthcare provisions in that legislation. So, what we're going to do today is to highlight what's there. Actually, Kathy and I contemplated a dramatic reading of the entire bill to take up the hour we had to speak with you today.

Kathy Reep **04:29**

But I couldn't play Karen very well.

Martie Ross **04:31**

Exactly, so we just gave it up. So, we're going to talk about those provisions. We're going to talk about now what happens, given that most relief we were afforded expires March 31, and as Kathy will discuss, maybe even earlier than March 31. But then we'll talk about sort of where we stand here at the beginning of the second Trump administration, beginning on Monday, and what we can anticipate. Kathy and I are not big crystal ball folks, but we'll give you some idea of what we think is on the table, at least. And then with our extra time, we thought we'd cover some other developments of interest, which include the Medicare Advantage proposed rule and advanced notice, those proposed changes to the HIPAA security rule that stuck out before the end of the year in 2024, and then this new Consumer Financial Protection Board final rule on medical debt. I never thought I would be doing a webinar on the Consumer Financial Protection Board, but here we are. So, those are our topics for the day.

Let's start with ARA 2025. Okay, just for context, the same week we had the, shall we say, the big bill going, they released the annual healthcare expenditure report. So, this is just for context of what health the healthcare industry has grown into through 2023 so overall healthcare expenditures grew by seven and a half percent to $4.9 trillion annually, or just shy $15,000 per head. We sit now at 17.6% of GDP. That is only going upward. There're predictions that by 2030 that's going to be right at 20%, one out of every $5 spent on healthcare in this country. So, if you're talking about rightsizing government, reducing spending, jump-starting the economy, you cannot ignore healthcare. And part of our issue, however, is that significant chunks of healthcare are mandatory spending, so we pay the bill when the bill comes in. That includes Medicare spending, which grew by over 8% in 2023, it is now 21% of the overall healthcare spend in the United States. Medicaid is not far behind that combination of federal and state dollars, it sits at 18%. Private health insurance is sitting at 30%, and then what we pay out of pocket is still 10%. Then you finally see here how you segregate that by industry segment. You see a hospital expenditures still top out at the highest at $1.52 trillion, physicians are about two thirds of that, just shy of a billion, of a trillion dollars. Sorry, it's a B, it's a T and it's an M, I always get them confused, but that's just shy of a trillion dollars. And prescription direct spending is at right at half a trillion dollars in 2023. Again, we expect

these numbers were higher in 2024 we'll wait to see. But this is context, right? You can't deal with the economy without dealing with healthcare, given its size and impact overall. So, Kathy, with that, what did Congress do in light of that?

Kathy Reep **08:03**

Well, on those four pages, we didn't get a lot. And there were things that, because of that big bill that we had seen, we were thinking there was going to be a lot of meat in here and a lot of things to talk about. And then they just started whacking away. So, essentially, and we're going to talk about this March 31 date at the end of this slide, but we have a three-month extension on a number of provisions that we have had in place, and it's just to tide us over until Congress does something else. But for the low-volume hospitals and the Medicare-dependent hospitals, they continued those programs and the current payment methodologies for those programs. The add-on payments for ambulance services, that's the 3% add-on for rural hospital, rural ambulance providers, 2% for urban, and I think it's over 22% for the super-rural providers, those are continuing again only until March 31, so be careful, we don't know what's going to come after that.

From the physician perspective, the calculation of the work GPCI, the Geographic Practice Cost Index under the Medicare Physician Fee Schedule, they kept that in place. That was the floor, the 1% floor product predominantly applying to rural hospitals. Acute hospital at home waivers, they again are going to continue, again, March 31. And we got another push down the road for the expected over four years, the $32 billion reduction in Medicaid disproportionate share. This was actually, it was going to be 8 billion a year. This has been pushed for year, after year, after year from when it was originally intended. It needs to be either wiped out or wiped out. There were also some adjust some provisions related to graduate medical education, the extension, again until March 31. Now, the reason I say this is a tricky date is because the programs have been extended until March 31; however, as far as government funding goes, I think Martie mentioned that we were looking at December 20 as being the day we ran out of money, and that the government would shut down. Well now we're looking not at March 31 as the day the government would shut down if there is not funding, but it's March 14. So we, literally yesterday Martie and I were talking about a webinar that we want to do for y'all at the end of March, talking about what all they included in that March 31 packet. What we're going to have to look at as well is what is going on as of March 14? Are they going to push things further down the road and just do a little, you know, short term? Or are we actually going to see that March 31 legislation happen mid-March?

Martie Ross **11:16**

One other topic that was included in the American Relief Act was the extension of the Medicare telehealth coverage waivers. We did not forget, we just wanted to take a deeper dive on this. The original bill had extended the pandemic waivers through the end of 2025. Again, the short bill only goes through March 31 of this year.

So, where do we stand today? Because this becomes very confusing, because you have the overlay of the work that CMS did in the 2025 Medicare Physician Fee Schedule Final Rule, and then you have where we are now through the end of March. So, where's this all originate? This whole issue originates in Section 1834M of the Social Security Act, which defines the Medicare coverage benefit for telehealth services. And as you'll recall, there were a number of restrictions in that statutory provision for coverage, most significant of which are referred to as the geographic and originating site restrictions. This means, pre-

pandemic, we only had Medicare coverage if the beneficiary was physically present at a facility such as a hospital, or an FQHC, or an RHC, physically present at the facility located in a rural area at the time the services are delivered. So, geographic has to be rural, originating site has to be physically present at a facility. Not surprising. You know, utilization of telehealth prior to the pandemic was barely a blip on the screen, Congress steps in, if you remember March 2020, can't believe that's almost five years ago now, but they step in and say, we're going to waive those restrictions for the duration of the public health emergency. And then, and so we saw an incredible spike in telehealth utilization, which has continued about the most recent report, I think, showed about 24% of all Medicare beneficiaries receive at least one telehealth service a year as of, I think, the most recent report was now released is October 2024 data.

One thing Congress did do in 2021 in a massive end of the year legislation, I had to go back the Consolidated Appropriations Act of 2021, it was a mere 4100 pages long, so…but actually, obviously, we were dealing with a lot of pandemic issues back then at the end of 2020. But as one of those many provisions in the CAA 21, Congress made permanent the exception from the geographic and originating site restrictions for telebehavioral health services. So, regardless of what happens on March 14, 15th, or through the 31st, there will continue to be coverage for telebehavioral health services offered regardless of location in a patient's home urban area. It doesn't matter.

What will become effective on April 1 is the requirement that there must be an in-person visit within six months prior to the initiation of telebehavioral health services for newly-initiated services. If you're already providing telebehavioral health services to an individual, there's no need to have them run into the office. So, I can see your face-to-face to continue providing the services. No, it's only the new initiation of services, and we'll see that requirement go online then on April 1, absent any other action. The other component of these extensions that were critical was expanding the list of telehealth providers, again going back to 1834M, it specifies that only physicians and non-physician practitioners can be reimbursed for telehealth services. Again, through series of legislation during the pandemic, Congress expanded that out to effectively any individual or group practice that can bill under the Medicare Physician Fee Schedule can bill for telehealth services. So, that included the therapists, the clinical psychologists, and the like. That provision allowing that extended range of telehealth providers, again, remains in effect through March 31 but again, skinnies back down absent congressional action by April 1.

Then, because the statute only says physicians and non-physician practitioners, the assumption had been that RHCs, rural health clinics, and federally-qualified health centers could not be reimbursed for telehealth services. Again, pandemic, we waive that requirement. CMS creates a methodology to pay rural health clinics and federally qualified health centers for telehealth services. In the ARA Congress extended that authority for RHCs and FQHCs to be distant site providers, i.e., bill for Medicare telehealth services. It's interesting, though, here's where we get that overlay with the final rule, because CMS in the final rule amended 42 CFR 405.2464, which is the provision that provides for payment to RHCs and FQHCs. And effectively being permanent through regulation, the ability of RHCs and FQHCs to get paid for telehealth services, they're paid at an average cost, average reimbursement rate, as opposed to their error rate or their PPS. But that methodology appears in the statute to go forward. So, that's one of those questions I have. If we reach April 1, will in fact, our HCS and FQHCs be able to continue to submit claims by the regulation? It appears they can.

Finally, we have the issue of audio-only telehealth services, again authorized by the statute. But you have to look at what CMS did in the 2025 Final Rule. There, they added a provision in 42 CFR 410.78 to define

the statutory language, which is interactive communications technology. It defined that to mean audiovisual, except in circumstances where three things are true. First, that the patient is physically present at their home at the time the service is delivered. Second, the practitioner, the provider delivering the service has the capability to do audiovisual. And third, the patient either does not have the capability for audiovisual, or they do not consent to visual. If those circumstances are true, then you can provide telehealth services via audio only. If that is not true. It needs to be audiovisual. That's a shift, because what we had at the end of 2024, when you took a look at that list of approved telehealth services, there was a column that said, is audio-interactive alone sufficient? The wording is a little different than that, but that's what it meant. And there would be that No, no, yes, yes, yes, yes, yes, as you listed every CPT, HCPCS code that's on the approved list. You'd look at that column, and that column would tell you whether you could provide that service audio-only or if it required audiovisual. If you look at the list for 2025, that column is gone, because CMS said it is no longer tied to the specific service, whether that will be reimbursed, if it's audio only. Instead, any service potentially can be audio only, but only if those three things are true, right? Patient at home, provider capability, no consent or capability on the part of the patient. In those instances, you would bill the service with an 83 modifier, RHCs and FQHCs use the FQ modifier.

Again, CMS has eliminated the audio-only EM codes. Those are no longer reimbursable. It did not adopt the set of CPT editorial board codes for telehealth services. They only they didn't adopt those instead, opted for this audio only approach they use. That, of course, is going to change with the coverage for services that doesn't impact coverage. It just tells you the manner of delivery of the services. So, to say that things are just a tad confusing right now when it comes to Medicare telehealth coverage may be a little bit of an understatement. But appreciate that we are in a holding pattern for the primary issue of coverage, which is geographic and originating site. Now, interesting conversations we've had with folks around this. They're like, well, this is definitely going to go, definitely, definitely extending…

Kathy Reep **20:23**

Martie, in the December 18 related to telehealth…

Martie Ross **20:27**

Right, it would have been December 31, 2025.

Kathy Reep **20:31**

So, there's only a one-year extension.

Martie Ross **20:33**

Only a one-year extension, we had hoped for two. We got one. And folks are sort of presuming that the bill that comes up will have the further extension. The issue you have, we've discussed this previously on this webinar series, is you've got a Congressional Budget Office that scores the telehealth expansion, as they call it, at $4 billion over two years. And so, you've got to come up with the money. Congress has to find a way to finance this expansion, given the CBO score, and certainly, as we're going to talk about, we're going to be in a cost-cutting mode at least early in the Trump administration. So, finding, you know, a spare $4 billion somewhere to finance this may, in fact, be challenging.

Now then, of course, there's also the argument that CBO is off its rocker. That's kind of a that's sort of tough, isn't it? Maybe CBO is using a methodology I would not agree with, ergo, they're off their rocker, right? But they say that telehealth services cost so much because they're additive, so we're already paying for this many in-person visits, where, if we include an expansion of telehealth, we're adding more cost to the system. So, that's how they get to their $4 billion price tag. Interestingly, if you go over to CMS, when CMS is calculating the conversion factor under the 2025 fee schedule, they're saying, well, we know that telehealth is likely to go away. I mean, it is going away right now. Our assumption and building our model has to be that there is no coverage in 2025. But we don't think that matters, because we just think people are going to go instead of receiving telehealth services, they're just going to go in person. So, you've got two ways of looking at this, one of which is the obstacle to expansion of telehealth services because of CBO scoring this and Congress having to come up with the cash.

So, a little deeper dive on that front, but it is certainly an interesting area. If you are folks with the vested interest in this, it's certainly important to be, your voice being heard as to the importance of telehealth services moving forward. It continues to be out there.

Kathy Reep **22:41**

So, when we look at that big bill that was out there December 18, that then got whittled down to four pages as it relates to healthcare, what was in that in addition to that extension of telehealth coverage as we know it right now, through the end of December?

First of all, a very important item was that there they were going to adjust the current reduction in the Physician Fee Schedule, the conversion factor, and we have a reduction of 2.83% for 2025 based upon what CMS did. Congress was stepping in, and they were modifying this so that it wasn't as big of a reduction. There was still a reduction.

The other thing that we just want to remind you of, because we know we've got people who are very concerned about the Physician Fee Schedule and then others who think, it doesn't mean anything to me. Recognize that if you are a hospital and you provide outpatient PT, physical therapy, speech pathology, occupational therapy, or mammography services, those are paid under the Physician Fee Schedule. So, if you are seeing that 2.83% reduction the conversion factor for physician services, you're also seeing it for your mammography services and your outpatient therapies. So, recognize we need Congress to step in. They did, but that got knocked out of the final bill.

Martie Ross **24:14**

Interesting, Kathy, because we had the same issue last year.

Kathy Reep **24:18**

Yes.

Martie Ross **24:19**

And what happened is Congress stepped in in March and said, we'll provide a 2.83% bump for one year. Well, not even a year, just to the end of December, and it was not retrospective.

Kathy Reep **24:31**

Right.

Martie Ross **24:32**

So, we had two fee schedules. We had 24a and 24b, because the services provided before March 7 were paid at that lower, you know, 2.83% less. We get to this issue because Congress had only provided a one-year extension of that payment increase, and so come January 1, that was gone. That's why we ended up with the cut in conversion factor.

Kathy Reep **24:52**

So, again, something that we need to see, that Congress was stepping up and they were fixing it, but that got knocked out. For alternative payment systems, alternative payment models, the advanced APMs, the incentive payments that were targeted to be 3.53% for performance year 2025 which would actually been 2027 payment year? That was included. It is not in the final bill that we have right now.

Something that was rather scary and that maybe we don't want included in the final bill, or actually, we definitely don't – it's not there now, it was in the one that didn't pass – but this was legislation that would have required a separate National Provider Identifier and attestation by an executive within the hospital for any off-campus hospital outpatient departments. So, that was struck from the final bill but recognize that this could very easily come back because it has been passed in both the House and the Senate over the last two years.

Site neutral payment for drug administration? This is essentially saying, if you have drugs that are, you know, drug administration that is done in an off-campus outpatient setting, it would pay as if it was provided in a physician office. That was included. It's not in the final. Is it coming back? And then lots of changes related to Pharmacy Benefit Managers and the regulations there. I think it's a little bit detailed to go into right now, but just recognize that this was something that was there. They were starting to tackle what they perceived as an issue, but again, it got dropped. So, will we get these? Will we get a physician fix? Will we get the incentive payment? And hopefully we will not get the separate attestation and NPI number for off-campus or have to face that off-campus drug administration issue as well.

Martie Ross **27:08**

The other thing out there that never made it to the big bill. So, this was not in the compromise. There had been, as Kathy has discussed previously, there have been a whole bunch of provisions around price transparency.

Kathy Reep **27:20**

Oh, yes.

Martie Ross **27:21**

They passed both the House and the Senate, and that was part of what fell on the cutting room floor before the bill on December 18. So, we'll see if that one comes back as well. But they were just trying to, you know, the first level of trying to streamline it. Those provisions fell out. We'll see what happens there.

Kathy Reep **27:42**

There, the executive order that has us where we are right now was under the first Trump administration.

Martie Ross **27:50**

Right. So, here's a scary slide. So, now what? As I said, Kathy and I, our crystal balls are very cloudy, but we're just going to talk about some of the practical issues that come into play here as we move forward with the new administration.

You probably heard this term, one big, beautiful bill, also taken from a…do you call them tweets, even though it's now X? No one's ever answered that for me. But it was a tweet by President Trump, excuse me, President-elect Trump, there we go. That he was asking speaker Johnson to move forward with one big, beautiful bill that would be focused around the priorities from the campaign. And the vehicle to accomplish that bill is budget reconciliation, and the reason we love or hate, depending on where you stand, the budget reconciliation process is because it is the one way to get around the Senate filibuster rules.

The process, which goes back into the 80s, is a provision that allows Congress to make adjustments to the budget. So, a budget reconciliation process is based on a budget resolution that comes out of committee. It directs what can be included in the reconciliation bill. The test is it has to be something that impacts the budget. So, its primary purpose is to resolve budget-related issues. So, there is certainly, we've had number of pieces of legislation over the years that have used the budget reconciliation process; typically, because you've got a party in power, particularly in both houses, but they can't beat the filibuster. And that's where we stand at what is it? 53/47. So, that's the interest here in getting the big, beautiful bill under budget reconciliation process. What do we know that's going to be in there? I mean, the top priority, as we understand, is the extension of the 2017 tax cuts, which are said to expire later this year, as well as making good on candidate Trump's promise to eliminate federal tax on tips.

Also, what will go in here, most likely, is the debt ceiling. Going back to what we saw at the end of December, what President Trump was particularly interested in, in this final, what became the American Relief Act, was to include a provision that would have extended the debt ceiling. Which would, again, allow the federal government to continue borrowing money, borrowing money, not default on its debts and obligations. And we've heard the debt ceiling debate, it's gone on for a number of years now. Keep increasing the amount, increasing the amount. What, understandably, president-elect Trump wanted was to have that issue resolved prior to taking office and not have to go through a debate around the debt ceiling, because the expectation is you need Democratic votes to get that done, and the Democrats wanted to hold that as leverage for future negotiations, so they were not interested in including the debt ceiling in this final package that went forward. What's very interesting is that you saw the pressure from the coming administration on the Republicans to pass this legislation, and what we ended up with was the debt ceiling provision not in that bill. And you had the pressure from again, again, a group of about 35 Republicans in the House who objected. They said they wanted to separately debate the debt ceiling, because they see it as an opportunity, again, to argue in favor of reductions in government spending.

So, that's interesting, because we've had a lot of, you've got a very close majority right now in the House, closer than it was before the election. I think it's one vote difference right now, but it could go back, no,

it's three now, could go back up to five. Which, five is where we were before the election. So, you have to wrangle your people carefully. To have 35 Republicans who have already said, no, we disagree with the administration, we're not going to include this in the legislation. Creates a pretty interesting dynamic going forward, one which we will watch closely. So, but at some point, we have to deal with the debt ceiling or default on our obligations, which we can only imagine what that would do to the global economy.

The other priority in this budget reconciliation process is border security and all of the issues related to immigration; there have also been mentions of energy, to expand drilling; defense, to increase defense spending as appropriate. And then you kind of having this general conversation around spending cuts focused on mandatory spending. And mandatory spending is the entitlement programs, Medicare, Medicaid, Social Security. But what you're hearing from Speaker Johnson, this is his quote, we will not cut Medicare benefits, quote, in any way or anything.

Kathy Reep **32:51**

But that's benefits. To patients.

Martie Ross **32:54**

Bingo, exactly.

So, the question is, what does that due to provider payments? That's why we have these concerns around telehealth. We have these concerns about the Physician Fee Schedule. Because all of those carry dollars with them, and if you're trying to cut trillions out of the federal budget, it makes a difficult case trying to take this forward.

In the context of the reconciliation process, appreciate this thing called the Byrd Rule. Good old Senator Byrd from West Virginia. They require, it requires that a reconciliation bill cannot affect the Social Security program. So, there's no opportunity to cut Social Security through this reconciliation package. That, again, is leaving Medicare and Medicaid out there as the targets for potential mandatory spending. They've said they won't cut Medicare benefits. They have not said the same with respect to Medicaid benefits. So, we leave that as it is. The other element of the Byrd rule is you cannot add to the deficit for more than 10 years. That's why, for example, the original Trump tax cuts would sunset when they did, which be the end later this year, is because of the 10-year rule on the deficit reduction. So, that's the other restraint that we're dealing with in all of this.

The commitment by Speaker Johnson is to have a bill on the President's test by Memorial Day, which, to me, says this heats up all the oxygen in the room for the first several months of the 119th Congress. How exactly do we get the extension?

Kathy Reep **34:29**

March 14th and March 31st.

Martie Ross **34:30**

Exactly, and then how? Yeah, that issue like, oh, we're running out of money too. But how do we get the attention of healthcare? You know, again, despite the fact it's now 18% of our GDP, how does this line up and have the attention we need in the provider community moving forward? Kathy? Oh, is this me or you?

Kathy Reep **34:52**

It's both of us.

Martie Ross **34:53**

Okay! So, what do we think they are going to do at some point the 119th Congress? I mean, there will be, we will live past Memorial Day. What do we think they're going to look at? The first on the list we're going to see price transparency legislation, no doubt. More requirements, more…

Kathy Reep **35:07**

Price transparency, ASCs, labs, etc. Absolutely.

Martie Ross **35:13**

It looks like you're doing something, and it doesn't cost anything, right? I mean, that's kind of the perfect…

Kathy Reep **35:19**

Well, it doesn't cost them anything.

Martie Ross **35:21**

Exactly, exactly, cost us a lot. But costs them, like….Whether the Medicare Advantage debate is going to be fascinating, because you've got the provider community and you've got more of the general public concerned about Medicare Advantage plans, and prior authorizations, and denials, and kind of…Medicare Advantage is getting the same negative publicity that commercial insurance is generally. Sort of that reaction to the assassination of the United Healthcare Executive, and the public's response to that. Very difficult to read those tea leaves. But at the same time, you've got Dr. Oz, our presumptive CMS administrator, who has said publicly, I think Medicare Advantage is great. I think the federal government needs to get out of Medicare. Okay, sorry.

Kathy Reep **36:13**

You could automatically be enrolled in Medicare Advantage, and then if you don't want that, you have to opt in.

Martie Ross **36:21**

He has, he has noted that. It will be interesting to see where that goes. Obviously, that would require legislation, so it'll be very interesting to see where the Medicare Advantage debate goes.

We will have something that looks like ACA repeal, or at least is labeled ACA repeal. I think what that means is we're going to see the re-emergence of limited benefit insurance coverage. [Gagging sound] that's on behalf of every hospital and clinic administrator. [Gagging sound] because what you end up with is

health insurance that is pretty much only catastrophic, but people think they have insurance, right? And so, we'll see that. Be prepared. And it's something where we really need to be educating folks about, limited benefit really means limited benefit.

Probably more noise going on drug pricing, the progress that has been made to date, will we continue expanding out that list of medications for drug pricing negotiations? The 340B program, I worry, oh, I worry that this becomes leverage in the PBM debate. They said they'll regulate PBMs, but they'll give them what they want under 340B, which, of course, would be devastating for many of our safety net providers that really depend on 340B revenue. There's the opioid epidemic. Fentanyl is a synthetic opioid, so it falls under this as well. Again, highlighted as a real concern for President-elect Trump, and what we'll see around potential dollars going in to solve the issue, or do restrictions placed on the usage of opioids.

The AI debate, need I say more? How do you regulate AI and prevent it from becoming super intelligence that takes us all over. That's another story.

Near and dear to our little rural hearts, is the rural emergency hospital program. Some modifications to that program to make it more appealing, such as 340B status, swing beds, those really obstacles to many hospitals doing a conversion that otherwise would make sense for them. We'll see if we have legislative solutions them.

And then, these last two bullets are more general. Sort of, how does this generally affect what's going to happen with healthcare in Washington? Generally, you have Robert Kennedy Jr.'s Make America Healthy Again agenda and how that will roll out? There are some real concerns that there are going to be parts of HHS that may go away or be subsumed into other parts of agencies, such as the Agency for Healthcare, Research and Quality, which has been a target previously. Do we see that either rolling into NIH, rolling over to HRSA? So, there could be some changes. Certainly, what's going to go on at FDA, that will be interesting to watch, and how that impacts us going forward. And then you have the DOGE. Yes, Kathy, I called it the DOGE, even though I want to call it doggy because I think that's a better pronunciation of the acronym. But the Department of Government Efficiency, which is not really a department, it is a, what's the word? I want to say shadow, but I don't want to use the word shadow. But it is a non-governmental taskforce that is looking into agency operations to identify waste and make recommendations to Congress as to eliminating waste in federal agencies. This is sort of this target of, this is the Elon Musk Initiative, where he wants to eliminate $2 trillion and that's beyond what he wants to do with mandatory spending. But what recommendations we'll see coming out of that? Certainly, something worth watching, definitely.

Kathy Reep **40:01**

One thing we didn't include on that list, Martie, that is huge, is the No Surprises Act. Because we're going to, first of all, we're still dealing with lots and lots of interim rules, interim final rules. We've actually got a proposed rule that we have no action on yet, and we've got litigation that, and so we're going to have to address No Surprises Act as well.

Going on to, okay, so we just and we're going to talk about some rules that have just been published and things like that. So, what happens with these things that happened under the current administration, when

we move into a new administration on Monday? Essentially did some research figuring out what does happen next. And so, there are several options that are out there for rules that have already gotten through the notice and comment rule-making. They are final rules, okay, and their effective date is out there and is passed. First of all, those could actually be delayed in terms of the effective date, it could be delayed, but it would have to be published in the Federal Register that they are going to delay implementation of a particular rule. What could we be looking at there?

Nursing home staffing levels. Huge. That could actually even be turned around and, you know, totally repealed, absolutely. HIPAA reproductive rights. What will be the status there? Some of the provisions related to 1557, again, we've got a lot of litigation around that one. Will the administration step in and modify the rule? Anything that was finalized after August 1 of 24 can actually be rescinded by Congress. They can say, no, we don't want to do this. So, next step, we got that one.

There could be a moratorium on those rules that are not yet in effect. So, we're going to talk in a little bit about the rule from the CFPB, the Consumer Financial Protection Bureau, that could be delayed from an effective date perspective. It gives the new administration some time to review the legend what's been included, and to think about it. So, that would be an opportunity there. If they we got a lot of guidance documents that are out there, those could actually be repealed or amended. There would not be a notice and comment provision related to those that only is going to apply to something that was published in the Federal Register. We've got proposed rules that we're dealing with, right and left. We're going to talk about the HIPAA Security Rule. Could they put a moratorium on rules that are under development? We've got the Medicare Advantage, the Part D rule. Will they delay implementation, or will they delay of the publication of a final rule? So, we don't know what's going to happen, but there are a lot of opportunities under the Congressional Review Act that allows them to, the new administration, to modify what was done under the prior administration.

Martie Ross **43:36**

Stay tuned.

Kathy Reep **43:39**

Fun. So, with that….

Martie Ross **43:40**

Stay tuned. Well, we've got 15 minutes quality time with you all, so, we want to cover three other regulatory developments, starting with what's up with Medicare Advantage, and the proposed rules and the advanced notice that have been published by CMS. So, Kathy, you want to start talking about the ’24 rule, kind of provides us some perspective on what now is happening with the ‘26 rule?

Kathy Reep **44:04**

Sure, and I'm just going to be very, very quick on the ‘24 rule, because it was effective last year. Okay, we should be following this actually, I should say the Medicare Advantage Plans should be following this rule now. And this related to compliance with traditional Medicare policies, related to national drug National Coverage Determinations, the Local Coverage Determinations, coverage and benefits. The areas that we have seen, the biggest, I'm going to use the word noncompliance with, relates to the inpatient-only

list and the two-midnight benchmark. We have seen that the plans have said, no, I don't really think that's an inpatient, let's make an observation. So, there has been a little bit of a reduction in the plans use of observation, long-stay observations, but very minimal. So, recognize this continues to be an issue that needs to be addressed in regulation, again. And if the plan is, it wants to develop its own internal coverage criteria for something that does not have criteria under the fee for service Medicare program, they must use actual clinical evidence related to the policy that they're creating. They've got to be able to cite. Where did I get this information? And it's not from Dr. Brown, who thinks it's a good idea. It's from the American Society of the specialty so that they are actually making sure that the information is truly a good clinical recommendation. That information has to be made publicly available, publicly accessible. I can find it even if I'm not a part of that plan, you can find it even if you're not participating with that particular plan. So, recognize that information has got to be out there, and it's got to be able to demonstrate that their policy doesn't cause harm.

You have seen slide over and over and over again from Martie and I, but we're just going to keep reemphasizing that this February 6, 2024 FAQ, that was a document from CMS to the plans themselves. These were questions that were asked by the plans. What do you mean by…? This is so important that you have a copy of it, have it readily available when you are arguing a point made by a plan. Please go back to this letter, cut and paste, because these were the instructions to the plans. As an example, my favorite one is, what do you mean by a Local Coverage Determination? Can I, I'm in Florida, can I use the local determination of the MAC in Kansas, because it's a Local Coverage Determination? No. Local means local. So, really scary that they ask that kind of question, but make sure you have this as a provider and are using it as you argue what the plans are trying to impose on you. So, now Martie, what's coming next?

Martie Ross **47:24**

Well, so to CMS' credit, when they imposed these new rules for 2024, they promised that they would do monitoring of plans' behavior and that they would use that as a basis for proposing additional changes for 2026. And that's exactly what they did. So, this rule, which was published in December, they're still open for comments through January 27, and it revisits many of the same issues that were addressed in the '24 final rule, but goes into more specificity. So, it's taking a lot of what's in that guidance document and now bringing it into the actual regulatory text. Such as, please, I know it drives everyone crazy, they authorize a procedure and then deny payment on it, or they authorized admission and then deny payment. So that would prohibit, prior authorization means authorization that we're going to pay for it. Again, tightening up the standard….

Kathy Reep **48:18**

But Martie, part of this was included in last year's rule.

Martie Ross **48:24**

Yeah, yeah. They're just saying we're just going to …

Kathy Reep **48:26**

We really mean it this time?

Martie Ross **48:28**

Well, they mean really, when we say local, we mean local. It's sort of what this is. It's really, it sounds redundant in large part because we've been reading it out of the February FAQ. So, they are moving forward with this and continue to be serious.

Marketing, I think is some very interesting provisions. If you hate the generic MA plans' ads as much as I do, finally, they are now going to be subject to pre-approval. So, previously, you had to mention a particular Medicare Advantage plan or sponsor before you had to go through the pre-approval process. But if you were just generally promoting Medicare Advantage, those ads could say anything they wanted to say, because they weren't subject to pre-approval. And now for the '26 plan, here they will be. There are also new requirements for broker disclosures, specifically that brokers now have to inform patients that if you are in traditional Medicare and you move to Medicare Advantage, if you later choose to go back to traditional Medicare, it is likely that you will see a significant increase in your Medicare supplemental costs, or you'll simply be denied coverage by Medicare supplemental plans. So, that is intended clearly to highlight, finally, for seniors, that there is a risk when you go into an MA plan. If that plan, if you choose to go away from that plan, for whatever reason that it's going to be difficult for you to get back into traditional Medicare because of that additional cost on your Medicare supplemental. They'll now be required to disclose that.

There's some changes to expenses that you can include in medical loss ratio, particularly refinements of quality payments made to physicians and other providers that the MA plan has to make a direct correlation to quality improvement. And then, for Part D, the thing that we've all paid attention to is that broader coverage, or GLP1s. Previously, the coverage was limited to individuals that had diabetes, and we're now going to provide coverage for individuals diagnosed with obesity. So, a significant expansion, proposed expansion, that Part D coverage.

The other piece of the puzzle, and remember, we're on a very strict schedule when it comes to MA because it all comes to the date that MA plan bids are due, which is June 1. And those bids are due June 1 because we start marketing the product in October, so you have to meet the plan year requirements. So, in addition to that rule that came out in December, which was regulation of plans, we also received earlier this week, what was it, last Friday? Excuse me, last Friday, we received the annual advance notice, and this is sort of what CMS proposes to pay to MA Plans. Again, comments are due on this are due on February 1, and comment and CMS promises that it will publish the final rate announcement by April 1, which is what it's required to do. What we saw in the advanced notice, was a projected net increase of 4.33% that's $21 billion in plans to MA, that's the overall increase. What's critical? Go ahead.

Kathy Reep **51:25**

Docs are getting a 2.83% decrease.

Martie Ross **51:30**

Yeah. Well, the real number is 2.23 because that's the increase on the benchmark payments, right? That's the actual increase

Kathy Reep **51:39**

But it’s still an increase.

Martie Ross **51:40**

Yeah. Because in 2025 is a 0.16 reduction. So, it is a significant increase. And it could be more, and we'll likely see the plans arguing for more, because how they got to 4.33 is they start with the effective growth rate and then they make adjustments. So, the two critical adjustments that drove down the payments to MA plans is the Graduate Medical Education Cost judgment, which CMS has been phasing in now for two years. They are making that adjustment to the growth rate to make MA pay its share of graduate medical expense costs. If we did not continue that phase-in, that would be $7 billion more to the plans. And then we, of course, have the implementation of the 2024 risk adjustment model, which again phased in over three years. With the final year of phasing that in, CMS says if we paused that, it would be another $3.4 billion in payments to MA plans. CMS takes the position that MA programs are stable right now, we have good access to the programs, we have coverage of state beneficiaries, adequate level of supplemental benefits. That is, it is not necessary to make this what would be, what, 10 and a half billion dollars in extra payments to the plans? We'll see where the debate goes on that. So, pay attention to that. Very interesting. Proposed updates to HIPAA Security Rule, which came out end of December. To you, Kathy.

Kathy Reep **53:04**

Yeah, this is published on January 6, comments are due March 7. Neither Martie or I are experts on HIPAA security, nor do I think we want to be, but we've got a guy, and so I'll touch on a few things related to this rule. But we're going to tell you at the end about an upcoming webinar by PYA’s very own Barry Mathis, also known as Scary Barry, to really talk about this rule in depth. Comments only…

Martie Ross **53:34**

Because he was a Marine, that's why we call him Scary Barry.

Kathy Reep **53:38**

Okay, sure, never mind, but the Security Rule was originally published in 2003, it was updated last in 2013, now 2025 we're looking at some changes. And these changes are going to be significant, and I'm probably also going to say extremely time consuming and costly. Okay? That's the best way I can do it. I've given you, on the slide, the effective date, comments due March 7. There is going to be a final rule that would come out. The effective date would be 60 days after the final rule comes out, but then compliance would be required 180 days following that.

Let's go through some of the provisions that are actually out there, that they are saying. First of all, we know that with the current security rules, cyber security rules, we have certain specs that are required and others that are addressable. Let's, according to this rule, eliminate the idea of addressable. Everything is going to be required. Okay? Going to eliminate addressable. Let's go with required only. They're going to update definitions that reflect changes in tech. Technology and terminology, what we start looking at, or what are we going to define? We're going to define risk, we're going to define threat, we're going to define implement, and we're going to define a number of other words that have been used in the existing rule that need better clarification, apparently, for some individuals. There is going to be the requirement for written

documentation of all of your security policies and procedures. There's going to be requirements for vulnerability scanning at least once every six months, and penetration testing at least once every 12 months. Development of an asset inventory and network map that is maintained on a at least annual basis. Provision, I think what is really interesting is that you must have a backup system that would contain exact copies of electronic protected health information that would be no more, would be less than or equal to 48 hours older than the ePHI maintained in your regular electronic health systems. In other words, you're going to have to have a backup, a current backup, of all of your docs, your data. You're also going to have to be able to disable an individual's access to within no more than an hour following termination. You're going to have to report on those individuals who have whose access has been changed or terminated. You're going to have to have written procedures to restore ePHI and data within 72 hours. Encryption, required both at rest and in transit; multifactor authentication, required; anti-malware protection, required. A lot of provisions required on the business associates as well. So, recognize huge task ahead of you, make sure that you have someone within your organization who A) listens to Barry's webinar, and B) reads this and comments. Again, comments due in early March.

Martie Ross **57:25**

So it's a lift, but it goes from best practice to regulation. I think that's exactly where we're going with the HIPAA Security Rule. Okay, Kathy, wrap us up, financial protection.

Kathy Reep **57:34**

This is one that when we went back to, what could the Trump administration do to this? We're going to run into some politics, but the Consumer Financial Protection Bureau issued a rule, final rule that came out in January that says that a consumer credit reporting agency may not use information that was reported to it related to medical debt. In providing a credit score, a lender cannot use medical debt in assessing a borrower. So, as a provider, you're going to need to make sure that you are really focused on collections. Upfront collections, not the idea of, I'll turn it over to collection agency, and people will be concerned about its impact on buying a house, on buying a car, etc., because this will be thrown out completely, both by the lender and by the credit reporting agency.

The rule says that they expect that this provision, this new rule, would boost credit scores by an average of 20 points for those who have medical debt. This rule, even though it's final, is now being challenged in our friendly Texas federal court. They have said that the Consumer Financial Protection Bureau has overreached with this. The Republicans, who now have control of all branches, have criticized the CFPB. There's no one who will be leading this. No one's been nominated yet. Elon Musk had at one point tweeted, "Delete the CFPB", but it's a voter issue, because voters are the individuals who have the medical debt where it's prohibiting them from buying a home, buying a car, etc. So, very concerning about what can the administration do with this when it becomes such a voter concern? Martie.

Martie Ross **59:46**

Made it to the end. Just to highlight upcoming Healthcare Regulatory Roundup webinars. January 30, that's a Thursday, as opposed to usual Wednesday. We're going to do a 90-minute CPE webinar on the TEAM model. Kathy and I have corralled some real experts to talk about some key elements in the TEAM model as the countdown continues to that January 1, 2026 implementation date. On February 12, I'm going to be joined by Lori Foley to do our annual "what's up with Chronic Care Management and Remote Patient

Monitoring?" We always do our 2025 updates of our white papers on those subjects, and we'll roll out the details and interesting facts around CCM, RPM, and other types of care management reimbursement. And then, as promised, February 26, Scary Barry will do a deep dive into the HIPAA Security Rule, giving you sufficient time to garner your thoughts to submit comments by that March, 7 deadlines. So, Happy New Year, everybody. I'm sure it's going to be interesting, and we look forward to bringing you Healthcare Regulatory Roundup twice a month. Jennifer, back to you.

PYA Marketing **1:00:55**

Thanks to our presenters, Martie and Kathy, later today, you'll receive an email with their confirmation contact information and recording of the webinar. Also, the slides and recordings for every episode of PYA's Healthcare Regulatory Roundup series are available on the Insights page of PYA's website, pyapc.com. While at our website, you may register for other PYA webinars and learn more about the full range of services offered by PYA. Please remember to stay on the line once the webinar disconnects, to complete a short survey and post any questions you may have. On behalf of PYA. Thank you for joining us. Have a great rest of your day.