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The Health Wonk Shop: Beyond *Chevron*: How the Court's Decision Will Change Health Policy Legislating and Rulemaking

Larry Levitt:

Hello, I'm Larry Levitt from KFF. Welcome to the latest episode of the Health Wonk Shop. About once a month, we dive into timely and complex health policy topics with experts from a variety of perspectives. One thing we've seen in recent years is that courts have increasingly played a role in health policy. Just look at the number of cases related to the Affordable Care Act as evidence, including the very consequential decision by the Supreme Court to make Medicaid expansion effectively optional for states. Just recently in the so-called Loper Bright decision, the Supreme Court overturned what's known as the Chevron defense to federal agencies. Neither Chevron nor Loper Bright have anything to do with healthcare, but this decision could have big implications for health policy. We could see more legal challenges to federal health regulations, federal regulators may get more cautious, and Congress might try to get more prescriptive, which may or may not be successful.

We have four lawyers on today to discuss what a post-Chevron world will mean for health policy, but rest assured, this is not going to be a law school class, which I feel fortunate for as the only non-attorney in the group. These are all experts in policy, rulemaking and legislating. Our plan is to look at what a post-Chevron world might look like for healthcare policymaking. Cindy Mann is partner at Manatt Health and former Deputy Administrator of the Centers for Medicare and Medicaid services. Dean Rosen is a partner at Mehlman Consulting and former Chief Healthcare Advisor to Senate Majority Leader, Bill Frist. Kaye Pestaina is Vice President at KFF and Director of our program on Patient and Consumer Protection. Laurie Sobel is associate director of KFF's Women's Health Policy Program. I haven't added it up, but I'm pretty sure we collectively have well over a century of experience here.

A little bit of housekeeping before we jump in. If you have questions, submit them at any time through the Q&A button in Zoom. I promise we'll get to as many of them as we can. Also note that this session is being recorded and an archived version should be available later today. Okay. Let me start with you to level set the discussion. What actually was the Chevron deference? Is there a new standard that the Supreme Court has now established in overturning it?

Kaye Pestaina:

Thank you. Yeah, Chevron deference was a framework that federal courts used to make decisions when certain federal regulations were challenged in court. It came from a 1984 case called Chevron v. Natural Resource Defense Counsel. Under the Chevron deference framework, federal courts were to give deference to a reasonable agency interpretation of a law when the agency was interpreting either an unclear or ambiguous provision in a law or an issue in which the law was silent. That meant that federal courts would defer to an agency regulation that a court found to be reasonable, even if there were

other reasonable interpretations of that provision that a judge might think were a better interpretation of the law. But nevertheless, the court had to uphold that agency regulation unless it found that somehow it was arbitrary or inconsistent with the statute.

Basically, not every challenge to a federal regulation implicated Chevron. For instance, there's certainly some disputes on agency regulations that don't involve ambiguous language or there's some laws that specifically delegate to agencies certain decisions. But for those scenarios where Chevron deference was relevant, it was a foundational concept in administrative law that was used for over 40 years. Definitely, over those 40 years, there were policy debates over whether Chevron deference was the right approach. Opponents often argued that unelected agency regulators shouldn't be making, have the final word on certain decisions, and that it undermined the separation of powers under the Constitution by giving executive branch folks more authority than some thought they should.

On the other hand, proponents of Chevron deference argued that federal agencies are best suited for this role as they are tasked with implementing the law and that they are the subject matter experts knowledgeable of the data and the policy nuances needed to make decisions and are ultimately accountable through an elected president. In recent years, the Supreme Court itself has rarely relied on Chevron in evaluating agency regulations, but it nevertheless, Chevron deference was still precedent that was followed by lower federal courts until the court overruled Chevron in the Loper Bright decision. That's what Chevron deference was.

Is there a new standard now that we had the Loper Bright decision? The short answer is no. In overruling Chevron, the court, Justice Robert speaking for the majority basically said, "Chevron deference runs counter to the Administrative Procedure Act, the APA. That's a law that sets parameters for federal administrative processes. According to the Roberts opinion, under the APA, it is courts that decide legal questions by applying their own independent judgment and not deferring to agencies when resolving issues around ambiguities in laws, and that it's up to courts to decide the best interpretation of the law for these challenges, and that agencies don't have any particular competence to resolve statutory ambiguities. Quote from the opinion.

There's no new framework on how courts are to exercise this independent judgment or to make the best reading, so that's where we are. We have to see how lower courts take that new decision in Loper. There are some language in the opinion, which I'm sure we'll talk about today, that might give some wiggle room that might give agency some discretion and I'll leave that to discussion.

Larry Levitt:

Well, I think we're in for quite a ride. Thanks, Kaye. Cindy, let me turn to you. You, when you were sitting at CMS, wrote a lot of rules or your people wrote a lot of rules. Getting the head of someone who's sitting there in a federal healthcare agency, how do you think this is going to affect the rulemaking process? Oops! Cindy, I think you're on mute.

Cindy Mann:

You have to learn this. Is that better? Sorry. I do think it'll have quite a significant impact in the short run, and I think how big the impact will be depends on some of the issues that Kaye raised. Certainly, agencies, their general counsels, their leadership, will be more cautious about undertaking rulemaking,

more cautious about changing their rules over time and more exhaustive in drafting rules and the agency justifications for those rules, which are required under the APA in rulemaking, but which have gotten more and more extensive over time.

Additionally, in a case that has gotten less attention, the court was very explicit that agencies are supposed to respond point-by-point to every comment that's raised in the course of rulemaking. But that said, as Kaye notes, this has been the trend over the last several years. I wouldn't say it's a bright light line change, but a confirmation of a trend that we've been seeing as we've seen more courts abandon the Chevron deference or doctrine, not use it at least, and the appointment of judges that are more inclined to move in a direction of affording federal agencies less deference.

But as we think about both the short-term and the longer-term impact of Loper Bright, I think we should be thinking also that there may be even more impact to the extent that it spreads to other areas of agency rulemaking. For example, I want to point out two examples. One is we have statutes, and this is certainly true in the Medicaid statute, which I have become closely intimately familiar with, where the statute explicitly gives the agency discretion to make rules in an area. That wasn't the case in Loper Bright, but Medicare and Medicaid, there's been lots of delegations of authority, sometimes very specific. Like Congress says, the secretary shall establish rules to determine income eligibility and sometimes very general, which for example, the statute says that the state shall use methods of administration found by the secretary to be necessary for the proper and efficient administration of the program.

In other areas, there may not be a specific delegation of authority, but it's clear that if Congress' intent is going to be actualized, there needs to be some more details. For example, the statute says in Medicaid that rates paid to manage care plans should be actuarially sound, a concept that is clear as mud. CMS regularly issues regulations and guidance to states on how to come up with a methodology for determining actuarial soundness. Robert's opinion says courts should respect at least explicit delegations of authority. He doesn't talk much in the case about those need to fill in the gap. But it's really unclear what that actually means, and we would be, I think, ignoring recent trends and articulated concerns in some circles about the administrative state if we weren't alert to the possibility of lots more litigation, lots more questions coming at us. And that in turn, going back to your question, Larry, will make even now some of the agencies and their councils more reluctant, more concerned, more cautious about moving forward.

Larry Levitt:

Thanks, Cindy. Dean, let's switch to the other branch of government, Congress, which you've been very involved with for years. There's two sides to this coin. There's the rulemaking and then there's the statutory side as Cindy was talking about. From your work on The Hill over the years, what do you think this is going to do to legislating? Will Congress be successful in adding details and clearer delegation as Cindy laid out? Or, is that going to be hard for Congress to actually accomplish?

Dean Rosen:

Yeah. Well, thank you, and thanks again, Larry, and everyone for having me join. I think that's the fundamental question when it comes to legislation. As I think about the case, I think there are two sets

of questions. One is, what current laws and regulations on the books will be challenged going forward? The second question relating to what you asked specifically is, how will future legislation be impacted? I think, as both Kaye and Cindy's conversations raised, I think part one is, what about all these regulations that are already on the books? I know we'll probably get into some dialogue around the impact of those in healthcare, but to me, that's the first question. Where is their clear current delegation or clear specificity in the statute? With respect to your specific question about moving forward, I think it will make legislation more challenging potentially. There's no question, at least in some areas.

I remember, when I was a young staff person on The Hill about 120 years ago, I was in a committee executive session. We were marking up legislation and a senator offered an amendment that was very, very vague, and it passed the committee unanimously, and the senator said, was kind of congratulated for getting his amendment passed and he said, "We wouldn't have had any unanimity without ambiguity." I think that that's true often of how Congress does go about things. It's clearly a negotiating strategy. Let's leave this a little bit vague.

The specificity in some cases to your question will, I think, make it harder. I think it's also going to pose pragmatic challenges for some of the things that Cindy commented on, which is just ... we're going to have courts who are now sitting and making judgments, but you're going to have Congress a lot of the time where they're not just trying to punt for political reasons, but they're legitimately punting because they don't know the answer and they won't know the answer until stakeholders weigh in in a regulatory process that's more specific.

I think there will be some political challenges to getting agreement because of the specificity requirements that are clearly going to emanate from the case. I think there will be some pragmatic challenges in just these members of Congress who are not detailed experts on things like actuarial value or other things in the future writing the regulations.

Last thing I'll say is, I do think that it will put a premium to me on bipartisan legislation or legislation where we have one side that has a bigger majority, things we haven't seen very much in the last couple of congresses. We're at a 51 49 Senate right now and one of the closest House majorities in history, for example. And so, if you're going to go about legislating in the future and you need to get to some level of specificity, it will be more likely, I think, to occur where there's more general agreement about direction and where the agencies are involved, as Cindy was in her past job, in providing technical assistance directly to the legislation as it's being written. There'll be a priority, I think, on those areas. A lot to be seen, but I think as your question implies in some areas, particularly around challenging, more partisan, more technical areas, I think there will be more difficulty legislating in the future.

Larry Levitt:

Dean, let me just ask a quick follow up. Some of these areas are very complicated. They're technically complicated, like defining actuarially sound rates for Medicaid managed care plans. But then, they're politically complicated as well with lots of stakeholders involved as you suggested. How do you see the role of congressional staff potentially changing in this kind of environment as well? The members of Congress are the ones who are out front, but we do know that staff play a big role behind the scenes working out these details.

Dean Rosen:

Yeah. No, I think there's already been some preliminary conversations among some of the folks that I talked to all the time about, well, do we need to hire a different kind of staff person? Do we need to provide some additional budget for maybe a different kind of advisory? As you know, and others who've worked on Capitol Hill, staff people have a lot of support already. They have technical support from legal experts called legislative counsel that help with the actual drafting. They have expertise and input from folks like the joint tax committee or Congressional budget office to help refine legislation.

I think, to your follow-up, it could put more of an emphasis on having staff, on hiring staff, on looking at staff that bring that kind of additional expertise, or at least are able to bring in technical guidance from agency experts, again, like Cindy was or legal experts internally, and it could also put more, I've seen some articles on this too, it could also put more pressure on outside or importance on outside advocates and lobbyists like me and others to provide those kinds of things as they're seeking legislation or changes to legislation.

Larry Levitt:

Right. Laurie, let me bring you in. One area where we've already seen the lack of the Chevron deference already be implicated in cases is in reproductive health and family planning, in particular and non-discrimination in healthcare. We talk a little bit about what these cases are and where you see this playing out in particular around reproductive health access.

Laurie Sobel:

Sure. Thanks Larry. I think, to Dean's point, Title X is one of the examples where the language is ambiguous because that's what was able to get past. This section in Title X, that is always sort of back and ... well, historically, this language has been interpreted to include, let me say what the language is. Section 1008, which is definitely ambiguous, is that no federal funding appropriated under the program, which is again, Title X, The Federal Family Planning Program, shall be used in a program where abortion is a method of family planning. And so, throughout the history of the program, this language has been interpreted in regulations to include non-directive counseling and referral for abortion, except under the Reagan administration and under the Trump administration.

The Reagan administration regulations, which prohibited the counseling and the referrals, was actually litigated all the way to the Supreme Court in a case called Rust v. Sullivan. The Supreme Court ruled under Chevron that that section of the statute was ambiguous and the court deferred to the agency's interpretation. The question today is, well, the Robert decision said, well, we're going to not re-litigate everything that has already been litigated, but it was the opposite of what the Biden administration regulations are now, which require the counseling and referrals to be done under Title X. That was upheld by the court as an acceptable reading.

This is playing out right now in litigation that's ongoing. The Biden administration, which requires the counseling and the referrals, has taken away funding from Oklahoma and Tennessee saying, "You're not willing to do this." The states are actually the grantees under the program and the state says, "We're not going to provide this type of services. We're not going to provide counseling and we're not going to provide referrals to people who ask for abortion services."

It's played out differently in both of those cases. In Oklahoma, the court said, "You took this money knowing what the rules were, so sorry, Loper Bright doesn't change that." Last week in the Sixth Circuit, there was a robust discussion about whether Loper Bright changes this and whether this should be re-litigated. Tennessee is arguing, "Well, this is not a reasonable reading and this is not the best reading," which is really what a court would substitute their reading of this for the agency's reading, and so the court should decide what the best reading is. And so, this is one of those cases where it's very unclear whether the underlying regulations will be re-litigated, even though they were litigated under the Reagan administration regulations.

With regard to 1557, again, this is another area. 1557 is of the Affordable Care Act, bars discrimination based upon age, disability, race, national origin, color or sex by any healthcare program or activity that receives federal funding. Every one of those terms needs some defining, especially the last part, by any healthcare program or activity. What does that mean in terms of funding? Is it anybody who gets any federal money? How broad is that? This is another area where regulations have changed from each administration. The Biden administration has issued regulations that include sexual orientation and gender identity in the definition of sex, which is now being challenged. Most recently, there's been a flurry of activity that has been citing Loper Bright, and right now, there's a nationwide injunction now in place blocking the Biden administration's regulation defining sex to include gender identity. Then, just going to mention medication abortion, but we can hold that if you want to hold that.

Larry Levitt:

Yeah, why don't we come back to that? I want to pick up on something Laurie talked about, which is these cases where we see regulations flipping back and forth from administration to administration, whether it's 1557 non-discrimination rules or family planning funding and the rules surrounding that. We think of Chevron or overturning Chevron as something that's been pushed by industry to sort of reduce federal regulation and reduce the power of agencies. But this could play in both directions with different administrations. Cindy, talk a little bit, particularly in Medicaid. We've seen democratic administrations try to be active in using regulatory authority to make changes in Medicaid, but we've seen conservative administrations try to make changes as well. How do you see that playing out here?

Cindy Mann:

I think it partly goes back to the discretion question that I touched upon earlier, and whether the statute really gives the agency the authority to do that, and whether that interpretation is reasonable. To the extent that there's discretion and expertise and an agency can lay that out clearly and thoughtfully and reasonably, you could have switching back and forth. But I think the Loper Bright decision is very clear that when agencies go back and forth in their determination, that there will be much less deference to their interpretation of what the law requires, because the law hasn't changed back and forth. I do think those situations are more vulnerable. That being said, going back to what Kaye said, "Then what standard do you apply?" Because as Laurie said, the words don't jump out at your page. I think the point made is really right, that there's legislation that's done where the Congress not only cannot anticipate all of the nuances, so wants an agency to fill in the details, but doesn't want to fill in the details and can't get political agreement about the details.

One other issue I just want to flag that comes up in Medicaid, which also presents conundrums potentially for those who are writing statutes, is there are federal standards in federal. It's a federalism program. States have lots of discretion to do things, but subject to certain national standards. It's a mix. What happens when the agency promulgates regulations about those national standards, which of course it will do from time to time, and then different states litigate it in with different judges. Maybe the issue will rise back to the Supreme Court and they'll adjudicate it to the nation as a whole. But what you can well see is this notion of patchwork of decisions that are very different and what then happens to what Congress wanted to have happen very clearly, which is that there will be some national standards that undergird the discretion that states have.

Larry Levitt:

We have a lot of questions, and I want to get to them. I had a number of questions about what is the scope here. We've talked a lot about formal rulemaking, where there's a whole process for issuing rules, determining statutory authority, responding to comments from the public, but there's a whole bunch of other things that federal agencies do. In Medicaid, there are approvals of waivers, which are not formal regulations. There are FAQs, there's guidance. We know under the ACA, it's driven me crazy, but there are hundreds, if not thousands of FAQs across several agencies that you have to sort through. Kaye, let me turn to you. Do those all fall under this non-deference to federal agencies as well? Can there be litigation over FAQs or guidance?

Kaye Pestaina:

Well, typically, we're talking about the agency's final word on a topic or an issue, so we tend to think about just final regulations as being the topic, and that's usually what it is. We certainly see courts look at some guidance and deem it similar to a final regulation, final word on something, so it's possible that some, we call it sub-regulatory guidance might also get some scrutiny. But I think there's also the argument that we might see agencies look to non-binding best practices, sub-regulatory advice in the absence as a more strategic way to get information out about a new requirement. There's some argument that you might see more sub-regulatory guidance, even though we've already seen a lot of it.

But no, courts can also look at guidance and deem it the final word and say, "We're not going to really give it any deference, certainly, but not even look at it." I am reminded of a recent case where they were looking at some new HIPAA rules with respect to tracking software, and they deem some guidance from HHS' Office of Civil Rights as the final word, and as binding, and basically said that the agency had gone beyond its authority to require regulated entities to comply with it. Yeah, I think we're going to see more sub-regulatory guidance and we might also see more deemed as a final rule.

Dean Rosen:

Larry, can I add things too? I think that the question in Kaye's comments triggered two things for me. One is, there's various different kinds of guidance. On the one hand, you may get CMS saying, "Here is some best practices for enrollment under Medicaid in the states." That's a lot of what we think about as guidance. I'm thinking about a number of things that I'm working on currently that other HHS sub-agencies have put out. I've seen the FDA basically come up with guidance that's really a regulatory scheme that's not just like, "Hey, you may want to think about this," or "This is an interpretation, but it's

really fundamentally, in some cases, changed the way that various different devices or drugs are delivered." I think to Kaye's point, there's going to very likely be challenges in the future because, again, this isn't self-actuating. There's going to be challenges in the future to a number of things that are guidance that rise to the level of what people feel are effectively regulations.

The second point I wanted to make on the APA, and I think there's been a lot less coverage about this, but I think it's important it goes hand in hand with that. There was another decision this term in July or late June in a case called Corner Post, which I think you almost have to read, at least with respect to APA challenges in the future as going hand in hand, which the Supreme Court said something that I think was not dictated as much as we knew where Chevron was going because of past rulings.

But in Corner Post, they basically said that the effective date, the statute of limitations effectively for an APA case was not six years from a final regulation but six years from the date that it had an impact on an injured plaintiff. Meaning, back to my point originally, that you could have regulations that have been on the books for years and years and years, but when they're applied to a new class or a new plaintiff entity, they could be challenged anew. I think that's an important point, not in the broader scope of guidance, but on the APA challenges that I think we will see specifically that you have to, I think, read Corner Post hand in hand with Loper Bright.

Larry Levitt:

Yeah. That opens up just an enormous number of regulations from many, many years ago to potential legal challenge. Laurie, let me bring you back in. Dean mentioned a couple of things here. One is Corner Post and this issue of reopening decisions from quite a while ago, and then second was the FDA. I want to come back to medication abortion, which you were starting to talk about. That's being litigated now, the FDA's approval medication abortion at various times. Was Chevron implicated in that challenge or could it now be implicated particularly along with Corner Post in a new challenge?

Laurie Sobel:

Well, I think to Dean's point, Corner Post definitely opens up a new set of challenges, particularly for the approval of Mifepristone, which was approved in the year 2000. As we know, the plaintiffs that litigated most recently were a newly-formed group, and so they could claim that their injury was new, much like in Corner Post, whether Loper Bright opens the door to the court second-guessing the FDA's decision approving drugs based upon scientific evidence is not really quite clear. The court noted that agency fact-finding and policymaking decisions would be considered under substantial evidence and arbitrary and capricious standard. But it's possible that a future court would entertain potentially conflicting evidence that's brought by plaintiffs to say, "Well, the FDA didn't quite look at this or that."

Decision approving a drug is a final agency decision. I think, in the past, the court has never overturned a drug decision, but I think we might see ... there's challenges ongoing around Mifepristone and whether the court delves into the evidence that the FDA used to base their decision to approve Mifepristone and change the rules around its dispensing is yet to be seen. It's an open question, I think.

Larry Levitt:

Cindy, we've had a number of questions, and several of you have raised this issue of states and how they relate to all this and Medicaid's a perfect example as a federalism program. A lot of what happens in

CMS' relationship with states are, again, not these formal regulations, so I'm thinking of Medicaid waivers, for example, and one that's been very contentious, that was very contentious under the Trump administration and was certainly litigated as work requirements under Medicaid, and there have been renewed proposals to do that. How do you see this playing out with these Medicaid waivers? You mentioned the possibility of potentially different structures or rules that could apply in different parts of the country as litigation occurs in different regions.

Cindy Mann:

On Medicaid waivers, in particular, in the work requirement waivers, which is and was a hot issue, and again, continues to be litigated, the courts have pretty much not relied on Chevron as they've reviewed the challenges to those waivers. They have gone right in and do what the Supreme Court said you should do. They have not found the statute ambiguous, let's put it that way. They found the statute as saying what the primary objectives of the Medicaid program were, and then relied on the APA to say, "Well, the agency needs to grapple with that and needs to have a thoughtful way of explaining how this waiver in fact promotes the objectives of the statute." I think we'll continue to see a lot of contention and litigation around waivers, but I think Chevron hasn't directly affected that because for the most part, Chevron really has been applied to situations of notice and comment when there's a regulation with notice and comment, not so much sub-regulatory guidance, and it hasn't come up as much in the waiver world.

But I do want to just say something about states because states are different things depending upon who we're talking about. There's governors and there's legislators, and then there's state Medicaid programs and the leadership in those programs. If there's one thing I think that state Medicaid programs want, and they have a long wish list and it's not uniform, but what's pretty uniform is they want to know what the rules are. They want to have some certainty. They want to be able to promulgate their rules, they want to be able to have contracts with their health plans, they want to be able to set up their IT system so that it effectuates what the rules are. For all sorts of reasons, they need some certainty in this, and I think this Loper Bright and potentially its progeny really create a lot of uncertainty. The Corner Post case also really adds to that as people have identified, because litigation can just happen if a new entity comes on the scene and says, "Oh, I'm here," and I think that regulation that you promulgated 15 years ago is a real problem.

Larry Levitt:

We've also had a lot of questions about what this means for judges. Dean talked about the expertise that Congress may need in writing statutes, but judges, the whole point here is judges may exercise their own judgments and not necessarily defer to federal agencies where statutes are unclear or ambiguous. Kaye, as far as I know, I don't think we have any current litigators on the call, but Kaye, I know one area that's been very complex in litigation is ERISA, for example. Incredibly, not that long a statute, but incredibly complicated. How do you think about this from what you've seen in previous cases? How do you think about this need for judges to now understand potentially very, very complicated areas of regulation?

Kaye Pestaina:

Yeah, it's funny you mentioned judges and ERISA. I think a lot of judges often joke, it's like if you're the lowest on the totem pole and they give you the ERISA case, because judges don't want to deal with that statute. It's complicated and lower courts have to take the cases in front of them, and to the extent that very technical issues require more their independent judgment and more time. Even judges might be overwhelmed with what they have to address, and they may not be able to do a, we call it de novo review for every type of thing that they see, particularly ERISA claims issues for which actually today you have deference to the insurer's decision often. But for judges and litigants, well, we are already starting to see more ERISA litigation, and so that's a continuation whether we had Loper Bright or not.

We're starting to see folks ask questions about who's a fiduciary on the healthcare side. Things like, what is full and fair review, that's an ERISA term for claims and appeals review. What about the use of artificial intelligence and standards with respect to prior authorization for our behavioral help? We're already in it with ERISA and judges are not going to be able to ignore it, and so we're going to see, for better or for worse, a lot more digging in on things that may be regulated entities in the ERISA space have been used to not having to deal with. Even judges won't be able to ignore it.

Larry Levitt:

Dean, we've had a number of questions about the effect of CMS regulatory actions, particularly in Medicare on industry, whether it's hospital payment, physician payment, now, the Medicare drug price negotiation process. Do you see this as a potential opening for industry to fight back against CMS decisions, whether it's hospitals or drug companies around the adequacy of the negotiated prices or the hospital prices?

Dean Rosen:

Yeah. I certainly think that it provides a potential for some of the cases that have been brought on constitutional grounds in the drug pricing area to maybe be thought about being re-litigated on these grounds or future cases that might argue an APA violation. We just saw one with respect to some of the risk scores in the Medicare Advantage area that was successful, that maybe they add a Loper Bright deference claim to it or cases that may have been brought. I think, Kaye, you've referenced this a little bit earlier on unconstitutional deference of authority or delegation of authority. I think you may see this added, and I would almost bring Cindy into the discussion too, I know as the Medicaid side and Laurie and others, but I think a lot of the Medicare payment rules, there is some level of actual authority, there's some non-reviewability of those determinations.

I think this is a great example of the pragmatic places too, which is you write the Medicare Physician Payment Rules a decade ago, and there's, by definition, supposed to take into consideration changes in the current market, changes in things like margins and other things. I think, in the Medicare area, there may be specific payment areas, and again, we'll see, but there may be less challenges to specific rates, but there may be more challenges to things that involve coverage or where there's an intermingling of coverage and rates. I don't know. I think Kaye said earlier, there's not a new framework here, so this is a little bit like a statement as a Loper Bright as opposed to a specific roadmap, and I think we're all going to be following along this roadmap for the next several years and maybe several decades. But my sense is, and I'd invite some of the other expert panelists to comment here too, is that some of the strict

payment regulations under Medicare may be less challengeable for those reasons than some that mingle coverage or involve coverage or some of the Medicaid areas that Cindy mentioned.

Larry Levitt:

Dean, let me stay with you for a sec, because we also had a question about, is there a boilerplate language that Congress can now use to immunize statutes against challenges without the Chevron deference? You mentioned, for example, the Medicare payment rules, which in some cases have non-reviewability, have very specific delegation authority. Are you aware of discussions about how to develop language that will be more effective at making things immune to challenge?

Dean Rosen:

Yeah. I think in the very early stages of discussions, things like non-renewability, explicit delegation, delegation with parameters are all the kinds of things that I think will be as a rule of thumb included. I think the challenge becomes, again, we're talking a wide range of different kinds of even healthcare rules from FDA approvals here to Medicaid waiver approvals to Medicare rules, and those are all really, really different. I think it's going to be hard to come up with a single template or a number of things that the Legislative council and staff can just pull off the shelf and say, "We're good here." I think it's a good question. I think there will be some mechanisms that likely develop over time as you see Congress really trying to protect a legislation just as we've seen things like severability and other things being used as standard form. But I think, in some of these cases, there's such a diversity of potential laws and regulations that it's also going to be difficult.

Larry Levitt:

We're unfortunately coming to the end of our time, and we've touched on a lot of issues, I don't think we resolved anything. In fact, as I think all of you said, uncertainty is the word here. We don't know exactly what's to come. I wanted to just take a minute and give each of you to talk about ... well, you could talk about either, what you are most concerned about? What area of rulemaking or legislating you're most worried might be vulnerable here or what is you're potentially optimistic about, what opportunities this might open up. Cindy, maybe I'll start with you.

Cindy Mann:

Sure. Well, maybe jumping off a little bit the back and forth with you and Dean on the last question. Medicare is much more prescriptive, for example, in its statute than Medicaid. It's a national program that federalism concept is not a feature of the Medicare program. There are changes in our healthcare system that happen all the time that CMS has to be mindful of as it thinks about its rulemaking. One of the things that I think is most worrisome and maybe can be addressed by Congress, because you see it in some delegation provisions. I saw one recently with respect to the Social Security Administration, which is that empower the Secretary to be able to take into account not arbitrarily, not make things up, how things change over time.

When CMS first issued managed care regulations, managed care was very limited. There was no long-term care in managed care, and there was a thousand different issues that didn't exist. You have an

agency that is replete with real experts and that is constantly working with the program on the ground. We cannot ossify the program rules, so I'm worried about that and worried that we've got to really come. Regardless of political direction, we've got to come to some ability to have rules evolve and modernize as the world changes without Congress stepping in every five minutes to adjust its statutory pronouncements.

Larry Levitt:

Yeah. There's an irony here that in an effort to take away power from agencies and maybe create a more market-based approach to dealing with some of these problems, you lock regulations into a structure that may not be relevant anymore.

Cindy Mann:

That doesn't exist anymore, yeah. Yeah, exactly.

Larry Levitt:

Laurie, let me turn to you. What area of regulation do you think might be particularly vulnerable here?

Laurie Sobel:

I think the ACA is an interesting example with preventative services where Congress did delegate how preventative services were going to be ferret out to three different agencies, and that is currently being litigated, saying that that was unconstitutional the way it was delegated, and so right now, the Fifth Circuit has ruled that the delegation to USPSDF was not constitutional with regard to HRSA and ACIP, but it was okay, but now it's back at the district court. That litigation, I think, is going to inform potentially how much Congress can delegate. That was an example where they saw that the need for preventative services would evolve over time and that they would change. No one knew that we had COVID, things have changed. I'm watching that to see how that plays out, and I think there's instructions there on how much Congress might be able to delegate in the future.

Larry Levitt:

Interesting. Kaye?

Kaye Pestaina:

I guess I would ... my initial worries are around this very, very long list of regulations that have come out over the last decade to stand up the health insurance marketplaces from premium tax credit, eligibility to risk adjustment and new rules that come out annually, and to the extent that they might be vulnerable to challenge for the first time, that would upset a whole framework for access to coverage. But I should say something optimistic as we get to that end. Regulations are still going to be a tool for implementing the law, and they still have the force of law until overturned. But agencies also have enforcement responsibilities and enforcement tools that can also be used at the same time, and we may in fact see agencies more focused on using those enforcement tools to avoid some of the regulatory challenges that are ahead.

Larry Levitt:

Dean, you get the less word. You can be concerned or optimistic or both.

Dean Rosen:

Well, I'll do one of each, and then, with all these great questions, you may want to think about a sequel here given how much this is going to probably change the whole balance of power. I guess as somebody who's seen both sides of regulatory frameworks, I think that you mentioned before, Larry, that some of this is driven by corporate stakeholders or others. I think I view it as much as a conservative legal doctrine that's been emerging for a long time with a goal at least of re-balancing. I think there is a lot of areas that I see all the time of agency overreach, and I think that I view that as a positive. I think people will have to be more cautious, people have to be more careful, and there'll be, I think, a greater re-balancing of the three branches of government.

I think, generally, that's a positive thing for our constitutional democracy. With that comes what I'd say is the downside or what I'm concerned about, which is that that creates uncertainty about the future. I'll be interested to see how courts decide and what parameters they provide around things like congressional delegation and how much that solves and how much specificity there needs to be. Then, I guess, maybe just to conclude with where I think I'm most worried, and Cindy referenced this term, ossified, is I worry in areas where it may be. In such a divided country we have now, where people may challenge things so they think it's the right thing, they feel strongly about it in areas like public health, which we haven't talked a lot about today, where there's broad delegations of authority that have been provided under federal law, post-9/11 and other public health authorities.

We've certainly seen with COVID and other things where there may be challenges and the agencies may not be able to move quickly enough or accurately enough or timely enough to make critical changes or to protect citizens. We've talked a lot about Congress, but this gives courts a whole new role. I've never clerked before, but I can't imagine that the clerks are experts at all these different areas that are going to come before them in the federal law. That, sometimes need for speed and lack of expertise that the courts have, not just the congressional staff, is something that I'm going to be watching, and I think, right now, gives me some initial concern. Hope, but concern.

Larry Levitt:

Well, I think that's a perfect place to end it. Thank you all for a terrific discussion. I agree with Dean, that we always scratch the surface and given the uncertainty here and the scope that we're dealing with, we may very well need to return to this for a sequel. Thanks, again. I learned some things here, which is always a good sign. Thanks to the audience for being with us as well. Look for a recording of this later on today. Thanks so much.