
# Ep. 1: CDC Guidance, HHS Appointments, ACA Prospects

**April 6, 2021**

**Matt Hittle:** Hello, and welcome to the inaugural edition of *OnAir: Health Care*, a new health care podcast by Akin Gump. Health care policy is a concern for patients, health care providers, policy makers, employers and, of course, voters, and all for different yet interrelated reasons. Interest in health care is even more acute amidst the pandemic, which has tragically claimed over half a million American lives. It's never been more important for people inside and outside of the beltway to understand the relationships between cutting-edge medical science and wonky health policy, and how they square with the realities of bare-knuckle Washington politics. Hi, I'm Matt Hittle, a senior policy advisor at Akin Gump.

**Dr. Mario Ramirez:** And I'm Dr. Mario Ramirez, a consultant with Akin Gump and a practicing emergency physician. We're your hosts for this inaugural episode of *OnAir: Health Care*. In each episode, Akin Gump will bring you seasoned policy experts to savvy political operatives and practicing clinicians to help you make some sense of the latest health care issues and anticipate what's around the corner.

But before we jump in, we want to introduce ourselves and our guest. I'm Mario Ramirez. I'm a consultant with Akin Gump, and in 2014 I had the honor of serving in the Obama administration as a White House fellow. In that capacity, I served as a senior advisor to the secretary on issues related to the Ebola outbreak of 2014 and 2015. In 2015, I served as the acting director for Pandemic and Emerging Threats in the Office of Global Affairs. At the end of my federal service, I went back to practicing emergency medicine. In addition to my work with Akin Gump, I'm the managing director at Opportunity Labs, a nonprofit consultancy based out of Asbury Park, New Jersey.

**Matt Hittle:** And I'm Matt Hittle. I'm a senior policy advisor here at Akin Gump. Before arriving at Akin, I spent two years at the Centers for Medicare and Medicaid Services as a senior advisor to the administrator. And before that, I worked in the House of Representatives as the legislative director to then-Representative and now Governor Kristi Noem, a member of the Ways and Means Committee. Then I started my career at Ways and Means working on a variety of issues in the Oversight Subcommittee.

**Dr. Mario Ramirez:** Excellent. And with that, let's welcome our guest, Kelly Cleary.

**Kelly Cleary:** Hi, Mario. Hi, Matt. Great to be with you, and congratulations on your inaugural podcast. I'm already a fan.

**Matt Hittle:** The first subscriber.

**Dr. Mario Ramirez:** Thanks for joining us.

**Kelly Cleary:** I'm glad to be here. I'm a partner at Akin Gump's health care and life sciences practice. And what I do, in a nutshell, is help our health industry clients understand and navigate the complex and constantly changing body of health care regulations and also the processes for influencing those regulations. I've spent most of my legal career here at Akin Gump, except for the three years when I had the privilege of serving at the Department of Health and Human Services as the Chief Legal Officer for CMS.

While I was at HHS, I got to advise the CMS Administrator—Matt's boss at the time—and other HHS leaders on legal matters that arose during the regulatory process, including the very frequent lawsuits challenging the agency's regulations. I also was involved in program integrity matters as well.

**Dr. Mario Ramirez:** Great. We're so glad you could join us, Kelly. So now that you know who we are, let's dive in. Here at *OnAir: Health Care*, we're going to cover a wide variety of topics from medical science to the administration's regulatory agenda to what's happening in Congress. As our listeners undoubtedly know, Congress just passed the massive $1.9 trillion American Rescue Plan, almost entirely along party lines with one Democrat voting against it in the House. We at Akin Gump monitored the legislation closely as it navigated Congress, and we provided a robust write-up on our website. We'll add the link to our description. [see here]

**Matt Hittle:** And Mario, as Congress takes a breather after that intense budget reconciliation process, we're focusing our inaugural episode of *OnAir: Health Car*e on all things regulatory. That's right, we're going deep inside the bowels of the Hubert Humphrey Building. So we're starting today with a segment we call, "The Doctor Is In," featuring Akin Gump's resident physician, Dr. Mario Ramirez.

[*Hi folks, Matt here. I'm recording this note a few days after we recorded the first episode of the podcast. As you know, CDC's COVID guidance can change quickly. In fact, it just did. This episode reflects the guidance for vaccinated people that was available at the time of recording, but in the intervening days, CDC issued new guidance. In our next episode, Dr. Ramirez will discuss that new guidance, how it squares with the guidance he talks about in this episode, and the implications for travelers, as well as employers and employees as workplaces reopen. Be sure to tune in, but for now, we'll continue on. Back to the podcast.*]

Now, Mario, all eyes have been squarely on the CDC for the last year. And in recent weeks, as COVID-19 vaccines have become increasingly available to the general public, everyone has been eagerly awaiting any and all information related to CDC guidance for vaccinated people. So CDC just recently unveiled new guidance, a couple of weeks ago, related to what fully vaccinated Americans

can and can't do. Mario, before our vaccinated listeners run off to the bar, can you give them a brief overview of the guidance?

**Dr. Mario Ramirez:** Certainly, Matt. So about a week and a half ago, the CDC released their first set of public health guidance documents for fully vaccinated persons. And in some ways, it was the first look at what the country will look like as we start to open back up again. Now to begin with, I'd like to make sure that everyone knows that these recommendations only apply to persons who are two weeks after they've received their second dose of the Pfizer or Moderna shots or two weeks after their single-dose Johnson & Johnson vaccine. The recommendations do not apply to people who have only completed a single shot of the two-vaccine series or who haven't allowed enough time to pass since completing their vaccine series.

Now, for fully vaccinated individuals, the guidance says that fully vaccinated persons can visit with other vaccinated persons without wearing masks or physical distancing. It also says that they can visit with unvaccinated persons who are low risk for developing severe COVID-19, indoors without wearing masks and without distancing, and that they can refrain from quarantine if they're around an infected person but remain asymptomatic themselves.

They also recommend continuing to avoid large gatherings and continuing to avoid travel, unfortunately. When visiting with groups of unvaccinated persons, they recommend that all parties continue to wear masks and try to gather outdoors or in well-ventilated areas.

**Matt Hittle:** Well, it sounds like the bottom line here, Mario, is that our vaccinated listeners ought not to go to the bar right now. I know some have been disappointed as they have waited a year with the expectation that a vaccine would result in the ability to revert back to their pre-pandemic behavior. What you're telling me is it sounds like this is not the case. Dig a little deeper for our listeners and give us a sense for the good and the bad and any limitations.

**Dr. Mario Ramirez:** Sure, Matt. We're seeing significant variability at the state and district level about how different jurisdictions are choosing to implement this guidance. There are clearly some states that have felt and recommended that vaccinated persons can fully reenter society with little caution. And there are others of us who really feel like the better part of caution is to go slowly here. I think these guidelines are a good first step, but there are significant holes that I'm sure listeners are more aware of.

Now, specifically these guidelines don't address children and they don't address whether children who are not vaccinated can mix with vaccinated persons unmasked. As a whole, children are at lower risk for serious disease, but we know that there are some children with underlying conditions who are certainly at higher risk for complications from COVID-19. These guidelines don't specifically address those kids. Second, the guidelines also don't address travel or gyms or places of worship or other congregate settings that are part of our normal everyday lives, other than to say that a lot of these areas should continue to be avoided.

Now it's clear that pandemic fatigue is setting in, right? And even if the answer is to say that more time is needed, I think it would have been helpful for these

guidelines to really let the public know when a new update would be forthcoming, to give some expectations.

And then lastly, the guidelines say that if you have an exposure that you don't necessarily need to quarantine if you don't develop symptoms. And previously, they had said that that policy was valid for about three months after vaccination. These guidelines don't specifically extend that window, and it's unclear how long that policy is going to stay in place or how long protection is afforded after vaccination. Pretty soon, we're going to get to the point when those earliest vaccination recipients are more than three months out from their shots, and we need some idea of whether those folks need to continue to quarantine or re-quarantine if they have an exposure.

**Matt Hittle:** It's really hard to please all the people all the time. Is CDC being too cautious though? Where is the science here?

**Dr. Mario Ramirez:** Well, I think it's quite mixed, Matt. I will say this, as somebody who has both been on the clinical side of health care, but has also, as you said, been in the bowels of the Hubert Humphrey Building when an epidemic is raging, what I would say is that we've got to remember that this is uncharted territory for most. The last time that we had a pandemic this serious was 1918. And we didn't really even have a full understanding of the scope and scale of that pandemic until many years later.

One of the things that I came away with so impressed after the Ebola outbreak of 2014 was just how difficult it can be to make sense of all the data that's coming in at once during one of these things. It can be extremely hard to make policies around some of these topics in real time as you're trying to gather and make sense of what the data says.

Now, I think the scientists who are working on this pandemic get fresh information every day. And every piece of the puzzle changes the way that we think about this outbreak. So I think some patience is certainly in order. But at the same time, we have to acknowledge, as I said, that pandemic fatigue is very real. And we're losing the ability to continue to realistically ask people to shelter in place for much longer. Now, the consequences of a wrong public health decision can be massive with lives on the line. But as many have said, it's both lives and people's livelihoods. And policymakers have the difficult task of trying to balance those things, which sometimes feel like they're in opposition.

**Matt Hittle:** Yeah. Having worked at CMS during part of the pandemic, I can attest to the hardworking folks at CDC who are bringing in reams of information every day and trying to make educated decisions based on it. I know that is an almost impossible job. But to your point about lives and livelihoods, some would call it lives versus livelihoods. What would you respond to that?

**Dr. Mario Ramirez:** Well, Matt, I think that's the way that this is often framed, which is unfortunate because I think as a health professional, I personally disagree with that characterization. I think we can have both, but it takes thoughtful policy and probably a bit of continuing sacrifice on the part of all to really try and achieve both of these things. We can reopen our schools and our businesses and our places of recreation, but it takes a combination of significant vaccine uptake from the population, as well as continuing observation and protective measures, until we can really drive case counts down to much lower levels. If we open our

society up before enough people are vaccinated, there is significant risk for this thing to take back off again.

Now, I think we can certainly achieve all of these goals, but it's not going to be overnight. I think if people are willing to wear masks and keeps some social distance while we continue to vaccinate people, I'm confident that we can save many lives while we continue to push towards economic recovery.

**Matt Hittle:** Mario, thanks for that in-depth analysis of the CDC guidance. But CDC is only one of the several agencies important to our listeners. I am sure there are many questions brewing in their minds about what's going on inside that beautiful Brutalist box at the base of Capitol Hill, the Hubert Humphrey Building—affectionately called the ugliest building in Washington, and headquarters of the Department of Health and Human Services, one of the most influential Cabinet agencies.

**Dr. Mario Ramirez:** Absolutely, Matt. Let's talk about the goings-on in the Humphrey Building. For that, we turn to a segment we call, “Bureaucracy Brief.” With HHS Secretary Xavier Becerra confirmed and CMS Administrator Chiquita Brooks-LaSure only just at the start of her confirmation, we're seeing political appointees enter HHS at a pace that's slower than I think many of us had anticipated. The administration pumped out a flurry of executive actions in recent weeks, many related to the pandemic and other health care issues. And now, the agency has a sweeping $1.9 trillion law to implement. And I think the question is: Who in the Humphrey Building is doing this implementation?

**Matt Hittle:** Mario, that is a great question. Many of the offices in which you and I and Kelly worked in previous administrations are currently sitting empty. The folks are coming on slowly. Now thankfully, during the transition, the Biden-Harris administration installed very skilled career staff as acting leaders. Until Secretary Becerra was confirmed within the last week, Norris Cochran served as acting secretary. His day job is a senior leader in the Office of the Assistant Secretary for Financial Resources. And until Chiquita Brooks-LaSure is confirmed, Acting CMS Administrator is Liz Richter. And she's normally a senior leader in the CMS Center for Medicare. But key political positions remain unfilled, and like you said, Mario, that could threaten to hamper the administration's designs on quick, aggressive regulatory action.

**Dr. Mario Ramirez:** So what kind of positions are we talking about here, Matt?

**Matt Hittle:** You know this as well as I do: The media and the DC rumor mill focus primarily on high-profile Senate-confirmed jobs—Secretary, Administrator and others. These positions are clearly important. But there is a bevy of mid-level political appointees who work closely with career staff and they really drive the administration's priorities on a day-to-day basis. And to date, only two positions at CMS—the director of the Office of Legislation and the director of the Innovation Center—have been filled. These are not Senate-confirmed positions, but they are very influential.

**Dr. Mario Ramirez:** Now why are these non-Senate-confirmed positions so important?

**Matt Hittle:** Well, they're the day-to-day policymakers, the people who make the dozens of little decisions that need to be made in the development of a regulation—an

Innovation Center demonstration, even the wording of a press release that signals something to the public. All of those decisions that aren't necessarily individually momentous, but they're ultimately reflected in what comes out of the door of the administration and even the policy options that are put on the Administrator's desk or the Deputy Secretary's desk and ultimately, the Secretary's desk.

For example, the CMS Administrator doesn't often find herself haggling with agency lawyers like Kelly over arcane provisions buried thousands of pages inside of a prospective payment system rule. But that's the job of the Director for the Center for Medicare, a job that's currently unfilled even as CMS is working on many of these important payment rules. And it's important to remember that while those principals—the Administrator and the Secretary—make the final call, a lot of the initial policy development occurs at a lower level. And in some cases, principals are making decisions based on a suite of options that's prepared for them by just the kind of people we're talking about. This is especially true in areas in which the principal just doesn't have a lot of experience.

HHS and CMS are gargantuan agencies with vast reach. A leader cannot be expected to be expert in every area. So a leader with expertise in say, Medicare, might lean more on aides when they're making a decision about Medicaid.

**Dr. Mario Ramirez:** So what are the implications here? How should stakeholders try to navigate this situation?

**Matt Hittle:** The first key is to understand everybody in town is trying to get ahold of the few political appointees who are in the agencies, and to be patient if it takes some time to set up a meeting. Not only are they getting up to speed inside of a massive agency with many moving pieces and new people, but in most cases, they're doing it remotely with a laptop and a phone, with questionable childcare, in the middle of a pandemic. So we're facing a very unique set of circumstances here. So I think it's important to give folks a little grace. But it's also important that you don't forget about the career staff.

**Dr. Mario Ramirez:** So, Matt, tell us about that. Who are the career staff and why are they important?

**Matt Hittle:** Well, Mario, they're the bureaucrats. They're the people who work at the agencies no matter who is in the White House. They were at their desks January 19th, and they're at their desks January 21st—it doesn't matter who sits in the Oval Office. Listen, it's totally appropriate to think of the Administrator or the Secretary as the decision makers, the people who speak for the President, but you cannot overlook those career bureaucrats. They are experts. They have institutional memory that spans administrations, and they do have more power than one might think. They know the ins and outs of the various programs better than anyone. And they are key in the policymaking process. They're the ones who helped the non-Senate-confirmed political appointees develop the policy options that will later make it onto the Administrator's desk or the Secretary's desk.

So, while we wait for political appointees to be named, it's totally appropriate, and I think a great idea, for stakeholders to use this time to really build relationships with the career staff, so they can have a solid rapport with them, and so the staff can have a solid base of knowledge when those politicals come on board.

**Dr. Mario Ramirez:** Thanks, Matt, for that very informative peek inside the Humphrey Building. I know we're all very curious to see how this unfolds over the next few weeks. Let's stick with this theme for our final segment that we're calling, “The Regulatory Roundup.” Now in The Regulatory Roundup, we dive into the complex world of health care regulation. To help guide us today, we're joined by our friend and one of Akin Gump's world-class regulatory attorneys, Kelly Cleary.

**Kelly Cleary:** Thanks, Mario. You're too kind. Let's get to it.

**Matt Hittle:** Kelly, it is a treat to feature you and your expertise on our inaugural podcast. We're really, really excited you're here. I'm going to defer to Mario, because I know we could swap stories about our respective tours at HHS all day long, but I really think that our listeners are interested in hearing your perspective on the Biden-Harris regulatory environment.

**Dr. Mario Ramirez:** So, Kelly, let's start with one of the Biden-Harris administration's key priorities, the Affordable Care Act. President Biden has said that, "It is the policy of my administration to protect and strengthen Medicaid and the ACA, and to make high-quality health care accessible and affordable for every American." Now, what actions do you think that HHS is going to take to protect and strengthen the ACA?

**Kelly Cleary:** As I'm sure you'll recall, when the ACA passed many states decided that they didn't want to operate their own exchanges, so the federal government stepped up to do it. And because the federal government is running these exchanges, and that's what HealthCare.gov is, it gets to set the rules like when enrollment periods open and close. So one thing we certainly expected the Biden-Harris administration to do is something they have done, which is open a Special Enrollment Period.

So back in February, President Biden announced that there was going to be a new Special Enrollment Period opening, citing the increased need for coverage during the economic and health crisis that we're currently facing. And then earlier this week, he announced that he was going to further extend the Special Enrollment Period through August the 15th. And this is so that people who may have decided not to purchase coverage before—maybe they were priced out of the coverage before—can take advantage of the new temporary tax credits that Congress authorized in the most recent aid package.

Beyond that, I think we'll see more federal dollars flowing to things like advertising and outreach campaigns. I think we're also probably going to see some changes to the ACA regulations. Now, these are typically done in an annual rulemaking. So I don't know that there is opportunity to make too many major changes in the final rule that's expected to come out later this spring, because it was proposed in the previous administration. I think inside the Humphrey Building folks are still getting in place and ramping up, and I would expect to see maybe bigger changes in the rule that comes out next year.

The final thing I'll mention, just because I think it's a fascinating topic, is the topic of cost-sharing reductions, or CSRs. This is something that the Biden-Harris administration is going to have to grapple with. Just as a refresher, CSRs are something that the ACA provided for on top of premium tax credits. So, under the

CSR requirement, plans have to further subsidize cost sharing for individuals with incomes between zero and 250% of the poverty level. And plans do this and the requirement is that HHS is supposed to reimburse plans for the cost of these subsidies.

And we could really devote an entire podcast series to what happened with the cost-sharing reductions, Matt and Mario, so just keep that in mind. But basically, I'll fast-forward through the saga to the part where the government is not paying these subsidies now. There is still a court battle ongoing over whether the government needs to pay plans for cost-sharing reductions—damages, essentially, at this point—in perpetuity or until Congress decides to appropriate money that would allow HHS to start paying plans again. This debate brings up "silver loading," which is something the plans did to help offset the costs of the cost-sharing reductions that they by law had to offer to certain individuals.

So, anyway, it's still playing out in the courts and now it is the Biden-Harris administration who are parties to the litigation. They're going to have to decide what to do there. So I don't really have any good predictions, but it's definitely going to be something that I'm watching.

**Dr. Mario Ramirez:** It's super interesting, Kelly. Now, of course, we know that you can't talk about the ACA without talking about Medicaid. What do you think we'll see there?

**Kelly Cleary:** So, Medicaid will continue to be a big part of the overall coverage strategy. It was a big part of the ACA. As we know, there are still a number of states that have decided not to fully expand their Medicaid programs to the full extent that the ACA allows. And as we also know, according to the Supreme Court, the federal government can't force them to do it. That dynamic really can't change. But against that backdrop, I think we can expect to see a few things from this new administration.

First, I would expect them to do a rewrite of the policies for approving state requests for demonstrations, and really take aim at walking back some of the approvals of things like work requirements, which they've already done for Arkansas and New Hampshire demonstrations, and other demonstration features that were approved in the prior administration like healthy behavior incentive programs, and some other commercial-like features that were being built into state Medicaid programs and built-in in such a way that non-compliance with those programs came with consequences, and in some instances led to a reduction or a loss in coverage. So I think they're going to reverse some of those policies that they believe had an adverse effect on coverage and access to care.

I also think they could use the demonstration authority in a way to incentivize states to further enhance or expand coverage. The demonstration authority itself is very, very broad. It allows states to change a lot of the rules of the game. So there is a default set of rules, and then this waiver authority allowed states to make changes to those rules and try to provide more modern Medicaid programs that can be customized to the unique needs in their states. Another big part of that authority is the expenditure authority. It allows the government to approve of Medicaid expenditures that otherwise would not be allowed under traditional Medicaid rules, including covering people that that might not otherwise be covered. So there is a lot of room there to get creative, and I have to imagine that

with that tool at their disposal, they're going to be using that to try to bolster coverage in some states.

**Dr. Mario Ramirez:** Super interesting. Thanks, Kelly. President Trump proposed some significant drug pricing policies during his term. There was a lot of talk about drug prices during his administration, but he waited to move some of his more significant drug pricing policies out until the very end of the administration, like the “most favored nation” model and the rebate rule. What do you think the status of these rules is, and do you think the Biden-Harris administration is going to carry them forward?

**Kelly Cleary:** That's a great question. And this is one of those instances where the rules around procedure, which will put most people to sleep, they're very wonky but fascinating to me. If you break the rules of procedure, you could have the best idea in the world and it might not see the light of day, because a court will tell you to go back and start over. That's what happened with at least one of these rules. I'll start with the most favored nation model.

As you said, this rule was talked about for a very long time. There was an advance notice of proposed rulemaking, lots of work went into it, and then the last administration waited until November 27th to publish the rule. And they did it through what's called an interim final rule. So instead of doing a formal notice of proposed rulemaking and collecting more comments, they skipped that step and went straight to an interim final rule, which under the law you're not supposed to do unless you can articulate good cause for forgoing public notice and comment. What the rule does, or would do, is it would effectively create a new reimbursement system for the 50 highest-cost Medicare Part B drugs. And as the title of the model suggests, it would look at prices paid in other developed countries as a benchmark to set what price the Medicare program would pay.

As soon as this came out, interested parties across the country filed lawsuits seeking to stop the rule from taking effect. Several key players in the pharmaceutical industry filed lawsuits, in four different jurisdictions. The arguments they raised were similar. They all included violations of the Administrative Procedure Act; that's the law that tells the agency how they have to go about issuing their rules and when and how they have to provide notice, solicit public comment, and ultimately finalize the rule. Of those cases that were decided, they were all losses for the government. And the death blow came from the district court in California, which vacated the MFN rule until CMS completes the notice-and-comment rulemaking process that's prescribed by the APA.

So, the Biden-Harris administration is now at a point, they're surveying the battlefield, probably thinking: Do we want to move forward with this, march back into battle with the pharmaceutical industry—in four different jurisdictions, remember—and defend this very novel use of CMMI's demonstration authority, or maybe do we want to work with Congress and see if there is something else we can do here that might not get us sued? So I don't know. I don't have any great predictions—I mean, I do have great predictions, they're not necessarily informed by anything I've heard. But that's the decision that they're facing right now, and we'll get an answer to that in the not too distant future.

And then the other rule you mentioned, Mario, the rebate rule, this was a regulation that comes from the HHS Office of Inspector General. They're the

watchdogs and they promulgated regulations related to the Anti-Kickback Statute, which prevents individuals or entities from paying kickbacks or bribes in exchange for referrals of business, of federal health care program business. So what this rule does is it would remove safe harbor protections for rebates paid by drug companies to pharmacy benefit managers and health plans, and effectively replace it with a new safe harbor for discounts going directly to patients at the point of sale. Like the MFN rule, it would be really disruptive to the status quo.

But what happened here was—and again, Matt, Mario, if you're looking for podcast ideas, you could do another whole podcast on this story, as well—with this one, they pushed the rule out late. But what they'd done in the year prior to it was they said, at one point, it was imminent. It was in the final clearance processes. The rule was going to be finalized. And then, at a certain point, the White House said, no, we're not going to do it right now. So they withdrew it from that clearance process. And there was some debate: Is it really dead? Is it half dead? Is it going to be revived? I wrote a blog on it saying it can be revived and it'd be perfectly fine. There was a recent court decision that disagrees with my theory, not on this rule.

So that's another one where there is litigation. The PBM industry sued the agency on the rule, which was supposed to go into effect in 2022. They were successful in getting the government to concede to delaying the rule until 2023. So there is a little bit of time there, but this is one where the pressure is on. The Biden administration is going to have to make a decision on what to do, because the court is going to probably force their hand here. I also don't know which way this one is going to go, but that's another one I'm going to be watching closely.

**Matt Hittle:** Kelly, it just shows the breadth of the stuff that you work on when on one thing you're saying that it is boring and wonky, and the other thing you describe as a pitched battle. I think it just really goes to show all of the diversity in your practice. So thank you for sharing that. I want to plumb the depths of your speculatory abilities here. If you were queen for a day, what policies under the Trump-Pence administration, the Trump-Pence HHS, would you like to see kept?

**Kelly Cleary:** Oh gosh, Matt. Well, the one we just talked about, the rebate rule. As a taxpayer, I think that it really would disrupt the status quo—this my personal view only—in a very good way. I think it's smart policy. That's one I really am holding out hope that the Biden-Harris administration will defend and will push forward. As an advocate, I really hope that the Biden-Harris administration and the new HHS Secretary will keep the good guidance rule.

This guidance, also called regulatory dark matter, has caused many headaches for lawyers and our clients. Of course, guidance comes out, and sometimes it's only loosely based in the law itself. And what the good guidance rule did, among other things, was it created a petition process where if guidance affects you in an adverse way, and you think it was issued not in accordance with the proper procedures, for instance, you didn't know about it, you didn't get advance notice, you didn't have a chance to comment on it, and you want to comment on it because you either think it's wrong or it should be done a different way, you can petition the government. They can take a look at it, and they can say, you're right, this probably should have gone through notice-and-comment rulemaking, so we're going to pull it down. So I think that having processes like that in place are really, really important, really helpful, important for purposes of transparency and

accountability, and I think something that at least the clients I work with really value.

**Matt Hittle:** Kelly, thank you for that. We appreciate your insight here, so thank you for joining us on our inaugural episode of *OnAir: Health Care*. It was a pleasure having you here. I think we've kept you and Mario longer than the allotted time, so I think it's time to close it out.

**Dr. Mario Ramirez:** Absolutely. That was great. Kelly, thanks for joining us. And to all of our listeners, thanks for tuning in.

**Matt Hittle:** Folks, be sure to like and subscribe wherever you get your podcasts. If you have a comment or if you want to share a suggestion for a future podcast—Kelly has already given us two—or if you want to compliment us on our radio voices, you can drop us a line. Our email addresses are listed below.

**Dr. Mario Ramirez:** Our thanks again to Akin Gump regulatory attorney Kelly Cleary for being here. And thank you, listeners, for joining us for the first installment of Akin Gump's *OnAir: Health Care podcast*. I'm Dr. Mario Ramirez.

**Matt Hittle:** And I'm Matthew Hittle.

**Dr. Mario Ramirez:** We'll see you next time right here at the intersection of policy, personnel, and politics at Akin Gump's *OnAir: Health Care*.