Ep. 38: Health Care and COVID – Regulation, Fraud and Enforcement

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Jose Garriga: Hello, and welcome to *OnAir with Akin Gump*. I'm your host, Jose Garriga.

Unsurprisingly, one of the sectors that have most felt the impact of the COVID-19 pandemic has been health care, both from the standpoint of serving as the front line for prevention, care and treatment of patients and of being an industry receiving considerable legislative and regulatory attention.

We have with us today Akin Gump health care and life sciences partners Kelly Cleary and Robert Salcido. They'll be speaking about the impact the pandemic has had on the industry and on the laws and regulations that govern its workings, as well as the ways in which the topics of fraud and enforcement are being discussed and addressed in light of the impact of COVID-19.

Welcome to the podcast.

Kelly, Robert, thank you both for appearing on the show today. This is an interesting topic, so let's get right to it. To start, to give the audience a look at the bigger picture, how has the pandemic affected the health care industry from the regulatory perspective? Kelly, if I could ask you to lead off.

Kelly Cleary: Absolutely. The pandemic has been a major disruptor in the health care regulatory space. I think, dating back to as early as January, we saw Health and Human Services Secretary Alex Azar declared a public health emergency and, really, the major changes to the landscape started with the President's declaration of a national emergency back on March the 14th. That action was what really triggered this cascade of downstream regulatory activity that's still continuing today, and the ground is still shifting underneath much of the health care industry. A lot of it was geared toward regulatory relief, so there has been a deluge of new guidance that's come out, array of temporary regulatory waivers, new rules that are designed to give the system maximum flexibility to be more nimble to respond to the crisis at hand.

There are many examples; I'll offer just a few. HHS lifted rules to streamline testing, expanded Medicare reimbursement for telemedicine—that's something that we hear about a lot in the press these days—relaxed some of the HIPAA [*Health Insurance Portability and Accountability Act*] privacy requirements to allow patients and doctors to communicate over platforms that might otherwise be viewed as unsecure, and even let distilleries produce hand sanitizer, which, at least in my neighborhood, continues to fly off the shelf. A lot of these regulatory changes are temporary. When the national emergency ends, whenever that may be, hopefully soon, so too does the agency's authority to waive these rules on the rule books.

But some things might have staying power. Telehealth, which I just mentioned, I think is an example of one of those things that the expansion might be here to stay. Something that's been popular in the private sector for some time, but the federal government has been very slow to adopt it. And I think, we have technology today that really makes it possible to have a health care visit with a practitioner without having to physically be together with the practitioner. I think that's really appealing to people. Policy makers are interested in extending that policy. There's obviously a lot that's going to have to go into that. I think there's an opportunity to reconsider these regulatory policies that have been a barrier to innovation and efficiency and maybe replace them with something better. It definitely involves a good conversation.

Jose Garriga: Thank you. Let's stay, then, on that topic of regulation. Now, from what I understand, the Centers for Medicare and Medicaid Services recently pushed out the deadline for publication of a final rule concerning the Stark Law. Could you give us, first of all, just a brief sense, an outline of what the Stark Law treats and then the reasons behind this decision by CMS and its practical impact?

Kelly Cleary: Sure. The Stark Law—which was named after Pete Stark, who was the sponsor of the law; it's actually called the Ethics in Patient Referrals Act—this is a law that is designed to prohibit financial conflicts of interest for physicians. It, effectively, prohibits physicians from referring patients to entities with which the physician either has an ownership interest or has some sort of other financial arrangement with the entity such that the physician is making more money the more services that he or she orders. It was really designed to prevent those financial conflict of interests from getting in the way of medical judgment. It's been on the books since the 1980s. It is turned into an incredibly complex set of regulations that span many, many pages in the *Federal Register*, and it's really outdated. It's built on this, what we call it a fee-for-service payment system, where doctors get paid for every procedure they do.

Today, we are seeing the health care delivery system innovate more. They're taking on risk, forming new types of arrangements to deliver better value to patients, and there are new payment models. People that pay for health care, like Medicare, or private payers are more and more looking to pay for outcomes and value as opposed to procedures. The idea behind the Stark Law regulations that you'd referenced was to modernize the rules to allow for these kinds of outcomes-based, value-based payment arrangements to flourish. Because, right now, the rules are antiquated and just don't account for those kind of innovative arrangements. That notice ginned up a lot of speculation. Unfortunately, the answer is pretty boring. It was really just a procedural step that the agency needed to take to comply with Medicare rules.

Not to get too in the weeds, but, in short, there's a provision in the Social Security Act requires the Secretary to set up timelines. And if those timelines slip, the Secretary has to publish a notice in the *Federal Register*, giving a new timeline. Here, the timeline

slipped, which is not all that surprising given that the agency has had to divert so much of its attention to COVID response. One thing I will say, while it is true there is no practical impact of the recent notice, it does serve as a reminder to many of us that have worked on these regulations and have been really hoping to see them come out, they've been lingering for a very, very long time, and, so, it's disappointing to those that are waiting for that flexibility to innovate, but remain stuck with out-of-date rules.

Robert Salcido: From a False Claims Act perspective, I do not think that the delay in promulgating the final rules with respect to the Stark Law will have much of a practical import at all. The reason I believe that is, in the proposed rules, CMS put forward its best thinking, its latest thinking, on the proper scope and interpretation of the Stark Law, including several critical concepts, such as how to think of fair market value or how to think of commercial reasonableness or, with respect to a provider, what does it mean to take into account the volume and value of physician referrals?

Just because CMS guidance, based on experience and expertise, has not been formally adopted as part of a final rule doesn't mean that it is not CMS's current best thinking on the topic. With respect to False Claims Act enforcement, the rule of several circuits, if a provider has a reasonable interpretation of an ambiguous rule or regulation, then a provider acting in accordance with this reasonable interpretation is not a violation of the False Claims Act because the False Claims Act requires that defendant act with reckless disregard or deliberate ignorance of the truth or falsity of the claim.

And the only way in which a reasonable interpretation of an ambiguous rule can be acting with reckless disregard or deliberate ignorance as the courts find is there has to be governmental guidance to warn the defendant away from that reasonable interpretation. So, if a provider were to rely on CMS's latest understanding of what the Stark Law entails, then I think it would be very difficult to have an effective False Claims Act enforcement action. And the False Claims Act is the primary vehicle by which the Stark Law is typically enforced.

The one thing a provider cannot do is take an interpretation that CMS has already directly considered and rejected. But if it's the more-common scenario where CMS has taken varying perspectives on a particular topic over time, and a provider were to rely on CMS's latest thinking in terms of what the various regulatory and statutory terms like “fair market value” or “commercial reasonableness” or take into account the volume and value of referrals and any number of other examples, if the provider were to take into consideration CMS's latest thinking and applied that and had a reasoned basis for doing so, then the practical import of delaying it another year should not deter providers from adopting their reasonable interpretations.

Jose Garriga: Thank you, Robert and Kelly. Let's turn now to Capitol Hill. Certain provisions and programs in the Coronavirus Aid Relief and Economic Security Act, or CARES Act, as it's most commonly known, have stirred up controversy. To what extent has the federal government been successful in its oversight of all these programs up to the present moment? Kelly, if you would, please.

Kelly Cleary: Certainly. Yes, Congress has written some very big checks with taxpayer dollars. I believe the CARES Act was the largest, with roughly two trillion in new spending, and Congress writes the checks, and then it is the executive branch agencies that are in charge of spending that money in the manner that Congress directs. I think that agencies with this task had to make a decision pretty quickly: Do we pay out these funds slowly and carefully with fraud controls on the front end to make sure the dollars only go

where they're supposed to be going? Or do we get the money out fast to those that really need it and build in fraud recovery on the back end? And at least with respect to some of the relief funds that HHS, Health and Human Services, is responsible for administering, they chose the latter.

And I think they had to, given the unprecedented challenges that our health care delivery system and the frontline providers were facing. The biggest pot of money and the one I think has probably been in the news the most coming out of the CARES Act for Health and Human Services is the Provider Relief Fund. There is about 175 billion that Congress appropriated for that fund, and it's supposed to go to eligible providers, defined broadly to include hospitals, physicians, other care providers that have lost revenue because they had to close or seeing increased expenditures because they had to retrofit a wing to serve as triage for symptomatic COVID patients, increased expenses as a direct result of COVID. HHS is making payments on a rolling basis, and I think right now about 77 billion is accounted for. But just to provide context and background on the fund, it's that fund itself.

And on the question of have they been successful in oversight? I think a lot of that oversight activity is just starting to ramp up. I think it was just last month, in August, the HHS Office of the Inspector General, which is responsible for overseeing federal programs where taxpayer dollars are expended, they announced their first audit of providers that received provider relief funds. They're going to be looking at whether these providers complied with federal requirements both in terms of their eligibility to get the funds and also whether the providers are complying with some of the reporting requirements and that the expenditures they're making are allowable expenditures. I do think that probably the OIG and those that watch federal fraud enforcement are very much expecting some fraud to be uncovered. But I think, at this stage, it's too early to say how much.

Jose Garriga: Thank you. A reminder, listeners, we're here today with Akin Gump health care and life sciences partners Kelly Cleary and Robert Salcido, discussing the impact of the pandemic on the health care industry.

You mentioned fraud, Kelly, and I want to tie that into something that Robert was discussing before. How has False Claims Act enforcement been affected by the pandemic and its surrounding legislation? Robert, what do you think?

Robert Salcido: Well, you can address that question in a couple ways. One is looking at current enforcement, and a second is future enforcement stemming from the legislation itself. In terms of current enforcement, that has slowed down to a trickle. And part of the reason for that is where actions are currently pending, and you're at the motions practice stage, meaning that the lawyers are filing motions to dismiss, and the government or the private plaintiff are filing oppositions, those lawsuits are moving forward. But lawsuits where there's discovery or which are in the preliminary stages, meaning the government's investigating, have slowed down. And the reason for that, naturally, is that for the government to know whether it has a viable action, frequently you'll need to interview or interact with individuals, and the ability to do that has been limited. Similarly, with respect to discovery practices and in-court hearings, those have slowed down dramatically. The pandemic has affected the current stream of False Claims Act cases.

With respect to what may happen in the future as a result of current legislation, I think we could say a couple things. One is that it is uncertain the extent to which there'll be future False Claims Act cases stemming from the current legislation. And the reason

why it's uncertain is, as noted before, the False Claims Act is the government's primary weapon to enforce fraud actions committed against the government. And the False Claims Act has a very long time fuse associated with that.

The way an individual brings a private lawsuit, which is the way most False Claims Act cases start, is that they file the action under seal. As noted previously, once it's filed under seal—meaning that it's done privately, it's not put on the court's public document—the government has a significant time period to investigate the allegations. The statute provides 60 days, but also provides the government with a means to continue to investigate, and frequently the time lapse of the investigation will last for years. It's safe to say that those that are currently drawing governmental funds as a result of the legislation that was promulgated this year, we will not see publicly the results of the government enforcement action because of the seal requirement, because of the government's long time period to investigate, until probably early next year, till the mid part of next year. That's the uncertain part.

The certain part, I believe that there will be a significant spike in *qui tam* actions, False Claims Act actions. And that is based on essentially an understanding of False Claims Act history. The False Claims Act, as some people may be aware, was initially promulgated in 1863 as a result of the Civil War and abuses that arose then such as selling sawdust as gunpowder to Union troops. It was significantly expanded once federal expenditures were expanded. The next time it was expanded substantially was during World War II. Then again it was expanded during the time period of the great recession, roughly 2008, 2009, and the stimulus payments that the government issued at that time as part of 2009 legislation and the 2010 Affordable Care Act.

And with each instance of additional governmental expenditures, whether it be World War II, the Cold War defense buildup or, more recently, with respect to stimulus legislation in 2009 and Affordable Care Act in 2010, after each event, we saw a significant spike in False Claims Act actions because the number of actions generally follow the amount of federal payments. Now, obviously, with respect to the CARES Act and other legislation passed this year, we've seen a dramatic increase in federal payments. If history is any guide, over the next year to two years, we're going to see a significant spike in False Claims Act enforcement activity as a result of passage of this legislation.

Jose Garriga: Thank you, Robert. Let's look at something else. Let's turn our gaze to, if you will, to a different aspect of health care that had already been a big story prior to the pandemic, and that's drug prices. Kelly, to what extent has the drug pricing debate been influenced by the rise of COVID-19?

Kelly Cleary: I'm not sure that it has. I do think that the battle lines, they've been drawn for some time, where they were drawn before the pandemic. They are, I think, largely still in the same place. If anything, the pandemic may have quieted the debate somewhat. The agencies that would be responsible for implementing some of the President's drug pricing policies and also lawmakers who are interested in drug pricing legislation, everyone has been focused on pandemic response. It's really just sucked all the air out of the room. However, we've seen in recent days, drug pricing is back in the headlines. And July, late July, the President signed four executive orders, all geared towards fulfilling his campaign promise to lower drug prices. The two most significant of those orders have yet to be implemented.

One is the order regarding the most favored nations model. This one would be a demonstration model that would be in the Medicare program, and it would effectively tie Medicare reimbursement for Part B drugs—these are the drugs that are typically administered in a physician's office, like a chemotherapy drug, an injectable—would tie Medicare reimbursement to prices that are being paid in other countries, which are oftentimes much lower than what the United States is paying. That one is still lingering out there. The President has said he's trying to strike a deal with the pharmaceutical industry, so that that's one it's still unfolding, I think, as we speak.

The second pretty significant order is around what is called the rebate rule. This is an executive order directing Health and Human Services to finalize a rule that was proposed back in 2019, and it would effectively remove safe harbor protection under the Anti-Kickback Statute. That's the statute that prevents payment of kickbacks or bribes in exchange for federal health care business. It would remove protection for rebates that are paid by pharmaceutical companies to pharmacy benefit managers, who are sometimes called the middlemen. That one is, again, another one that the agency still has yet to implement, but that is lingering out there as well. Many of the industry are waiting to see when and how the agencies are going to be acting on these executive orders.

Jose Garriga: Thank you, Kelly. Let's sum up. For the listening audience, what short- to medium-term takeaways would each of you offer those outside the health care industry regarding prospects for regulation and enforcement in the health space? Kelly, if you'd lead off, and then, Robert, I'd be interested in your thoughts.

Kelly Cleary: Sure. On the regulatory front, I think what I'd say is we can expect to see continued focus on regulatory relief effort, removing burden, especially on providers that are still devoting a lot of their resources to COVID response. Also on efforts to foster innovation, particularly around telehealth; I think that's going to be a major focus of regulators for months to come and lawmakers as well.

Robert Salcido: In terms of takeaways that I have, particularly takeaways for those who do business in the health care area, I have a few thoughts, and that is obviously the government has issued a lot of guidance regarding, for example, the Paycheck Protection Program or entitlement to relief funds or the scope of the various blanket waivers that CMS has issued over time.

In terms of thinking about that deluge of government guidance and rules, there's a couple False Claims Act defenses to keep in mind. One is one that I mentioned earlier, that a reasonable interpretation of ambiguous rules is a dispositive defense under the False Claims Act as long as there's no official governmental guidance that would warn defendant away from that interpretation. And two, there's another significant defense stemming from a 2016 Supreme Court case, *Universal Health Services versus U.S. ex rel. Escobar*, which states that, if the government knows of the purported regulatory breach and continues to pay notwithstanding that knowledge, then that's strong evidence that the regulatory breach wasn't material to the government's decision to pay.

In light of the new legislation and rules, I would offer four tips as takeaways for those doing business in the health care industry. One is to stay actively abreast of governmental rules and regulations regarding government payment and forming a reasonable understanding of what those rules require. This goes along the lines of a reasonable interpretation defense. A second one is to communicate, when applicable, that understanding to the government whenever the issue arises. So, if there's

communications with government officials, correspondence during audits, providers should feel free to articulate, when appropriate, their understanding of the rules. And if the government continues to pay notwithstanding hearing from the provider, then that sets up an *Escobar* defense at the end of the day, that even if the government or private relator later says that there was a regulatory breach, if the government continues payment, it tends to show that, whatever that breach purportedly was, that it wasn't material to the government's decision to pay.

Third, what those in the industry should do is continue to monitor official government pronouncements and court decisions to evaluate whether the guidance contains information that would warn the company away from its reasonable interpretation because, under those circumstances, the company's reasonable interpretation, arguably, would no longer be reasonable.

And fourth and finally, companies should maintain centralized and retrievable records of the rules, regulations and government guidance; communications with the government; and any documents that reflect the company's deliberative thought process in terms of what the rules require, because under the worst-case scenario, if there is an investigation or a subpoena down the road, having those documents readily available would likely forestall the investigation or limit its duration if those documents are readily available and can be shared with the government.

Jose Garriga: Thank you. Listeners, you've been listening to Akin Gump health care and life sciences partners Kelly Cleary and Robert Salcido. Thank you both for making the time to appear on the show today to offer these great insights and tips on these hot topics in the health care space. I'm sure the audience will find them both useful and informative.

And thank you, listeners, as always, for your time and attention. Please make sure to subscribe to *OnAir with Akin Gump* at your favorite podcast provider to ensure you do not miss an episode. We're on, among others, iTunes, YouTube and Spotify.

To learn more about Akin Gump and the firm's work in, and thinking on, health care and life sciences and enforcement topics, look for "health care" or "False Claims Act" and the related practices on the Experience or Insights & News sections on akingump.com and take a moment to read Kelly and Robert's bios on the site as well.

Until next time.