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Thu, 6/24 1:43AM 43:25

SUMMARY KEYWORDS

physicians, manufacturer, hospital, false claims, patients, financial arrangement, inducement, providing, safe harbor, employee, intent, government, called, arrangement, drug, advisory opinions, inducing, anti kickback, talk, referrals

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Hello, my name is Renee mallet. I'm here to present today of fraud and abuse issues, whether it's from hospitals, to physicians, physicians to hospitals, manufacturers involved drug distributors. So we're going to spend the next hour talking about the federal anti kickback statute, false claims and a little bit about Stark law. To introduce myself, I am a nurse and attorney, I've practiced 15 years, started out in a medium sized Community Hospital then went to an academic setting. And also now I work for a manufacturer. So with further ado, we're going to go ahead and go through the backgrounds of these laws, we're going to talk about the basic prohibitions, what you cannot do, we're going to talk about the safe harbors and some exceptions, we're going to go through a legal framework just to kind of walk through a situation how you would apply your legal analysis. We're also going to talk about case laws and federal settlements. Oftentimes, when you read these case laws or the settlements, that's a great idea and opportunity, whether you're in House Counsel or an outside law firm, you can go in and make sure your clients are not doing because some of these things that were found by the investigators, we're also going to talk about the federal corporate compliance program, and how you can actually be proactive and make sure these items are not happening within the walls of your organization. So let's talk about the anti kickback and false claims. We know these statutes were enabled or enacted in 1972. So they're about 47 years old. And basically, they were to provide protection to the patient, the patient is the core of our foundation, that's where our moral compass is, they just wanted to make sure physicians, hospitals, manufacturers, were not providing unnecessary medical expenses and taking away from patient safety and ultimately compromising quality of care, because either they were not providing the adequate services, or they were providing more services than what the patient really needed at that time of care. So everything is in the best interest of the patient. Also, we're taxpayers, right, so 60% of our tax money is for federal health care entities. There's 60%. There's the federal government, there's the VA system, there's the Children's Health Insurance

Program, there's Medicaid, so 60% of our health insurance is part of those federal or state entities. So that's why it matters. We pay taxes as individual taxpayers for these programs to be administered appropriately. So when we talk about the anti kickback, really, it's an intent based statute, meaning you have to have if your intent was to do any sort of inducement, referral, any kickbacks, any bribes, right, there is your intent. It's a criminal statute. It also has civil and criminal penalties associated with it, obviously, civil penalties or fines, and then the criminal penalties would be prison or jail time. So let's just kind of talk about what that means as far as an inducement referral, etc, it could be directly so whether a hospital trying to induce business having physicians refer something to me, that's obviously direct and directly engaging in that activity with those physicians or it could be indirect, meaning perhaps they're paying a lab and that lab is the one who's inducing those physicians to send the order. So just keep in mind, it can be a direct inducement and direct doucement. It could be money or any kinds of services. And we'll kind of talk about what in kind would be whether it's inducing for

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not bogus, speaking engagements, or its inducement of luxurious seedings for sporting events or hotel arrangements, lavish meals, etc. So, basically, the intent behind that is you're trying to get business versus like allowing the healthcare patient or the healthcare provider, just you know, with a free competition, select their type of Healthcare Services, their types of products and services, their types of medical devices, the appropriate drugs that they need to care for that patient. So it's you're inducing, you're trying to get some sort of compensation, rather just allowing the market to free flow as it was intended to be. So you back away from that in turn, so maybe your initial thought was I want physicians to be able to prescribe more and if I take them out to a to a lavish meal, they're more likely to prescribe this drug. But then if you realize, Oh, that's illegal, I cannot do that. The rest of the arrangement, even if it's legal may just fall apart because you had that initial intent. So again, just always keep in mind the anti kickback is intent based. You're so once you violate that you have violated the statute. So let's talk about false claims. So false claims basically, it's if you falsely or fraudulently have submitted a claim whether you come up with a ghost patient means meaning that that patient is not the right patient or you create patients for services. If you decide to unbundle healthcare services, usually the government has a bundled package. But if you decide to take those then independently bill for those that's called unbundling, that's fraudulent in itself, if you decide to appcode So say, for example, if the provider is providing only a level one care, but they decide, I'm going to go ahead and build this for a level five care, which is the highest billing, they've coded that service. So claims submitted to these programs are a violation. And oftentimes, when they're investigating any anti kickback situations,

they can fall into the false claim. So again, like we just kind of review, a false claim is anytime you falsify or make a fraudulent claim, you falsify the record, you falsify the material facts of those situations, it's considered a fraudulent claim. And actually, the false claim that many of you might know if your historians came around from the Lincoln law. So during the Civil War, a lot of suppliers were providing false or fraudulent items. And then during the Civil War, they enacted the false claim, because the government was paying for these these weapons, these military services, and they were not up to speed. They were, there was a lot of issues with them. So they created the false claim act because the government was paying for these supplies. health care fraud enforcement. So it's interesting over the last nine years, the Department of Justice has recovered $36.2 billion in false claims. Within the last year in 2018, there was actually 645 cases made. They're called key Tam cases. And basically, anybody can make that. And typically, it's the employees, whether they're in the walls of the healthcare organization, working with the manufacturer, they actually have moved forward and made these claims because they were working and they were told to do something, and they know it was fraudulent. So they, they became whistleblowers and actually reported these and the government intervened and got involved. So in 2018, like I said, there was 645 cases, and that actually, the government record

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recovered $2.1 billion. So let's talk about these key Tam suits. They're interesting. They're private individuals, and a lot of them are ex employees or employees who are currently working in the organization. Perhaps they went to their compliance department, perhaps they went to their legal counsel, perhaps they went to their managers and supervisors and reported these improprieties, but they continued. They felt very uncomfortable with those situations, and they did the right thing. And they became whistleblowers. So we're also seeing increased corporate realtors, where it's actually managers and directors or people in a corporate capacity. That's also a learning and becoming whistleblowers. And it's interesting, we are seeing a lot of sophisticated law firms take these cases, it's no longer an attorney who's maybe investigating this. It's it's corporate law firms who actually have whole departments that are that are assisting these, these realtors or these individuals moving forward. And why is that? Because actually, if the case is proven correctly, and there's evidence there and it's substantiated, these individuals receive a percentage of the money that's recouped back. So it's an interest for these law firms to become sophisticated, understand healthcare law understands the operations of a hospital, manufacturer, etc. So let's just talk about the stark law that actually came forward in 1991. And it was a decision made exclusively that it's going to be a civil statute, and it's going to look at the arrangement of a physician. So if a physician has a financial arrangement, meaning maybe they own a part of a clinical laboratory, they own a part of an occupational health, there's designated health services, from ot to labs to radiology, they cannot directly induce or refer patients to them, right. So they have a financial arrangement. They have an interest, there's, they're more than just an employee and this organization, so it was really aimed at looking at those financial arrangements, as physicians

became more individual stakeholders, they owned ambulatory surgery centers, they became an investors in these freestanding health care facilities. So therefore, we didn't want any impropriety with their arrangement, and then referring, so like I said, it is this civil law. It's a reimbursement law, and it's strict liability. And what do I mean by strict liability? It's basically it's prohibited. If they're caught, they're strictly liable. They're held liable. It's, you cannot there's prohibition. So the That's what type of legalities it's set up. So the penalties or repayment of these improprieties, civil fines can be up to $23,000 per claim. They can also bring in the False Claims Act. So if not only are you doing illegal referrals, but they'll also look how were these build where they falsely fraudulently billed, were they up coded, etc. And then you can always be excluded from Medicare Medicaid, so not only is it criminal times, loss of the physicians license, but they can no longer ever build Medicare or Medicaid. So we kind of talked about just keep in mind, the basic prohibitions of the stark law is a physician that has a financial arrangement cannot refer any type of patients or services to any entities that he has a financial investment, whether he's an owner, whether he's compensated, he just cannot make those referrals to himself or have others make those referrals if he has a financial arrangement, or if he has relatives that have a financial arrangement and those companies. So let's go to kind of go back to the anti kickback just to kind of refresh and talk about why anti kickback is really important. So we know it's an intent base. We know if it's a person who knowingly or willingly solicits or receives renumeration, and renumeration is defined as anything of value. So we talked about meals, sporting events, cash, or anything of value that that person is given with the sole purpose is to extend services here, to write more prescriptions to use this type of medical device, even if it's off label or on label. So it's basically you're inducing them to, to, to make a purchase that they may or may not have made, we want the healthcare products and to speak for themselves. So therefore, we don't want any inducements or anything offered in value. So as I said, the anti kickback, you cannot actually induce if it was past referrals, or if you're trying to seek current referrals. So no, no inducements at all for any types of services. So let's just kind of talk about the five factors that you need for an anti kickback

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violation. So we know we talked about that financial arrangement, whether it's in kind or monetary, if it's between healthcare providers, if it's between a manufacturer and a healthcare provider, a drug distributor, a supplier or any sort of vendor. And if there's a referral source into that we talked about it could be direct or indirect. So you could go through the indirect route by meaning maybe a manufacturer Ohio's hires a marketing firm, but that manufacturer has given that marketing firm guidance on here's the physicians I want you to employ. Here's the physicians, I want you to pay. Here's the payment structure. So they're indirectly inducing that marketing firm or that Research Farm, or they're directly obviously paying a physician to write more prescriptions to order these type of DMS, equipments and supplies, etc. And then, of course, we want to make sure that there's a federal healthcare entity. So was medicare medicaid involved for charging or billing of these services or payment was that the VA system was that the Children's Health

Insurance Program. And then, of course, we talk about the financial arrangement. And then the one intent was the intent to induce products and services versus allowing those products and services to speak for themselves to sell for themselves. So we talked about safe harbors. So it's interesting. So there is a trade association called AB event, and many of you may know about that. But it's basically it represents healthcare manufacturers and distributors. And so the industries that will kind of timeout, let's talk about dealings and interactions. And we know as manufacturers, oftentimes we're going to sell in bulk, or we're going to sell a large amount of devices, and we want to be able to give a discount or offer rebates. So we said normal businesses are able to provide these sort of discounts, rebates, group pricing practices. So can we apply some common sense business practices in the world of health care? So the government said, Absolutely, that makes sense. And they're called safe harbors that the safe harbors are, you have to follow them to a tee. They're strict guidelines around them, and if you don't follow them, and obviously everything has to be in writing. And if you don't follow them, then that could, that that that will no longer allow you to provide that safe harbor exception. So a lot of times, you can go to the Office of Inspector General who enforces the anti kickback statute and there's advisory opinions. But you have to read through those advisory opinions closely. Because basically, it's maybe a manufacturer or a health system coming to the oaG and offering an example, here's a structure we'd like to provide is this within the Safe Harbor. So oftentimes, those advisory opinions are based upon those certain facts of the of the situation. So just be mindful, when you look at advisory opinions,

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you have to make sure your certain fact pattern falls into that advisory opinion if you're looking at that.

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So we talked about the safe harbors, so we'll kind of get into some examples of what they are. But again, there's just exceptions if you follow that safe harbor, and it's exception, but however, even if you follow that safe harbor, and you meet the exception for a safe harbor, let's go back to the intent of the statute. If your intent was to seek referrals to seek inducements, that is all tarnished, so you can no longer follow that safe harbor, because then you violated the anti kickback statute in and of itself, your original one purpose, your intent was to seek an illegal gain. So as we talk about safe harbor list, we also the most common ones, from a manufacturer standpoint, to a healthcare entity is oftentimes we're going to discount have rebates, we're going to sell to a group, purchasing organization or a GPO, we're also going to maybe we're individually going to ask a nurse or a physician because we want them to speak on the disease process. So we're going to enter what's called a fair market value, a consulting agreement, we're going to base that hourly rate on there certain criteria we look at is that is that physician, the leading practice,

industry leader, have they had recent presentations and have spoke about this disease have they published in this disease, so there's certain criteria that we're going to look at to base our fair market value. And that's perfectly acceptable, because oftentimes, manufacturers don't have those health care providers don't have those certain medical directors with that skill and ability that can speak on that medical device. So that's all within the realms of anti kickback. So if you look at that PowerPoint presentation, you're going to have a list of the safe harbors, what's acceptable and what's not. But then you have to look at each one of those safe harbors, and make sure you're following the intent of that safe harbor. So let's talk about your analytical framework as if you were inside the walls of a hospital or a manufacturer, and somebody came to you and said, I want to make sure this is not violating the anti kickback statute. One, you're just going to draw out the financial arrangements. So take a piece of paper kind of draw out the financial arrangement. It's you know, the manufacturer to the healthcare provider, or it's the hospital to the healthcare provider and determine what is that revenue stream, that referral stream, and make sure that that is a viable option. You're going to review what we talked about the basic prohibitions about the anti kickback, you might at that point, you might already see there's a potential violation or the intent was already established that they wanted that inducement, you're going to stop right there. So step three, is perhaps you've drawn this out, it looks good. For now you're going to look to see if there's any safe harbors that you can apply. And then you can kind of restructure maybe the financial arrangement to meet one of those safe harbors. And again, you're gonna look at advisory opinions, you might determine that an advisory opinion permitted this or an advisory permit opinion did not permit this. So those are kind of how you're going to look at your analytical framework, one is just always mapping it out. What is the arrangement? What is the referral stream? Is there any conflicts of interest? Is there any ownership financial investment, making sure that one intent statute was not violated, and then you can apply the applicable safe harbor if if there is as they prefer to apply? So kind of let's talk about some of the interesting cases that has recently been settled. So TiVo actually entered into a $54 million settlement in 2020. And it had what was called a bogus speaker program. So it was interesting, actually to former sales rep for the whistleblower, in this case. So TiVo sales reps were told to retain physicians to become speakers and those physicians were selected because they were the highest volume of prescribers. So they weren't the physician that maybe was the most, the one that had the most speaking, presentations or publications or even the physician that practice in this area. They were the physicians based upon the highest prescribing practices within this, this type of prescription utilization. The nominations came from the sales and marketing folks it did not come from usually manufacturers have what's called a clinical and a medical affairs department, and they're the ones who can actually recommend Speakers then they recommend the speakers again, by those speakers that are widely published have spoke before, have provided educational opportunities and really understand the pathology, the type of patients, their practicing physicians or perhaps their practicing researchers. Again, they were nominated by sales and marketing. And those nominations, as we talked about were because they were the highest prescribers of those certain physicians. Also, a lot of times the the speaking

engagements really didn't have

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meaningful people attended had maybe the physician spouse, maybe I'd had actually the sales representatives in attendance, there were bogus sign in sheets, so it really wasn't offered. And if you're going to offer a speaking engagement or any continuing legal or continuing medical education or continuing nursing education hours, you're going to go through the accreditation body standards. And obviously, they did not meet those accreditation standards. And they were the same physicians that were rotating, coming up with the exact same speaking presentations. The speaking presentations were General, they weren't specific, they were the exact same speaking presentation. And typically, those physicians would come back every three or four months and present the exact same material. And again, if you looked at the list of attendees, it was their family members or was sales people. It wasn't people out in that they had, you know, put on their website offered this did what they were supposed to do, as far as accreditation standards go to widely publicized this to make sure it was offered to healthcare providers that can actually benefit from hearing these presentations. So the next case is interesting. It's here in Ohio, I'm from Columbus, Ohio, and it's with avenir pharmaceuticals. So it's a situation they settled for $103 million dollars in 2019. It involves two physicians and two sales representatives were indicted. And actually there was a series of text messages in which it was a sales representative texting his his manager or supervisor. And really a lot of it was we have to increase we have to increase we have to have these physicians doing the certain activities. They also provided these physicians got involved in this game. So they actually provided transfers of value. So they paid them for speaking arrangements. They actually paid them for firearms training. They gave a meals and coffee and provided fax machines and assessories in their offices. Also they assisted with prior authorization. So the sales representative was actually getting protected health information. So it was names of patients their medical diagnosis is they were actually providing pre authorization and as manufacturers you cannot provide any type of guidance on how to build Medicare, how to code for services, or actually how to complete their paperwork. That is the the physicians responsibility. That's the hospital's responsibility. They have their own billers, their own coders. They should be the ones who are seeking this information versus a manufacturer. So part of this speaking arrangements when they kind of looked at these speaking bureaus, there was little or education opportunities. There was fictitious signups, also one physician received $331,000 for these speaking arrangements. On the physicians, what they did on their end is they falsely diagnosed patients for this certain type of medical diagnosis that this type of drug treated, they falsified diagnosis is symptoms and they had these fictitious pre authorization forms completed. So another situation was specific hospital and evolve with us Dr. Daniel caban. And 2019. So Pacific hospital is in California, Long Beach particular. And this CEO does this Michael robot decided he wanted to conspire with doctors, chiropractors and markers specifically in the California Workers Compensation Program. And so this doctor cabin in particular was a spinal

surgeon. And basically, he was getting inducements referrals to to bring his final cases here. And then also, there was a company that they worked with that had this medical hardware specifically that was affiliated with specific hospital. So that was the kind of interesting in which he was told this is where you're going to order your spinal services of etc. And then not only to follow up these patients, they were asking him to refer their patients to these specific hospital affiliated entities that provide a urine drug testing for these types of patients. So improprieties, in which you had a hospital CEO or the hospital owner, come and bribe this physician, this doctor Captain to refer all his spinal patients. And by the way, here's where I want you to buy your recommend that we buy all your spinal hardware processes. And here are some other organizations in which I want you to order some diagnostic testing. So In the years of 1998, in 2013, this doctor cabin had built approximately $142 million of claims to this worker's comp. So as you can see, a lot of you know, if you would kind of look back at those claims, one, were they medically appropriate, what types of does these patients need these diagnostic testing? Did they need these spinal surgeries etc.

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So as you know, both the physician and the hospital CEO are currently serving prison time, and then the hospital CEO had to pay back and make restitution for these illegal bribes. So here's another interesting situation. It was a rural hospital in Missouri and the former CEO was a David Burns. So he acquired and basically through this management company of themselves through this Putnam County Memorial Hospital, he had purchased this hospital and came up with a menu, a management agreement, and he basically went out to all these as we know, we're in the midst of an opioid crisis. So he went out to all these sober living homes, these mental health and chemical dependency treatment centers, and basically solicited that they send their samples, kind of pass them through this Missouri Memorial Hospital to another entity. So he was seeking referrals and arrangements and he was working with this private laboratory owner to get these referrals made passed. So it was an interesting situation, whether these patients needed these, these periodic drug and testing, they weren't they were actually found not to be medical illnesses that this is there. And again, he was using an outside diagnostic testing laboratory that he he was getting referrals back to and being compensated from an anti kickback situation. Olympus settlement. So Olympus sells endoscopy scopes. So this is an interesting in 2016, they settled for $646 million. So it's interesting, they were providing these scopes, and they were actually allowing the physicians to evaluate them and use them but these physicians actually kept on evaluating them longer than 90 days. So the government does allow manufacturers to provide either a device or sample of disposable types of equipment for the you know, for the physicians to use it to try to determine Is this the type of cert or equipment I'd like to use on my patient. so in this situation, Olympus was actually giving the scopes and not monitoring them. And part of the arrangement was, they knew that this hospital actually was building a new hospital. So they donated, they actually personally donated to the hospital knowing once this hospitals being built, they're going to purchase all these types of endoscopy scopes. So again, it was a no charge loan

program, they were exceeding the 90 days, they weren't having counting, they weren't getting the scopes back. So they were offering things to this hospital to these physicians etc. And also, once they had these, you can either have a purchase agreement where you purchase these scopes, or you can have a type of lease agreement. And their agreements were structured under these leases, but they weren't asking to make payments, monthly payments, they weren't seeking these monthly payments. So they were basically forgiving, doing some debt forgiveness on on these scopes. And knowing that if they forgive the debt, the hospital was going to order more scopes from them. So again, they settled with the government for $640 million. Glaxo smithkline, settled for 3 billion in 2012. And what they were doing as they, they sell drugs, pharmaceutical drugs, which we know for mental health reasons, it's Paxil, Wellbutrin, and they were selling them and promoting them off label. So as you know, when you manufacture a drug or manufacturer or a medical device, you go through rigorous clinical studies, and part of those clinical studies are going to tell you exactly whether that treatment or that that drug, treated this certain diagnosis, whether it's depression, etc. And you have to, you have to make the claim. So you have to make the medical claims. And so basically, if if they don't meet those claims, because the clinical trials only tested patients for depression, you have to use what's on the on label. So this drug was specifically tested for depression, it was found that it was effective. They monitor the number of adverse reaction side effects. So those are on label so that's what that drug could be sold for. What they were doing is promoting off label practices. And they were also providing physicians they were providing them lavish vacation concert tickets paid speaking engagements where they were really promoting both on and off label so you cannot promote promote off label. We know sometimes physicians and health care providers are creative and they might use a certain drug to treat something that maybe is not on up is not on the label, but it's an off label purpose. They can do that but we as a manufacturer, do distributor we cannot promote anything off label.

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So Christ hospital This was in Cincinnati, Ohio. And it was a situation it was one of the very first ones in 2010. And it was basically Christ hospital was paying and compensating outside cardiologist to send them patients there at a hospital for procedures, etc. So that was one of the first anti kickback cases that the federal government It was interesting Christ to hospital for you read the newspapers and kind of what happened is they were intent not to settle this or, or fall on their sword and say that they were guilty. And basically the government said you have an option, you can either sign a corporate integrity agreement and rectify this, or we will pursue criminal activities and statutes. So the government was basically able to get them to cooperate. But that first they were in this big denial that they had not done anything illegal. Abbott Laboratories and paid in 2003 $622 million. So this was interesting. The federal government specifically the FBI was very creative in the situation. And they represented themselves as a DMV. So they actually rented a building in Missouri. And then it was interesting. So Abbott was selling internal pumps, so feeding pumps and those feeding sets. And so they thought they were dealing with a legitimate DMV

company, but it was the FBI. So they were telling the FBI, or this DMV suppliers, here's how to Bill, here's how to reimburse and part of the agreement was, if you purchase a set amount of feeding sets will give you a pump, that's fine. So if you, you know, if you want to drop the arrangement that you know, if you purchase these set volumes of feeding sets, so maybe it's 15 feeding sets, or 20 feeding sets, we're going to be able to give you a pump, that is fine of itself. But what they were doing is then telling the DMV, by the way, you can go ahead and bill for that pump, you can put it on your cost report, you can excetera so but basically what Abbott should have done is they should have given an invoice that reflected $0, because that pump was provided with the contingency, you order these feeding sets. So they were basically telling the nursing homes, the DMV go ahead and bill for these pumps that you purchase these pumps are and so we as a manufacturer, Abbott as a manufacturer could not do that. So they were really providing monetary encouragement to these dmvs, nursing homes, etc. So let's talk about how to get yourself out of those situations or how to be proactive. So the government, the Department of Justice actually just published here in the summer of 2019, a document. And it's basically here's how to run an effective corporate compliance program that could be applied for manufacturers for healthcare entities. So basically, the government said, here's the manual, we really want you to follow it. If you do find yourself in trouble, and we're talking and discussing with you, we're going to see if you had many of these elements, then maybe you just had a bad actor. But at the same time, here are some things that we really want you to follow. And it's really, we'll go through some of these, these fundamental questions. So how well designed is your corporate compliance? Do you have you have buy in from the board? Do you have a corporate compliance board committee? Do you have your senior leaders at key meetings that are understanding what corporate compliance means? Is the program being applied in good faith? Or is it just papered up? Do you just have policies? Do you just have board meetings, but you're really not enforcing your program? And then does the corporate compliance program work in practice? The salespeople know, I can pick up the phone and call my compliance officer, or I can consult legal services or who's ever acting in that role of a compliance officer. So are you visible? Are you making the program available to the ones that are interacting with those health care providers? So some of the things that is in this document is a risk management process. So how are you going after high risk areas?

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Are you just looking at low risk areas? Are you really going under those agreements? Are those transactions that you would have with perhaps government, hospitals, state hospitals? So how, what is your risk score? And then what are the resources? So do you have people that are actually looking at possible vulnerabilities whether it's HIPAA risk, whether it's your sampling process, whether it's your giving out equipment that's longer than 90 days, so how you're structuring your your purchasing agreements, your lease agreements, so really going after those high risk and then maybe even if you're a drug distributor, looking at the the type of drugs and your number one

drugs and who's purchasing those drugs and are they purchasing them accurately and correctly, in using on label, so it's really just getting into your high risk and constantly constantly looking at things and devising risk management plans or documenting, I've looked at that risk, everything looks good on a compliance. And so when you look at policies and procedures that the design of your policies and procedures and really you want to give your employees direct, people want to do the right thing. So give structure your policies and procedures where you have maybe job aids where you have standard operating procedures, maybe you have a global policies, all your policies, if you're a global organization, they're all translated into the appropriate language. So employees that are predominantly Spanish speaking, predominantly Chinese speaking can understand what those policies and procedures are and have them appropriately translated. Of course, you want to make sure they're translated and applicable in their country guidelines, etc. And how comprehensive are they? Are they just kind of outline ones? Or are they really detailed of, here's how you go talk to here's what happens if you have something that you doesn't look right. Who do you call for that? What is your sample process? How do I know if I'm sending out the appropriate amount of samples? And then how do I make sure I get a device back if I loaned it so really detailed operating procedures that gives guidance to your frontline sales folks? Or if you're a healthcare entity, those physicians that you directly employ? How do they know that they can adhere to proper billing, coding, etc? Who are their resources within the hospital? And then it's set up some gatekeepers. So if you're in a hospital, it's you know, who is who was monitoring the coding practices who are monitoring your billers, those are your gatekeepers do have those appropriate controls in place. Also, for a manufacturer, maybe it's your purchasing department, they can be the greatest gate gatekeepers possible. So what sort of resources policies and procedures have you given them? So if they see something suspicious? Who do they go to? Who do they talk to? Who do they provide this information to? So training in your communication? So what are your training plan platforms? Are they live training programs? Are they a computer assisted training program? Do I have the appropriate documentation? So I have a reference that I can look back? And and look at that training? If I have any questions? Is all employees accounted for? Do you have percentages of how many people have been trained and how often they've been trained? So you can produce those records to make sure, so if you are investigating within the walls of your hospital, and you see an employee that's constantly kind of violating? Can you also look at how often have they been training? Have they been provided that training? How what was that type of training? Was it one to one? Was it a large classroom setting, etc? And just the content and the effectiveness of your training? Have you surveyed individuals to make sure that they're fully understanding that training? Or have they provided you feedback that I needed this type of training, really within my first six months of employment versus waiting a year for me to get that type of training, and just availability of guidance documents, so an employee can pull those and have that reference material? So let's talk about confidential reporting and investigation. Again, this is really important. So you want to be able to have a business conduct line you want. If an employee sees something, they want to be able to say something or their guts telling them that this is just not, I'm feeling uneasy. Who do I report to? This to? So do you have an

online email box? Do you have a phone number that I can pick up is an anonymous? Am I protected? Am I safeguarded as a whistleblower? How is that investigation going to be investigated? Do you have investigators that are trained? So when you do receive something on your corporate compliance hotline? How do you respond or react to that? Who do you call? How do you start that investigation? How do you document that investigation? Is it fact based? Who can verify your documentation? So you just want to make sure you have these special procedures in place from the quality of your investigation to the resources to the type of system

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that you're using? Is that assessable? is it available? And then are you tracking those metrics, meaning, the time that an employee would file as an issue? How often when is that investigated? So what are the timelines? Are you showing that to your board? Are you showing it to your senior leaders? So for example, if you have a compliance hotline, and you're monitoring, it takes maybe within 20 to 30 days to complete that invasion vestigation or we're monitoring that that employee if they've elected to disclose their identity, they're getting called within 24 hours of that initial investigation. So make sure you're monitoring and you have key metrics. And then of course, you're always continuously improving. So if you see that it's taking you more than 30 days to complete an investigation, and you want it to be down to within 20 days. What are your continuous improvement plans, you have the appropriate number of investigators Do you have people that's monitoring this compliance line? periodically and making sure those investigations are act upon and closed out. And, and whether they're substantiated or unsubstantiated, those ones that are substantiated, what is your next move to make sure you've corrected and remedy that situation. So let's talk about incentive and disciplinary measures. So some hospitals that I've interacted with have great systems where they're rewarding people to bring things forward, whether they're sending them a thank, you know, giving them what's called, you know, maybe a small token of letting us know. So it's really just incentivizing them and encouraging versus, you know, the last thing we want an employee to do is if they're a whistleblower, we wouldn't want them to be retaliated against, right, we want to want them to be disciplined. We want to make sure we're protecting that person. And then likewise, if you are substantiating What is your disciplinary practice as a healthcare entity or as a manufacturer, so perhaps if you have guidelines and policies on meal limits, and you're seeing that they're constantly being violated, either by a group of physicians or, or the sales representatives, how are you monitoring that? How are you disciplining them? Is the discipline consistent? Is it effective? Is it strong enough to make sure this practices not routinely happen? So just make sure you're tying that in not only are incentive incentivizing people to come forward and do the right thing, and let the organization know if there's situations that need to be acted on? Or there's vulnerabilities within the organization? And then once you have certain key individuals that are constantly being your bad actors, how are you disciplining them? And really, how are you removing them from the organization because obviously, they're not abiding by the foundation of the organization, its

mission, its goals, what what they're doing, you know, what they're doing to provide? That is the extent of my presentation, I thank you for listening. And again, it's really just, some of it is just making sure you have sound processes in place and understanding. And oftentimes, it's just really looking at that financial arrangement. And as I articulated, it's an intent base. So what is the original intent of this

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of this program that you're trying to offer? So with that being said, I thank you for participating.

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With this outro one more time, do the intro outro. When you see this is a for the present. Oh, okay. Yep. I thank you for listening today. And these are just the beginning principles of the anti kickback false claims for both a manufacturer healthcare. Again, the number one takeaway is the anti kickback statute was intent based. So when you're looking at that financial arrangement, when you're looking at that engagement, that consulting arrangement, perhaps you want to pay physicians to come in and speak exactly what is that intent. Again, it has to be a legitimate business purpose, purpose. So just be mindful of those. Then again, there's case examples to look at and make sure that that's not happening within the walls of your organization. And always look at that federal compliance program that the federal government put in place. And again, if you're utilizing it, and you're enforcing it, and you're doing everything that guideline says, if you would find yourself in a situation hopefully you can use that as a mitigating factor to mitigate the situation.