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Compliance and Risk Mitigation with Lisa Melamed

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A brief background on how a former litigator became focused on driving business strategy while managing enterprise risk. The law firm that I was associated with 19 years ago had extensive coverage in Florida, and their business model was to assign clients to a lead lawyer who would become familiar with that client's policies and processes, as well as their department heads which promoted efficiencies and customer service. One of my Florida clients managed several Long Term Care facilities throughout the country, and through my representation, I developed an understanding of senior housing, and the nuances of an "owed duty" between assisted living, independent living, CCRCs and SNIFs. Due to my understanding of the complexities around senior housing, that client reached out and asked me to join their team as in-house counsel. I decided to take the leap as an in-house lawyer, and that's really where my understanding of how to drive business strategy while mitigating risk journey began.

How do you drive efficiencies and strategy in a compliant way?

Senior housing is a very regulated industry, as we all know, and joining the team gave me a crash course in Medicare, insurance payers, and how to advocate for residents from a clinical and a compliance perspective. So that's where my foundation of driving strategy and risk mitigation began. From there, I went to an MSO that managed/owed spine surgery physician practices and ASCs. We were one of the first in the country to perform minimally invasive back surgeries in an ASC setting with a direct to consumer model. Patients would travel up to 200 miles to get their back surgery done in an ASC setting. I become their general counsel and chief compliance officer, as well as managed their risk mitigation efforts as a licensed healthcare risk manager. It was an incredibly exciting time as we changed the standard of care in the spine space, and I quickly learned what's possible in a changing regulatory environment. By way of example, our MSO led the change to Pennsylvania law with respect to anesthesia in an in-office setting, as well as the certificate of need requirements in Rhode Island. From there, I joined an MSO in the Lasik space which managed 130 physician practices in multiple states. Through the years, I continued to grow professionally and hone my skills on driving operational strategy while mitigating risk, thereby holding the roles as Chief Legal Officer, and eventually becoming the MSO's President, CEO and Board Member.

How do you define Compliance and Risk Mitigation

Compliance is a multilayered system of checks and balances to promote quality of care and avoid fraud, waste, and abuse. Risk mitigation is about taking steps to reduce adverse effects. Both functions are crucial tools for a healthcare organization's viability and profitability in a heavily regulated area. We can all agree that "Compliance" and "Risk Mitigation" are very broad terms which have a direct impact on every healthcare organization's day to day decision making, and potential liability exposure for their employees, C-suite, Board Members and owners/investors. So, what does a well-built Compliance and Risk Mitigation team look like? It looks like a team that has the broad knowledge of what compliance and risk looks like within a healthcare organization

while still understanding that that organization has to generate profits. They have to drive business. Accordingly, our team focuses on how to get our clients to a "yes", but in a compliant manner. We understand that there's a business element here and we have to support strategic initiatives within the parameters that healthcare organizations have been given. You can say that compliance is rooted in standards from the federal government, states, standards of care in a particular community or practice area, as well as those internal standards established by the practice's policies and processes.

How can compliance and risk mitigation support growth strategies?

When I joined the Lasik MSO, the practices were seeking ways to expand their offerings beyond LASIK and general ophthalmology by providing lens replacements (i.e. cataract surgery), a procedure which can be billed to insurance. Medicare has historically demanded that the procedure be performed in an ASC setting, though there has been slow movement over to a physician practice setting. The goal was to leverage the Lasik's cash pay business' resources towards cataract surgery which is an insurance reimbursable. Unfortunately, when I arrived at the Lasik MSO, many of the newly implemented business initiatives had to be unwound and restarted de novo due to unvetted compliance requirements. While we locked arms as a management team to figure out how to penetrate the cataract space while leveraging Lasik practice resources, we did it at an investment of additional costs, resources and time. In the end, we were successful building out a new stream of revenue, it just took longer and cost more additional monies because compliance was not at the table when the initiative was originally explored. So, my point is compliance and risk mitigation is not only a safety net, it can also help you determine the best path down the road towards new initiatives and sustainable revenue streams.

How do you measure analytically and systematically compliance across an organization that does have so many different needs

You can't bubble wrap everything, but you can learn from other organizations that have made mistakes in the past. You can leverage guidance from states and federal government, and model your programs after other similarly situated healthcare organizations.

The goal is to implement processes, systems and policies that allow employees to drive the business' strategy within certain parameters, and then you audit or monitor those processes.

I think a really big part of compliance and risk mitigation is your organization's culture. Your clinicians and employees want a culture of compliance to support their focus of providing excellent care to their patients. They want to see that same commitment to compliance from the top down, and that the organization has a mission and a value of doing the right thing while they are taking care of their patients. And so ultimately, it's creating that patient centric culture so that your employees are conditioned that if they see something, they call the integrity hotline. If your organization's hotline is not ringing, if you're not getting any phone calls with employees raising their hand, your organization should question whether there is a cultural breakdown.

In compliance, are there KPIs and process driven controls that can be implemented that have that type of scalability and automation?

There are, and those controls depend on the organization's department's role and responsibilities. By way of example, is the organization's department regularly audited by payors? Are there insurance carrier claw-backs? Have there been letters from insurance carriers asking for a chart audit/review? These types of letters/actions are a sign of potential issues that require attention/correction before a regulatory body comes in-house to investigate a problem. One of the automated tricks that I've implemented in the past relates to leveraging an organization's EMR and provider documentation processes. The provider that inputs a note in a patient's EMR may be prone to forgetting to sign that note/order before the encounter is submitted for payment. Without that provider signature, there could be an issue with demonstrating medical necessity, therefore leading to potential non-payment issues which impacts organizational profitability and RCM performance. Our solution? We modified the EMR system so that it would not allow a provider to move beyond documenting that encounter without a signature. A seemingly easy IT fix which built in a safety net so that the organization isn't sending out a claim that doesn't have a signature and hence risks non-payment or audit.

How do you look at quality of care in terms of compliance?

CMS switched from quantity to quality-based metrics via MACRA and other related initiatives. The shift of their focus from how many patients can a provider treat to publishing what a provider's annual outcomes demonstrates the importance of the government's commitment to patient care. As a result, many internal compliance programs are increasingly leveraging the government's standards for their patient quality/patient care programs. If you think about a physician practice, there are also internal clinical policies that establish their internal compliance standards. By way of example does a patient need to stop taking their blood thinners before a procedure? That is an internal practice standard that based upon their specialty, their experience, and the type of procedures that they're performing. Those internal standards, that from a compliance perspective, establish how that practice's patient should be

treated in order to have the optimal outcome. So if the question is, "Does compliance impact quality?" Absolutely. If the practice has a particular standard on how they're going to treat patients, employees need to work within those parameters to ensure that the patients have the optimal experience.

From an operational perspective what are you uncovering during a due diligence process that a typical, traditional legal review might not uncover?

I typically focus on the practice's privacy program and adherence to the OIG's 7 elements to demonstrate an effective compliance program:

1. State and Federal privacy requirements
2. Policies that actually match a practice's processes
3. Education and training that demonstrate competency of the subject matter
4. Auditing/monitoring of functions to detect fraud, waste and abuse
5. Appropriate business associate agreements
6. Is there a compliance officer with governing body access
7. Is there compliance committee that meets regularly
8. Is there a mechanism to report non-compliance
9. When a compliance issue is detected, is there action to correct the issue

I suspect a traditional legal review attempts to check the box on whether the above items exist, however the Scale team works closely with management to find the optimal solutions to any and all deficiencies that will result in a optimal outcome for patients and more compliant organization.

We don't just look at the infractions but we focus on best practice in every aspect and some of the most effective and sustainable solutions taking into consideration the practical realities of implementing change – we are operators as much as we are compliance experts. I think a great example was in our coding department.

We found some under-coding and over-coding during a recent acquisition audit to which the potential investors began to question the practice's reported revenue and future liability. Our team put those findings into context recognizing that based upon the practice's size, specialty CPT code and use of licensed providers under a supervision model, it was not unanticipated finding. We were able to mitigate concerns through education on the use of proper CPT codes, as well as documentation to ensure correct reimbursement for their encounters. SCALE's approach is more holistic identifying solutions which mesh with business objectives to ensure compliance going forward, as well as offering solutions to mitigation potential liability for deeds already done I think that's the piece that an experienced is well positioned to go through - it's the rationalization and practical understanding of what needs to be done to fix a problem as opposed to just highlighting the issue.

What are your thoughts on the role of onsite surveys and in person observation, when it comes to measuring compliance and risk mitigation in the practice world?

That's a great question. And I think that we are really used to providing diligence from a paper perspective only, and I think it's effective. It gives you a foundation, but ultimately if you really want to understand the culture, the compliance, the risk mitigation efforts made, you have to go on campus. I recall a time when we were on the 11th hour to close a deal and the last member of our onsite diligence team had made friends with the to be acquired practice's office manager who divulged, "Hey, I need to tell you exactly what's going on before the deal is closed." The practice had done a really good job at hiding their lack of compliance to state requirements And so if not for that in-person connection, I think we probably would've ended up with a practice that had some real issues that needed some major work. I found out years later, just coincidentally, that practice's physician owner was charged criminally and lost his professional license for his non-compliant behavior. In that example, being on site was crucial to understanding what we were purchasing and with whom we were about to partner with.

Are there other soft variables that people should consider when they try to triangulate to get a holistic view of compliance when they step into a new organization that they don't know so well?

As another example, we purchased a practice and probably six months into it came to understand the reputation that a particular physician had in the community, which wasn't great. And that could have been identified through just a phone call as part of pre-close diligence - somebody within your network. "Hey, we're buying this practice from a particular physician. They've been in the area for 30 years. What's his reputation?" I agree evaluating a physician's online reputation, but also who are you partnering with? Who are you buying the practice from? And what's their history from a practice sales/purchase perspective. I think you used the word "triangulate." I love that because I do

think that when you go in and you do due diligence, you do your best to capture everything, but you're not going to capture everything. You can look at practice's policies, at their online digital presence and reputation, but also make that outreach into the community to see their reputation. So it's really that totality of circumstance or totality of efforts that gives you an idea of what it is that you are purchasing.

How should a group of operators think about their compliance department? What are the number of compliance positions that should be populated in a group of 50 providers versus 10 providers versus 200 providers?

There are certain mechanisms, irrespective of size, that you would expect to see in any practice. Are there policies with respect to gifts, false claims, how to submit claims, how to address over payments? Does the organization have a mechanism to report non-compliance such as an external hotline? Or rather, does your organization have an open-door policy? Things that you can implement on a smaller scale that can also grow as you become a larger organization. As you become a larger organization, you would expect to find that those policies, those processes have become more sophisticated because there is more risk to evaluate. So as the organization gets bigger, by way of example the organization now has a call center, you would expect there to be call center policies and monitoring functions implemented that supplement the foundational policies/processes.

To answer your question, there are foundational aspects of a practice's compliance program that would apply irrespective of size and revenue, however as that organization grown, there is an expectation that their program would also become more targeted towards mitigating risk.

So, in a multistate practice, do you see normally that the compliance program may have different rules within those different states in terms of what state laws allow versus don't allow? And if so, can you give me an example of where you've seen that?

When you're in multi-state, you have to adhere to each state's law where you are located. So there's two scenarios. One is a practice that doesn't take federal dollars and that practice will need to adhere to that state's standards, requirements,etc. Or there's a practice that takes federal dollars so you have to rely on the applicable state and the federal law with respect to standards, requirements, etc. By way of example, many practice's would like to leverage paid referrals as part of their patient acquisition process. In some states, it is permissible for physicians to pay for a referral,

other states limit paid referrals to anyone who is not a physician, while the remaining states prohibit any paid referrals irrespective of source, similar to the federal prohibition. An organization which sits in multiple states must understand the laws which govern them – whether state or federal, and truly appreciate the nuisances between state laws and federal requirements.

How excited should the compliance space be with the introduction of automated data analytics and smart compliance based on processing large volumes of data, looking for statistical anomalies as another aid to individuals that are highly experienced walking through practices.

The case study for utilization of data analytics is the federal government Over the years, the federal government has been utilizing data driven algorithms to identify fraud, waste, and abuse to pick out those outlier providers and deploy their 3rd party auditors in an effort for recoupment. To demonstrate their effectiveness, the OIG dedicated $329M for oversight of the Medicare and Medicaid programs in 2021, and their ROI for their efforts was $3B. In light of the federal government's monetary windfall with utilizing data driven analytics in their fight against fraud, waste and abuse, states have also begun bringing independent enforcement actions against providers based on provider utilization Leveraging data analytics has proven to be an effective enforcement tool, and I suspect we will see more enforcement agencies, as well as internal compliance programs utilizing statistical abnormalities to detect non-compliant behavior in the future.

Special thanks to Lisa Melamed for her insights in this discussion.