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Health Care Compliance Association
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General Session

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9:00 – 9:30 a.m.
Music City Center
201 Rep. John Lewis Way South
Nashville, TN 37203

HHS OIG Enforcement and Compliance Update

Theme: A Hero's Journey

Good morning, everyone. Thank you for the invitation to speak with you. It is an honor to be invited. HHS OIG has helped write the story of health care compliance in the United States over the past 30 years. And as much as OIG has helped write that story, so has HCCA. The OIG has grown together with HCCA and together we are writing the next chapter in health care compliance in the United States, with you, its membership.

This morning, I would like focus on a different -- but related -- story. Your story, as a compliance professional. Why are you here at 9:00 a.m., on April 15th, at the Music City Center, in Nashville, Tennessee? In the story of your life, how did you get here? What made you take on the serious and huge responsibility of being a compliance professional?

In preparing for this speech, I was reminded of the beginning of COVID, when hospitals and medical centers and houses and highways had signs celebrating the heroism of front-line health

care providers and first responders. Those people are heroes – they showed up every day in the face of unknowable risks to themselves, their families, and their lives. They pursued the mission they had chosen, to care for the sick, under enormous pressure. I have always admired people who have dedicated their lives in the service of others. In the story of my life, whenever I have been injured, or sick, or needed medical help, it seems like the first person to help me has always been a nurse. Long before COVID, I always thought nurses were heroes.

And for as long as I have worked at HHS OIG (which is more than 24 years), I have also thought compliance professionals are heroes too. Every day you face the challenges of putting patients over profits, of resisting financial pressures that decrease quality, of building partnerships to keep your organizations on the straight and narrow. You sometimes must hold the very last line that represents doing the right thing in the face of the crushing business pressure of keeping your organizations thriving for the patients. I know that you take a lot of pride in the work you do. That you haven't forgotten about the difference between right and wrong. And that you care deeply about doing the right thing. This is no less significant than good versus evil. And I can assure you, at HHS OIG, we see you.

As compliance professionals, your hard work to ensure compliance with the law furthers OIG's mission to protect taxpayer dollars and patients. We know you are out there every day putting your professional reputation and everything else on the line to protect patients, government programs, and the complicated and sometimes delicate system we rely on in this country to deliver health care. People's lives are literally at stake.

You are not alone. We think each and every one of you is a health care compliance hero. For some of you, your journey in compliance began long ago. The synergy between OIG and the health care compliance industry started nearly 30 years ago with the National Medical Enterprises Corporate Integrity Agreement in June of 1994, followed by the 1998 OIG Self-Disclosure Protocol and Compliance Program Guidance documents. We know the importance of transparency, integrity, leadership, and accountability in your everyday lives.

Our partnership over the years has been a force multiplier for the impact OIG and you have made in the health care community. We identify risk areas, conduct audits and studies, investigate fraudsters, and issue compliance guidance. You take our work to the next level – using it to monitor your risk areas, spot outliers, challenge your organizations to do better, and spread the word at conferences like this.

Today I am going to tell the story of a **Hero's Journey**. Following the same template that is found in literature, I am going to walk through certain stages or events in the professional life of a compliance officer. Although the story is a composite picture that highlights the purpose and meaning of a compliance officer's work, every part of this story is based on case examples we worked on at OIG.

The Hero in this story is You.

In your journey to where you sit today, you have faced challenges and decision points, made brave choices, and met helpful friends and mentors along the way.

What were you doing before you answered the call to become a compliance professional? Did you have a clinical background? Were you an auditor or an attorney? Maybe you had a background in billing and coding or in health IT. I suspect you were very good at your old job. You could have kept doing it for many more years and had a successful career. But there was some spark inside you that called you to serve in a different way. And that spark ignited. You wanted to be a guardian and to protect health care entities and their patients.

Do you remember your first day on the job? Think about how it felt when you heard, and you answered the call to work in compliance. How did it feel when you got your first opportunity to serve in the compliance department of a health care entity? You wanted to be a leader at the bow of the ship. You saw the risk areas for health care businesses, and you wanted to steer the ship – and the people on it - out of harm's way. You admired compliance leaders who make the good happen. Maybe some of them were your heroes.

Imagine that you were offered your dream job as the Chief Compliance Officer at a hospital that serves people who desperately need essential health care. You were so excited to get that offer. Maybe you even went out for a celebration dinner. But after dinner, your enthusiasm went down when it dawned on you that the Hospital's last three compliance officers left after each of them had served only a year or so, leading you to question the Hospital's commitment to compliance and support of the position.

You knew that a strong compliance culture must come from the top of the organization. Were the prior compliance officers pushed out after trying to make positive change? Were they frustrated with the support they were not getting from Hospital leadership? You knew that you couldn't change the culture on your own, and this new opportunity might be an uphill battle. What would you do? Would you answer the call? Would you take the job?

Maybe you were worried about whether you would be successful at the Hospital where the other compliance officers had failed. You certainly had your doubts and maybe you said "no" at first. Maybe you doubted your ability to turn a reluctant compliance culture into a great organization?

How would you make this decision? Who would advise you?

Imagine you went to a compliance conference, much like this one, and you ran into your professional mentor. Would you explain your concerns and ask for advice? Take a moment and ask yourself: who is your mentor? Perhaps that person is actually here in the room with you today. Who is your Obi-Wan, or your Yoda?

What influence would your mentor's encouragement have on your decision? Imagine she reminded you that you have never shied away from a challenge. What if she said your integrity, hard work, discipline, and smarts were the ideal skill set you needed to succeed? What if she told you a story from her career, when she was faced with a similar challenge?

At the conference, you are reminded of all the valuable resources available to support you. For example, OIG has a number of resources designed to support compliance officials, including:

The OIG's **General Compliance Program Guidance or "GCPG"**: This can be a map for a Hero who is temporarily lost. It brings the ethereal concept of "do the right thing" down to Earth with concrete steps for a compliance officer to take. The GCPG was released in November, and in writing it, we looked at the best of the best – what are they doing? It represents a culmination of what we have learned over the last 30 years and our look to the future. It contains a handy table of contents that takes you directly to the different elements of a compliance program, and it has practical tips for any sized entity.

- *In a session at 10:30 today, OIG experts will be speaking about OIG's GCPG with practical tips for using the new document.*

We have heard from compliance professionals that the practical tips, questions, and scenarios presented in the GCPG are especially useful. The GCPG aims to serve as a tool that compiles many of the applicable rules and guidance in one place, so compliance officials don't have to spend time hunting for them.

We are going to follow this up, starting this year, with industry specific CPGs or "ICPGs" that will be tailored to fraud and abuse risk areas for each industry subsector. OIG intends to publish ICPGs focused on Medicare Advantage and nursing facilities later this year. And we just announced on February 20th, that after addressing these segments, OIG anticipates publishing updated ICPGs for hospitals and clinical laboratories.

HCCA and OIG also worked together a few years ago to provide another helpful resource for your compliance journey. The **Guide to Compliance Program Effectiveness** has hundreds of questions to ask to help figure out if your compliance function is looking at the right things. It can help you focus on what to tackle first, and how to ask the right questions.

- *Later today, OIG will speak about compliance program effectiveness, and yesterday, you may have heard one of our sessions about risk assessments as an essential piece of every compliance program.*

Another valuable tool to support you in your journey is **OIG's Corporate Integrity Agreement page**. OIG's CIAs are with different types of entities and highlight best practices and compliance risks for many different industry sectors.

- You can hear OIG speakers talk about some of our industry specific work in several sessions here. For example,
 - *We have a cross-disciplinary team of OIG experts speaking on Tuesday about "Enforcement and Compliance in Managed Care."*
 - *One of OIG's highest priorities is keeping nursing home residents safe, and tomorrow, we will speak on "Realizing the Promise of Nursing Home Care for Residents: an OIG Perspective."*
 - *If you are curious about how your organization should be thinking about the new Information Blocking penalties, definitely attend our session on Wednesday.*
 - *And an All-OIG team will also speak Wednesday on OIG's Hospital Compliance Audits.*

Returning back to your journey, the hero's journey, after you talked to your mentor at the conference, you were reminded of all the support available to help you make the right decision

and be confident in your compliance expertise. Pumped up by your mentor's faith in you and these valuable resources -- you realized that you, like many heroes, are not alone on your journey.

You accepted the position as the Hospital's Chief Compliance Officer. You left behind your familiar world of clinical practice, or coding, or auditing or law, and you crossed into a new world. You viewed the path ahead as long, but you were optimistic about the potential and the good you could do.

You remembered hearing about other Compliance Officers who had taken on this sort of challenge and succeeded. They had discovered a whole range of compliance issues and you have read the self-disclosures that resulted from these discoveries. You know that all of these compliance officers went through skeptics, naysayers, and obstacles to have their message heard.

You know that you have the tools to do the same, and to make the Hospital's care better. So, you start right away by evaluating the Hospital's various risk areas.

But once you began working at the Hospital, you realized the Hospital's financial condition was worse than you expected and there were problems at every turn. You were going to have to confront many tests and many challengers, while creating allies.

You reviewed a compliance audit that showed several doctors had not paid rent under their space leases in years. Billing audits showed consistent upcoding in various departments. So far, no

one had contacted the doctors using the free space and the Hospital had not repaid the upcoded claims.

You knew that kickbacks can corrupt medical decision making – where the motives behind medical interventions are influenced by money rather than patient need. At OIG, we have also maintained our focus on kickbacks and other illegal remuneration, and we continue to be concerned about the corrupting influence of money, resulting in patients getting care that may not be in their best interests, but that instead is the result of an illegal arrangement. Recently, the government has seen:

- Sham medical directorship agreements with doctors that were vehicles to pay kickbacks for nursing home referrals.
- Hospitals paying doctors amounts greater than fair market value to induce referrals to the hospital and paying bonuses for referrals made.
- And labs and marketers disguising payments to doctors for referrals as “returns on investment” from a fake company.

Your most significant concern was a preeminent surgeon in their field of study and the Hospital’s highest revenue doctor. This highly respected physician was a pillar in the community. In fact, one of the hospital wings was named after him. The doctor was receiving free staff from the hospital in addition to the largest office suite. You were concerned that the Hospital had not monitored the doctor’s practices for potential risk. You suspect that your predecessors tried to, and were met with resistance, leading to their departures.

You discussed your concerns with the CEO who told you the doctor's demands must be met otherwise they would take their surgeries to another hospital. The doctor expected to call the shots and refused to with cooperate with any oversight efforts by the Hospital. The CEO sounded distressed by the situation, but felt her hands were tied.

Something didn't feel right to you about this surgeon, and you resolved to conduct a review to protect the Hospital and its patients. You found a recent compliance audit that revealed this same surgeon spent more time in the OR than any other doctor in this specialty. The anonymous hotline revealed calls from the OR nurses complaining about the doctor's care.

You raised these concerns to the Chief Medical Officer. There were no resources to engage an outside medical expert, but you hoped the issues would be presented for peer review. The CMO seemed to think that it was normal that the surgeon had the most time in the OR given his prominent background and was not impressed with the nurses' concerns.

You knew that the government has investigated other hospitals and doctors for similar issues.

You knew that quality of care concerns can occur in any medical setting. Just recently:

- You recall hearing reports that some residents in nursing homes received medically unnecessary psychiatric medicine to control their behavior.
- You remember a recent False Claims Act settlement involving poor quality neurosurgeries.
- You also learned about allegations involving other entities that lacked sufficient staff to maintain a safe environment and did not actually provide the care that they were paid for.

- And in one recent settlement, you saw that a practice billed for medically unnecessary chemotherapy, biopsies, and PET scans.

You are at a crossroads, and you decide to be tenacious. You know the Chief Medical Officer and the CEO are close, and you push forward anyway because it's the right thing to do. You were deeply concerned about the quality-of-care patients were receiving in the hospital.

As you discovered more alarming facts, you realize that you are entering territory that could be risky for your career. Still, you press on to the next stage your journey. At this point, you really are in the belly of the whale, where it is dark, and you can't see anything.

You grew more alarmed as the Hospital ignored these red flags and continued its risky financial relationship with the doctor. It felt like the doctor had more influence than you did as the Chief Compliance Officer. And it felt like the Hospital, and its leadership, were much more concerned with the Hospital's finances than with compliance. The CEO and the CMO were not listening to your concerns or taking your role seriously. You wondered: is this why the prior Compliance Officers left?

Were you willing to put your job and reputation on the line? You had choices to make: 1) You could leave. 2) You could stay and find allies. Or 3) You could find the leader you need.

What would you need to stay at the Hospital? What would make you trust that the Hospital cares as much as you do about its future? Do you want more resources? Empowerment? To be heard? Respect? Something else?

As you reflected, you remembered the old adage that the door to leadership opens inward. You came this far. You saw the issues, examined the risks, and made the commitment to improve compliance. You realized that you were the leader the Hospital needs.

You decided to directly express your concerns to the Board of Directors. To your surprise, you realized you already had several allies on the Board. They had been paying attention to OIG's guidance over the years, and a couple of them had served on Boards previously for entities under CIAs and attended HCCA conferences. They have carefully read OIG's guidance for Board members and have actually shared it with some of their colleagues. They understand their responsibility is to question the Hospital's leadership in good times and in bad, and this seemed like one of the bad times. They convinced the other Board members to listen to you, and the Board jumped into action to support you.

Imagine that the Board hired an expert to review the surgeon's care and billing. It was much worse than anyone expected. Patients were subjected to -- and harmed by -- medically unnecessary procedures and surgeries performed by the surgeon. Government programs were billed for those services. The Board engaged auditors to examine the upcoding, and problems were found in several other departments. Your concerns were validated.

The Board turned to You for expertise and guidance. You advised that the Compliance, Legal, and Clinical Quality Departments should work collaboratively on the next steps. You knew that

self-disclosure to OIG was the gold standard to avoid a years-long investigation, disruption to patients and staff, and uncertainty.

With those three Departments working hand and glove, the Hospital took the following actions. It:

- Reported your findings about the doctor to OIG, the medical board, and the National Practitioner Data Bank.
- Ended the relationship with the surgeon and notified patients about the care concerns.
- Made a submission to OIG's Self-disclosure protocol about the Hospital's liability for the doctor's surgeries, the upcoding, and the kickback violations.
- And examined and revised policies to bolster the quality of care provided by the Hospital.

Days later, it became public that the government was pursuing the Doctor criminally for performing medically unnecessary surgeries on his patients. Your timely and patient-focused work protected the Hospital from being further swept up in the criminal investigation and prevented other patients from potential harm. The Hospital agreed to cooperate with the government in its investigation of the Doctor.

Your devotion to patients, your compliance expertise, and your commitment to find allies guided Hospital through the crisis. In fact, it was your leadership that led the Hospital through the storm. As a result of your guidance and the result you achieved, the Board embraced compliance and you were given the seat at the table that you needed to effectively do your job. You finally trusted the Hospital's commitment to doing the right thing. But you also knew that you and the Hospital must stay diligent.

The months that followed were very difficult. Negative media coverage caused staff morale to suffer. But your team made meaningful change. It mattered.

The compliance team implemented new policies and got more resources. Compliance gained a voice that is heard in decision-making. The Hospital merged with a local health system and became more financially stable.

You knew how important it was to have leadership committed to a culture of compliance and excellence. Owners and directors have been indicted, excluded, or paid steep fines for their role in health care fraud. And OIG continues to hold individuals and entities accountable to protect people. You were aware that recently, executives have directed fraud, by:

- Approving false marketing messages in order to get Medicaid to pay for a drug or service.
- Creating and selling templates of doctors' orders for DME and medicine in exchange for kickbacks.
- Creating a business model that relied on false physician orders for urine drug testing at labs.
- And depriving nursing home residents of sanitary and safe living conditions by failing to put qualified management in place or to follow regulatory requirements.

You were relieved when new, independent Board members were added to the Board and the CEO and CMO were replaced.

You are proud of what you accomplished and how it improved the care for members of the Hospital's community. Doing the right thing boosted staff morale and added trust among the Hospital's leadership and staff. It's a new day.

Your hard work and the knowledge you've gained along the way gave the entire Hospital community the freedom to live out its mission in line with its values, and to deliver care to people who need it.

You returned to the annual compliance conference and gave a presentation about your experience and leadership lessons. What did you learn? Perhaps you would tell your colleagues:

- 1) Never underestimate the importance of speaking truth to power.
- 2) You don't have to do this alone: there are allies in the compliance community who will help you. In fact, partnerships are key to accomplishing the goal.
- 3) Trust your instincts.
- 4) Know the importance of independence. And hold that independence in creative tension with a connectedness to your organization. Leverage the combination of those two values together, to achieve your higher purpose of leading an effective compliance program.
- 5) Move forward with the confidence to know that your journey in compliance has prepared you for the risks your organizations face today and in the future.

Even though you have shared your lessons with other compliance officials, you know your journey continues—and you know the risks that organizations face today and in the future. To arm the heroes in the audience here today, I will briefly mention two of those risk areas as they relate to compliance.

First, artificial intelligence. In the early 2000s, I likely worked with some of you in this room on the government's pneumonia upcoding national project, where hospital billing consultants who were paid a percentage of the hospital's increased Medicare reimbursement left a trail of qui tam settlements behind them after they helped the hospitals "find" supposed evidence in the patient's medical record supporting the use of a billing code that grouped to a higher paying DRG. Ask yourself: how would that pneumonia upcoding have been different if the consultants had been using artificial intelligence to accelerate the scheme or, on the flip side, if the government had been able to use artificial intelligence to catch the fraud earlier. Or if compliance officers had used AI to catch the upcoding in an audit and remediate it. Either way, I expect that as compliance professionals you are going to be among the very first to spot where the AI has created a program integrity vulnerability, and maybe you will be using your own AI tool to detect it. When the new technology is rolled out in your organization (and maybe it already has been), and processes are further automated, I anticipate that the compliance department will likely be on the front lines dealing with situations where the provider used AI algorithms to bill for things that did not actually happen, or services that the patient did not need.

Another risk involves private equity. One of the topics that I have challenged our office to consider is the growing prominence of private equity and other forms of private investment in health care, and how this investment raises concerns about the impact of ownership incentives (for example return on investment) and how those incentives may affect the delivery of high quality, efficient health care that is in the patient's best interests and that is accurately billed to the federal government. When a private equity company gets involved in running the business of

its health care portfolio companies, perhaps in connection with a large management fee it is receiving, I anticipate that you, the compliance professionals, are going to be first to identify instances where the private equity company has influenced the medical decision-making or has cut the staffing in a way that means patients are not getting care that is in their best interests, but instead is in the profit-making interests of the investors.

Although these are relatively new risk areas, in many ways they are simply new chapters in an ongoing story. With your passion, your skills, and your experience identifying, evaluating, and remediating compliance issues, move forward with the confidence to know that you are prepared to handle them. It is your leadership ability that will make the difference for your organizations.

Compliance professionals, I want to end by telling you that at HHS OIG we see you. We know that every day you make decisions and influence your organizations to do the right things. Your hard work saves lives and improves lives. It is meaningful. It matters. Your commitment is inspiring. So, Compliance Heroes, rise up to meet your challenges. And know that HHS OIG has been and will be with you on Your Hero's Journey.

Thank you very much.