




Compliance TODAY

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A professional portrait of Marla Berkow, a woman with curly brown hair and glasses, wearing a dark blazer over a white top. She is standing with her arms crossed against a blurred background.

Compliance and behavioral health

an interview with
Marla Berkow



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Marla Berkow, CHC
 Corporate Compliance Officer
 Gateway Foundation
 Chicago

an interview by Adam Turteltaub

Meet Marla Berkow

*This interview with **Marla Berkow** (Msberkow@gatewayfoundation.org) was conducted in October by **Adam Turteltaub** (adam.turteltaub@corporatecompliance.org) Vice President of Strategic Initiatives & International Programs, Society of Corporate Compliance and Ethics & Health Care Compliance Association*

AT: I want to start with your educational background. A lot of people come into Compliance with a legal background. You studied behavioral science and organizational behavior. On the face of it, that sounds like a great background, but has it proven to be?

MB: I have no regrets and would not trade my residential liberal arts education for anything in the world. My undergraduate degree is actually in Cultural Anthropology. I studied child language acquisition. My

first regulatory position was in the Legal department of a vitamin and supplement manufacturer, reporting directly to an international regulatory attorney first and then to the Assistant VP of Legal, so working under a licensed attorney was necessary, I believe, to complement my educational background and to gain an understanding of legal review and due diligence. Additionally, once I began overseeing regulatory implementation, it was clear that legal education would help me. But as far as perspective, having a behavioral science background really helps when working through employee relations issues and in developing training and corrective action plans. My liberal arts education has served me well, and I would not have done it any differently, given the opportunity.

AT: What are some of the key tenets of organizational behavior that you think more compliance professionals should know?

MB: For me the most significant take-away from studying organizational behavior was the evolutionary psychology approach that has been applied to management. When in graduate school, I built on my undergraduate research and reviewed evolutionary theory, but applied it to organizational development instead of as pure academic research. Evolutionary psychology focuses on how evolution has shaped the mind and behavior. Applied to an organization, that information is used to better understand human behavior in order to create a better work environment. Understanding human nature and what the evolutionary psychologists call, “hardwiring” and working with it, rather than against it, is really important in corporate compliance. Particularly when you are working preventively, people have to accept where you are coming from and be motivated on an intrinsic and not always a conscious level to cooperate.

AT: How have you handled not having the legal background that so many have?

MB: Not being a licensed attorney keeps my role totally distinct and separate from any other service. However, I was fortunate that my years working in international regulatory affairs were spent reporting directly to a licensed attorney. This helped me immeasurably, because I learned firsthand that the standards a regulatory attorney holds herself to are extremely high and often unforgiving. Additionally, drafting letters that will be reviewed by and/or signed by an attorney taught me a lot about claims substantiation and adequate documentation. Regulatory affairs work provided invaluable lessons that carried into corporate compliance.

AT: Let’s move into the specifics of your career. It’s interesting to me that you’ve had compliance roles in three different healthcare-related fields: nutraceuticals, health insurance, and the provider arena. How similar or different have you found the compliance challenges as you moved from one to the other?

MB: While I have made some significant career shifts, many compliance challenges remain constant: keeping up with regulatory changes, learning the key components of relevant laws, and making certain that compliance is perceived as a valuable resource for the business. Working for a non-profit healthcare provider can be a roller coaster ride in our current political climate, but I love the work. It is also a very exciting time in healthcare, so I am enjoying being in the midst of a politically charged and meaningful debate. As you may know, the opioid epidemic is shining a spotlight on access to addiction treatment. The OIG Work Plan was also recently revised to include a review of Medicaid managed care in five states in order to evaluate why behavioral health services are so limited. Parity laws have been in effect since 2008 and were extended to small group and individual insurance plans in 2010. Parity is now extended to Medicaid managed care plans and Medicaid benchmark plans federally, but access to coverage remains a barrier to treatment. Parity laws ensure that mental health and behavioral health services are covered in a way that is comparable to and not more restrictive than for medical or surgical benefits. Full implementation and enforcement of parity rules will help consumers get access to treatment.

AT: How did your experiences with each job affect how you met the compliance challenges of the others?

MB: The most significant change that I have experienced through each transition is my relationship with legal counsel. I have gone

from working directly under the attorney, to a more consultative relationship, and finally to a collaborative yet distinct working relationship. As time goes on, I become more secure with my comments and recommendations and get a better sense of which issues need my immediate attention and review from a risk management perspective, and which things should go to legal counsel.

AT: Let's dig deeper into some specifics of the challenges of each position. When you were at Nutraceutical International Corporation, you had a global job, as the company's name implies. What were some of the non-US healthcare compliance challenges you were managing?

MB: The regulatory requirements on food, vitamins, and supplements outside of the U.S. are similar to drug requirements. For example, in the U.S. no health claim may be made on a food or dietary supplement label unless it has been evaluated by the Food and Drug Administration (FDA). A health claim could be made, but if it has not been evaluated, the product label must also contain a disclaimer that the claim has not been evaluated by the FDA. The FDA rules allow for qualified health claims upon review of scientific evidence to support the relationship between an ingredient or supplement and health benefits, but it is not required. There are very few published FDA-approved health claims. One is the calcium, vitamin D, and osteoporosis claim. Additionally, the process for claim review in the U.S. is very different than for Canada and Europe.

When I was working with Europe and Canada, health claims were required to be made and substantiated with evidence, and traditional uses qualified as evidence. Certain countries also required special testing and quality certification for ingredients, beyond what is required when you

do not import. So importation requirements were a big challenge, plus product registrations were required for Canadian distribution. Each product had a dossier filed with Health Canada's Natural Health Products Directorate.

AT: What were some of the key takeaways from your non-US work that helped you manage domestic compliance issues?

MB: Working with other countries has helped me to keep in step with the regulatory changes that protect consumers after the passage of the Affordable Care Act. Working with Canadian and European regulations positioned me to effectively understand how regulators think. It set me up to work well within highly defined regulatory requirements and to have an idea of the possible direction that the US healthcare industry may be going in.

AT: From there you went to work for Health Care Service Corporation (HCSC), which is an independent licensee of the Blue Cross and Blue Shield Association. What were some of the surprises from a compliance perspective when you walked in the door?

MB: The health insurance industry was new to me, and certain aspects of the business came more easily than others. Working to help get ready for the new marketplace and the first year of the health insurance exchanges was exciting and a new experience for everyone involved.

AT: From HCSC you moved onto Gateway Foundation, which provides substance abuse treatment. Was moving to the provider side of things a bit of a shock?

MB: The change was pretty major and was a good one for me. I am much more comfortable working for the provider and

with clinicians. I had worked with lab and clinical staff in my previous role and missed that level of review. I am more engaged with quality now, which really excites me. Of course, privacy and confidentiality regulations are my specialty, and substance use disorder treatment records are subject to some of the most stringent regulations, in order to remove a potential barrier to treatment. Learning the Confidentiality of Substance Use Disorder Patient Records regulations found at Title 42 of the Code of Federal Regulations Part 2 was a big part of Gateway Foundations compliance program. Fortunately, we engage renowned and highly recognized outside counsel for certain matters, and I have had wonderful on-the-job training from our outside counsel as well as our seasoned staff. Having worked in the Privacy Office at HCSC, I was able to bring a lot of structure to the programming.

AT: How well were you able to apply what you had previously learned? Did anything not work so well?

MB: I had to practically start from scratch when I moved into health insurance. Once I got situated in the field, it became clear that privacy regulations would become my niche. After I found my groove, my previous work became foundational and helped me to excel and forge a path in the healthcare compliance field. I started to find my niche in the Privacy Office at HCSC. I could not have done the work or gotten hired at Gateway Foundation without my law school course work and CHC certification.

AT: You're a one-person shop there. What advice would you give to others who have to do it all?

MB: The best advice I could give is to build strong partnerships and alliances within the organization. Besides the CEO or the person

to whom you report directly, your general counsel is probably the most necessary ally for compliance. Build trust with the executive management and executive directors of the program and with board members, too. On a practical level, I deal most directly with Human Resources to resolve compliance matters. For privacy and confidentiality issues, I want everyone to be able to call me. I have worked hard to get program directors and clinical staff to call me. Some really good advice I got when I first started was from a friend who is also a business coach. She said to let people get to know me, because when they contact the compliance officer, they aren't contacting the position—they are contacting you, Marla.

AT: In the midst of this career, I should point out, you also took Hamline University School of Law's Healthcare Compliance Certification program. With all this on-the-job experience, what made you pursue the program?

MB: Even though I had been in regulatory and compliance for a number of years, my role had shifted, and the healthcare industry was in a very unique period, going through significant reforms. I wanted to get a handle on the situation, make the most of it, and turn it into an opportunity.

AT: What did the course bring to your compliance work?

MB: Taking law school courses was critical to working successfully in the Compliance field. Gaining an understanding of compliance laws, regulations, and case studies sharpened my ability to identify potential legal risk and swiftly make operational changes to mitigate identified risk. My course work also allowed me to sit for the CHC exam, which introduced me to the professional industry organization, the HCCA.

AT: Finally, yoga is a passion of yours. Do you think it helps your compliance work?

MB: Yoga has been my hobby and beloved pastime for over 30 years, and it helps me with everything else in my life. I practice daily at home, after my morning coffee, which prepares me mentally for the day ahead and also grounds me physically. Meditation is also part of my morning routine, and solutions to complex issues often come to me during and after meditation. Compliance professionals see the worst mistakes and decisions that people make, and it can be discouraging. Particularly in healthcare, it is important to maintain a healthy and balanced perspective, recognizing that most of our co-workers have a strong dedication and commitment to patients. Regular yoga practice, mindfulness practices, meditation, and even simple mindful breathing can have an immediate and calming effect, helping to promote a slower heart rate, clearer thinking, and more rational decision-making. Yoga absolutely helps improve the quality of my work, not to mention the quality of my life.

AT: Thank you, Marla for sharing your insights with us. ☺

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