



# Compliance

## TODAY

April 2017

A PUBLICATION OF THE HEALTH CARE COMPLIANCE ASSOCIATION

WWW.HCCA-INFO.ORG

A portrait of Ryan Meade, a middle-aged man with short, light-colored hair, wearing a dark suit, a light blue shirt, and a patterned tie. He is smiling slightly and looking directly at the camera. The background is a blurred interior space with large windows and what appears to be a library or study area with bookshelves.

## The mission of making Compliance an academic discipline

an interview with **Ryan Meade**  
Director, Center for Compliance Studies  
Loyola University Chicago School of Law

See page 16

**24**

Understanding MACRA's strategic and compliance implications

Bruce A. Johnson and Marissa R. Urban

**33**

Caution: Hospital nurse practitioners may raise Stark issues

Charles Oppenheim and Amy Joseph

**39**

McDonnell's impact on the evolution of the Anti-Kickback Statute

David L. Kirman and Cameron G. Smith

**48**

2016 False Claims Act review: A truly extraordinary year

Michael A. Morse



## FEATURES

- 16 **Meet Ryan Meade**  
an interview by Art Weiss
- 24 **Understanding MACRA's strategic and compliance implications**  
by Bruce A. Johnson and Marissa R. Urban  
Potential strategic trends and compliance-related headaches for the value-based payment and care delivery systems under Medicare Part B.
- 33 **Caution: Hospital nurse practitioners may raise Stark issues**  
by Charles Oppenheim and Amy Joseph  
Medicare billing rules for shared services are unclear, which can bring up some tricky issues when a hospital-employed nurse practitioner performs part of a physician's duties.
- 39 **McDonnell's impact on the evolution of the Anti-Kickback Statute**  
by David L. Kirman and Cameron G. Smith  
Recent case law may provide a compelling defense for conduct that is designed to build beneficial relationships with customers, but there is still a legal gray area.
- 48 **2016 False Claims Act review: A truly extraordinary year**  
by Michael A. Morse  
A brief overview of the larger recoveries and historic milestones in the 30<sup>th</sup> anniversary year of the FCA.



*Compliance Today* is printed with 100% soy-based, water-soluble inks on recycled paper, which includes includes 10% post-consumer waste. The remaining fiber comes from responsibly managed forests. The energy used to produce the paper is Green-e® certified renewable energy. Certifications for the paper include Forest Stewardship Council (FSC), Sustainable Forestry Initiative (SFI), and Programme for the Endorsement of Forest Certification (PEFC).

## COLUMNS

- 3 **Letter from the CEO**  
ROY SNELL
- 22 **Exhale**  
CATHERINE BOERNER
- 31 **Managing Compliance**  
LYNDA S. HILLIARD
- 37 **Connectivity**  
NANCY J. BECKLEY
- 46 **The Compliance–Quality Connection**  
DONNA ABBONDANDOLO
- 53 **Privacy Ponderings**  
ERIKA M. BOL
- 59 **Computer Tips**  
FRANK RUELAS

## DEPARTMENTS

- 6 **News**
- 12 **People on the Move**
- 82 **Newly Certified Designees**
- 84 **New Members**
- 86 **Blog Highlights**
- 87 **Takeaways**
- 88 **Upcoming Events**



**Ryan Meade**  
 Director  
 Center for Compliance Studies  
 Loyola University Chicago School of Law

an interview by Art Weiss

# Meet Ryan Meade

*This interview with **Ryan Meade** (rmeade@luc.edu) was conducted in December of 2016 by **Art Weiss** (art\_weiss@tamko.com) Chief Compliance & Ethics Officer at TAMKO Building Products in Joplin, MO.*

**AW:** Please give us some background on yourself.

**RM:** I am a law professor at Loyola University Chicago School of Law where I direct the Center for Compliance Studies and oversee the curriculum for our compliance-related courses. We have over 40 courses now, between the on-campus and online programs. I teach a variety of classes, including a basic compliance course, advanced compliance, privacy and security, and other

regulatory and administrative law-related courses. I also am a managing director at Aegis Compliance & Ethics Center, LLP, and I still practice law through Meade, Roach & Annulis, LLP. I went to college at Northwestern in Evanston, Illinois and law school at Cornell in Ithaca, New York.

**AW:** What positions have you held inside organizations?

**RM:** Within my law and consulting career, I have held the usual positions of associate and partner. I was an associate at Mayer Brown, a large international law firm based in Chicago, and a partner at Katten Muchin Rosenman, another large law firm based in Chicago. In 2004, I helped

form a boutique law firm and consulting firm focused on compliance. At Loyola I am Director of Regulatory Compliance Studies. I have taught at Loyola since 1998 when I began as an adjunct and, a few years ago, I transitioned to the full-time faculty in order to lead Loyola's Compliance Studies initiative. I work with the on-campus JD students who are taking the Compliance concentration track, as well as our online Masters program students who are taking the Compliance concentration. We have an online Master of Jurisprudence (MJ) program for non-lawyers and a Master of Laws (LLM) for students who are already lawyers.

**AW:** Tell me a bit more about the Center for Compliance Studies. Students are actually studying Compliance for a degree?

**RM:** Yes! It's remarkable how far Compliance has come in 20 years. We have dozens of on-campus law students in the Compliance concentration, and we have about 150 online MJ and LLM students who are focusing on Compliance. Our MJ and LLM programs are broader than just Compliance, but Compliance makes up about one-half of our online students. If they wish, the compliance students can narrow their studies to one of five "areas of focus": corporate compliance, healthcare compliance, privacy compliance, life sciences compliance, and global compliance.

We've divided the courses into two types. The first type deals with compliance program structures, such as the basic elements and how to use the elements to manage legal and regulatory risk. We have a number of courses related to compliance and ethics programs that are focused on specific elements, such as Compliance Training, which gives students exposure and practice in training, and Drafting Policies and

Procedures, which gives students training in taking complex regulations and writing them in plain language for the workforce. The second type of courses involves a deep dive into specific regulatory areas and tying them to compliance programs. For example, we have several courses on privacy, a number on life sciences that extensively teach FDA law, as well as securities, anti-trust, and international law courses and a big bundle of regulatory courses focusing on the healthcare industry.

**AW:** So is the Center for Compliance Studies just focused on courses?

**RM:** Oh no, not at all. We have a lot of activity happening. Of course, our primary focus is on the students. First and foremost, I am a teacher, so the students come first, but the Center has an overall mission of making Compliance an academic discipline. It's a tall order, but we are well on our way. Compliance is firmly established as a profession, and now it needs to be studied and be recognized as an academic discipline. To that end, we have established a law review dedicated to Compliance, the first of its kind. It's called the *Loyola Journal of Regulatory Compliance*, and I'm Editor-in-Chief. I have a large student board that assists in the editing and production, the usual way a law review works. We publish scholarship on Compliance and Ethics, both practical and speculative, though the publications tend to be more focused on theory. We want to fill the gap in journals that look at regulations and compliance theory.

The Center also runs a blog, *Inside Compliance*, which the students maintain and write on. The blog allows the students to tackle timely topics, and they are able to build a public identity as someone on top of an issue. It contributes to compliance

commentary and it helps students get visibility in the Compliance community.

We also have an annual symposium that brings together scholars from all over the country to discuss compliance, ethics, and regulations. Our first symposium was a great success in the fall and, as far as I am aware, it was the first academic symposium dedicated to Compliance.

**AW:** Why do you think there is a need for Compliance to be an academic discipline?

**RM:** That's simple—because people want to make Compliance their profession, and they are interested in sustained study of Compliance. People now want degrees in Compliance to show their accomplishments and distinguish themselves. I never would have thought this would be the case even 10 years ago, and especially 20 years ago, when I first started working with compliance and ethics programs. But it makes sense. Before there were law schools, there were lawyers; before there were medical schools, there were physicians; and so on. Compliance professionals are a permanent part of business, and now we need the academy to study and train for the role.

If we look over the history of professions, we see the same patterns. The market needs something and people fill that need, professionalize the skill, organize themselves, and pretty soon we see that a new profession has taken hold organically. Then the next question comes when people start wondering, "How do I enter that profession?" One way is to study the profession and train in the skills; that's what we do for the students at Loyola and why Compliance needs to be recognized as an academic discipline. There are other reasons too, of course, that Compliance

needs to develop as an academic discipline in that Compliance deals with speculative and practical ethics, organizational theory, psychology, finance, behavioral theory, and law. We need people who will help tie together the themes.

**AW:** Are Loyola's students able to sit for any of the Compliance certifications (CCEP, CHC, CHPC, CHRC)?

**RM:** Yes, our program is one of the academic programs accredited by the Compliance Certification Board. Our students must take a certain number of credit hours in the accredited courses, and then they can sit for any of the CCB certifications. Many of our students take the certifications that give them a leg up in the job market. There is a fairly extensive process for accreditation. All of the Compliance-related courses are reviewed by the CCB and an on-site visit occurs. Our students greatly appreciate the accreditation because it gives the program instant recognition in the Compliance field.

**AW:** Does studying Compliance for a degree mean we are entering a new era of compliance?

**RM:** Most definitely. Everyone working in Compliance today has fascinating stories on how they got to be a compliance professional. Some of them are usually pretty amusing stories—last-person-standing, drew-the-short-straw, the CEO-stopped-me-in-the-hallway type stories. I always tell my students the best way to network with compliance officers is to ask them how they got into Compliance! I think it's fair to say that most people working in Compliance today got into their first compliance job not knowing what compliance was all about and then grew to like it, but before

they liked it, there was probably first a lot of wandering in the desert. I think those ways of getting into the profession will always be there for Compliance, but now there is a new narrative taking shape. People are studying Compliance, doing internships in compliance programs, and getting a much better sense of what the job is about before they start. My students aren't landing in compliance jobs by default; they are purposefully studying Compliance in order to get compliance jobs and make it a career.

If you turn the clock back 10 or 20 years, most compliance officers likely didn't know if being a compliance officer was a long-term position for them or they were simply filling a corporate role for a while. We now have students wanting Compliance as a career. I'd say that is a new era for Compliance. We are also seeing compliance programs maturing enough that there are many entry-level opportunities for graduating students.

**AW:** How do you get professors who can teach Compliance if it has only been an academic discipline for the past five minutes?

**RM:** That's the easiest part of my job. I find compliance professionals are excited to impart their knowledge to a younger generation coming into the profession. It's really remarkable how much compliance officers like teaching students. Because Loyola's MJ and LLM programs are online, our professors can be anywhere in the world. Our professors are mostly compliance

professionals, some are compliance officers of major organizations, and they take the time out of very busy schedules to teach. Our professors don't just teach compliance, they live it in their day jobs. We are lucky to have a talented and generous faculty. Professors who are not compliance officers are lawyers and government officials working in the compliance and regulatory space and consultants who advise companies on compliance. In fact, a number of my students are being hired by major consulting firms after finishing their degrees.

**AW:** Speaking of consultants, you've been one. What is the role of a consultant?

**RM:** Consultants serve a lot of roles. It's probably best to list a few of the roles; the only way I can tie the roles all together is to say that consultants are helpers. The different roles show how a consultant provides

short-term help. One role is to fill a gap. In Compliance we see organizations needing in-house compliance professionals faster than they can be hired or recruited, so consultants fill the gap by serving in interim roles. This is a big part of the compliance consulting business right now.

Another role is to be an outside voice. Sometimes organizations need a third party to take a look at a situation and give some advice on whether things are on the right track or adjustments need to be made. It's the same reason we all need to regularly go to the doctor for a physical, even if we are feeling OK—everyone needs a checkup. Just like

I'd say that is a new era for Compliance. We are also seeing compliance programs maturing enough that there are many entry-level opportunities for graduating students.

it's not good to diagnose yourself, you also can't audit yourself.

A third role is to help an organization implement complex rules and regulations. When there is a new law or regulation or a major corrective action that needs to be implemented, organizations sometimes need extra help in operationalizing the regulation—maybe that's adjusting business practices to conform to the regulation or developing training material or helping to establish and write policies. As a consultant, you see how other organizations are trying to achieve compliance, and you bring that cumulative experience to bear on an engagement. My students find consulting a great practical training ground for going into in-house compliance positions, because they see a lot of different situations and organizations quickly.

**AW:** You tell your students to ask people how they got into Compliance. So, how did you get into Compliance?

**RM:** Although I have always been on the outside of regulated entities as their lawyer or consultant, I fell into Compliance the same way most compliance officers today got to their job. I was in the right meeting at the right time. When I was out of law school and an associate, I worked mainly on regulatory issues for healthcare organizations, especially health insurance issues and False Claims Act-related government audits and investigations. One day in 1997, I was meeting with the general counsel of a client on some regulatory issues, and he had just come back from a meeting in which he was asked to help build the organization's compliance program. He asked me, "Do you know anything about compliance programs?" I said I didn't, and he said, "It doesn't seem like

anyone does. Do you want to learn?" He gave me a project to help develop their compliance program, and 20 years later, here we are. I've been fortunate since then to serve as legal counsel or as a consultant for some fantastic clients who want to do the right thing by developing structures to help comply with complex regulations and establish business ethics frameworks.

I've mostly counseled or advised healthcare organizations, higher education institutions, and organizations in the life sciences arena. But now, with Loyola my portfolio is much wider, and I interact with just about every type of major industry from manufacturing to aviation to energy and even athletics compliance. Believe it or not, I have a number of students right now who are going into athletics compliance, mostly for universities.

**AW:** A difficult question for everyone is how to assess an organization's compliance and ethics program? That seems well worth academic study.

**RM:** It is, indeed. The Federal Sentencing Guidelines and many administrative agencies expect "effective" compliance and ethics programs. The trouble is, the word "effective" is not defined. Everyone does this a bit differently, because there is a lot to debate over what "effective" means. It can't mean never having non-compliance—that's an impossible standard. Until there is a good definition of "effective" that is measurable and either set out by the government or agreed upon by industry, we need to start with the basics of the seven elements. Personally, I look at whether the organization has the seven elements, whether the elements are "dynamic" in that they are revised and improved based on experience,

how the organization responds to suspected or real non-compliance, and then I study the expectations of the government agency that regulates the entity. For deeply regulated organizations, this can involve hundreds of questions; we live in a world of heavy regulation and high compliance and ethics expectations by the government and the public.

**AW:** You mentioned earlier that ethics is part of the Center for Compliance Studies' mission, but you haven't talked much yet about that. How does ethics play into compliance programs?

**RM:** Ethics is one of the most understudied areas of Compliance. We shouldn't forget that the Federal Sentencing Guidelines refer to "Compliance and Ethics Programs." It puts "ethics" in the title, but we often don't know what to do with the "and ethics" part. Ultimately, a compliance program is about doing the right thing, whether that means conforming to the law or doing right by the workforce and public. Regulations can be difficult to figure out and comply with, but ultimately there is something in black and white to analyze. The same goes for a policy. When a company adopts a position and issues a policy, then there is something in black and white—and hopefully it is clear enough for the workforce members to follow. Ethics on the other hand is challenging in compliance programs. Ethics isn't written down anywhere, though I certainly hope the relevant law and policies are informed by ethics! Ethics fills the gap when law and policy do not give a compliance program direction.

Compliance programs and those of us studying and teaching Compliance need to do a better job of grappling with

the "and ethics" piece. How do we know what the right thing to do is? The circumstances and facts change, but in my view, the framework of doing the right thing doesn't change. In my classes I tend to throw out all the modern books on ethics and go back to the classics. In one compliance course I teach, we go straight back to Aristotle and read the *Nicomachean Ethics*. The course takes age-old wisdom and then sees how the principles apply to modern facts. Most compliance programs are based on Aristotle's approach to ethics, and they don't even know it! Aristotle identified four basic virtues of ethics: justice, fortitude, prudence, and temperance. He and his later commentators broke them out into lots of sub-categories. Today we still know justice by its name and the definition that Aristotle gave to justice—giving every person what is rightfully due them. We still use the other virtues today, but we usually refer to them with different names such as balancing risk, self-respect, loyalty, humility, courage, integrity, and honesty. We don't need to make up new virtues, but we do need to study how they play out in our current age and in organizations under tough business and legal pressures.

Exploring ethics today is a big part of the Center's mission. But when it comes to a compliance program, sure, the compliance professional needs to be ethical and advise ethically, but it's just as important to develop a culture in which the workforce members are empowered and encouraged to make ethical choices. How we do this today is what we hope to study and explore in the coming years.

**AW:** Thank you, Ryan for sharing your insights with us. ☺