

An Interview with James Junger on 340B and Compliance – What Compliance Leaders Need to Know Now



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Snell: You graduated from the University of Wisconsin and have built a nationally recognized practice in healthcare law. What originally inspired you to pursue a career in law, and what ultimately led you into healthcare compliance?

Junger: I have to start by speaking up for the University of Wisconsin and its law school. Wisconsin's guiding principle is "Law in Action," and that has always resonated with me. Lawyers need to understand not only what the law says, but how it operates in the real world, affecting people, institutions, and communities. That was a tremendous foundation for a career in healthcare law, where the best advice requires understanding how a rule will affect patients, providers, compliance teams, operations, finance, and governance.

I did not grow up around lawyers, so my path to law school was not especially direct. At first, I actually thought I'd become a band director, and I even got admitted to the percussion studio at UW-Eau Claire and nearly transferred there. I ultimately stayed in Madison, where I double-majored in political science and Spanish and thought my career might take me toward public service, politics, or foreign affairs. I also had the opportunity to work on projects with Nancy Lynch, then an in-house attorney for the university and later its General Counsel. She is analytical, practical, and calm. She could take something complicated,

identify the real issues, and help the institution move toward a workable solution. That helped me see law as a profession built around service, judgment, and problem-solving.

Healthcare compliance became a natural fit because the advice has immediate practical consequences. My advice may affect how a hospital bills a service, how a pharmacy operates, how a board understands risk, or whether a safety-net provider can keep the doors open and the lights on. I'm drawn to work that requires technical analysis and practical judgment while serving a public mission.

Snell: Looking back at your career, were there one or two mentors or experiences that had the greatest influence on the attorney and advisor you've become today?

Junger: I have been fortunate to learn from several people who shaped how I practice. Nancy Lynch was an early influence because she showed me what institutional lawyering can look like at its best. She approached problems with rigor, but also with practicality and a clear sense of the institution's mission.

At Hall Render, three people stand out in particular: Katherine Kuchan, Ritu Kaur Cooper, and Todd Nova. Katherine and Ritu have long been leaders in our compliance practice, and Todd built our 340B practice from the ground up. Early in my career, Katherine gave me opportunities to work on compliance investigations, compliance program assessments, and training engagements. Those projects taught me that compliance advice must be clear, operationally realistic, and grounded in the organization's actual risk environment. Working with Ritu reinforced that sophisticated compliance counseling requires both legal precision and sound judgment about people, process, and institutional culture.

My work with Todd became especially important beginning in 2020, when drug

manufacturers began imposing restrictions on 340B drug shipments, and covered entities across the country needed guidance. Todd needed help coordinating that work, and I had the opportunity to help develop an organized, practical response for those clients. That work eventually became a major part of what is now the Hall Render Pharmacy and 340B Collaborative.

Those experiences changed how I think about client service. Clients rarely need a lawyer simply to recite the rule. They need help deciding what to do next, often with incomplete information and real operational consequences. They also showed me that the best work usually is not done alone. At its best, law is a team sport.

Snell: Your practice spans legal counseling, compliance, pharmacy operations, and data analysis. How has that broad experience shaped the way you advise healthcare organizations today?

Junger: One lesson I've learned is that healthcare organizations rarely experience legal problems in isolation. A regulatory issue quickly becomes operational, financial, and governance-related. If you only look at problems through a legal lens, you risk missing how they affect the organization as a whole.

Because my practice has broad roots, I have the opportunity to see those connections. That perspective has reinforced the importance of practical advice. The most useful legal guidance is not always the most elaborate answer. It is the answer that helps a client understand the choice in front of them and what will follow from it.

I also think it reflects one of Hall Render's greatest strengths. Because we are focused entirely on healthcare, we can often help clients see around corners. We can identify emerging risks, recognize patterns developing across the industry, and help clients prepare before those issues become immediate problems. That is often why the right lawyers create the most value.

Snell: You spend much of your time helping organizations navigate difficult regulatory issues. What does “business integrity” mean to you, and why is it becoming even more important in healthcare?

Junger: To me, business integrity means being honest about risk when the easy answer would be to look past it. In healthcare, the hard questions usually are not whether something is obviously right or wrong. They are questions where the rules are complicated, the business pressures are real, and the organization has to decide what position it can responsibly defend.

In healthcare, integrity is especially important because organizations are entrusted with more than financial assets. Fundamentally, they are entrusted with patients’ health and lives. Decisions about compliance, reimbursement, operations, and strategy can ultimately affect patients’ access to care. That places a special responsibility on healthcare leaders to think beyond short-term outcomes.

Integrity also shows up in the everyday habits of an organization. Do people feel comfortable raising concerns? Are hard questions welcomed early, or only after a problem has become unavoidable? A strong compliance culture does not eliminate risk, but it gives the organization a better chance to see problems clearly and address them responsibly.

Snell: When organizations face pressure between financial performance and regulatory compliance, what principles should leaders rely on to make the right decisions?

Junger: I try not to frame those issues as compliance versus financial performance. Healthcare organizations have to remain financially viable, and compliance advice that ignores that reality is not very useful.

Leaders need to understand the risk they are accepting and be able to explain why the decision was reasonable when it was made. That requires a clear view of

the facts, the legal uncertainty, the operational consequences, and the assumptions built into the decision.

I also encourage leaders to ask a simple question: if this decision were reviewed by a regulator or reporter several years from now, would we still be comfortable explaining why we made it? That question does not answer every issue, but it often provides useful perspective when organizations are navigating difficult tradeoffs.

That kind of discipline is especially important in healthcare because today’s decision may be judged years later with the benefit of hindsight. The goal is not perfection. The goal is to make a decision that was careful, informed, and mission-oriented.

Snell: Compliance professionals often find themselves dealing with ethical gray areas rather than clear legal violations. How do you recommend approaching those situations?

Junger: The most challenging issues in healthcare are rarely the ones where the options are clearly legal or clearly illegal. More often, organizations are working through situations where the facts are evolving, the guidance is incomplete, and reasonable people can disagree. Those situations test both compliance programs and leadership teams.

I usually start by separating the legal question from the broader judgment question. Something may be legally defensible and still be unwise because of how it affects patients, employees, payor relationships, or public trust. That does not mean the organization cannot proceed, but it should be honest about the full set of considerations.

The process matters. Who was consulted? What facts were available? What alternatives were considered? Why did the organization choose this path? Those are the questions that help an organization make a gray-area decision in a way it can explain later.

I also think organizations should be comfortable acknowledging uncertainty.

In healthcare, uncertainty is inevitable. The important thing is to make a thoughtful decision, document the basis for it, and revisit it if the facts or the law change.

Snell: In your experience, what ethical qualities distinguish truly outstanding compliance leaders from those who simply meet regulatory requirements?

Junger: The best compliance leaders I have worked with understand that their role is not simply to enforce rules. They help the organization make better decisions. Technical competence matters, but it is not enough by itself.

The compliance officers I admire most understand how their organizations actually work. They know enough about operations to give advice that can be implemented, and they have enough independence to say when a proposed path creates unacceptable risk. They also listen when providing their advice. If the people charged with carrying it out have reservations, you need to know why.

Outstanding compliance leaders also have the courage to raise difficult issues, even when doing so is uncomfortable. Every organization encounters situations where the easiest path may not be the right path. Effective compliance professionals are willing to ask difficult questions, challenge assumptions, and ensure that leaders understand the potential risks associated with a decision. Importantly, they do this in a constructive way that facilitates problem-solving rather than assigning blame.

Perhaps most importantly, exceptional compliance leaders understand that trust is their most valuable asset. Trust is earned over time by being consistent, objective, well-prepared, and fair. When leaders believe that the compliance function is focused on helping the organization fulfill its mission while managing risk responsibly, compliance becomes far more effective.

Snell: You've worked with executives, compliance officers, pharmacists, and boards across the country. What management practices have you seen consistently produce high-performing compliance teams?

Junger: The strongest compliance teams I've seen are not always the largest or best funded. What distinguishes high-performing teams is their ability to focus limited resources on the areas of greatest risk and strategic importance. That requires line-of-sight into organizational strategy. The best-funded compliance function can't be effective if it doesn't know where the organization is heading.

Successful compliance programs also tend to have regular contact with the people who make operational decisions. Pharmacy, revenue cycle, finance, legal, compliance, and operations should not be meeting for the first time when a 340B audit starts, or a problem has already surfaced. Regular communication is what allows issues to be identified while they are still manageable.

I have also found that effective compliance teams create a culture where employees feel comfortable raising concerns and asking questions. Most significant compliance issues do not appear overnight. They often begin as small concerns that somebody notices but may hesitate to mention. Organizations that encourage open communication are often able to identify and address risks before they grow into larger problems.

Snell: If you were mentoring a young compliance professional who hopes to become a Chief Compliance Officer or healthcare executive, what advice would you give them today?

Junger: My first advice would be to learn how the organization actually works. Spend time with clinicians, pharmacists, finance teams, revenue cycle staff, and operational leaders. Ask what slows them down, what

decisions they are trying to make, and where compliance issues tend to appear in practice. That knowledge will make every compliance judgment better.

Second, become known as someone who helps solve problems. It is important to identify risk, but the real value comes from helping the organization understand its options and choose a path that works in the real world.

I would also encourage young professionals to invest in their communication skills. Much of compliance leadership involves teaching. Whether you're training employees, advising executives, presenting to a board, or responding to a regulator, your effectiveness often depends on your ability to explain complicated issues clearly and earn the trust of your audience.

Finally, stay curious. Healthcare changes quickly, and compliance leaders need to keep learning. The people who have the greatest impact over time are often the ones who keep asking good questions and keep paying attention to what is changing around them.

Snell: The 340B Program continues to evolve rapidly. What are the three biggest compliance challenges organizations should be preparing for over the next few years?

Junger: The first challenge is managing uncertainty. For much of the program's history, covered entities could rely on relatively stable rules and operating assumptions. Today, organizations are navigating manufacturer restrictions, rebate and payment reduction proposals, ongoing litigation, changing state laws, and continuing questions about HRSA's authority. Compliance leaders are increasingly being asked to help make important operational and strategic decisions in an environment where the rules are still developing.

Second, organizations need to be prepared for greater scrutiny of the data that

supports their 340B programs. Whether the issue is duplicate discounts, contract pharmacy arrangements, patient eligibility, or manufacturer demands for claims information, more stakeholders are seeking data, and not always for clear or controllable reasons. As a result, organizations should continue investing in strong documentation practices, reliable processes, and the ability to explain how their programs operate.

Third, I think healthcare organizations need to be prepared for continued pressure on the resources that support compliance efforts. Hospitals, health systems, federally qualified health centers, and other safety-net providers are facing significant financial challenges at the same time that the regulatory environment is becoming more complex. Compliance leaders will increasingly need to find practical ways to manage risk while working within real-world operational and budget constraints.

The organizations that will handle these challenges best are the ones that treat 340B compliance as an ongoing discipline, not a periodic audit exercise.

Snell: Manufacturer restrictions, rebate proposals, contract pharmacy issues, and litigation have created tremendous uncertainty. What should compliance officers be monitoring most closely right now?

Junger: I would encourage compliance officers to focus on the places where legal developments could require operational changes. 340B can feel chaotic right now. Compliance officers reading the news need to separate the signal from the noise and know how these developments affect risk and strategy. It is important to stay informed about litigation, manufacturer policies, state legislation, and developments involving rebate models, and how those developments may affect their organization.

Covered entities also can't lose sight of what's local. That means closely

monitoring contract pharmacy arrangements, duplicate discount prevention processes, claims data, and internal documentation. As manufacturers and regulators increasingly focus on how organizations administer their 340B programs, covered entities need to be confident that they can explain and support their compliance decisions.

Compliance leaders should also pay close attention to developments at the state level. State legislatures have become increasingly active in addressing 340B-related issues, and organizations may find themselves operating under a combination of federal requirements, state laws, manufacturer policies, and litigation outcomes. That creates additional complexity that requires ongoing attention.

Snell: HRSA audits can be intimidating for many organizations. What are the most common mistakes you see during audits, and what practical steps can organizations take to avoid them?

Junger: One of the most common mistakes I see is not maintaining documentation in a way that allows the organization to clearly explain how its 340B program operates. Many organizations have compliant processes, but when an audit occurs, they struggle to locate supporting records, explain key decisions, or demonstrate how policies are implemented in practice.

I also see organizations underestimate how decisions made outside the pharmacy department can affect 340B compliance. For example, a change in a Medicaid managed care contract may require a different billing workflow. If claims are then submitted under a different NPI, that change can affect how a state Medicaid agency or manufacturer evaluates claims data and may lead to questions, inquiries, or audits. Similar issues can arise from restructurings, provider employment changes, acquisitions, new service lines, or information system updates.

For that reason, the organizations that perform best during audits are often those that have strong communication across departments. They have processes that ensure pharmacy, compliance, finance, revenue cycle, reimbursement, and operational leaders understand when a proposed change could have implications for the 340B program. Just as importantly, they document those decisions and retain records showing how and why changes were implemented.

Ultimately, the organizations that navigate audits most successfully are not necessarily the ones with perfect programs. They are the ones that understand their programs well, maintain appropriate documentation, and recognize that 340B compliance is affected by decisions made throughout the organization, not just within the pharmacy department.

Snell: As someone who advises healthcare organizations across the country, what emerging trends or changes in the 340B landscape should compliance professionals begin preparing for today so they aren't caught off guard tomorrow?

Junger: One trend I expect to continue is the growing intersection of 340B compliance, reimbursement, and data reporting. Historically, many organizations viewed 340B primarily as a pharmacy program. Today, decisions involving billing, reimbursement, managed care contracting, provider enrollment, information technology systems, and organizational structure can all affect 340B compliance. To be clear, that isn't a complete list. As a result, I think successful organizations will increasingly approach 340B as an enterprise-wide responsibility rather than a pharmacy-specific function.

Compliance professionals also need to prepare for continued manufacturer efforts to reshape the program through unilateral policy changes. Manufacturers have imposed contract pharmacy restrictions, advanced rebate-based purchasing models,

and sought increasingly detailed claims data, often without clear statutory support and without formal government oversight. Whether particular policies survive legal or regulatory scrutiny, they have already created significant operational challenges. More importantly, they present what I view as an existential risk to the program itself. If manufacturers can condition access to 340B pricing on compliance with a growing number of manufacturer-created requirements, the practical operation of the program could look very different from the program Congress established.

A third trend is the growing complexity created by overlapping legal and regulatory frameworks. Organizations today may find themselves navigating federal requirements, state laws, manufacturer policies, contractual obligations, and ongoing litigation simultaneously. That complexity creates challenges, but it also creates opportunities for organizations that are proactive and adaptable.

In practice, that means 340B can no longer sit only with pharmacy. The program

now touches contracting, reimbursement, data systems, government relations, legal, and executive leadership. When that many stakeholders are in a room, compliance needs to be there, too.

Snell: And can you leave us with a suggestion for a book that we might consider reading related to business management, ethics, and integrity?

Junger: I will admit that I do not carve out as much time for professional reading as I would like. Most of my reading tends to be tied directly to the project in front of me. That said, I do recommend *Atomic Habits* by James Clear. The book stuck with me because I tend to think in systems. In compliance work, law practice, and personal productivity, good outcomes usually come from building reliable processes, not from relying on willpower or one-time bursts of motivation.

Snell: Thank you so much for taking the time to talk with us.

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