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**Disruptive Compliance: Practical and
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Cutting-Edge Healthcare Company**

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DISRUPTIVE COMPLIANCE: PRACTICAL AND ETHICAL CONSIDERATIONS IN ADVISING THE CUTTING-EDGE HEALTHCARE COMPANY

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I. INTRODUCTION: THE FUTURE IS NOW, BUT THE LAW USUALLY ISN'T

A. Where No Relator Has Gone Before

Out on Rigel IV, a Class M planet in Deep Space Sector X-7, the situation grew increasingly dire. The grim-faced man in the gold velour shirt snapped at the doctor, “Bones! I’ve told you we only have 36 solar minutes to get this man’s leg reattached so we can beam up! Otherwise, the unstable anti-matter core of this planet will blast us all the way from here to the Neutral Zone!”

“Dammit, Jim, I’m a doctor, not a welder!” snarled the blue-shirted medico, his Georgia accent reasserting itself as his tone got angrier. “Anyway, this crewman has the Blue Sword-Red Shirt bronze plan, and that won’t cover treatment with the Acme Extremity Resynthesizer. They say it’s experimental! Not approved by the Federation Device Authority! I’ve been on the communicator with some numbskull clerk in the Precertification Department for over a solar hour, and all she’ll tell me is that I can appeal to the Galactic Medical Director Review Panel when it meets next month. Dammit, Jim, I’m a doctor, not a bureaucrat!”

The other blue-shirted member of the team, a saturnine figure whose skin-tone suggested a latent liver disorder, spoke for the first time. “Doctor, a question: Would not the bronze plan cover reattaching the crewman’s limb using Thanagarian syntho-thread with an exterior coating of Fontana Regenerative Paste? I believe that is the orthodox treatment for a patient presenting with ICD-27 Code 1673876309719, ‘Extremity Amputation Resulting from Armed Physical Altercation with Cardassian Warrior of Enlisted Rank, Left Side’, is it not?”

“Of course it does!” the irascible doctor snapped, “but that’s not the best treatment for this man. He needs the Acme Extremity Resynthesizer, but his insurance won’t pay for that! They won’t pay for anything unless it’s been done for 20 solar years or more!”

The saturnine man responded, “Doctor, under the circumstances it seems that the logical thing to do would be to perform the Extremity Resynthesizer procedure but document and bill it as if it were the syntho-thread procedure. Perhaps you could throw in charges for some additional medical testing to get the reimbursement back up to an appropriate level.”

“Do it, Bones!” the man in the gold shirt snapped. “Maybe it’s not strictly by the manual, but these stupid regulations can’t keep this man from getting the care he needs! And anyway, how is the Federation ever going to find out you intentionally billed for the wrong thing anyway? You can always say you just hit the wrong buttons on your Tricorder Interstellar Electronic Health Records device! It’s not like anyone’s around to blow the whistle on you. Now get going! We have to beam up in exactly... twenty ... two ... point ... four ... minutes!”

In the shadow of a conveniently placed space boulder, the young Russian ensign smiled enigmatically to himself as he tapped notes into an encrypted file on his own Tricorder. *Once I talk with that lawyer on Deneb VIII, he thought, I’ll be rich enough to buy my own starship and fly it straight to Moscow*

B. Yesterday’s Rules, Tomorrow’s Technology and Today’s Compliance

The healthcare industry in the United States, as advanced and effective as it is in many ways, is criticized for lots of things. It is criticized for purportedly wasteful spending of resources on unnecessary “defensive medicine”. It is criticized for an inadequate focus on preventive care and population health. It is criticized for socioeconomic and race-based inequities in access to care. It is criticized for its emphasis on prolonging life over providing for a humane and dignified process of dying. Oh, the criticisms leveled at healthcare in this country are numerous. And almost no one ever mentions one thing the United States healthcare system is really, really good at.

What is that thing? Regulating and paying for what happened yesterday.

Spurred on in part by the changes in delivery and reimbursement models promoted by the Affordable Care Act, there is an enormous focus today on innovation in healthcare products, services and payment systems. Large sums of capital are being poured into healthcare services companies, device and technology companies, and other industry components, largely in search of the operator that will be able to provide the next big thing, the new breakthrough.¹ Under the

¹ See, e.g., Steven Loeb, *What does the future of healthcare look like?*, vator.tv, Nov. 23, 2016, available at <http://vator.tv/news/2016-11-23-what-does-the-future-of-healthcare-look-like> (“In the first quarter of [2016], even as [venture capital] funding sunk to a two-year low, healthcare accounted for nearly a third of all venture capital investments, with \$4.1 billion across 191 deals. [¶] As of the beginning of [November 2016], the healthcare space had raised \$13.1 billion, ... which has been spread across ... 1,287 deals.”); Phil Wickham, *Venture Capital Is Facing an Impending Health-Care ‘Avalanche’*, fortune.com, May 5, 2016, available at <http://fortune.com/2016/05/05/venture-capital-health-care/> (interview with venture capital fund partner about investor perspectives on dynamics driving innovation in healthcare); John Sculley & Bruce Broussard, *It’s Time To Disrupt the \$3 Trillion Healthcare Industry*, forbes.com, Nov. 16, 2016, available at <http://www.forbes.com/sites/sciencebiz/2016/11/16/its-time-to-disrupt-the-3-trillion-healthcare-industry/#24cfb9272534> (“Numerous major players--from Silicon Valley innovators, to health care professionals, to government leaders--are looking to use technology to transform healthcare. [¶] Silicon Valley is focused on harnessing technology through the power of entrepreneurship to disrupt an industry that’s one-sixth of the U.S. economy. According to Dow Jones VentureWire, ‘venture-capital funding in U.S. healthcare companies rose to a record \$16.10 billion last year, a 34% jump from 2014.’”); Bob Herman, *Why venture capital firms are pouring money into health insurance*, modernhealthcare.com, Mar. 19, 2016, available at <http://www.modernhealthcare.com/article/20160319/MAGAZINE/303199964> (“Health-insurer and insurance-

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