

FDA PILOT AND ACA REFORM: LAW AND POLICY WORTH CONSIDERING AND SOME NOT SO MUCH

By Howard Burde



While Congress has yet to repeal or enact reforms to the Affordable Care Act, the Food and Drug Administration was busy initiating a new approach to the evaluation and certification of medical software products, including a precertification program for the assessment of trusted companies that consistently perform high-quality software design and testing.

The attempts to repeal or reform the ACA had virtually no impact on the

health IT innovation community. Health IT entrepreneurs and investors continue to develop new innovations to address the healthcare industry's most vexing problems. Indeed, the amount of investment and number of investors in the first half of 2017 both grew at record pace.

The record number of investors and dollars (depending upon the survey: roughly 35% increase in total investment, 25% increase in deals and 40% increase in unique investors. See Start-up Health; Rock Health and Mercom for the surveys) reflects a focus on addressing patient engagement, data analytics, population health, telemedicine and remote monitoring, to name a few categories of solutions. The common denominator: these types of solution are not influenced by the debate over the structure of health coverage.

By contrast, the FDA's proposal to create the Software Precertification Pilot Program, <https://www.fda.gov/MedicalDevices/DigitalHealth/UCM567265>, is a step forward. The FDA intends to develop a precertification program that could replace the need for a premarket submission in some cases and allow for decreased submission content and/or faster review of marketing applications for software products in other cases.

Now, the FDA pilot is just that, a pilot. The FDA's admirable goal is to implement a permanent pre-certification program to reduce further bureaucracy for innovation. And, according to its announcement, the FDA will create this expedited approach for experienced trusted companies. Meaning, that newer innovators may be at a regulatory disadvantage getting to market by comparison to established companies. However, it may create new markets for innovators: the experienced companies with precertification approval may become conduits for smaller companies. Effectively, the FDA precertification program may create a new market for innovators and a new business for established health care software vendors, both of which create opportunities for entrepreneurs, investors and bankers.

Howard Burde, Principal, Howard Burde Health Law
howard@burdelaw.com



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IS THE HOSPITAL EMR MARKET NEARLY DEAD?

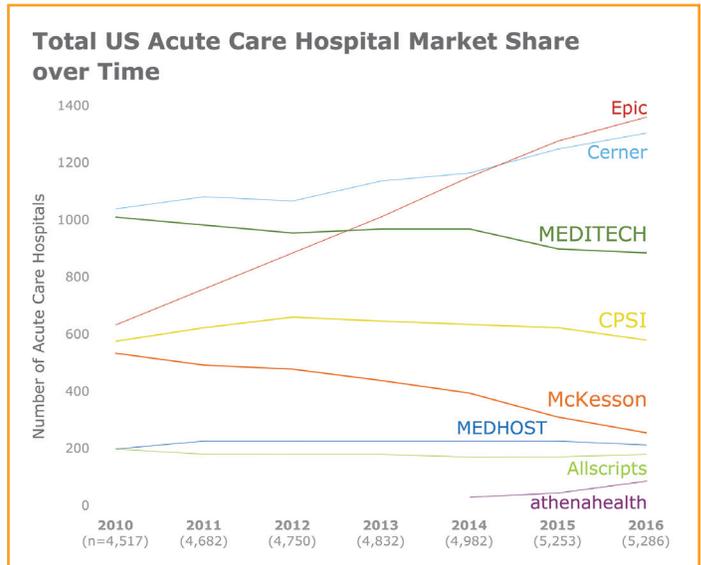
By Ben Brown

Not by a long shot. Saturated, yes. But dead in no way. Cerner and Epic continue to dominate the hospital EMR replacement market, now garnering more than 50% combined market share. With Allscripts recent announcement of acquiring McKesson's remaining HCIT IP & clients, including the Paragon HIS and Horizon platform, it will be quite the challenge for any EHR company to disrupt Cerner and Epic's growth. But, with change comes opportunity.

Much of the EHR replacement opportunity exists in the smaller community hospital market. 80% of the hospital EMR decisions last year were under 200 beds. That will continue as there remain hundreds, if not nearly 1000, community hospitals that currently have a legacy platform in place that will eventually need to be replaced. Meditech, Cerner, CPSI and now Allscripts (McKesson) have older platforms that hospitals will need to decide when they will move to a contemporary platform for the long term.

Since athenahealth acquired Razor Insights, they have aggressively grown their market presence in the community hospital space. They more than doubled their hospital market share in 2016 and had the third largest market share increases, behind Epic and Cerner. eClinicalWorks has had limited traction entering the hospital market while appearing to have taken one step forward then two steps back. Meditech, Medhost, CPSI and McKesson's market share all declined last year.

EMR M&A activity has been a factor driving for buying decision. Continued hospital consolidation will drive more moves to a



single platform over time. Many small hospitals are using older EHR systems that will eventually need to be replaced. There will be additional churn due to new strategic initiatives, a market moving towards value based care, a lack of progress delivering meaningful new technological innovations, true integration, interoperability and not becoming a strategic IT partner aligned with providers growing needs.

So, the EMR market isn't close to being dead. It's ripe with opportunity to grow, especially for the EMR companies that continue to consistently deliver tangible outcomes.

Ben Brown, Vice President, KLAS Research
ben.brown@klasresearch.com



HOW DO YOU VALUE YOUR COMPANY? THE ART AND SCIENCE OF BUSINESS VALUATION

You work for years and maybe decades, and the ultimate question is, "What is your business worth?"

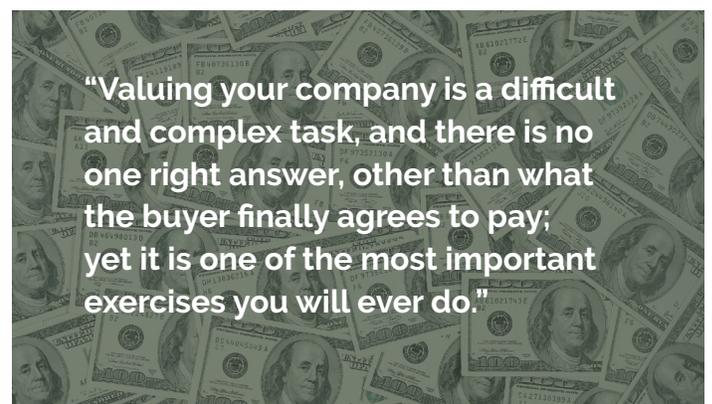
By Scott Holbrook and Terry Pitts

This is a question that ultimately every business owner asks. Yet, we all see the elephant differently from different viewpoints and perspectives, right? Is there a specific single universal method for valuing a company? If there is, what is it? If not, then how do you go about valuing what you have worked so diligently to create? There is a scientific and an often forgotten strategic component of the value of your business.

The Science of Valuing a Company

The scientific method of identifying a value for your business is comprised of multiple metrics such as top line revenue, Gross Margins, EBITDA, revenue per FTE, recurring revenue,

backlogged revenue, weighted pipeline and on and on. These basic metrics seem straight forward and easy to determine. Each of these measurements can then be compared against other similar companies. There are several companies that publish



current comparative valuation trends and these are helpful for comparisons to a point but usually not specific enough for you. The scientific component of what your business is worth is somewhere between 65%-80% of the total value of your company depending on the market space in which you operate.

The Strategic Value of Your Company

The strategic value your company is very different than the scientific calculation. These metrics are pricing, market acceptance, market penetration, year over year growth, business model, product solutions, customer retention, named accounts and other items that provide a fundamental value quite different than the scientific basis of your company.

The strategic value of your company can be worth 20% - 35% usually. However, there are situations whereby the strategic value may be worth more than the scientific. Each case is different and unique. There are situations where the strategic value is multiple times the scientific value due to the circumstances of the buyer and what you have to sell. The combination of the two methods

produces a potential range that you can initially utilize. MSA uses over 40 different metrics that form the underpinnings of the company's value.

Valuing your company is a difficult and complex task, and there is no one right answer, other than what the buyer finally agrees to pay; yet it is one of the most important exercises you will ever do. Financial metrics are often used as the only guiding principle when calculating your company's value but don't forget to properly assess and include the strategic value when making this important determination. Remember everyone looks at the elephant differently.

Scott Holbrook, Principal,
Mountain Summit Advisors
sholbrook@mtnsummitadv.com



Terry Pitts, Principal,
Mountain Summit Advisors
tpitts@mtnsummitadv.com



PATIENT-GENERATED DATA: ARE HOSPITALS READY FOR WHAT IS NEXT IN HEALTHCARE?

By **Blain Newton**

As the US healthcare market nears universal EMR adoption and advanced analytics capabilities become increasingly more complex and sophisticated, a new wave is rising – patient-generated data. With this potential explosion of data comes opportunities and challenges. Are hospitals ready?

Based on recent research HIMSS Analytics conducted in conjunction with the Personal Connected Health Alliance, a significant majority of healthcare organizations believe that personal connected health is essential to their success in an era of payment reform. Further, most feel that they are at least moderately prepared to achieve their goals related to personal connected health and are increasingly investing in next-generation patient engagement technologies including remote patient monitoring devices and consumer wearables.

Hospital-driven patient data initiatives pale in comparison to current consumer-driven data initiatives. Availability of technologies generating innovative health and wellness data will further this disparity. Based on research by Health 2.0, more than \$2.4 billion was invested in consumer-facing health technology companies in 2016 alone, indicating that we are still in early days of this wave.

This explosion of consumer health data from disparate sources can be overwhelming for healthcare providers, especially as the research has shown that a majority of patients expect aspects of the data to be incorporated in their health record. Healthcare organizations are responding in certain circumstances by incorporating at least some patient-generated data into health records – typically in the treatment of chronic disease. That



said, significant barriers exist in the effort to leverage large-scale patient-generated data with perceived challenges in data quality and relevancy.

It is clear that the era of massive consumer-generated health and wellness data is upon us. Major companies like Apple and Google are making large bets on the future efficacy of this data as have hundreds of smaller companies and the investors that support them. Healthcare organizations recognize the potential in this data to drive better outcomes in a value-based environment. The question is not when, but how will hospitals overcome the barriers to leverage this powerful new information.

Blain Newton, Executive Vice President,
HIMSS Analytics
blain.newton@himssanalytics.org



HIT·IQ | THE LAST WORD

Featuring profiles of leading entrepreneurs



Dr. Indu Subaiya

For our first issue, we profile Dr. Indu Subaiya, EVP of Health 2.0. HIMSS recently acquired Health 2.0 and restructured it as a new HIMSS business unit.

Indu, Congratulations on your merging with HIMSS and changing future for Health 2.0. Please tell us about your entrepreneurial journey and the formation of Health 2.0.

Indu: Health 2.0 began as an accidental company. My co-founder Matthew Holt and I met in 2006 around our common interest in how Web 2.0 (as it was called at the time) and user-generated content would impact healthcare, social connectivity, and social sharing using the internet.

The first early online health communities were rising, and we faced the radical notion that patients and consumers could use the internet to connect with each other and disintermediate care providers. We were intrigued, so we took a chance that others were equally fascinated and would pay to attend a small meeting of like-minded individuals to talk with and hear from technology innovators who were building solutions to leverage the internet as a new community building tool.

We scheduled the first Health 2.0 conference “User Generated Healthcare” in 2007 hoping that 100 people would register so that we would not lose our shirts on what was probably a one-time experiment. With virtually no paid promotion (we had limited funds and were new at this) over 500 people registered and the event was a sold-out success. Right away, we knew we had a business, so we incorporated the conference as a company, quit our jobs and started on our entrepreneurial journey.

What does the transition into HIMSS mean for the HIT investment and entrepreneurial community?

Indu: Health 2.0 will use the HIMSS platform to support the founding and maturity of emerging technologies. We will host the Health 2.0 Annual Meeting in Santa Clara and a Health 2.0 during the JP Morgan conference January 8 to 11, 2018. These meetings, will build toward the expanded investor and entrepreneurial programming at HIMSS Annual Conference March 5-9, 2018 in Las Vegas.

Lisa Spellman, Founder, Rapid Creek Group LLC
lisa.spellman@rapidcreekgroup.com



CALENDAR OF EVENTS

Health 2.0

October 1-2, 2017 (Santa Clara)
<http://health2con.com/>

VCs Talk New Trends in Investing: Panel Moderator on Monday Oct 2, 2018

Howard Burde, Principal, Howard Burde Health Law, to moderate an investor panel on critical environmental factors for health IT investment.

Connected Health Conference

October 25-27, 2017 (Boston)
www.connectedhealthconf.org

Presented by PCH Alliance and Partners Connected Health, the 2017 Connected Health Conference becomes the largest event dedicated to digital and connected health, promoting the application of personal connected health technologies to support new models of care delivery, health and wellness. This year's theme, The Connected Life Journey: Shaping Health and Wellness for Every Generation, will reimagine health and wellbeing throughout the life cycle, emphasizing new research, evidence and real-world examples, business models and actionable knowledge to support the adoption and implementation of personal connected health at any age and stage of life. Representatives from HIMSS, KLAS and Mountain Summit Advisors will be available to meet. Please contact: Ben Brown, Scott Holbrook, Terry Pitts or Blain Newton.

Global Digital Health Forum

December 4-6, 2017 (New York)
<http://www.globaldigitalhealthforum.org/>

The theme for this year's Forum—The Evolving Digital Health Landscape: Progress, Achievements, and Remaining Frontiers—captures the spirit of progress made in the past several years to scale digital health systems and also encourages us to look critically at the continued need for innovation, as well as integration, to improve health outcomes in a changing political landscape.

HIMSS 2018 Annual Conference with Venture Connect

March 5-8, 2018 (Las Vegas)
<http://www.himssconference.org/about/general-info/himss18-save-date>

Many more details to come about this exciting week of new and expanded special events for entrepreneurs, bankers and investors. Watch this space!