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Jessica L. Bailey-Wheaton, Esq., Editor
Todd A. Zigrang MBA, MHA, ASA, FACHE, Publisher

The New Kid on the Block: The Micro-Hospital Regulatory Environment

The healthcare environment has become increasingly regulated over the past several decades, with the *Patient Protection and Affordable Care Act of 2010* (ACA) arguably containing the most "*red tape*" of any healthcare law in recent memory.[1] While the current Administration has continued its attempts to roll back various federal regulations in multiple sectors,[2] including those created by the ACA,[3] hospitals (including micro-hospitals) are still subject to a number of licensing, certification, and other restrictions at both the state and federal levels. This second installment in the *Health Capital Topics* series regarding micro-hospitals will discuss some of the current regulatory hurdles and requirements for micro-hospitals within the current healthcare environment, and how they impact the feasibility and sustainability of this novel healthcare entity.

As healthcare providers, micro-hospitals are subject to the same broad-reaching healthcare regulatory standards, e.g., fraud and abuse laws, as other healthcare entities; however, because they are relatively new to the market, micro-hospitals have not yet garnered any legislation specific to their operations. While the federal government has not (as of yet) implemented many changes that affect micro-hospitals in particular, the *Centers for Medicare and Medicaid Services* (CMS) has issued guidance (in September 2017) clarifying their viewpoint on Medicare's statutory definition of *hospital*: "*Hospitals must have at least two [active] inpatients…[and must be] primarily engaged in inpatient care and satisf[y] all of the statutory requirements…*"[4] CMS also clarified that to determine if a hospital is "*primarily engaged*" in providing inpatient services, benchmarks for average daily census (ADC) and average length of stay (ALOS) will be utilized, along with other factors.[5] The CMS guidance is being adopted by surveyors, based on announcements from the Joint Commission, the Healthcare Facilities Accreditation Program, and DNV, who have stated that they will not conduct surveys unless the subject healthcare facility has at least two active inpatients.[6] This means that facilities below this inpatient threshold (which threshold would likely most significantly affect micro-hospitals) would not be allowed to provide medical services or would be paid at a lower rate (as a free-standing facility).[7]

In addition to federal regulations affecting micro-hospitals, there are certain state-based regulations that have impacted the receptivity of specific geographic areas to micro-hospital development. It is important to note that the states in which many of the initial micro-hospitals have been concentrated (e.g., Colorado, Arizona, and Texas) tend to be states that lack *Certificate of Need* (CON) legislation.[8] A CON application for a new hospital can be lengthy, costly, and inefficient for micro-hospitals, which typically only cost anywhere from $7 to $30 million to build.[9] The primary business case for pursuing micro-hospital development, i.e., they are "*cheaper and faster*" to build than a typical hospital,[10] can be defeated by the cost and time associated with the CON approval process. Notably, one Missouri micro-hospital avoided Missouri CON review by creating their three-bed facility for $953,750, a mere $46,250 shy of the $1 million threshold requiring a state CON application.[11]

In addition to CON laws, other hospital regulations and certification requirements often vary by state. For example, Wisconsin's construction codes for hospitals are relatively rigid, requiring more capital cost than would be fiscally reasonable for a micro-hospital.[12] In another example, Texas requires that hospitals set aside space for information technology and medical records, which is difficult to accomplish within the small square footage of most micro-hospitals.[13] However, for states that lack stringent hospital design regulations, micro-hospitals, while typically utilizing architecture similar to other acute care hospital facilities (both for federal regulatory and branding purposes, if attached to a healthcare system), have relative freedom in determining what facilities and amenities are necessary to serve the needs of its community.[14] While some mandated construction items, e.g., handwashing sinks and storage, are always included in a hospital's design, along with conveniences often expected by patients and families, e.g., family zones, micro-hospitals can eliminate or reduce expenditures for amenities often seen in traditional hospitals, e.g., formal waiting rooms, dietary services.[15]

Despite their capability to streamline design, independent micro-hospitals (i.e., those that are not affiliated with a larger hospital or health system) are still seen by some as a losing proposition. The current healthcare delivery environment rewards providers that are large enough to take advantage of economies of scale.[16] Independent micro-hospitals, while typically located in more affluent areas with a fast-growing

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population,[17] still lack the benefit of scale and have increased liability risk due to the limited number of services provided.[18] For those micro-hospitals located in states with specific design requirements that are better suited to traditional hospitals, the regulations may be too restrictive for fiscal survival. Architectural regulations, in combination with state-specific CON laws, and CMS's updated 2017 guidance regarding hospital eligibility requirements for Medicare reimbursement (which will be discussed further in the third installment of this series), render the proposition of micro-hospital construction difficult in some states. In addition, the growing popularity of micro-hospitals is likely to attract attention from regulators, inviting further rule-setting, and possibly increasing barriers to market entry. As declared by one stakeholder, "*Microhospitals are getting so popular that they won't be there for very long*."[19]

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Todd A. Zigrang, MBA, MHA, ASA, FACHE, is the President of **HEALTH CAPITAL CONSULTANTS** (HCC), where he focuses on the areas of valuation and financial analysis for hospitals, physician practices, and other healthcare enterprises. Mr. Zigrang has over 20 years of experience providing valuation, financial, transaction and strategic advisory services nationwide in over 1,000 transactions and joint ventures. Mr. Zigrang is also considered an expert in the field of healthcare compensation for physicians, executives and other professionals.

Mr. Zigrang is the co-author of "*The Adviser's Guide to Healthcare – 2nd Edition*" [2015 – AICPA], numerous chapters in legal treatises and anthologies, and peer-reviewed and industry articles such as: *The Accountant's Business Manual* (AICPA); *Valuing Professional Practices and Licenses* (Aspen Publishers); *Valuation Strategies; Business Appraisal Practice*; and, *NACVA QuickRead*. In addition to his contributions as an author, Mr. Zigrang has served as faculty before professional and trade associations such as the American Society of Appraisers (ASA); American Health Lawyers Associate (AHLA); the American Bar Association (ABA); the National Association of Certified Valuators and Analysts (NACVA); Physician Hospitals of America (PHA); the Institute of Business Appraisers (IBA); the Healthcare Financial Management Association (HFMA); and, the CPA Leadership Institute.

Mr. Zigrang holds a Master of Science in Health Administration (MHA) and a Master of Business Administration (MBA) from the University of Missouri at Columbia. He is a Fellow of the American College of Healthcare Executives (FACHE) and holds the Accredited Senior Appraiser (ASA) designation from the American Society of Appraisers, where he has served as President of the St. Louis Chapter, and is current Chair of the ASA Healthcare Special Interest Group (HSIG).

John R. Chwarzinski, MSF, MAE, is Senior Vice President of **HEALTH CAPITAL CONSULTANTS** (HCC). Mr. Chwarzinski's areas of expertise include advanced statistical analysis, econometric modeling, as well as, economic and financial analysis. Mr. Chwarzinski is the co-author of peer-reviewed and industry articles published in *Business Valuation Review* and *NACVA QuickRead*, and he has spoken before the Virginia Medical Group Management Association (VMGMA) and the Midwest Accountable Care Organization Expo. Mr. Chwarzinski holds a Master's Degree in Economics from the University of Missouri – St. Louis, as well as, a Master's Degree in Finance from the John M. Olin School of Business at Washington University in St. Louis. He is a member of the St. Louis Chapter of the American Society of Appraisers, as well as a candidate for the Accredited Senior Appraiser designation from the American Society of Appraisers.

Jessica L. Bailey-Wheaton, Esq., is Vice President and General Counsel of **HEALTH CAPITAL CONSULTANTS** (HCC), where she conducts project management and consulting services related to the impact of both federal and state regulations on healthcare exempt organization transactions and provides research services necessary to support certified opinions of value related to the Fair Market Value and Commercial Reasonableness of transactions related to healthcare enterprises, assets, and services. Ms. Bailey-Wheaton is a member of the Missouri and Illinois Bars and holds a J.D., with a concentration in Health Law, from Saint Louis University School of Law, where she served as Fall Managing Editor for the *Journal of Health Law & Policy*.

Daniel J. Chen, MSF, is a Senior Financial Analyst at **HEALTH CAPITAL CONSULTANTS** (HCC), where he develops fair market value and commercial reasonableness opinions related to healthcare enterprises, assets, and services. In addition, Mr. Chen prepares, reviews and analyzes forecasted and pro forma financial statements to determine the most probable future net economic benefit related to healthcare enterprises, assets, and services, and applies utilization demand and reimbursement trends to project professional medical revenue streams, as well as ancillary services and technical component (ASTC) revenue streams. Mr. Chen has a Master of Science in Finance from Washington University St. Louis.