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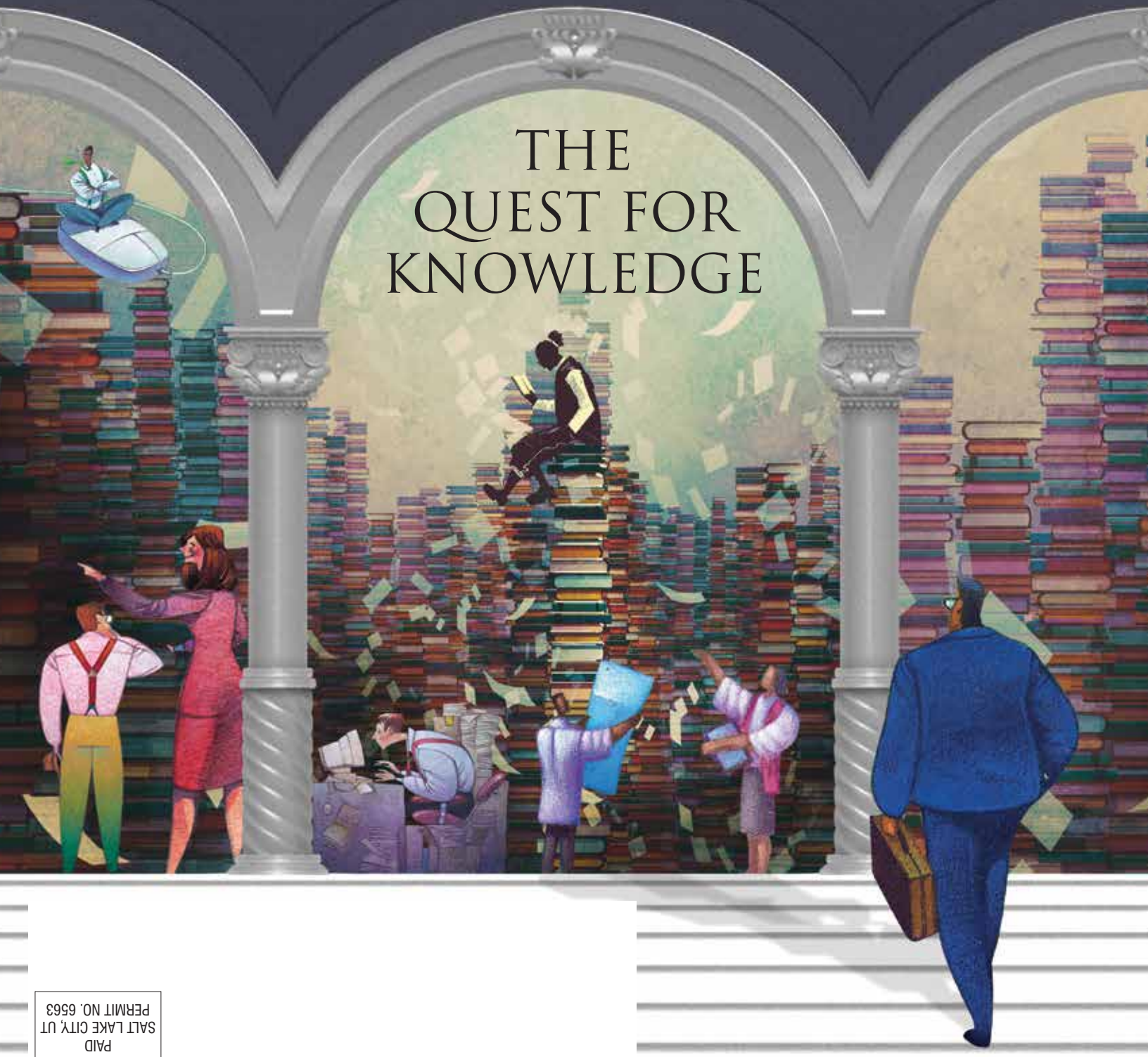

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HEALTHCARE INSIGHTS

THE DUE DILIGENCE IMPERATIVE: HEALTHCARE REGULATORY ENVIRONMENT

(Part Three of a Six-Part Series)

By Todd A. Zigrang, MBA, MHA, FACHE, ASA

The first part of this six-part series set forth an overview of the due diligence imperative for valuation professionals, in the context of the *Four Pillars of Healthcare Value*, i.e., Reimbursement, Regulatory, Technology, and Competition.[1] The second installment discussed due diligence in the context of the reimbursement environment.[2] This third installment will review the due diligence process as it relates to the healthcare regulatory environment.

As discussed in the first installment of this six-part series, due diligence may be generally defined as:

(1) "such a measure of prudence, activity, or assiduity, as is properly to be expected from, and ordinarily exercised by, a reasonable and prudent man under the particular circumstances; not measured by any absolute standard, but depending on the relative facts of the special case"

(2) "an investigation in order to support the purchase price of the business."[3]

There are two distinct classes of information generally required in completing the requisite due diligence related to a healthcare valuation engagement:

(1) General research—Research that is not specifically related to, or obtained from, the subject enterprise, asset, or service being appraised; and,

(2) Specific research—Information specific to the subject enterprise, asset, or service, that is typically obtained from the client or the appropriate contact designated by the client.[4]

With the passage of the 2010 Patient Protection and Affordable Care Act (ACA), i.e., "Obamacare," providers are facing even more extensive regulatory scrutiny, much of which attention is focused on the increasing number of rules and the strict prosecution of fraud and abuse violations.[5] Although significant efforts have been expended attempting to "repeal and replace" the ACA,[6] the landmark legislation remains standing, and the sweeping nature of the ACA will continue to drive ongoing changes in the structure and financial operation of many healthcare provider enterprises, likely resulting in an even further increase in the pace of hospital/physician practice integration/transactional activities, as well as an increase in the number of U.S. physicians who are

1 "Healthcare Valuation: The Financial Appraisal of Enterprises, Assets, and Services" By Robert James Cimasi, MHA, ASA, FRICS, MCBA, AVA, CM&AA, Volume 1, Hoboken, NJ: John Wiley & Sons, Inc., 2014, p. 2; "The Due Diligence Imperative – For the Valuation of Healthcare Enterprises, Assets, and Services" *The Value Examiner*, NACVA (November/December 2017).

2 For more information, see the second installment of this six-part series: "The Due Diligence Imperative: Healthcare Reimbursement Environment" *The Value Examiner*, NACVA (January/February 2018).

3 For more information, see the first installment of this six-part series: "The Due Diligence Imperative – For the Valuation of Healthcare Enterprises, Assets, and Services" *The Value Examiner*, NACVA (November/December 2017).

4 *Ibid.*

5 "Patient Protection and Affordable Care Act" Public Law 111-148, 124 Stat 119 (March 23, 2010), as amended by "Health Care and Education Reconciliation Act" Public Law 111-152, 124 Stat 1029 (March 30, 2010).

6 For more information about the efforts to repeal and replace Obamacare, reference "Obamacare Repeal and Replace – In the Heat of the Night: Now You See it, Now You Don't" Health Capital Topics, Vol. 10, Issue 7, July 2017, https://www.healthcapital.com/hcc/newsletter/07_17/PDF/ACA.pdf (Accessed 11/20/17).

currently employed by hospitals.[7] These increases have, in the past, served as a catalyst for enhanced regulatory scrutiny from the Office of Inspector General (OIG), the Internal Revenue Service (IRS), and the Department of Justice (DOJ), through the development of such initiatives as the Fraud Enforcement and Recovery Act (FERA) and the Healthcare Enforcement Action Team (HEAT).

Among the valuation issues arising from these regulatory concerns are:

(1) The need to establish the very existence of tangible and intangible assets within a healthcare enterprise;

(2) The determination of whether (and under which circumstances) it is legally permissible for those assets to be acquired; and,

(3) The need to take care in the selection of the applicable valuation methodologies, approaches, and techniques related to establishing the Fair Market Value (FMV) of healthcare enterprises, assets, and services. [8]

> This increased scrutiny of the healthcare industry, at both the federal and state level,[9] requires the analyst to conduct a thorough and robust due diligence exercise, due to the significant inherent risk in the industry.

In conducting the general research related to the subject interest being appraised, the analyst should first develop an understanding of the controlling laws and regulations pertinent to the engagement, which may change depending on factors such as the state in which the enterprise, asset, or service is located; whether the provider(s) receive(s) reimbursement from Medicare, Medicaid, or other government payors; and/or, whether any of the enterprise(s) involved in the engagement is tax exempt. In addition, the analyst should be conversant with federal fraud and abuse laws such as the Stark Law (Stark), the Anti-Kickback Statute (AKS), and the False Claims Act (FCA), that, in general, state that physician compensation, for example, cannot be tied to the volume or value of referrals,[10] and that a provider may not submit any requests for reimbursement to the government when the provider is materially noncompliant with the program regulations.[11] Some of the (publicly available) laws and regulations that the analyst may want to review, both to bolster their knowledge and determine the applicability and relevance of the regulations to the subject engagement, include, but are not limited to:

(1) Federal and state fraud and abuse laws;

(2) OIG advisory opinions,[12] special fraud alerts,[13] and work plans,[14] which set forth guidance related to the relevant fraud and abuse laws;

(3) Federal and state antitrust laws;

(4) The applicable provisions of current healthcare legislation, such as the 2010 Patient Protection and Affordable Care Act (ACA);

(5) Proposed U.S. healthcare reform legislation; federal and state licensure, certification, and accreditation regulations;

(6) State Certificate of Need (CON) laws;

(7) State Corporate Practice of Medicine (CPM) laws;[15]

7 "Hospitals' Race to Employ Physicians – The Logic behind a Money-Losing Proposition" By Robert Kocher and Nikhil R. Sahni, New England Journal of Medicine, Vol. 364, No. 19 (May 12, 2011), p. 1790–1791.

8 "Healthcare Valuation: The Financial Appraisal of Enterprises, Assets, and Services" By Robert James Cimasi, MHA, ASA, FRICS, MCBA, AVA, CM&AA, Volume 1, Hoboken, NJ: John Wiley & Sons, Inc., 2014, p. 263.

9 "Laws Against Health Care Fraud Resource Guide" Centers for Medicare and Medicaid Services (September 2015), p. 1.

10 "Limitation on Certain Physician Referrals" 42 U.S.C. § 1395nn (2010); "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C. § 1320a-7b (2015).

11 "False Claims Act" 31 U.S.C. § 3729 (2009).

12 "Advisory Opinions" Office of Inspector General, U.S. Department of Health & Human Services, https://oig.hhs.gov/compliance/advisory-opinions/index.asp (Accessed 11/21/17).

13 "Special Fraud Alerts" Office of Inspector General, U.S. Department of Health & Human Services, https://oig.hhs.gov/compliance/alerts/index.asp (Accessed 11/21/17).

14 "Work Plan" Office of Inspector General, U.S. Department of Health & Human Services, https://oig.hhs.gov/reports-and-publications/workplan/index.asp (Accessed 11/21/17).

15 Almost all states have provisions against the Corporate Practice of Medicine (CPM). Although the regulated content of CPM provisions vary across states, these laws generally prohibit unlicensed individuals or corporations from engaging in the practice of medicine by employing licensed physicians. "Corporate Practice of Medicine Doctrine 50 State Survey Summary" By Mary H. Michal, J.D., et al., National Hospice and Palliative Care Organization, September 2006, https://www.nhpco.org/sites/default/files/public/palliativecare/corporate-practice-of-medicine-50-state-summary.pdf (Accessed 11/27/17), p. 2.

(8) Relevant state case law;

(9) State provider taxes.

As part of the requisite due diligence in conducting general research related to proposed legislation, the valuation analyst should consult government websites, such as www.regulations.gov, which includes information on proposed bills, as well as current legislation.[16] State laws should also be researched for any CPM or CON issues, as these regulations may have a significant effect on the subject interest's competitive position, by acting as a barrier to entry for new healthcare providers.[17] It is vital to the due diligence exercise that the analyst determines the pertinent current laws and proposed legislation that may have an impact upon the ultimate value of the healthcare enterprise, asset, or service.

Specific to the subject interest, the valuation analyst should search the Secretary of State (SOS) office of the state(s) in which the subject interest operates to ensure that the enterprise is in good standing and that there are no liens against the subject interest. To conduct these searches, the analyst should visit: (1) the Business Services section of the SOS office website and search the business to determine that the business entity is active and in good standing; and, (2) the Uniform Commercial Code (UCC) section of the SOS office website to determine who (if anyone) has an interest in the personal property of the subject interest. The analyst should also consult federal legal databases, such as Public Access to Court Electronic Records (PACER),[18] and state court databases, such as Missouri's CaseNet,[19] to ascertain any past or pending litigation against the subject interest. Additionally, the analyst should conduct a search of national and regional news services related to the subject interest and related parties in order to gather further (and potentially pertinent) information.

16 "General Information" Regulations.gov, https://www.regulations.gov/faqs (Accessed 11/10/17).

17 A useful source for tracking state legislation is the *National Conference of State Legislatures*, http://www.ncsl.org (Accessed 11/21/17).

18 "Public Access to Court Electronic Records" United States Courts, www.pacer.gov (Accessed 11/21/17).

19 "Missouri Case.net" Missouri Courts, https://www.courts.mo.gov/casenet/base/welcome.do (Accessed 11/21/17).

It should be noted that subsequent events, i.e., events that would not have been known or knowable as of the valuation date, but which also may have a deleterious effect on the value indication for the subject property, must, according to professional standards, be disclosed within the valuation report to the client. However, these subsequent events will not have an impact on the valuation opinion reported, as of the valuation date, and may require a decision by the client as to whether an updated valuation report, i.e., with a valuation date after the subsequent events, should be undertaken.

Specific research is information and data that is directly related to, or obtained from, the subject enterprise, asset, or service being valued. As the name suggests, specific research is client specific and changes depending on the specific facts and circumstances related to that engagement. In most cases, the valuation analyst will compile a preliminary documents and information request for the client, which documents and information may include, but are not limited to:

(1) Any documents (or drafts of documents) that set forth the terms of transaction, such as physician employment agreements (PEA) and professional service agreements (PSA), term sheets, and asset purchase agreements;

(2) Financial statements representing the financial operation and economic position of the subject entity for, at least, three annual periods ending on the valuation date. Fully audited financial statements are preferred, but so long as it is disclosed within the report, an accountant's compilation or management drafts of financial statements may also be relied upon;

(3) Copies of all licenses, certifications, accreditations, permits, and other regulatory approvals including, if applicable, CONs;

(4) The tax status of the entity;

(5) Tax returns for the entity; A summary and copies of documents related to any pending litigation in which the subject entity is currently involved;

(6) Membership structure of the entity, including relative membership percentages, of all individuals, entities, and physicians in the entity;

(7) Any business performance reports prepared by or for the enterprise related to regulatory position.

There has been a paradigm shift in the healthcare industry over the past several years; most notably manifested in the various provisions of the ACA, which has already resulted (at least in part) in healthcare transactions becoming increasingly complex and subject to emboldened regulatory review, requiring that the risk averse analyst seek out and obtain robust general and specific research data and information in conducting a complete and thorough due diligence process (that will withstand scrutiny) related to a subject property interest being appraised, regardless of whether it is an enterprise, asset, or service. VE

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