HEALTH CAPITAL Topics

2018

written by the professionals of

HCC
HEALTH CAPITAL CONSULTANTS

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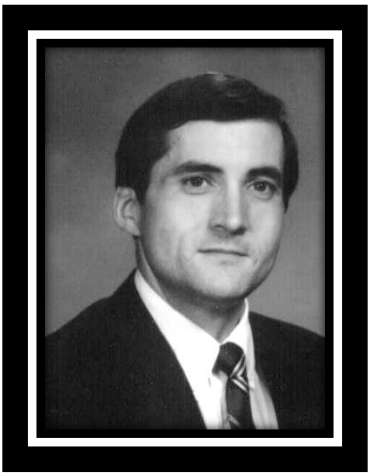
DISCLAIMER

This work includes information regarding the basic characteristics of various regulatory, reimbursement, competition, and technology aspects of the healthcare industry. It is intended to provide only a general overview of these topics. The author and publisher have made every attempt to verify the completeness and accuracy of the information. However, neither the author nor the publisher can guarantee, in any way whatsoever, the applicability of the information found herein. Further, this work is not intended as legal advice or a substitute for appropriate legal counsel. This information herein is provided with the understanding that the author and publisher are not rendering either legal advice or services.

DEDICATION

As we mark this significant milestone in HCC's history, we extend our sincere gratitude to our friends, colleagues, and most importantly, our esteemed clients, who have consistently expressed their trust by allowing us to work with them to pursue their organization's goals over the past 25 years. We look forward to the continued pursuit of excellence on behalf of our clients nationwide, and meeting the new, exciting challenges presented in this ever-changing era of healthcare reform.

IN MEMORIAM



Bob Cimasi
1950 - 2017

When the *2017 Health Capital Topics* book went to press last December, HCC, as well as the valuation profession, experienced the tremendous loss of Bob Cimasi. In addition to founding HCC in 1993, he was a great friend, mentor, and professional colleague to us all. Bob was a nationally known lecturer on healthcare industry topics and a renowned author of nine acclaimed books; numerous chapters in legal treatises and anthologies; published articles in peer reviewed professional journals and industry trade publications; and, was often quoted by the healthcare industry press. He was a pioneer of the business and healthcare valuation profession, and devoted a significant amount of his professional life to selflessly giving back to his colleagues, through mentorships; answering colleague questions and requests for data; professional education; and, volunteer efforts on a wide array of association and society board and committee positions. In recognition of his contributions to the profession, Bob was posthumously awarded the *Thomas R. Porter Lifetime Achievement Award,* in June 2018, by the National Association of Certified Valuators and Analysts (NACVA).

Throughout this year, many stories about Bob were shared with us by friends, colleagues, and clients. In Bob's name, we continue our service to the profession, through teaching, writing, professional research, and serving as the go-to resource for all things healthcare. He is greatly missed.

PREFACE

Health Capital Topics is a monthly e-journal, which has been published by **HEALTH CAPITAL CONSULTANTS** since 2007, featuring timely topics related to the regulatory, reimbursement, competition, and technology aspects of the U.S. healthcare delivery environment.

It is sent monthly to over 20,000 healthcare executives, physicians, attorneys, accountants, and other professionals in the healthcare industry. Past issues of the *Health Capital Topics* e-journal, as well as special alert issues, may be found at www.healthcapital.com.

ACKNOWLEDGEMENTS

The assistance and support of a number of colleagues on the **HEALTH CAPITAL CONSULTANTS** (HCC) team were instrumental in the development of the *Health Capital Topics* articles, from which the writings in this book were excerpted. *Health Capital Topics* is a monthly e-journal published under the direction of **HEALTH CAPITAL CONSULTANTS'** President Todd A. Zigrang, MBA, MHA, ASA, FACHE.

Jessica L. Bailey-Wheaton, Esq., Vice President & General Counsel, serves as editor and directed the development of this book.

John R. Chwarzinski, MSF, MAE, Senior Vice President, and Daniel J. Chen, MSF, CVA, Senior Financial Analyst, who have excelled in representing HCC throughout numerous healthcare client engagements, assisted with research, writing, review, and comments.

Sean J. Wallace, Business Development Coordinator, was instrumental in the e-publishing, web archiving, and design of this book.

HCC's research and library staff, as well as, members of HCC's consulting and administrative support team, were of great help.

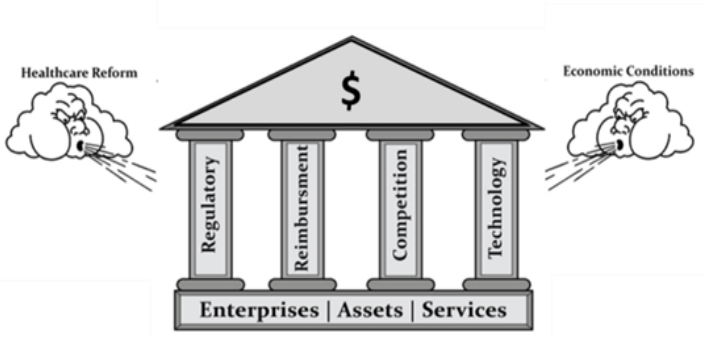
INTRODUCTION

In 2018, healthcare reform has returned once again to the forefront of public and political discourse, as it has become one of the top voter issues in the November 2018 midterm elections, driven, in part, by continued concern regarding: rising healthcare costs; the aging *Baby Boomer* population, which will further increase demand for healthcare services; and, additional challenges to the ACA, e.g., popular provisions such as the prohibition against pre-existing condition exclusions.

The healthcare industry landscape, historically subject to constant change, has become an unpredictable environment of new (or in some cases, modified) provider structures, strategies, and tactics to address these concerns. The continuing evolution of *value-based reimbursement* (VBR), upon which concepts emerging payment models and structures rely to incentivize providers to achieve better outcomes at lower cost, have driven the pursuit of alternative relationships between hospitals and physicians, through strategies such as practice acquisitions, direct employment, provider services agreements (PSAs), co-management, and joint venture arrangements. Corresponding with this growing trend toward hospital-physician alignment, and specifically toward vertical integration, there has been increased federal, state, and local regulatory oversight regarding the legal permissibility of these arrangements, intensifying confusion and uncertainty among providers regarding the future structure of the U.S. healthcare delivery system and its impact on the healthcare industry and markets.

In developing an understanding of the forces and stakeholders that have the potential to drive healthcare markets, it is useful to examine what value may be attributable to healthcare enterprises, assets and services as they relate to the Four Pillars of the healthcare industry, i.e., regulatory, reimbursement, competition, and technology. See figure below.

The Four Pillars of the Healthcare Industry



INTRODUCTION *(Continued)*

This book is a compilation of excerpts from articles originally published in the e-journal, *Health Capital Topics*, which have been loosely organized by topic in relation to the *Four Pillars* concept.

The included articles represent a retrospective look at a topic, as noted by the date of original publication that appears following the article title.

The intent of this book is to serve as an (admittedly abridged) brief annual primer and reference source for these topics. In the months and years ahead, we will strive to continue staying on top of key issues in the healthcare industry and publishing them in the monthly e-journal issues of *Health Capital Topics* and special alerts.

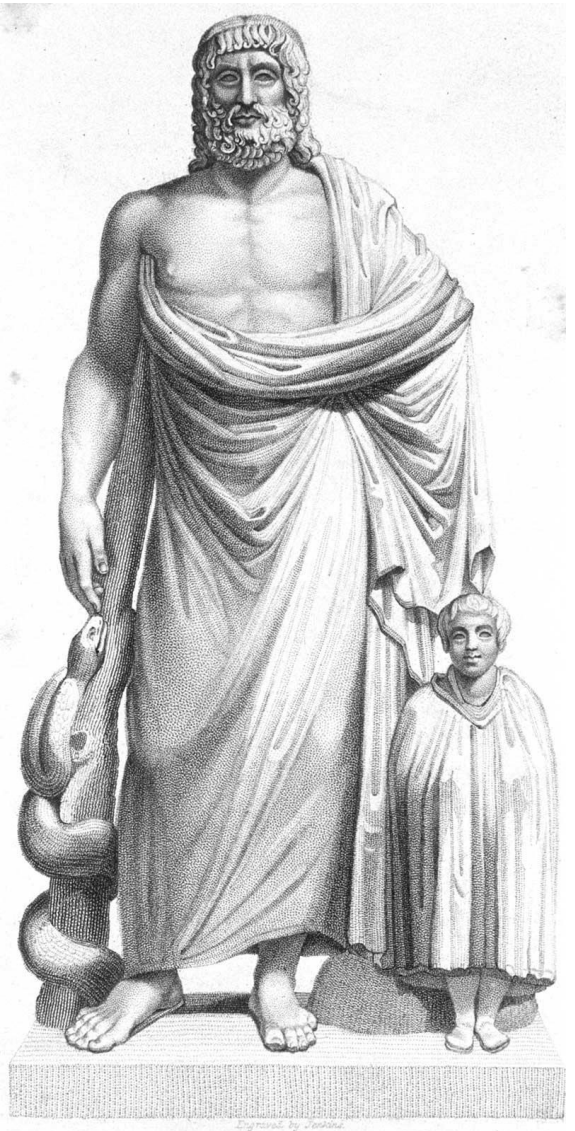
We appreciate the many comments and expressions of support for this research endeavor. HCC's research is the foundation for all of our client engagements and firm as a whole. We as always, solicit your continued input and recommendation of topics or subject matter that you may find useful for us to address.

Sincerely,

Todd A. Zigrang

MBA, MHA, FACHE, ASA

President



Asclepius, from the marble statue in the Louvre. Engraving by Jenkins. Greek God of Medicine & Doctors (London, ca. 1860)

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- John R. Chwarzinski, MSF, MAE
- Jessica L. Bailey-Wheaton, Esq.
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I. VALUATION TOPICS

The Due Diligence Imperative: For the Valuation of Healthcare Enterprises, Assets, and Services

[This is the first article in a six-part series regarding The Due Diligence Imperative. This installment was published in September 2017.]

With the emergence of *value-based reimbursement*, such as *accountable care organizations* (ACOs), *clinically integrated networks* (CINs), and bundled payment models, which rely on achieving the "*Triple Aim*" of healthcare at lower cost, U.S. hospitals are increasingly looking to change how services are being delivered by seeking more collaborative relationships with physicians, including vertical integration strategies such as the acquisition of healthcare-related *enterprises*, *assets*, and *services* (e.g., physician practices), direct employment, co-management, and joint venture arrangements with physicians and other providers.

The rise of these *emerging healthcare organizations* (EHOs) to address *value-based reimbursement* has led to a growing number and complexity of transactions in the healthcare delivery marketplace, accompanied by increased federal and state regulatory scrutiny regarding the legal permissibility of these arrangements. Most notably, government regulators (more specifically, the *Office of the Inspector General* [OIG] of the *U.S. Department of Health and Human Services* [HHS], and the *U.S. Department of Justice* [DOJ]) have, in some cases, more aggressively challenged an increasing array of these transactions under various federal and state fraud and abuse laws.

Therefore, now more than ever, conducting a level of *due diligence* appropriate to the scope and complexity of a given assignment is critical to the development of the valuation opinion. First and foremost, the appraiser serves in the role of a proxy for the *universe of typical investors and buyers* inherent in the requisite hypothetical transaction of the *fair market value* standard, which standard may not be exceeded in order to withstand regulatory scrutiny.

Due diligence may be 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*";[1]

(2) "*a fact-finding project….designed to find hidden risks*";[2] and,

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

There are two distinct classes of information generally required for due diligence related to healthcare valuation: (1) *general research*; and, (2) *specific research*.

General research is typically comprised of information and data related to

national and regional healthcare industry trends; *reimbursement trends*; *competitive marketplace assessments*; *medical industry specialty and technological trends*; *transactional data*; and, *investment risk/return data*, as well as, other research not specifically related to, or obtained from, the subject *enterprise*, *asset*, or *service* being appraised. General research is obtained for the purpose of providing a context within which the analyst considers the *specific research* and information gathered.

Specific research is related to information specific to the historical *operational performance* and *financial condition* of the subject *enterprise*, *asset*, or *service*, as well as, the *pertinent clinical related data*. Specific research is typically obtained from the client or the appropriate contact designated by the client.

In conducting the general and specific research required for the due diligence process, the analyst must develop an understanding of the market forces and the stakeholders that have the potential to drive healthcare markets. It is useful to examine what value relates to the four paramount market influences of the healthcare industry, i.e., the *Four Pillars of healthcare – reimbursement*, *regulatory*, *competition*, and *technology*.[4] These four elements of the healthcare industry marketplace shape the dynamic by which providers and enterprises operate within the current transactional environment, while also serving as a *conceptual framework* for analyzing the viability, the efficiency, the efficacy, and, ultimately, the value that may be attributed to property interests, whether *enterprises*, *assets*, or *services*.

General research may be attained from a variety of sources, including:

(1) Books and monographs;

(2) Journals and periodicals;

(3) Government agencies;

(4) Proprietary data aggregators and portals;

(5) Professional societies and trade associations;

(6) Conferences and webinars;

(7) Online databases; and,

(8) Academic and industry "*think tanks*" and research foundations.

While the process of obtaining *general research* provides the valuation analyst with an adequate grasp of the body of knowledge applicable to a particular property interest being appraised, it is the efficacy of the valuation analyst's subsequent application of generally accepted analytical methods to that data that determines the successful outcome of the assignment. The *technical tools* that the valuation analyst needs to employ to provide clients with the *observations*, *findings*, *conclusions*, and *opinions* that are to be deliverable under a particular engagement involves the *synthesis* of a substantial amount of *data* that may be pertinent to the valuation assignment, as well as the *appropriate analysis*, *calculations*, and *considerations* of the various types and forms of that data. Among the *technical tools* available to analysts is the

benchmarking process, i.e., a comparison of *specific research data* from the subject property interest to *industry indicated normative benchmark data*, and may include the performance of a *simple variance analysis* on a single characteristic, such as a patient outcome metric related to "*readmission within 30 days of discharge*," or may be comprehensive in scope, including the comparison of numerous *clinical*, *operational*, and *financial metrics*.

Benchmarking is used to establish an understanding of the *operational and clinical performance*, and *financial status* of a healthcare enterprise. Benchmarking techniques can also be utilized to illustrate the degree to which an organization *diverges* from *comparable healthcare industry norms*, as well as, providing vital information regarding trends within the organization's *internal operational performance* and *financial status*. For example, benchmarking in the healthcare services sector serves several purposes:

(1) Offers insight into the enterprise and practitioner performance as it relates to the rest of the market (e.g., allowing organizations to find where they "*rank*" among competitors, and as a means for continuous quality improvement);

(2) Objectively evaluates performance indicators on the enterprise and practitioner levels;

(3) Indicates variability, extreme outliers, and prospects;

(4) Identifies areas that require further attention and possible remediation (e.g., re-distributing resources and staff, and increasing operating room utilization);

(5) Promotes quality and efficiency improvement (e.g., improving average length of stay and other clinical efficiency measures); and,

(6) Provides enterprises with a value-metric system to determine if they comply with legal standards for *fair market value* and *commercial reasonableness*.[5]

In contrast to *general research*, *specific research* is information and data that is directly related to, or obtained from, the *subject enterprise*, *asset*, or *service* being valued. Specific research will often be comprised primarily of those documents received by the valuation analyst through the *information and data gathering process* (or *discovery process* in the case of *litigation support engagements*) including, but not limited to, *preliminary legal/organizational* and *transactional documents*, so that any material compliance issues may be identified. A sample of some of the requested *preliminary legal/organizational* and *transactional documents* in a healthcare transaction due diligence process are as follows:

(1) Legal/Organizational Documents:

  (a) Articles of Incorporation, LLC Formation Agreements, Partnership Certifications, Certificates of Trust;

  (b) Bylaws, Operating Agreements, Trust Agreements;

(c) Shareholder Agreements, Member Agreements, Partnership Agreements;

(d) Pertinent Executive Meeting Minutes;

(e) Existing Employment Agreements and Curriculum Vitae for Key Personnel;

(f) Real Property Lease Agreements;

(g) Personal Property Lease Agreements;

(h) Existing Buy-Sell Agreements;

(i) Existing Consulting or Management Services Agreements;

(j) Loan Agreements;

(k) Related Party Vendor/Supplier Agreements;

(l) Third Party Payor Agreements;

(2) Transactional Documents:

(a) Asset Purchase Agreements;

(b) Stock Purchase Agreements;

(c) Bills of Sale;

(d) Asset Contribution Agreements;

(e) Buy-Sell Agreements;

(f) Standstill Agreements;

(g) Non-Disclosure & Confidentiality Agreement;

(h) Letters of Intent;

(i) Transaction Term Sheets;

(j) Proposed Employment Agreements;

(k) Proposed Lease Agreements; and,

(l) Proposed Compensation Plan Details.

Upon the valuation professional's review and analysis of the preliminary documents and information provided, a customized supplemental request for documents and information should be developed in consideration of the unique attributes and circumstances in the healthcare transaction, including, but not limited to, the items set forth in Table 1, below.

Additional subject-specific information may also be obtained through the *site visit/management interview*. Some of the types of subject-specific information that may be collected during the *site visit/management interview* is listed below:

(1) History and Background Information;

(2) Premise/Location/Building Description;

(3) Transition to Electronic Medical Records;

(4) Quality of Staff and Depth of Management;

(5) Competitive Trend Analysis;

(6) Patient Base Trends;

(7) Managed Care Environment;

(8) Hospital Privileges and Facilities;

(9) Referral Sources and Patterns;

(10) Strength of Financial Management and Credit Collections Policy;

(11) Operational Efficiency Assessment; and,

(12) Future Plans, e.g., Growth, Transition to Value-Based Reimbursement.

As part of the requisite due diligence associated with a specific engagement, the valuation analyst should conduct independent research, specific to the subject enterprise, to supplement any information provided by the subject entity; in line with the old Russian proverb, "*Trust but Verify*."[6] For example, the valuation analyst may conduct a *Uniform Commercial Code* (UCC) search to determine if the subject enterprise has any undisclosed outstanding liabilities or whether the subject enterprise leases, rather than owns, their tangible personal property, i.e., furniture, fixtures, and equipment. Similarly, a search for filings related to the subject enterprise with the Office of the Secretary of State in which the subject enterprise operates should be performed to identify pertinent information related to the actual legal organization of the subject enterprise, as well as, performing a brief search of online legal databases, such as *Public Access to Court Electronic Records*[7] for federal litigation, and state litigation databases, such as Case.net[8] in Missouri, to reveal any past and ongoing litigation involving the subject property interest, including shareholder disputes, commercial damages and liabilities, and malpractice cases. Further information related to the subject *enterprise*, *asset*, or *service*, which might not have been disclosed, may be gleaned from state licensing and certifying agencies and disciplinary boards, and may have an impact on the reputation, as well as the *clinical* and *operational performance* and *financial status* of the subject enterprise. 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 may also have a deleterious effect on the value indication for the subject property, must be disclosed, within the valuation report, to the client. However, these *subsequent events* do not have an impact on the valuation opinion, as of the valuation date, and may require a decision by the client whether an updated valuation report, i.e., with a valuation date after the *subsequent events*, should be undertaken.

The valuation analyst should also restate and adjust the subject enterprise *specific* financial data received to: (1) facilitate *industry benchmark comparisons* of the specific line item allocations of the subject entity's financial statements to comparable industry indicated benchmark norms for those line items; and, (2) reflect the *true economic operating performance* and *financial status* of the subject enterprise. Accordingly, the valuation analyst should

carefully consider restating certain line items related to the revenue and expenses of the subject entity, e.g., owner compensation and benefits; discretionary expenses not required to support the projected revenue of the subject enterprise; and, extraordinary non-operating income and expenses. Likewise, the valuation analyst should consider restating certain of the assets and liabilities of the subject entity, e.g., remove non-operating assets; adjust tangible personal property (i.e., furniture, fixtures, and equipment) from book value to *economic fair market value;* and, removing those assets excluded from the property interest being appraised, such as accounts receivable and cash.

The next step in the due diligence process is to determine the extent and the probability of the continuity of the subject business' benefit stream and competitive advantage into the future. A valuation analyst who leads such a process must follow three credos to "*discover the truth*":

(1) "*Be Skeptical*" – Do not believe what you read or what people tell you, or at least be aware of the biased information you are receiving. Always seek corroborative evidence;

(2) "*D&D: Disclose and Disclaim*" – The due diligence process is, by its very nature, a documentation-intensive engagement. In addition to maintaining an organized filing system, it is important to disclose all findings, even those to be deemed immaterial; and,

(3) "*Follow the Scientific Method*" – Although there is an *art* to this work, a successful due diligence process uses the scientific method. In the world of due diligence it truly can be stated that "*the product is the process.*" The successful valuation analyst will generate hypotheses, establish method(s), test hypotheses, report results, and develop conclusions in an orderly, documented, and replicable manner. In keeping with the philosophy of scientific research, due diligence must be objective in its approach and conduct.

The *due diligence* process of a healthcare transaction is a critical exercise for the valuation analyst. This is especially important in consideration of the *Four Pillars of Healthcare Valuation*, i.e., *regulatory*, *reimbursement*, *competition*, and *technology*, which are unique areas of risk that shape the market forces within the U.S. healthcare industry, in the valuation of healthcare *enterprises*, *assets*, and *services*. A complete and thorough due diligence of the subject interest is an iterative process that requires a consistent and persistent approach, and is not for the faint of heart

TABLE 1: TYPICAL SUPPLEMENTAL DOCUMENT AND INFORMATION REQUEST (See Next Page)

Supplemental Document Request
Financial statements (including Income and Expense Statements and Balance Sheets) for the last five full years, plus updates to most recent quarter, or month prior to the date of the valuation.
General ledger, of detailed transactions, for the twelve month period following the "as of" date.
Tax returns (including detailed attachments and supplemental information) for the last five full years.
Fee schedules for subject enterprise, current as of date of valuation, reflecting standard fee, medicare fee and other pre-negotiated fixed fee for service or managed care fees.
Aged schedule of accounts receivable with payor detail for the period ending of each of the last five years and as of the date of the valuation.
Accounts payable with creditor detail for the period ending of each of the last five years and as of the date of the valuation.
Detailed inventory of medical equipment and office equipment (including furniture and fixtures) in use in subject enterprise as of date of valuation, with date and cost of acquisition. Detailed depreciation schedules should be included from tax return or accountants' records to verify schedule.
Estimate of the number of days of each category of supplies on hand (categorize by medical supplies, lab supplies, and office supplies) as of date of valuation.
Count of active patient charts, which have experienced activity within the last 1-1/2 to 2 years prior to the date of valuation. Also, an estimate of the total patient charts with the subject enterprise as of date of valuation.
A CPT coded schedule of the number and type of major and minor procedures by payor, performed in the subject enterprise for each of the last five years and as of the most recent quarter, or month prior to the date of the valuation. Please provide this information by provider and site of service.
A list of physicians and providers in the subject enterprise as of the date of valuation, including their productivity at the subject enterprise for each of the last five years and as of the most recent quarter, or month prior to the date of the valuation (number of procedures, types of procedures, site(s) of service, charges, collections, etc.) and a Curriculum Vitae. Please also provide a list of former physicians and providers including the dates of service at the subject enterprise.
A description and list of referral sources (including productivity, i.e., number of procedures and charges) as of the date of valuation.
Copy of all agreements or proposals for past transactions involving the transfer of an equity or ownership interest in the subject enterprise, prior to the date of valuation.
Any prior valuation reports, investment banking or venture capital, or other financial analysis that have been performed related tothe subject enterprise since inception.
List of any insurance, Medicaid/Medicare, and/or third party payor audits that have been performed or are pending for the subject enterprise, with date and outcome.
Summary and description of privileges at Hospitals where staff privileges are held and scheduling arrangement.
Copy of Declaration Page (cover page) of malpractice insurance.
A list of all patents and intellectual property rights owned by the subject enterprise.
Patient location/zip code distribution report (sorted by location/zip code).
Copies of all managed care contracts in use in the subject enterprise (or a summary of duration, reimbursement scenarios, etc.).
A copy of the organizational chart for the subject enterprise.
Roster of staff (including non-M.D. providers), indicating the type of employment (i.e., W-2 or Independent Contractor status), salary, title, duties and years of service for the subject enterprise.
Copy of any practice protocols, operations manual, employee policies & procedures manuals in use for the subject enterprise.
Copies of all licenses, certifications, accreditations, permits, and other regulatory approvals including, if applicable, Certificates Of Need (CON).
Information on management information systems including all software for accounting, coding, billing, reporting, patient records, etc. with the name of the manufacturer, product, modules, options, etc., as well as the version, release, and update numbers.
Provide a summary and copies of documents related to any pending litigation in which the subject enterprise is presently involved.
Copy of any operating or capital budgets or forecasted statements prepared for the subject enterprise.
A description of the provider income distribution plan in place at the PRACTCIE, including any periodic calculations.
Addresses, office hours and physician and provider staffing for main office and satellite offices.
A description of all sites of services (fixed and/or mobile).
A description of the call/coverage rotation schedule (if applicable).
Marketing materials (e.g., brochures, description of commercials, web site, etc.).
Floor Plan or layout of each of the office locations.

The Due Diligence Imperative: Healthcare Reimbursement Environment

[This is the second article in a six-part series regarding The Due Diligence Imperative. This installment was published in October 2017.]

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*"; and,

(2) "*an investigation in order to support the purchase price of the business*."[9]

There are two distinct classes of information generally required for *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.[10]

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*.[11] This second installment will review the due diligence process as relates to *healthcare reimbursement*.

Healthcare reimbursement may be defined as the payment received by providers for the services that they render to patients, most of which reimbursement is received from third party payors, e.g., public (government) and private (commercial) payors.[12] The U.S. government is the largest payor of medical costs, primarily through the Medicare and Medicaid programs; this significant market share allows the U.S. government to exert a strong influence on the healthcare reimbursement environment.[13] In 2015, Medicare and Medicaid accounted for an estimated $646.2 billion and $545.1 billion in healthcare spending, respectively, combining for approximately 37 percent of all healthcare expenditures.[14] The prevalence of these public payors in the healthcare marketplace often results in their acting as a *price setter*, i.e., being used as a *benchmark for private reimbursement rates*.[15] The healthcare reimbursement environment is currently undergoing a paradigm shift, from

reimbursement based on the *volume* of services provided, to reimbursement based on the *value* of services provided, which shift was recently manifested in the move away from the *sustainable growth rate* (SGR), and the passage of the *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA). This volatility requires the analyst to conduct a thorough and robust due diligence exercise, as the reimbursement trends of the past may not hold true in the future.

In conducting the *general research* related to the subject interest being appraised, the analyst should first develop knowledge base related to the healthcare reimbursement environment, obtain the data required to benchmark the reimbursement at issue in the engagement, and, based on that, reach an adequate understanding of the pertinent reimbursement trends in the marketplace, all of which will allow the analyst to develop their observations, findings, conclusions, and opinion, and determine any necessary assumptions to be made regarding these future trends related to the subject property interest being appraised . One of the principal valuation techniques for which the general research is used is *reimbursement benchmarking*.

In order to compare the reimbursement being received by the subject interest, the analyst may utilize industry normative benchmark survey data, depending on the type of reimbursement involved. For example, reimbursement rates may differ depending on whether: (1) the payor is public or private; (2) the services being provided is in an inpatient or outpatient setting; and/or, (3) the reimbursement at issue relates to the professional or technical component (i.e., whether it is payment for the work of the provider, or for the use of a facility). Upon an assessment of these factors, the analyst can then determine the type of reimbursement benchmark survey data that is most appropriate.

Some of the information that the analyst may want to determine in order to facilitate the benchmarking analysis may include, but not is limited to:

(1) Medicare payments in the base year;

(2) Medicare reimbursement rates on a specific date (of the project);

(3) Projected Medicare reimbursement for the next three to five years;

(4) Medicaid to Medicare fee index; and,

(5) Commercial insurance reimbursement rates.

The various sources of information (some of which sources are free and some of which are available for purchase) that may contain this information may include, but are not limited to:

(1) American Hospital Directory, which "*provides data and statistics about more than 7,000 hospitals nationwide… [and] includes both public and private sources such as Medicare claims data, hospital cost reports, and commercial licensors*";[16]

(2) GuideStar, which aggregates nonprofit reports and Internal Revenue Services (IRS) Form 990s for over 1.8 million non-profit organizations;[17]

(3) Medicare Cost Reports,[18] which contain various data points for a facility, such as "*facility characteristics, utilization data, [and] cost and charges by cost center*";[19]

(4) Physician Compare,[20] published by CMS, which allows the public to compare providers enrolled in Medicare across numerous data points, including utilization and payment data;

(5) Provider compensation and productivity survey data from associations such as:

  (a) *Medical Group Management Association* (MGMA);[21] and,

  (b) *American Medical Group Association* (AMGA);[22]

(6) The relevant Medicare Fee Schedule from CMS;[23]

(7) The state's workers' compensation fee schedule(s);

(8) The state's Medicaid fee schedule(s); and,

(9) Definitive Healthcare, which reports financial and clinical metrics (including net patient revenue, operating income, and average payment per claim by provider) for hospitals and healthcare providers;[24]

(10) FAIR Health, which aggregates information on medical claims (by CPT code) from a significant number of commercial insurers across the U.S.;[25] and,

(11) The Henry J. Kaiser Family Foundation, which provides the Medicaid to Medicare fee index (note that, the data is stratified by state, and by primary care, obstetric care, or other).[26]

The above information presents some of the data sources and means by which the analyst may perform the requisite analysis for comparing the subject reimbursement at issue to industry normative benchmarking data, and provides the context by which the current reimbursement environment can be contrasted with historic trends, to facilitate the analyst's assumptions and calculations necessary to predict future reimbursement.

As noted above, *specific research* is typically collected from the Subject Entity, and specifically from the client, or the appropriate contact designated by the client, e.g., chief information officer (CIO), chief financial officer (CFO), or legal counsel, when pertinent. As the requested documents and information are gathered, an engagement-specific database may be useful to *appropriately* account for the data in a manner that adequately *identifies*, *classifies*, and *stores* it, so that it may be *timely* and *efficiently retrieved* for use (ICSR).

The reimbursement data requested of, and obtained from, the Subject Entity should include both the charges and collections, as well as the amount actually received by the Subject Entity (i.e., the reimbursement). The information and documents to be requested from the Subject Entity may include, but are not limited to:

(1) An aged schedule of accounts receivable with payor detail for the pertinent period;

(2) Productivity reports (which reports should include admissions, payor mix, case mix, and revenue, by payor), such as incidence schedules by the appropriate reimbursement codes, for example:

  (a) *Relative Value Units* (RVU), for use in determining physician reimbursement;

  (b) *Current Procedural Terminology* (CPT) for physician procedures in both inpatient and outpatient settings;

  (c) *Diagnosis Related Groups* (DRG), for use in the hospital setting;

  (d) *Ambulatory Payment Classifications* (APCs), for use in the outpatient setting;

  (e) *Healthcare Common Procedure Coding System* (HCPCS), for classifying ancillary services and procedures;

  (f) *Resource Utilization Groups* (RUGs), for use in the skilled nursing home setting; and,

  (g) Covered lives, for use in relation to managed care companies; and,

(3) A list of any Medicare, Medicaid, and/or other third party payor audits that have been performed or are pending for the Subject Entity, including the audit date and the outcome of the audit.

In the alternative to requesting and obtaining the data piecemeal from the Subject Entity, the analyst may request that the client, or the appropriate contact designated by the client, provide them with a "*data dump*" from the provider's patient billing system, which will include most of the data required to analyze the reimbursement related to the Subject Entity. Most revenue cycle software packages, e.g., Epic Systems and Meditech, allow this data to be exported to a Microsoft Excel or a data delimited (e.g., .csv) file.

Note that, quite often, the valuation analyst will sign an agreement to be a Business Associate of the client for purposes of compliance with the *Health Insurance Portability and Accountability Act of 1996* (HIPAA).[27] Nonetheless, the analyst should request the Subject Entity that the information provided not include any *protected health information* (PHI), e.g., patient name, social security number, address, date of birth. The information may include the unique patient identification or medical record number, so long as it is not tied to PHI, and related to the information provided (e.g., productivity schedules).

The specific information received from the Subject Entity should then be utilized in conjunction with the general research conducted and obtained to assist in the development of growth rates and discount rates, in preparing revenue projections and other elements of the valuation analysis pertinent to the engagement.

The paradigm shift in the healthcare reimbursement environment is changing the scope and nature of due diligence requests going forward. The due diligence requests have necessarily expanded to include both trends in the Subject Entity's historical financial performance and financial condition, as well as, more recently, the quality metrics that influence reimbursement rates. The dynamic evolution of the reimbursement environment has already resulted (at least in part) in healthcare transactions becoming increasingly complex and subject to emboldened regulatory review, requiring that the analyst seek and obtain robust general and specific research data in conducting a complete and thorough due diligence process (that will withstand scrutiny) related to the subject property interest being appraised, whether an *enterprise*, *asset*, or *service*.

The Due Diligence Imperative: Healthcare Regulatory Environment

[This is the third article in a six-part series regarding The Due Diligence Imperative. This installment was published in November 2017.]

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*"; and,

(2) "*an investigation in order to support the purchase price of the business*."[28]

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.[29]

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*,[30] and the second installment discussed due diligence in the context of the *reimbursement environment*.[31] This third installment will review the due diligence process as it relates to the *healthcare regulatory environment*.

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.[32] Although significant efforts have been expended attempting to "*repeal and replace*" the ACA,[33] 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 currently employed by hospitals.[34] 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*. [35]

This increased scrutiny of the healthcare industry, at both the federal and state level,[36] 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*,[37] and that a provider may not submit any requests for reimbursement to the government when the provider is materially noncompliant with the program regulations.[38] 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,[39] special fraud alerts,[40] and work plans,[41] 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;

(6) Federal and state licensure, certification, and accreditation regulations;

(7) State *Certificate of Need* (CON) laws;

(8) State *Corporate Practice of Medicine* (CPM) laws;[42]

(9) Relevant state case law; and,

(10) 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.[43] 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.[44] 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),[45] and state court databases, such as Missouri's CaseNet,[46] 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.

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;

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

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

(8) 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*.

The Due Diligence Imperative: Competition

[This is the fourth article in a six-part series regarding The Due Diligence Imperative. This installment was published in December 2017.]

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*"; and,

(2) "*an investigation in order to support the purchase price of the business*."[47]

There are two distinct classes of information generally required for *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 subject entity, or the appropriate contact designated by the subject entity.[48]

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*.[49] The second and third installments reviewed the due diligence process related to the *reimbursement* and *regulatory* environments, respectively. This fourth installment will review the due diligence process as relates to *competition* in the healthcare industry.

Professor Michael Porter, MBA, PhD, of Harvard University,[50] the author of 19 books and over 125 published articles, is considered to be one of the world's leading authorities on competitive strategy and international competitiveness. In his book, "*On Competition*," Dr. Porter discusses the need to analyze the competitive environment within the framework of the "*Five Competitive Forces that Shape Strategy*," which asserts that all businesses operate within a competitive marketplace defined by an underlying structure comprised of the following five competitive forces:

(1) Threat of new market entrants;

(2) Bargaining power of suppliers;

(3) Threat of substitute products or services;

(4) Bargaining power of buyers; and,

(5) Rivalry among existing firms.[51]

Heated debate has persisted related to the potential benefits and costs of free market competition within the healthcare industry. While proponents of free market competition claim that competition can reduce costs, increase quality, improve efficiency, and provide an incentive to innovate,[52] opponents argue that there are unique differences between the healthcare provider and payor markets and the markets for other industry sectors; therefore, generally applied economic models cannot be adequately utilized to draw conclusions related to outcomes within the U.S. healthcare delivery system.[53]

The various regulations that govern competition in the U.S. healthcare industry also differentiate it from the other industries. For example, state *Certificate of Need* (CON) programs are aimed at restraining healthcare facility costs and facilitating coordinated planning of new services and facility construction.[54] These CON laws act as barriers to entry in the healthcare industry, restraining competition.

In conducting the *general research* for the competitive analysis related to the subject interest being appraised, the analyst should:

(1) Develop a working knowledge related to the competitive environment in the subject interest's location;

(2) Obtain the data required to conduct a financial benchmarking study of the competitors in the geographic area proximate to the subject interest; and,

(3) Based on that data, reach a requisite understanding of the competition in the marketplace.

This process will allow the analyst to appropriately develop their observations, findings, conclusions, and opinion, and determine any necessary assumptions to be made regarding the appraisal of the subject property interest.

Some of the valuation techniques for which the general research is useful are: (1) financial ratio benchmarking; and, (2) a determination of the specific competitors in the market service area of the subject interest.

In order to compare the subject interest's financial performance to others in the industry, the analyst may utilize industry normative benchmarking survey data, as well as the financial data of publicly traded firms, depending on the type of subject interest being appraised.

To determine the competitors in the market service area of the subject interest,[55] the analyst may consider factors such as: geographic location; types of services provided; the size of the entity; the ownership structure of the entity; and, the socio-economic demography of the relevant market service area. Upon constructing a list of competitors, the analyst may collect information pertaining to these competitors, such as: financial information, size, services provided, and type of facility.

Information that can assist the analyst in collecting pertinent data related to market service area includes, but is not limited to:

(1) Federal and state government antitrust laws that are applicable to the entity;

(2) CON laws of the state(s) in which the subject interest is located;

(3) Benchmarks for patient population;

(4) Physician information;

(5) Profiles of competitors; and,

(6) Financial information of competitors.

The various sources of information (some of which sources are free, and some of which are available for purchase) that may contain this data includes, but is not limited to:

(1) *American Hospital Directory* (AHD), which "*provides data and statistics about more than 7,000 hospitals nationwide… [and] includes both public and private sources such as Medicare claims data, hospital cost reports, and commercial licensors*";[56]

(2) *American Health Care Association* (AHCA), which provides "*cutting edge, comprehensive research and data concerning the long term and post-acute care sector*";[57]

(3) *United States Census Bureau*, American Fact Finder, which provides data, such as population, income, and the number and type of businesses in a state, county, city, town, or zip code level;[58]

(4) Specific websites of the state in which the subject interest is located (e.g., the Secretary of State website, state office of insurance regulation);

(5) U.S. *Securities and Exchange Commission* (SEC), *Electronic Data Gathering, Analysis, and Retrieval System* (EDGAR), company filings, which provides "*free access to more than 21 million filings*," which filings typically contain financial information and competitive market analysis;[59]

(6) The *Risk Management Association* (RMA) Annual Studies Financial Ratio Benchmarks (organized by NAICS code);[60]

(7) *Bizminer*, Multiple Year Industry Financial Report (organized by NAICS code);[61] and,

(8) *Microbilt Integra*, Multiple Year Industry Report (organized by specific NAICS code).[62]

The above materials present some of the data sources and means by which the analyst may gather information regarding the competitive environment in the healthcare industry, the laws and regulations governing it, and information about particular competitors, specific to the subject interest, to facilitate the

analyst's assumptions and calculations necessary in developing a *Fair Market Value* opinion.

As noted above, *specific research* is typically collected from the subject interest, and specifically from the client; the appropriate contact designated by the client, e.g., *chief information officer* (CIO), *chief financial officer* (CFO); or, legal counsel, when pertinent. As the requested documents and information are gathered, an engagement-specific database may be useful to appropriately account for the data in a manner that adequately *identifies*, *classifies*, and *stores* it, so that it may be timely and efficiently *retrieved* for use (ICSR).

The data requested of, and obtained from, the subject interest to determine the pertinent competitors should include information that may be used to define the market service area, as well as financial information, and strategies used by the subject interest to differentiate itself from its competitors. The information and documents to be requested from the subject interest may include, but are not limited to:

(1) Patient location zip code distribution report;

(2) Marketing plans and marketing materials;

(3) Any market service area analysis for the subject interest, including any documents and information which may address the origin (e.g., zip codes) of the subject interest's patients;

(4) Any utilization or demand forecast prepared by or for the subject interest;

(5) Strategic plans of the subject interest, including documents or information which relate to any increased expansion into new geographic areas or service lines; and,

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

As this research is client and project specific, the documents and the information required may change, depending on the facts and circumstances of the engagement.

Over the past several years, there has been a paradigm shift within the healthcare industry due to the increased number of transactions occurring among healthcare providers.[63] These transactions are increasing in both size and complexity, resulting in emboldened efforts at regulatory review, requiring that the analyst seek 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 the subject property interest being appraised, whether an *enterprise*, *asset*, or *service*.

The Due Diligence Imperative: Technology

[This is the fifth article in a six-part series regarding The Due Diligence Imperative. This installment was published in January 2018.]

As discussed in the first installment of this six-part series, *due diligence* generally may be 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*"; and,

(2) "*an investigation in order to support the purchase price of the business*."[64]

The requisite *due diligence* related to a healthcare valuation engagement is comprised of two distinct classes of information:

(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.[65]

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*.[66] The second, third and fourth installments reviewed the due diligence process related to the *reimbursement*, *regulatory* and *competitive* environments, respectively. This fifth installment will review the due diligence process as relates to *technology* in the healthcare industry.

Technology should be construed in its broadest sense when applied to the healthcare industry. Not only does is it include the tangible tools, pharmaceuticals, and software that providers use during the provision of clinical services, but technology can also refer to the management of patient records, as well as the procedures that constitute the standardized course of care.[67]

Medical technology should not be limited to the sophisticated machinery used by doctors to treat patients and map different parts of the body, but should also encompass the complex systems used to collect, maintain and analyze patient data and various other processes. The technologies represented by these processes help improve patient clinical outcomes (and help physicians treat

patients more efficiently), as well as enable cost reduction without compromising the quality of care.

The information that an analyst may want to gather to gain knowledge about current technological advancements and their effect on the healthcare industry may include, but is not limited to:

(1) Updates related to the *Health Information Technology for Economic and Clinical Health (HITECH) Act*;

(2) Developments in Information Systems and Technology as it relates to the healthcare industry, including but not limited to, diagnostic and therapeutic technology, and management information technology;

(3) Costs of implementing various systems; and,

(4) The type of technology prevalent in the area of expertise of the subject interest.

The various sources of information that may contain this data include, but is not limited to:

(1) Office of the Health Information Technology, US Department of Health & Human Services;[68]

(2) Healthcare Information and Management Systems Society;[69]

(3) FutureScan: Healthcare trends and implications; an annual publication, published by the Society for Healthcare Strategy and Market Development of the American Hospital Association and the American College of Healthcare Executives, highlights key trends affecting U.S. healthcare organizations;[70]and,

(4) MedTech, which is an association of over 100 pharmaceutical, biotechnology and medical technology companies, their suppliers and service providers, and research universities, that facilitates learning, collaboration, and a sharing of knowledge.[71]

The above information presents some of the data sources by which an analyst may gather information regarding the healthcare technological environment and the laws and regulations governing it, to facilitate the analyst's assumptions and calculations necessary to develop an opinion as to the *Fair Market Value* of the subject interest.

As noted above, *specific research* is typically collected from the subject interest being appraised, and the appropriate contact designated by the client, e.g., *chief information officer* (CIO), *chief financial officer* (CFO); or legal counsel, when pertinent. As the requested documents and information are gathered, an engagement-specific database may be useful to appropriately account for the data in a manner that adequately *identifies*, *classifies*, and *stores* it, so that it may be timely and efficiently *retrieved* for use (ICSR).

The data requested of, and obtained from the subject interest may include, but is not limited to:

(1) Information on management information systems, including all software for accounting, coding, billing, reporting, patient records, etc., with the name of the manufacturer, product, modules, options, etc., as well as the version, release, and update numbers;

(2) A detailed inventory of owned and leased medical equipment and office equipment;

(3) The cost to build existing equipment or systems;

(4) A list existing medical technology used by the subject interest; and,

(5) Capital budgets or forecasted statements prepared by the subject interest, listing the allocated capital expenditure for technological advancements.

As this research is client and project specific, the documents and the information required may change, depending on the facts and circumstances surrounding the engagement.

The healthcare industry has experienced paradigm shifts over the past several years due to the growth in the number of healthcare technology companies, led by the 2007 public listing of Athenahealth, a medical software company whose shares jumped by 97% on the first day after the *initial public offering* (IPO).[72] Additionally, the healthcare industry is constantly changing with increased emphasis on advancements and utilization of new technologies. For instance, the revenue stream of an enterprise may be dependent upon a specific technology, new sources of competition may arise from the development of new and improved technologies that render the old methods obsolete. For example, the introduction of Nexium, "*The Purple Pill*," which revolutionized the treatment of bleeding ulcer patients, significantly reduced both the need for surgery and the length of hospital stays,[73] thereby diminishing patient demand for surgical services from gastroenterologists and permanently affected the *cottage industry* of ambulatory surgery centers that had flourished prior to the introduction of Nexium. In performing the requisite due diligence for a healthcare enterprise, an analyst should undertake research to identify any potential future advancement that may disrupt (or enhance) the revenue-generating capabilities of a subject enterprise.

The emerging technology in the clinical treatment of patients will also shape the *reimbursement environment* that *rewards providers* based on *quality* over *quantity*.[74] For example, the growing importance of the *value-based reimbursement* may bring about an integrated *management information technology* system that includes data input by the patient, provider, and payor.[75]

Owing to the increase in medical technology companies, as well as technological changes and regulations introduced by the *2010 Patient Protection and Affordable Care Act* (ACA), healthcare transactions are increasing in both size and complexity, resulting in emboldened efforts at regulatory review, requiring that the analyst seek 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 the subject property interest being appraised, whether an *enterprise*, *asset*, or *service*.

The Due Diligence Imperative: Conclusion

[This is the sixth article in a six-part series regarding The Due Diligence Imperative. This installment was published in February 2018.]

As discussed in the first installment of this six-part series,[76] *due diligence* generally may be 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*";[77] and,

(2) "*an investigation in order to support the purchase price of the business*."[78]

The requisite *due diligence* related to a healthcare valuation engagement is comprised of two distinct classes of information:

(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.[79]

The first installment 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*.[80] The second through fifth installments reviewed the due diligence process related to the *reimbursement*, *regulatory*, *competitive* and *technological* environments, respectively. This series conclusion will review the due diligence process generally as it relates to the healthcare industry.

Each of the previous series installments set forth a detailed list of information and documents to be collected by the analyst specific to each of the *Four Pillars*. Obtaining and reviewing some general research items may be crucial before starting any project. For example, information related to current Medicare reimbursement rates (the date of which rates will be specific to the project), projected rates (for the next three to five years), and the Medicaid to Medicare fee index may be reviewed for use in *reimbursement benchmarking*.

Additionally, the analyst may be well-served to review the applicable provisions of current and pending healthcare legislation, such as the *2010*

Patient Protection and Affordable Care Act (ACA); *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA); federal and state fraud and abuse laws; and, other laws, regulations, and case law as applicable to the specific facts, circumstances, and location of the engagement. Additionally, in some situations, such as when the client plans to start a new practice or business, the analyst may need to research federal and state licensure, certification, and accreditation regulations; and, state *Certificate of Need* (CON) laws, to determine their applicability to, and impact on, the project.

In conducting a competitive analysis related to the Subject Interest, the analyst must develop a working knowledge of the competitive environment in the Subject Interest's market service area; obtain the data required to conduct a financial benchmarking study of the competitors in the geographic area proximate to the Subject Interest; and, review the financial profiles and financial statements of the competitors.

While the general research process provides the valuation analyst with an adequate grasp of the body of knowledge applicable to a particular property interest being appraised, it is the efficacy of the valuation analyst's subsequent application of generally accepted accounting approaches and methods to that data that determines the successful outcome of the engagement.

In contrast to *general research*, *specific research* is information and data that is directly related to, or obtained from, the subject *enterprise*, *asset*, or *service* being valued. Additional subject-specific information may also be obtained through the site visit/management interview. In some situations, the analyst might find it difficult to obtain the requested information and documents. It is instrumental that the analyst be consistent and persistent in obtaining the relevant information and documents required to conduct the due diligence exercise within the valuation analysis. Some strategies to communicate with the client may include, but are not limited to, the following:

(1) Determine the pertinent contact from whom to obtain the information, e.g., the chief financial officer (CFO), vice president of finance, accountant, billing manager, and contact them directly;

(2) Arrange a phone call with the client, management or the designated contact, immediately after sending the document request, to review the list and answer any questions and discuss any potential problems with the availability or accessibility of said documents;

(3) Send updated copies of document requests to the client to remind them of the outstanding documents and information; and,

(4) In the event that the client encounters difficulty in procuring the requested documents, recommend alternative routes to obtain information or suggest substitute documents.

Clients often cannot provide the documents and information requested by the analyst, because the client does not possess the information in the format it has been requested. In the alternative to requesting and obtaining the data piecemeal from the Subject Interest, the analyst may request that the client (or the

appropriate contact designated by the client), provide the analyst with a "*data dump*" from the software that stores the requested data, and convert the *data dump* into a usable format in which the analyst can sort/analyze the information. For example, a *data dump* may come from the patient billing system and may include (in the case of the subject interest being a hospital or a physician office) individual procedure data by: (1) Unique Transaction ID; (2) Current Procedural Terminology (CPT) Code; (4) Total Charges; (5) Total Collections; (6) Provider; (7) Site of Service; (8) Patient ID Number; (9) Patient Zip Code; (10) Payor Mix; and, (11) Referral Source. This information could further be used to analyze the reimbursement related to the Subject Interest. Note that, most revenue cycle software packages, e.g., Epic Systems and Meditech, allow this data to be exported to a Microsoft Excel or a data delimited (e.g., .csv) file.

Occasionally, the analyst may have to conduct independent research to construct the information or an adequate "*work around*," in the event that the client has no documentation of the requested information. For instance, as discussed the fourth installment in this series, the analyst may request from the client patient location zip code distribution report or any market service area analyses for the Subject Interest, including any documents and information which may address the origin (e.g., zip codes) of the Subject Interest's patients.[81] This information is used to determine the Market Service Area to be used for the valuation. Some clients will not have this information accessible and may not be able to provide it to the analyst. To conduct a successful competitor analysis without this information, the analyst can, in the alternative, equate the Market Service Area of the client with the Metropolitan Statistical Area, county (or group of counties), or state, and find providers of similar services within the selected region. This process should be conducted with the cooperation of the management of the subject entity to insure that the selected geographical area conforms to the perceived footprint of the subject entity.

As part of the requisite due diligence associated with a specific engagement, the valuation analyst should conduct independent research, specific to the subject enterprise, to supplement any information provided by the subject entity, in line with the old Russian proverb, "*Trust but Verify*." For example, the valuation analyst may conduct a *Uniform Commercial Code* (UCC) search to determine if the subject enterprise has any undisclosed outstanding liabilities or whether the subject enterprise leases, rather than owns, their tangible personal property, i.e., *furniture*, *fixtures*, and *equipment*. Similarly, a search for filings related to the subject enterprise with the Office of the Secretary of State in which the subject enterprise operates should be performed to identify pertinent information related to the actual legal organization of the subject enterprise, as well as performing a brief search of online legal databases, such as the Public Access to Court Electronic Records (PACER) database[82] for federal litigation, and state litigation databases, such as Case.net[83] in Missouri, to reveal any past and ongoing litigation involving the subject property interest, including shareholder disputes, commercial damages and liabilities, and malpractice cases. Further information related to the subject property interest, which might not have been disclosed, may be gleaned from state licensing and

certifying agencies and disciplinary boards, and may have an impact on the reputation, as well as the clinical and operational performance and financial status, of the subject enterprise. 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 may also have a deleterious effect on the value indication for the subject property, must be disclosed, within the valuation report, to the client. However, these subsequent events do not have an impact on the valuation opinion, 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.[84]

The due diligence process of a healthcare transaction is a critical exercise for the valuation analyst. 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, as healthcare transactions are increasing in both size and complexity, resulting in emboldened efforts at regulatory review, requiring that the analyst seek 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 the subject property interest being appraised. This due diligence process is especially important in consideration of the *Four Pillars of Healthcare Valuation*, i.e., *regulatory*, *reimbursement*, *competition*, and *technology*, which are unique areas of risk that shape the market forces within the U.S. healthcare industry, in the valuation of healthcare *enterprises*, *assets*, and *services*.

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Valuation of Healthcare Service Sector Enterprises for Purposes of Private Equity Investment: Introduction

[This is the first article in a three-part series regarding Valuation of Healthcare Service Sector Enterprises for Purposes of Private Equity Investment. This installment was published in November 2017.]

A growing number of *private equity* (PE) groups are approaching large physician-held groups and other healthcare service enterprises, including hospitals and outpatient enterprises, seeking investment opportunities in the clinical services industry. This influx of PE investment is not only ameliorating a dearth of financial capital available to healthcare service enterprise's, but are also allowing these provider groups to "*step up*" to the next phase of growth by providing the management capital (e.g., resources, knowledge, skills, and ability) to facilitate the provider's transition to *value-based reimbursement*.

PE is a capital funding source that is not available through a public exchange and is often utilized to: (1) expand a business; (2) fund new technology; or, (3) supplement an established entity's working capital.[1] PE investors often invest in an established (and perhaps faltering) business in hopes of restructuring the business and installing professional business management, with the ultimate goal of making the business more efficient and more profitable.[2] It should be noted that this type of investing is distinct from *venture capitalism* (VC), as VC investors generally invest in the creation of a new business, [3] with the goal of capturing returns resulting from the large growth opportunities of start-ups over a short period of time.

While the global economic insecurity throughout 2016 resulted in a sharp decline in overall PE deals – spurred by uncertainty arising from events such as Brexit and the U.S. presidential election – PE deals in the U.S. healthcare industry hit a decade high in 2016, reaching $36.4 billion.[4] This milestone (which will likely be surpassed in 2017, considering the current pace of deals[5]) continues the trend of significant growth in healthcare PE investment, during which PE deals soared from approximately $16 billion in 2013 to approximately $30 billion in 2014.[6] These numbers indicate that, over the past decade, an increasing number of investors have become more knowledgeable about, and more comfortable with, entering a perilous market with complex regulation and uncertain reimbursement.[7]

Despite rising healthcare costs and the aforementioned volatility of the healthcare industry,[8] PE investors have nevertheless been drawn to the stability provided by a reliably aging population with increasing demands for healthcare services; an influx of newly insured individuals due in part to the *2010 Patient Protection and Affordable Care Act* (ACA); and, an increasing incidence and prevalence of chronic disease.[9] Consequently, the healthcare industry has ranked in the top three industries in rates of return every year since 2011.[10] This achievement has not gone unnoticed, as new investors such as generalist PE investors; sovereign wealth funds; pension funds; family offices; and, providers themselves, have invested in healthcare service sector enterprises, creating a

new level of competition for general PE buyout funds.[11] The increased interest in healthcare PE investment targets has been undeterred by the uncertainty surrounding the future of healthcare reform, possibly due,[12] at least in part, to the sheer size and scope of healthcare (as it comprises almost 20 percent of the U.S. *gross domestic product*[13]).

Over the past couple of decades, the provider services subsector has ranked sixth in the healthcare industry in median returns.[14] These provider service sector enterprises garnered particular interest from PE investors over the past several years, partly due to the success of the buyout of both for-profit, publicly traded health systems such as Hospital Corporation of America (HCA), and large, privately owned healthcare service sector companies such as ManorCare.[15] More recently, the deal value for the U.S. provider sector increased from $7.3 billion in 2015 to $11.8 billion in 2016.[16] Some of the more popular healthcare service enterprise PE targets included retail health (e.g., physical therapy) and dermatology.[17]

Moreover, providers themselves are launching other investment arms to support their service enterprise's initiatives, focusing their investments in digital health, medical devices, and diagnostics.[18] For example, in December 2016, Inova Health System, a large health system in the Washington, DC metropolitan area, announced the creation and launch of *Inova Strategic Investments* (ISI), which "…*will invest in healthcare venture funds and will also invest directly into companies aligned with Inova's strategic priorities as part of Inova's vision to be a global leader in the delivery of personalized health*."[19] Mid-sized hospitals are also seeking to invest, for example, Spectrum Health, a midsized health system located in Grand Rapids, Michigan, created a $100 million fund in 2017 "…*to invest in personalized medicine, information technology, population health management and other emerging technologies*."[20]

Although the U.S. healthcare industry has been relatively unstable over the past several years, traversing: the paradigm shift from *volume*- to *value*-based reimbursement; the increasing regulatory scrutiny of healthcare transactions; and, the continuing uncertainty regarding the state of healthcare reform, the healthcare PE market is considered an opportunity for investors.[21] PE investors have turned to specific subsectors that are more likely to remain stable amid the healthcare industry's political, regulatory, and reimbursement volatility.[22] The consistently high returns on healthcare PE investments have kept investment interest in the healthcare service sector high, resulting in increased valuations and a diversification of investors.

The future installments in this three-part series will discuss the special valuation considerations of these going concern enterprises, and will compare and contrast this PE investment trend with the failed *physician practice management company* (PPMC) business model of the 1990s.

Valuation of Healthcare Service Sector Enterprises for Purposes of Private Equity Investment: Valuation Considerations

[This is the second article in a three-part series regarding Valuation of Healthcare Service Sector Enterprises for Purposes of Private Equity Investment. This installment was published in December 2017.]

As discussed in the first installment of this three-part series, *private equity* (PE) is a capital funding source that is not available through a public exchange and is often utilized to: (1) expand a business; (2) fund new technology; or, (3) supplement an established entity's working capital.[23] Although the global economic insecurity throughout 2016 resulted in a sharp decline in overall PE deals, the volume rebounded in the U.S. healthcare industry and hit a decade high in 2016, reaching $36.4 billion.[24] In addition to the traditional PE firms investing in PE funds, numerous healthcare organizations have been investing in PE funds as well; the main reason for this seems to be the perceived necessity to adapt to the changing healthcare industry to maintain a strategic advantage and remain relevant.[25]

The first part of this three-part series set forth an introduction to the current PE activity in the healthcare services sector. This second installment will discuss the valuation approaches utilized to develop an opinion as to the fair value of a target for the purposes of PE investment, specifically as it relates to the healthcare sector.

The best practice guidelines state that the most acceptable way to value investments by PE firms is at *fair market value*. The *International Private Equity and Venture Capital Valuation Guidelines* are issued with an objective "*to set out best practice where private equity investments are reported at 'Fair Value*'."[26] Additionally, the *Private Equity Industry Guidelines Group* set forth U.S. Private Equity valuation guidelines, and as their 2007 update states, "*The Guidelines seek to have all investments in portfolio companies reported at* ***fair value*** *on a consistent, transparent and prudent basis*."[27] [Emphasis added.] *Fair value*, as defined in accordance with *Generally Accepted Accounting Principles* (GAAP), is "*the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date*."[28] It is important to note that the standard of *fair value*, as defined by GAAP, is nearly identical to the valuation standard of value of *fair market value*.

The *Financial Accounting Standards* (FAS) No. 157 states that the three generally accepted approaches to be used to develop an opinion as to the *fair value* of a target are:

(1) Market Approach;

(2) Income Approach; and,

(3) Asset/Cost Approach.[29]

While FAS No. 157 allows for an analyst to use a single technique, it is prudent, and in conformance with professional valuation standards, to consider all applicable valuation approaches.[30] The most common approach used by PE firms is the *Market Approach*.[31] Valuation methods available to an analyst under the Market Approach include: The Guideline Transaction/Mergers and Acquisition Method; and, the Guideline Public Company Method.[32] Under the Guideline Transaction Method, transactions of companies exhibiting sufficient badges of homogeneity with the target are researched to use as guidelines (i.e., benchmarks) to value the target.[33] The Guideline Public Company Method values the target by using the valuation multiples of the freely traded, minority interest registered shares of publicly traded companies.[34]

The other methodologies that may be appropriate in certain circumstances, i.e., under the Income and Asset/Cost Approaches, include the: Discounted Cash Flow Analysis; Net Asset Valuation;[35] and, Leveraged Buyout Technique. These methodologies are not always feasible for PE firms since most of the targets are privately held and reliable financial information is not readily available. Often, PE firms invest in enterprises that might be in the turnaround stages or which typically do not have audited financial statements, such as family owned businesses, making it difficult to rely on their financial reports or to quantify any intangible assets that may be owned by the business.

The PE share of ownership varies in each investment made. A PE firm may own a majority share or a minority share in the target. Typically, the majority holders will have a control interest in a business; this should be taken into consideration when valuing a target, either through the application of a *control premium*, defined as: "*…an increase to the pro rata share of the value of the business that reflects the impact on value inherent in the management and financial power that can be exercised by the holders of a control interest of the business, usually the majority holders*,"[36] or through changes to the projected cash flows of the target reflecting the ability of a control position to alter the operations of the target. Likewise, if the PE firm is valuing a minority interest, the projected cash flows should be reflective of the lack of control available to a minority shareholder, or a minority discount or a discount for lack of control should be applied to a valuation of the target based upon cash flows arising from a control position. A *minority discount* is inversely proportionate to the *control premium*, and hence, is a reduction in the pro rata share of the value of business that reflects the minority shareholders' absence of control.[37]

As discussed above, there has been a surge in PE activity in the healthcare sector of late. Traditionally, PE firms invested in less complex healthcare

entities, mostly driven by private insurance or private pay as those enterprises offer high-reimbursement potential, such as; dermatology, dental, and pain management practices.[38] PE firms continue to have tremendous interest in these areas, but have also begun investing in the primary care space as well.[39] Motivation for this interest may be due to the fact that specialty practices are becoming more expensive relative to primary care practices.[40] In the first quarter of 2017, the physician medical group segment was the largest healthcare sub-sector, with a total deal value of $3.3 billion.[41] Physician practices require the constant attention of the practice physicians to efficiently run the business and ensure positive income growth for the practice. When a PE firm invests in a physician practice, it involves the rollover of equity, which allows the physician shareholders to own a significant share of the practice.[42] Equity rollover is typically an exchange by the seller of a percentage of its equity for stock as full or partial consideration for the selling of the stake in the company.[43] This ensures the physicians' share of the profit from future growth opportunities and incentivizes the physicians to remain involved in the business.[44]

With the acceleration of large healthcare mergers and acquisitions, PE firms typically pay higher valuation multiples, as they have to compete against strategic investors seeking synergies.[45] The limited supply of, and increased demand for, primary care practices has led to increasing multiples being paid for practices in recent years.[46] However, the average health services *enterprise value/earnings before interest, tax, depreciation, and amortization* (EV/EBITDA) multiple decreased slightly, by 0.2x, in the first quarter of 2017 to a level of 12.3x.[47]

The average holding period for PE firms has traditionally ranged between three to five years, although recent trends suggest that this may be changing.[48] In the past decade, the average holding period for PEs has increased from 4.5 years in 2006 to 5.8 years in 2016.[49] A PE firm's objective is to realize returns on their investment by the end of the investment horizon. A successful exit is the culmination of this process. There are several methods of exits available to a PE firm, including:

(1) An initial public offering (IPO) – The first sale of a private company's equity to the public;[50]

(2) A secondary buyout – The sale of investment companies by a PE firm to another PE firm;[51]

(3) A management buyout – The acquisition of a business by its core management team;[52] and,

(4) Merger/acquisition – The merger or acquisition of the business with a strategic buyer to purchase the PE.

In the first two quarters of 2017, mergers and acquisitions and secondary buyouts dominated the healthcare PE exits.[53]

In addition to the myriad valuation considerations related to healthcare service sector enterprises for purposes of PE investment, the complex regulatory

environment necessitates the consideration of the impact of various laws specific to the healthcare industry, with which such laws PE firms may not be intimately familiar. For example, most fee-splitting arrangements in healthcare, i.e., compensation or other financial arrangements based on a percentage of charges or revenue, are not legally permissible, potentially presenting a challenge for those PE firms that typically structure deals based on a percentage of revenue.[54] Additionally, PE firms generally may not own or directly invest in medical practices due to state *corporate practice of medicine* (CPOM) laws. While CPOM laws vary by state, they typically assert that only licensed providers (physicians) may employ other licensed providers, presenting a hurdle for PE firms seeking to directly invest in physician practices.[55] Many PE firms have been "*side stepping*" CPOM laws by establishing a *management services organization* (MSO) to purchase the assets of the physician practice, and provide management and other non-clinical services to the practice in exchange for *fair market value* compensation.[56]

Traditionally, PE firms operating within the healthcare industry have tended toward sub-sectors such as healthcare technology, pharmaceuticals, or durable medical equipment. However, PE firms increasingly are entering the healthcare services sector, investing in dialysis centers, infusion services, home health, and directly in physician professional practices. This provides an alternative route for those physicians who may be dissatisfied with private practice to divest of their ownership without aligning directly (through an employment arrangement) with a health system, which may be more attractive to some practitioners. From an industry-wide perspective, the expansion of PE investment should continue the trend of consolidation within the healthcare sector, albeit not through the traditional route of acquisition by a large health system. Although, with a PE firm's limited investment horizon and demand for short-term gains, PE firms can only be thought of as intermediaries in the consolidation project, seeking to quickly consolidate a market service area and capture any realizable synergy gains. In short, PE firms are not in the business of running a healthcare enterprise; instead, they are attempting to reap the rewards of removing inefficiencies from the healthcare industry through both horizontal and vertical integration.

It is, as yet, indeterminate as to the long-term effect of the trend of increased PE investment in the healthcare services sector. While, in the long run, consolidation may have beneficial effects to the healthcare industry, the short-term perspective of PE investors may lead to perverse results or unexpected consequences. Regardless, the investment of PE firms in the healthcare services sector will continue to drive competition for the acquisition of various healthcare service provider organization, which is a key factor to consider when performing the valuation of a healthcare entity or when advising a client regarding a potential merger and acquisition transaction.

Valuation of Healthcare Service Enterprises for Purposes of Private Equity Investment: Private Equity's Healthcare Future

[This is the third article in a three-part series regarding Valuation of Healthcare Service Sector Enterprises for Purposes of Private Equity Investment. This installment was published in January 2018.]

As discussed in the first and second installments of this three-part *Health Capital Topics* series on *private equity* (PE), investments from PE Firms experienced record growth in the healthcare industry in 2016,[57] and have realized greater returns on investment compared to other industries.[58] Nevertheless, concerns remain as to the similarity of this trend in PE investment to that of *physician practice management companies* (PPMCs) in the 1990s, which ultimately failed and left corporations such as *Phycor* and *MedPartners* with huge losses and stock prices that plummeted to under $2 per share (once above $30 per share).[59] During this period, PPMCs attempted to create value in the healthcare industry by supplying physicians with management services as well as an alternative means to access capital.[60] However, this model eventually failed because it did not yield a return on the acquisitions that exceeded the PPMC's weighted average cost.[61] Although PE investments do share similarities with PPMCs, PE arrangements may be able to prove more successful due to: (1) the drastic changes in the healthcare reimbursement environment under new legislation; (2) advancements in technology; and, (3) developments in data analytics.[62]

In the 1990s, PPMCs were marketed as a vehicle to accrue the necessary capital to achieve economies of scale for single and multi-specialty practices by: (1) building clinical information systems that would help manage care more efficiently; and, (2) creating bargaining power with vendors and payors for the member physician practices.[63] With the emergence of managed care contracts, PPMCs also applied their management expertise to address the complex negotiations requisite in this managed care era, as well as, the emerging challenges stemming in part from a massive drive toward consolidation in the healthcare industry.[64] While some physician practices were able to achieve small increases in revenues through PPMCs, most did not realize a large enough savings on practice operations to offset the costs associated with PPMCs.[65] Generally, PPMCs struggled to manage the systems that they had created, particularly through proper utilization of technology to create a more efficient operation.[66] Further, PPMCs failed to increase the bargaining power for the PPMC member physician practices because of the limited geographic proximity and the divergence of rates and expenses across state lines inherent in a given healthcare marketplace.[67]

Since the collapse of PPMCs in the 1990s, the healthcare industry has undergone significant reform through the passage of comprehensive laws such as the *2010 Patient Protection and Affordable Care Act* (ACA) and *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA); technological advancements, including the widespread implementation of *electronic health records* (EHRs); and, the emergence of *big data* and data analytics. The *Centers for Medicare and Medicaid Services* (CMS): (1) advanced the movement from *volume-based* to *value-based*

reimbursement, which built upon some of the bundled payment programs first developed under the ACA; (2) replaced the *sustainable growth rate* (SGR) formula for determining physician reimbursement with pre-determined payment updates through MACRA; and, (3) implemented multiple value-based measures and quality-centric programs under Medicare.[68] This shift allows providers, if properly managed, to capitalize on reimbursement incentives for providing high quality care to patients at a lower cost.[69] PE firms are capitalizing on these new reimbursement models to make physician groups more profitable and to realize an improved return on their investment.

Technological advancements have benefited the healthcare industry in myriad ways, and PE firms have taken advantage to conquer one major shortcoming of PPMCs. PE firms are utilizing this newer technology to increase their return on investment through the use of EHRs. Over the past several years, EHRs have received governmental backing (beginning with billions of dollars in support under the *American Recovery & Reinvestment Act of 2009*),[70] increasing significantly the number of physician practices utilizing this technology. In 2004, only 20 percent of physicians were using EHRs; as of 2015, approximately 90 percent of physicians had adopted EHRs.[71] EHRs have improved practice efficiency by decreasing the wait time for laboratory results; enhancing data confidentiality; and, improving practice management through integrated scheduling systems.[72]

PE firms may also be more successful than PPMCs because there has been a significant development in data analytics since the 1990s.[73] The healthcare industry has been collecting and analyzing data to identify trends and, more importantly, model and manage physician behavior and compensation based on those trends.[74] PE firms are making better use of benchmarking to analyze key performance data (both internally and compared to other industry participants) to increase their quality of care[75] and to take advantage of enhanced reimbursement opportunities, such as, bundled payment schemes under the ACA and MACRA. Achieving these goals is particularly difficult for smaller practices with access to fewer financial and management resources, but PE firms may assist these physician groups by providing the financial and management capital to be able to "*step-up*" to the next phase of growth and to facilitate the provider's transition to *value-based reimbursement*.

Although the PE investment trend resembles that of PPMCs in the 1990s, it is likely that the outcome for PE firms will be quite different. Because the healthcare industry has seen: significant changes in reimbursement; technological advancements; and, the emergence of *big data* and data analytics, PE firms have the available tools to manage physician groups more efficiently. PE firms seem to have noted the PPMC failures of the 1990s and accounted for those shortcomings in their search for above average financial returns.[76]

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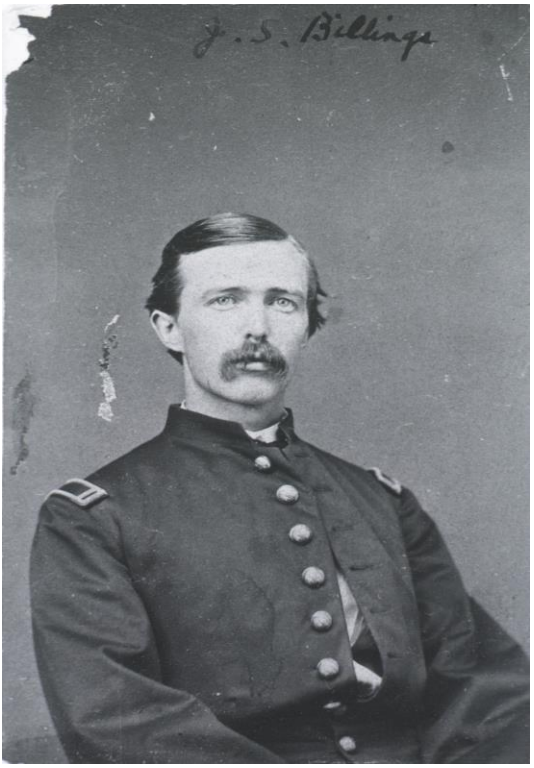

John Shaw Billings (1838-1913)
Modernizer of the Library of the U.S. Surgeon General's Office of the Army and First Director of the New York Public Library

What's Your Brand Worth? Valuation Considerations for Healthcare Enterprises

[This is the first article in a four-part series regarding What's Your Brand Worth? This installment was published in January 2018.]

Trademarks and trade names are symbols that represent an intangible quality of the good or service provided under the trademark/trade name. These qualities might include quality, reliability, and/or dependability, and they may be classified generally as *reputational*. Value for a trademark/trade name arises from its ability to transfer this *reputational* quality to a product or service.

The legal definition of a *Trademark*, as set forth in The Merriam Webster Dictionary, is:

> "*a mark that is used by a manufacturer or merchant to identify the origin or ownership of goods and to distinguish them from others and the use of which is protected by law*."[1]

Additionally, the legal definition of a *Trade Name*, as set forth in The Merriam Webster Dictionary, is:

> "*a name or mark that is used by a person (as an individual proprietor or a corporation) to identify that person's business or vocation and that may also be used as a trademark or service mark.*" [2]

Trademarks and trade names are both components of the brand of a business entity. Trademarks and trade names hold economic value, in that they have the capacity to bring recognition and "*brand loyalty*" to the subject enterprise through the perception of quality assurance in the goods and/or services provided by the branded organization.[3] Brands play an especially important role in healthcare, as the *quality* of the services provided by a healthcare entity can directly impact the quality of life of a patient or even the life or death of a patient.[4] Branding for healthcare entities has continued to proliferate in recent years. The Mayo Clinic, Duke Lifepoint, and Cleveland Clinic trade names have expanded the use of their trademark(s) and trade name(s) through affiliations across the U.S. These affiliations allow local providers to:

(1) Capitalize on the reputation of the brand;
(2) Provide access to a network of intellectual resources; and,
(3) Promote the brand for the licensing entity outside of their geographic area.[5]

The most valuable healthcare brand in the U.S. for 2017 was UnitedHealth, with an estimated brand value of 13.4 billion dollars.[6]

As is the case in the majority of valuation assignments, trademarks and trade names can be valued within the framework of the following general valuation methods:

(1) Asset or Cost-based approach;
(2) Market-based approach; and,
(3) Income-based approach.

Asset/Cost based approach methods seek an indication of value by determining the cost of reproducing or replacing an asset. There are several methods that may be utilized under the cost approach, including:

(1) *Cost of Reproduction Method* – This method estimates the value of the subject intangible asset based on the cost that would be incurred as of the appraisal date to construct a replica of the subject property; and,

(2) *Cost of Replacement Method* – This method estimates the value of the subject intangible asset based on the cost incurred to obtain a replacement intangible asset, which provides the same level of utility.

Valuation analysts should note that asset/cost based valuation methods may not account for all of the economic advantages that arise from the ownership of a trademark or trade name. Therefore, the cost approach is not always applicable in the valuation of trademarks or trade names, as it tends to *undervalue* the economic benefit accruing to the owner of the trademark or trade name.

There are several market-based approaches that can be applied when valuing a trademark or trade name, including the following:

(1) *Relief from Royalty Method* – This method is a hybrid income and market based approach that applies a market or income derived royalty rate to the future cash flows of a business entity or business segment and then discounts those projected cash flows to their present value equivalent at an appropriate risk adjusted required rate of return to arrive at an indication of value for a specified date; and,

(2) *Profit-Split Method* – This method is another hybrid income and market based approach that applies a market or income derived profit split to the future cash flows of a business entity or business segment and discounts those cash flows to present value at a risk adjusted required rate of return to arrive at an indication of value.

The market-approach based methodologies require comparable licensing agreements from market transactions to derive an indication of the appropriate royalty rate or profit split that should be applied under the subject trademark or trade name. Comparable royalty rates and profit split data can be found in several databases including, but not limited to, the following:

(1) *ktMINE*;[7]

(2) *RoyaltyStat*;[8] and,

(3) *RoyaltySource*.[9]

Lastly, the following income-based methods may be utilized to determine an indication of value for a trademark or trade name:

(1) *Incremental Earnings Method* – This income-based valuation method seeks to quantify the difference between the: (i) the earnings of the business segment or business enterprise with the use of the trademark or trade name; and, (ii) the earnings of the business segment without the use of the trademark or trade name; and,

(2) *Excess Earnings Method* – This income-based valuation method seeks an indication of value by subtracting the required return on the assets of the business enterprise from the total earnings of the business enterprise to arrive at an indication of the value of the earnings generated by the trademark or trade name.

Trademarks and/or trade names owned by healthcare entities have continued to grow in both significance and value. Valuation assignments involving trademarks and trade names may be evaluated using the framework above and will be further explored in the next three installments of this four-part series, which will specifically focus on the economic benefits accruing to the trademark or trade name grantor, grantee, and consumer (i.e., patients).

What's Your Brand Worth? The Benefits of a Brand to Consumers

[This is the second article in a four-part series regarding What's Your Brand Worth? This installment was published in February 2018.]

As discussed in the first installment of this four-part series, *trademarks* and *trade names* are symbols that represent an intangible quality of the good or service provided under the trademark/trade name. These attributes might include quality, reliability, and/or dependability, and they may be classified generally as *reputational*. Value for a trademark/trade name arises from its ability to transfer this *reputational* quality to a product or service.[10] Trademarks and trade names are both components of the brand of a business entity.

The first part of this four-part series set forth an overview of trademark and trade name valuation as it relates to the healthcare industry. This second installment will review the economic benefits accruing to the consumers of the trademark or trade name (i.e., patients).

In many markets, consumers face information asymmetries, where sellers have more information regarding the good or service, which information may play a crucial part in the consumer's decision making process. These information asymmetries faced by consumers in the healthcare industry are exacerbated by: (1) the third party payor system, as patients receiving the treatment are not always the ones paying for those healthcare services; (2) healthcare consumers are typically required to choose a physician or health system within the third party payor's network of providers; and, (3) physicians and other providers often have extensive expertise with regards to an individual's health and the medical necessity of the suggested course of treatment. With the *availability* of a variety of options and *unavailability* of all of the relevant information, consumers face difficulties in making the final, and correct, decision, regarding their choice of a provider that meets their needs and the choice of services to

be provided. Trademarks and trade names may render additional, valuable knowledge about the providers of services and may facilitate quicker and more efficient consumer decision making, and may increase the probability of a transaction materializing.

It is important to note that there are certain situations in which branding does not play a role in the patient's decision, especially during an emergency. However, depending on the severity of the patient's medical condition and the availability of time, when the patient has to make a conscious choice about healthcare providers, the trademark or trade name, and the brand it provides, can play a significant role.

While one of the primary methods for a patient to make a healthcare decision is based on their consideration of the physicians and the hospitals or clinics with which those physicians affiliate, a large number of patients, especially among the younger generations, continue to seek out additional sources of information to assist in making their healthcare decisions.[11] Easily identifiable trademarks or trade names reduce the indirect costs incurred by consumers in searching for their desired healthcare experience,[12] and the associated information can provide the consumers with a deeper understanding of the organization itself and the services to be provided and mitigate the uncertainty arising from the asymmetrical level of information existing between the healthcare consumer and the healthcare provider.

Dependency on a trademark or trade name, to some extent, relieves the consumer of the risk of relying on an unknown provider or service, whose information regarding their competence may not be readily available to the consumer. The economic benefit provided by a trademark or trade name to the consumer is the *decrease* in the uncertainty arising from the information asymmetry, i.e., *increasing* availability of relevant, but inaccessible, information through a brand name. Facing multiple seemingly homogenous good and service choices, the consumer tends to rely on the brand name to provide some assurance as to the quality of the good or service. In the context of healthcare, the number of physicians and healthcare systems providing similar services creates an equally daunting choice, and branding plays an important role in reducing the information asymmetries and thereby creating value for the consumer.

The consumer/patient may be willing to pay a premium for the service or care they receive in exchange for the quality assurance associated with a branded good or service. Brands play an especially important role in healthcare, as the *quality* of the services provided by a healthcare entity can directly impact a patient's quality of life, or even the life or death of a patient.[13] When a patient's wellbeing and life depends on their choice, they will generally be more willing to pay a premium for a brand associated with positive outcomes.

Mayo Clinic and Cleveland Clinic, considered the top two hospitals in the U.S. according to U.S. News,[14] are two of the biggest brand names in the healthcare industry. Approximately 8.4 million patients visited these two hospitals in 2016 for care.[15] The hospitals have propagated their mission to provide the best care

to patients,[16] along with positive patient experiences,[17] to build a reputation that commands trust from patients. Reputation of a hospital is one of the major factors considered by patients when choosing a provider.[18] Services offered by healthcare systems such as Mayo Clinic may be more expensive as compared to other providers and may lead to consumers paying a higher premium to avail of their high-quality services (especially if the hospital is outside of the patient's insurance network of providers),[19] but this does not appear to have been a deterrent in the case of these branded institutions, as evidenced by their ever-rising number of patient visits.[20] It is the trust built by these hospital brands that encourages patients to approach them for better care in spite of the potentially higher costs.

Part three of this four part series will specifically focus on the economic benefits accruing to the trademark or trade name grantee.

What's Your Brand Worth? The Benefits of a Brand to the Grantee

[This is the third article in a four-part series regarding What's Your Brand Worth? This installment was published in March 2018.]

As discussed in the first installment of this four-part series, *trademarks* and *trade names* are symbols that represent an intangible quality of the good or service provided under the trademark/trade name. These attributes might include quality, reliability, and/or dependability, and they may be classified generally as *reputational*. Value for a trademark/trade name arises from its ability to transfer this *reputational* quality to a product or service.[21] Trademarks and trade names are both components of the brand of a business entity.

The first part of this four-part series set forth an overview of *trademark* and *trade name* valuation as it relates to the healthcare industry. The second installment reviewed the economic benefits accruing to the consumers of the *trademark* or *trade name* (i.e., patients). This third installment will review the economic benefits accruing to the grantee (licensee) of the *trademark* or *trade name*.

Trademarks and trade names hold distinct economic value for each party involved. They reduce information asymmetries for consumers[22] and bring recognition and "*brand loyalty*" to the subject enterprise through the perception of quality assurance in the goods and/or services provided by the branded organization.[23] Healthcare enterprises have grown their business by licensing the use of their trademarks and trade names to others, i.e., granting permission to a licensee (grantee) to use the trademark(s) and/ or trade names(s) owned by the licensor (grantor). This phenomenon has become common in the healthcare industry, with enterprises such as Mayo Clinic, Cleveland Clinic, and Johns

Hopkins using affiliations with various other hospitals and physician practices to expand their reach beyond their Market Service Area (MSA) and across the U.S.

A grantee usually uses a trademark or a trade name to leverage the reputation and goodwill attached to that brand. Trademarks associated with successful and highly advertised products have developed tremendous goodwill with consumers.[24] It is this goodwill that the grantee can use to their advantage and derive benefit from it. Usually the grantor is a larger entity with greater reach and, in that situation, the grantee can "bask in the reflected glory"[25] of the grantor by using their trademark or trade name.

To avail themselves of these benefits attached to a trademark or trade name, the grantee agrees to pay a fixed price, i.e., royalty. One technique to estimate this royalty rate is through a comparison of the market for rates for similar transactions. Another technique may be to calculate the royalty rate based on the incremental income attributable to the trademark or trade name. The royalty rate can then be determined by dividing the total sales revenue of the grantee by the incremental earnings attributable to the trademark or trade name.[26]

The incremental earnings attributable to the trademark or trade name are the additional revenue that the grantee will realize from the increase in sales and the higher prices which can be demanded through the use of the trademark or the trade name.[27]

As discussed in Part One of this series, one of the ways a trademark or a trade name may be valued is through the income-based method of incremental earnings. This method may be one of the most relevant methods from the perspective of the grantee as it seeks to quantify the difference between the: (1) earnings of the business enterprise *with* the use of the trademark or trade name; and, (2) the earnings of the business segment *without* the use of the trademark or the trade name.[28] This can be quantified by calculating the difference in earnings between a branded product and an unbranded product, or by building assumptions as to how the business would change after the acquisition of the trademark or trade name and quantifying these changes. Analysts may find it difficult to measure these earnings accurately as it is difficult to predict the precise impact of a trademark or trade name on the operation of a business; additionally, the healthcare industry lacks generic products to which a brand can be compared, unlike industries such as food or retail goods.

Due to the lack of accurate information to predict incremental earnings by the use of a trademark or trade name, the analyst often relies on the relief from royalty method under the market-based approach. A market or income-derived royalty rate may be applied to the future cash flows of a business entity or business segment and the projected cash flows can be discounted to their present value equivalent at an appropriate risk adjusted required rate of return to arrive at an indication of value for the incremental economic benefit generated by the use of a trademark or trade name.[29] The relief from royalty method is an attempt, through normative industry market data, to quantify the

expected increase in revenues and profits that will accrue to a grantee due to their use of the acquired trademark or trade name.

The risks to the grantee in the acquisition of a trademark or trade name include the risk that the procured goodwill might fail to generate the projected increases in revenues and profits that supported the selected royalty rate. In addition, the grantee also exposes themselves to the risks arising from any future public relations embarrassments that the brand might suffer from the use of the trademark or trade name by the grantor or other grantees, such as a large case brought by the government for fraud and abuse, or a HIPAA (Health Insurance Portability and Accountability Act of 1996) violation, that would have a negative impact on the perception by consumers of the grantee's business.

Part Four of this four part-series will specifically focus on the economic benefits accruing to the trademark or trade name *grantor*.

What's Your Brand Worth? The Benefits of a Brand to the Grantor

[This is the fourth article in a four-part series regarding What's Your Brand Worth? This installment was published in April 2018.]

Trademarks and *trade names* are symbols that represent an intangible quality of the good or service provided under the trademark/trade name. These attributes might include quality, reliability, and/or dependability, and they may be classified generally as *reputational*. Value for a trademark/trade name arises from its ability to transfer this *reputational* quality to a product or service.[30] Trademarks and trade names are both components of the brand of a business.

The first part of this four-part series set forth an overview of trademark and trade name valuation as it relates to the healthcare industry. The second and the third installments reviewed the economic benefits accruing to the consumers and the grantee of the trademark or trade name, respectively. This fourth installment will review the economic benefits accruing to the grantor (licensor) of the trademark or trade name.

Trademarks and trade names hold distinct economic value for each party involved. They reduce information asymmetries for consumers[31] and bring recognition and "*brand loyalty*" to the subject enterprise through the perception of quality assurance in the goods and/or services provided by the branded organization.[32] Healthcare enterprises have grown their business, in part, by licensing the use of their trademarks and trade names to others, i.e., granting permission to a licensee (grantee) to use the trademark(s) and/ or trade names(s) owned by the licensor (grantor), subject to certain conditions and restrictions.

As discussed in Part Three of this series, the grantee benefits from the use of the trademark or trade name due to the goodwill that it generates. Licensing of trademarks or trade names is beneficial for the grantor as well. A trademark or trade name is valuable when it is recognizable, versatile, and identifies with positive attributes.[33] The economic value of a trademark or trade name to a grantor is based on the earning power of the trademarks and trade names. It is the goodwill built and associated with the brand that a grantee is willing to pay for, as it would lead to increased revenues and profits for the grantee. In addition to the financial benefit, a trademark or trade name may also generate other, non-monetary, benefits to the grantor, such as improvements in processes and the expansion of the grantor's geographic footprint.

A trademark or trade name "*may represent investment made in advertising and quality assurance testing*."[34] Extensive advertising undertaken by the grantor may lead to a reduction in marketing expenses to the grantee, thereby increasing the value of the trademark or trade name.

Additionally, a grantor may use the trademark or a trade name to expand their geographic footprint and reach beyond their market service area to gain entrance in new territories and markets with relatively little investment (e.g., building another hospital).[35] Licensing is a way for the grantor to increase its own brand recognition with every new affiliation into which the grantor enters (subject to appropriate guidelines and/or restrictions of use, as discussed below), by patients visiting one of the grantee's hospital, i.e., the grantor's branded hospitals (in contrast to a hospital physically owned and operated by the grantor), and perhaps considering the grantor's own hospital for healthcare services that may not be provided at one of the grantee's hospital.

As mentioned above, licensing provides grantors with financial benefit, principally by way of royalty payments received from the grantee. The grantor provides a grantee the right to avail itself of the benefits attached to a trademark or trade name, in return for a price, i.e., a royalty payment. This provides a passive source of income to the grantor, without losing ownership rights of the trademark or trade name. These royalty payments received from the grantee are the economic benefits of licensing trademarks and trade names to the grantor.

One technique to estimate this royalty rate is through a comparison of market royalty rates paid for similar transactions. Another technique may be to calculate the royalty rate based on the incremental income attributable to the trademark or trade name. The methodology for determining an appropriate royalty rate and valuing a trademark or trade name are discussed in detail in Part Three of this Four Part series.[36]

Before licensing a trademark or trade name, often the grantor is forced, by the virtue of developing a brand value, to standardize their services and processes. [37] These processes, which represent a brand, influence the technical and service quality, which may ultimately impact the outcomes of the business, such as, productivity and efficiency. [38] These standardized processes also provide a guideline or restriction of use to the grantee while using the trademark or trade name. This standardization of process may provide a benefit to the grantor by

enhancing the reputation of the grantor by widening the adoption of the policies and procedures preferred by the grantor throughout the industry.

One of the risks that a grantor faces when licensing a trademark or trade name is the possibility that the grantee may not maintain the required quality control, which may, in turn, diminish the grantor's reputation. Additionally, if the grantor allows many organizations the use of its trademark or trade name, the brand reputation may be diluted making it more difficult to control and protect the associated quality and the brand image of the trademark or trade name. Standardization of the services provided and processes performed by the grantee, or restriction(s) of use, under the trademark or trade name, can help to mitigate this risk faced by the grantor.

The licensing of trademarks and trade names has become a common phenomenon in the healthcare industry, with enterprises such as Mayo Clinic, Cleveland Clinic, and Johns Hopkins forming innovative affiliations with various other hospitals and physician practices. A variety of affiliations have been solidified (and expanded) in the past several years, with some of the most successful being the Cleveland Clinic's *Heart and Vascular Affiliation Program*, with approximately 18 affiliates nationwide,[39] and Mayo Clinic's *Mayo Clinic Care Network*, with more than 40 member healthcare organizations.[40]

The numerous benefits to the grantor listed above, such as the creation of an additional revenue stream; the expansion of the entity's geographic footprint; the standardization of core processes; the formation of strategic partnerships; and, many more, serve to encourage healthcare enterprises to license the use of the brand that they have developed, by way of licensing their trademarks and trade names to other organizations.

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Physics Professor Wilhelm-Conrad Röntgen
Discovered x-rays, won Nobel Prize in Physics in 1901

The New Kid on the Block: An Introduction to Micro-Hospitals

[This is the first article in a five-part series regarding Micro-Hospitals. This installment was published in May 2018.]

Previous issues of *Health Capital Topics* have discussed several strategies by which healthcare providers and stakeholders have attempted to remain financially viable while combating the rising costs of healthcare, e.g., vertical integration and horizontal consolidation,[1] and the market entry of non-traditional providers such as Amazon and Walmart.[2] Another, converse strategy – which involves the use of an increasing number of retail clinics and urgent care centers in an effort to provide better point-of-care access to consumers – can help avoid costly and unnecessary visits to a hospital emergency room for conditions such as upper respiratory conditions; ear infections; and, other non-acute conditions.[3] Over the last few years, a new type of healthcare provider has entered the market to bridge the gap between these urgent care centers and full service hospitals: the *micro-hospital*.[4] Despite the consolidation trends in the healthcare industry, micro-hospitals have emerged as a popular option for both patients (as they are typically conveniently located, and offer a shorter wait time than traditional hospitals), and providers (due to their relatively small overhead and the ability to bill at hospital rates, in contrast to the lower rates billed by urgent care centers).[5] This *Health Capital Topics* article, the first installment of a five-part series, will introduce the concept of micro-hospitals and briefly discuss how they have evolved within the current healthcare delivery environment. The following articles in this series will further examine micro-hospitals in relation to the *Four Pillars* that influence the value of entities within the healthcare industry, i.e., *regulatory*; *reimbursement*; *competition*; and, *technology*.

The term "*micro-hospital*" is still so new that it cannot be found in the dictionary or in any formal healthcare regulations. As such, the most commonly accepted definition for these entities has been broadly detailed by *Emerus*, creator of the first micro-hospital prototype, and current operator of more than 28 of these facilities across the U.S.[6] The *Emerus* micro-hospital prototype has the following characteristics:

(1) It is licensed as an independent hospital;

(2) Its size is 30,000 to 60,000 square feet;

(3) It contains 8 emergency beds and staffs board-certified emergency physicians;

(4) It contains 8 to 10 inpatient beds;

(5) It is staffed and open 24 hours per day, 7 days per week;

(6) It maintains transfer agreements with partner hospitals; and,

(7) It provides a core set of ancillary services (which can vary by location), e.g., imaging, surgery centers.[7]

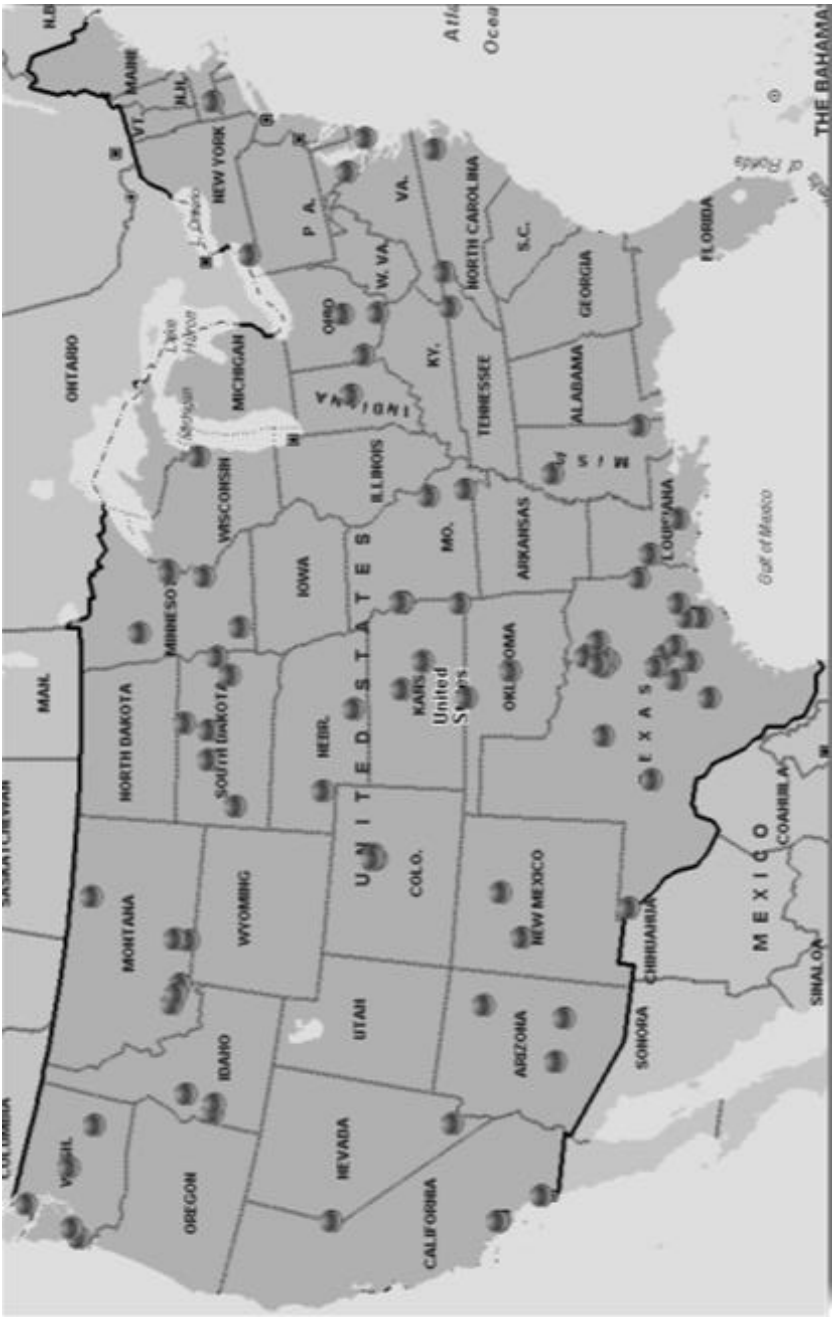
Hospitals (with the exception of *critical access hospitals* [CAH])[8] have not historically been subject to specific regulation with regard to size, and hence, a micro-hospital can vary considerably from Emerus's prototype with regard to number of beds; specific services offered; and, structure. However, as with any newcomer to the healthcare market, micro-hospitals are subject to many of the same trends and market forces that impact other providers. As such, these small facilities may face financial challenges in a market that rewards facilities for taking advantage of economies of scale and scope.[9]

As noted above, *Emerus* is the premier operator of micro-hospitals in the U.S. with more than 28 currently in operation and more than 20 additional facilities in development.[10] Notably, all of *Emerus'* functioning micro-hospitals were established in partnership with larger health systems, e.g., Memorial Hermann, Baylor, SCL Health,[11] which may allow these systems to utilize new micro-hospitals to expand patient access; better coordinate care; and, promote branding in new communities.[12] A representative map of locations for U.S. micro-hospitals (as of April 2018) is shown below.[13]

The Future for Micro-Hospitals in an Era of Reform

The rapidly shifting sands of healthcare reform over the past several decades, in concert with the continually rising costs of U.S. healthcare, have stimulated many of the trends currently occurring in the healthcare marketplace, e.g., consolidation, integration, and entry of innovative market providers and structures. Among these new innovations is the micro-hospital, which, while still relatively new, appears to be carving out a unique foothold in the marketplace by providing a balance between emergency and inpatient care and maintaining hospital services at the scale of an ambulatory surgical center. This new blended model of inpatient care, while successful in several markets thus far, has unproven longevity within the ever evolving healthcare marketplace. Investors and providers with an interest in pursuing micro-hospital ventures should be well-versed in general U.S. healthcare trends, as well as on the lookout for any new legislation, regulation, or reimbursement changes that may impact micro-hospital development and function. The following articles in this series will provide more detail regarding some of these trends of which savvy potential investors or developers should be cogniziant prior to diving into the waters of one of the latest innovations in U.S. healthcare.

Table: Representative Map of Locations for U.S. Micro-Hospitals 2018



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

[This is the second article in a five-part series regarding Micro-Hospitals. This installment was published in June 2018.]

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.[14] While the current Administration has continued its attempts to roll back various federal regulations in multiple sectors,[15] including those created by the ACA,[16] 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…*"[17] 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.[18] 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.[19] 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).[20]

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.[21] 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.[22] The primary business case for pursuing micro-hospital development, i.e., they are "*cheaper and faster*" to build than a typical hospital,[23] 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.[24]

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.[25] 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.[26] 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.[27] 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.[28]

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.[29] Independent micro-hospitals, while typically located in more affluent areas with a fast-growing population,[30] still lack the benefit of scale and have increased liability risk due to the limited number of services provided.[31] 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*."[32]

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

[This is the third article in a five-part series regarding Micro-Hospitals. This installment was published in July 2018.]

The U.S. healthcare reimbursement environment has been in flux over the last decade, with:

(1) The repeal of the *sustainable growth rate* (SGR);

(2) The introduction of several *value-based reimbursement* (VBR) programs;

(3) The continued implementation of bundled payment programs; and,

(4) Several other reforms as implemented under landmark legislation such as the *Patient Protection and Affordable Care Act of 2010* (ACA) and the *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA).

Previous issues of *Health Capital Topics* introduced the concept of micro-hospitals, and discussed the current regulatory environment surrounding these novel entities. In the third installment of this five-part series, the impact of the current healthcare reimbursement environment on micro-hospitals will be discussed in further detail.

Micro-hospitals are licensed as general acute care hospitals,[33] and they are reimbursed as such by public and private payors (e.g., under the *inpatient prospective payment system* [IPPS]). However, given their small size and volume of services compared to traditional hospitals, micro-hospitals may have the advantage of remaining exempt from certain reimbursement regulations, e.g., mandatory quality reporting under VBR programs such as the *Merit-based Incentive Program* (MIPS).[34] This exemption is beneficial for micro-hospitals because they can take advantage of the inpatient payment rates (which are typically higher than outpatient payment rates), but when compared to standard hospitals, micro-hospitals do not have the same financial overhead (core expenses) associated with inpatient costs. However, because of this potential advantage, i.e., having higher reimbursement rates than *ambulatory surgery centers* (ASCs) and other outpatient facilities, as well as less in overhead expenses, federal payors may be more stringent about the "*hospital*" status of micro-hospitals, and the associated reimbursement. For example, in 2016, a Pennsylvania-based, four-bed ASC-turned-micro-hospital, Wills Eye Hospital, was denied hospital Medicare coverage because it failed to show that its staffing levels and percentage of inpatient procedures significantly changed following its transition from ASC status.[35]

The *Centers for Medicare & Medicaid Services'* (CMS) attention to (and seeming disapproval of) micro-hospitals was further evidenced on September 6, 2017, when CMS released new guidance regarding how Medicare defines a "*hospital*" for reimbursement purposes.[36] The guidance states that an entity may only be defined as a hospital if it is "*primarily engaged*" in providing inpatient services.[37] While no specific definition of the term "*primarily engaged*" was given, CMS indicated that it would consider several factors when determining whether the entity is eligible for Medicare certification, including, but not limited to, the following guidelines for hospitals:

(1) *Average Daily Census* (ADC) should be ≥ 2;

(2) *Average Length of Stay* (ALOS) should be ≥ 2;

(3) The number of off-campus emergency departments should not be "*unusually large*";

(4) The number of inpatient beds in relation to the size of the facility should be *sufficient*;

(5) The volume of outpatient surgical procedures to inpatient surgical procedures should be *appropriate*;

(6) The ADC should *not consistently* drop to zero on the weekends;

(7) Staffing schedules should reflect a 24/7 provision of services; and,

(8) The facility should be advertised as a "*hospital*."[38]

In addition, CMS stated that if the facility under review did not have at least two inpatients present on the day of survey, it would not conduct the certification survey, necessitating rescheduling and a preliminary review of the factors listed above.[39] On December 12, 2017, *The Joint Commission* similarly announced that they will not conduct accreditation surveys at facilities "*without at least two active inpatients*."[40]

This regulation may be problematic for *independently* functioning micro-hospitals with a small number of inpatient beds and/or with a focus on emergency or surgical procedures with a short ALOS. However, for those micro-hospitals that fall under the same *CMS Certification Number* (CCN) as another hospital or health system, they will be judged as a collective, allowing the micro-hospitals to take advantage of the longer ADC and ALOS estimates of its larger counterparts in the system to maintain its hospital billing status.[41] *Emerus*, introduced in Part 1 of this series,[42] has developed most of its current micro-hospitals in partnership with existing healthcare systems,[43] which will allow them to continue qualifying as hospitals under this new CMS guidance.

In addition to Medicare's scrutiny of the status of micro-hospitals, it appears that the *Medicare Payment Advisory Commission* (MedPAC) is also focusing some of its recommendations on micro-hospitals. During its April 5, 2018 public meeting regarding reducing reimbursement for urban free-standing emergency departments,[44] MedPAC briefly discussed the commissioners' interest in further deliberating "*the micro-hospital issue*" in future meetings.[45] In particular, the commission expressed concern regarding the appropriate

utilization versus cost of point-of-care facilities used for unscheduled care, e.g., micro-hospitals, urgent care centers, and minute clinics; one commissioner described the conflict related to these entities as "*how to balance the gaming potential versus the legitimate innovation*."[46]

The reimbursement levels set by federal and state governments often act as benchmarks for all healthcare reimbursement, including commercial insurers and third-party payors.[47] As the largest payor of healthcare in the U.S., the federal government drives any potential expectation of future return on investment through stringent provider reimbursement regulation, as well as regulating the very existence of provider entities.[48] As a result, any potential future research and subsequent recommendations by MedPAC and/or CMS with regard to reimbursement for micro-hospitals is likely to have a significant impact on their future financial viability within the healthcare marketplace.

The New Kid on the Block: The Competitive Advantage of Micro-Hospitals

[This is the fourth article in a five-part series regarding Micro-Hospitals. This installment was published in August 2018.]

As discussed in the second installment of this *Health Capital Topics* five-part series on micro-hospitals, while market barriers to micro-hospital development (in some states) include certificate of need (CON) regulations and restrictive state architectural requirements, the relatively lower capital required to finance a micro-hospital makes it an attractive opportunity for existing health systems to expand patient access and establish new footholds for their brand in an innovative and cost effective manner.[49] Micro-hospitals, a/k/a "*neighborhood hospitals*,"[50] are typically developed in smaller, faster-growing communities with higher median incomes per resident, and more robust commercial payor coverage.[51] These areas are generally not large enough to support a typical full-service hospital, but are located within 20 miles of a tertiary care center for efficient referral of higher acuity patients.[52] As micro-hospitals fill a theoretical niche market position between that of an urgent care facility, or *freestanding emergency department* (FSED), and a full-service hospital, while still providing a variety of efficient, high quality services appropriately scaled to facility size, they can offer a very competitive service model at lower costs, putting them in position to be some of the "*winners*" in the shift to *value-based reimbursement*.[53] This fourth installment of the five-part series on micro-hospitals will review how this new provider type has carved out a relevant role in the current healthcare delivery system and the future implications of this strategy.

As mentioned above, micro-hospitals occupy a unique position along the healthcare continuum, by being able to provide: urgent/emergent services, like that provided by urgent care centers and FSEDs; ambulatory care, similar to *ambulatory surgery centers* (ASC); and, acute inpatient care, such as that provided by community hospitals.[54] In addition, while micro-hospitals serve patients with acuity levels similar to those seen at community hospitals,[55] they typically do not handle serious trauma or emergent specialty cases, e.g., stroke, allowing them to scale back space requirements to remain financially competitive, e.g., by avoiding construction of large triage areas, trauma bays, and interventional suites.[56] Additionally, by virtue of being able to selectively focus their service lines, these facilities can choose to provide higher-revenue services that make them more financially competitive, e.g., orthopedic surgery. For example, one independent micro-hospital in the Pittsburgh area has constructed four operating rooms in which it will provide a variety of high-revenue surgical procedures at a discounted price (by one-third to 50%) compared to other local competitors.[57] This selective focus allows micro-hospitals to be nimble as well, evolving their services to effectively care for an aging population with changing health needs.[58] For those micro-hospitals affiliated with a larger hospital or health system, they may be able to further reduce cost outlays and increase efficiencies by leveraging ancillary or support services of partner hospitals, e.g., supply contracts, sterile processing.[59] In this way, micro-hospitals that operate on a "*hub-and-spoke*" concept within a larger system may be able to produce better revenue margins than the typical community hospital.

Micro-hospitals have also been shown (in limited analyses) to provide higher quality and more efficient care in selected performance and outcome metrics when compared to the average hospital.[60] When *Emerus* (the premier developer of micro-hospitals, as discussed in the first installment of this series[61]) compared its micro-hospitals to national hospital averages, it found that its micro-hospitals performed better in multiple outpatient and emergency room metrics, including: average time from door to diagnostic evaluation (11 minutes for Emerus micro-hospitals versus 28 minutes for national hospitals); average time from emergency room arrival to departure (182 minutes versus 296 minutes); and, unscheduled 72-hour emergency readmission rate (1.2% versus 15.6%).[62] With the growing transparency of quality and performance metrics for hospitals and providers, micro-hospitals may have a significant advantage if they can demonstrate a notable and continued performance edge over traditional hospitals using standard metrics.

Currently, micro-hospitals have been shown to be most successful in smaller communities that are more affluent, but not large enough to support a traditional hospital.[63] In a healthcare environment with expected physician shortages in coming years, as well as continued issues associated with lack of access to care, the micro-hospital concept could be successfully adapted to rural or medically underserved areas.[64] The micro-hospital's adaptability, in terms of affordable building costs, as well as flexibility in the types of services offered, may be a

boon for investors that wish to take the micro-hospital concept and apply it to different communities with a recognized healthcare gap.

As mentioned in prior series installments, micro-hospitals have shown to be beneficial to investors thus far, as they can draw higher hospital reimbursement rates and can focus on high-demand and high-revenue procedures and service lines, all while decreasing capital and overhead costs. While the micro-hospital currently occupies a unique position along the healthcare continuum, some may argue that it remains a competitive concept only because of its "*newness*" in the market. It remains to be seen how long these facilities can "*fly under the radar*" o.f government regulators before they may face increasing barriers, such as increased CON restrictions or decreasing reimbursement, similar to the FSEDs they may be currently outperforming.

The New Kid on the Block: The Technological Environment of Micro-Hospitals

[This is the fifth article in a five-part series regarding Micro-Hospitals. This installment was published in September 2018.]

The prior four installments of this *Health Capital Topics* series on micro-hospitals have introduced the micro-hospital concept, and discussed its evolution within the existing regulatory; reimbursement; and, competitive healthcare environments. The fifth and final installment of this series will explore how various healthcare technologies have supported the expansion of micro-hospitals, and how it may contribute to the sustained success of this novel provider.

Technology has a broad meaning when applied to healthcare. It can range from the tangible tools and software that providers use during the provision of clinical services and the management of patient records to the procedures that constitute the standardized course of care. The advancement of healthcare technology (both clinical and information technology) is one of the leading reasons for the growth of micro-hospitals, along with the expansion of other outpatient services and providers, e.g., retail clinics and *ambulatory surgery centers* (ASCs). This general shift from *inpatient* to *outpatient* care has been observed for several years; the number of inpatient stays decreased by 6.6% from 2005 to 2014, with reductions in almost all service types, e.g., surgical (12% decrease), medical (5.3% decrease), and maternal and neonatal (9.1% and 7.8% decrease, respectively).[65] While the number of patient days has decreased, the average cost per stay has increased by an average of 12.7% over the same timeframe.[66] The increasing costs of inpatient stays, coupled with advances in clinical technology such as minimally invasive surgery, have incentivized hospitals to increasingly shift toward outpatient care models in an effort to stay

competitive.[67] As a result, many hospitals and health systems have decreased their inpatient bed volume or closed outright.[68] In essence, micro-hospitals have simply fast-tracked this trend by creating facilities with a much smaller bed capacity, allowing them to capitalize on the revenue generated by technologically-driven outpatient and ambulatory services to support a small number of inpatient beds.

One area in particular upon which some micro-hospitals have capitalized is the decrease in cost (and therefore, the increase in revenue), associated with providing certain minimally invasive surgical procedures, e.g., knee replacements, in an outpatient setting.[69] While this shift to outpatient care is not new to surgical specialties (the majority of eye and ear surgeries are being performed in outpatient facilities), some specialty procedures, e.g., joint replacements, have lagged behind other orthopedic procedures and surgical specialties, with only 4.2% and 4.6% of hip replacements and knee arthroplasty procedures, respectively, being performed in an ambulatory setting in 2014.[70] However, in the *2018 Outpatient Prospective Payment System Final Rule*, the *Centers for Medicare & Medicaid Services* (CMS) finalized the removal of the *Total Knee Arthroplasty* procedure from the *Inpatient Only* (IPO) list, effectively allowing providers to be reimbursed for performing these procedures for Medicare beneficiaries in the inpatient *or* outpatient setting.[71] As more clinical evidence is collected indicating that these types of procedures can be safely and effectively performed in outpatient settings at lower costs, it is expected that this trend will continue as reimbursement and regulatory reforms align. Micro-hospitals, like ASCs, will likely benefit from this trend.

The advent of virtual medicine, e.g., remote reading of imaging studies; virtual specialist consultations; remote physician and nursing support for staffing; and, telehealth suites, may also positively impact a micro-hospital's efficiency and patient access.[72] Telehealth and remote monitoring utilization was predicted to continue expanding in 2017 and 2018,[73] and the use of remote consultation services and telehealth technology could be used to provide appropriate and convenient outpatient follow-up for micro-hospital patients.[74] In addition, the utilization of remote specialist and consultant services is particularly useful for support of ancillary services, such as radiology and diagnostics, in order to reduce overhead and space.[75] Micro-hospitals can also reduce costs associated with staffing by making use of remote patient monitoring and taking advantage of remote specialist consultations (versus in-house staffing) for emergent cases that require stabilization before transport to a tertiary facility, e.g., cardiac or stroke care.[76] The utilization of telehealth in healthcare, while still expanding, is likely to continue garnering support; indicatively, during the *Medicare Payment Advisory Commission* (MedPAC) April 2018 public meeting, one of the commissioners noted that he felt that the government was "*underinvesting*" in telehealth, and that it was an issue that should be discussed further in future meetings.[77]

While the growth in clinical technology has fueled the movement toward outpatient care, the adoption and growth of healthcare information technology

such as *electronic health records* (EHR) and associated information sharing and cooperation among providers support the development of "*hub and spoke*" style micro-hospital operation in concert with larger hospitals and health systems.[78] In addition, on April 24, 2018, CMS announced an initiative to "*improve patients' access to their electronic health records*" by updating the *meaningful use* program to "*promote interoperability*" between patients and providers.[79] EHRs, information systems, and associated technology advances, e.g., app-enabled patient portals and alternative avenues for communication with patients (such as text messaging and social media) are poised to become more ubiquitous and, consequently, more intuitive and accessible for patients.[80]

The continuing growth and innovation related to healthcare technology appear to be beneficial to the sustained progress of micro-hospitals. By taking advantage of small inpatient bed size and resultant limited overhead costs; capitalizing on the ability to create revenue from outpatient procedures; and, efficiently utilizing telehealth and virtual technologies to support these aims, micro-hospitals could continue to flourish so long as regulatory and reimbursement barriers do not impede their projected progress. Micro-hospitals have rapidly evolved in the U.S. healthcare industry based on a combination of factors from the regulatory; reimbursement; competitive; and, technological environments. It is not yet certain, however, whether the current micro-hospital prototype will be able to continue making effectual use of technological advancements to solidify their niche market spot and withstand the unceasing changes under healthcare reform and expected downward reimbursement pressures and regulatory hurdles. As the Greek philosopher Heraclitus noted, and as the healthcare industry has seen time and time again, "*The only thing that is constant is change*."[81]

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Management Services Agreements: Considerations for Fair Market Value

[Excerpted from the article published in May 2018.]

In consideration of the *Fair Market Value* (FMV) for the provision of Professional Management Services, this *Health Capital Topics* article briefly discusses the current trends in the *Practice Management* industry, as these trends may directly and indirectly affect both the management company and the healthcare entity. This overview of the services provided by practice management groups, is followed by a discussion of the *competitive*, *reimbursement*, *regulatory*, and *technological* environments in which practice management groups operate.

Overview of Practice Management Services

Medical Practice management may be defined as "*a growing business strategy intended to help [organizations] overcome the challenges of fluctuating markets and adapt to the ever-evolving needs of consumers.*"[1] Medical practice management companies, also known as *Management Service Organizations* (MSO), carry out a variety of duties, including those related to:

(1) Financial Management;
(2) Business Operations;
(3) Human Resources Management;
(4) Information Management;
(5) Organizational Governance;
(6) Patient Care Systems;
(7) Quality Management; and,
(8) Risk Management.[2]

Although the foundation of *Practice Management* is to ensure that the healthcare entity is effectively carrying out day-to-day operations,[3] it is equally important that an MSO enables the entity to have the flexibility to adapt to market changes.[4]

Competitive Environment

Practice Management has become popular in recent years among healthcare entities, due to pressures within the healthcare industry to reduce costs, implement new technologies, and comply with increasingly complex regulations.[5] Three (3) main types of MSO companies exist, including:

(1) Large multi-specialty groups, which are publicly funded through stock;

(2) Large single-specialty groups, which receive investment from private equity funds; and,

(3) "*Under the radar*" larger single specialty groups, which are often funded through private financing, such as loans or private investment, but are not large enough for market interest.[6]

In the mid-1990s, many MSOs started investing in both independent physician practices and hospital-based physician groups; however, by 2002, 80 percent of the top ten public MSOs were in bankruptcy after failing to reach financial benchmarks.[7] It was not until after the 2010 passage of the *Patient Protection and Affordable Care Act* (ACA) that MSOs regained popularity, in part due to the ACA's restructuring of payment and delivery models, such as bundled payments and ACOs.[8] Not only are MSOs becoming more common, but they are also becoming larger, and raising capital for buyouts.[9]

Reimbursement Environment – Management Services Fees

There are a number of payment arrangements that an MSO can make with healthcare entities in regard to compensation for its services. Payment arrangements between an MSO and a healthcare entity include, but are not limited to: (1) fixed fee arrangements; (2) a percentage of an entity's revenues or profits; (3) a portion of cost savings that the MSO helped the entity realize; and, (4) a combination of the models listed above.[10] MSOs must be cautious as to what compensation arrangement will be made between itself and a healthcare entity, as such arrangements may be in violation of state laws that mandate how an MSO may structure its agreements.[11] For example, in New York, the New York State Department of Health questioned several hypothetical MSO payment arrangements, including: (1) "*per visit*" fees; (2) actual cost plus mark-up fees; and, (3) percentage of collection fees.[12]

Regulatory Environment

Healthcare enterprises face a range of federal and state legal and regulatory constraints, which affect their formation, operation, procedural coding and billing, and transactions. Federal fraud and abuse laws, specifically those related to the *Anti-Kickback Statute* (AKS) and physician self-referral laws (the "*Stark Law*"), may have the greatest impact on the operations of healthcare organizations. For example, MSOs must be particularly careful not to violate AKS through its fee structure. In a 1998 advisory opinion, the *Office of Inspector General* (OIG) expressed concern regarding MSOs receiving payment as a percentage of collections or revenue while performing marketing services.[13]

In addition to fraud and abuse laws, almost all states have provisions against the *Corporate Practice of Medicine* (CPOM).[14] Although the regulated content of CPOM provisions vary across states, these laws generally prohibit unlicensed individuals or corporations from engaging in the practice of medicine by employing licensed physicians.[15] CPOM was established with the intent of ensuring that licensed physicians could practice medicine without pressure from a lay person or being "*subject to commercialization or exploitation.*"[16] CPOM laws typically include exceptions, such as provisions allowing physicians to provide medical services via a professional corporation.[17] In summary, CPOM laws dictate what type of relationship healthcare entities may have with physicians (i.e., employment versus independent contractor).[18]

Technological Environment

Research indicates that implementation of *health information technology* (HIT) may lead to improved efficiency and quality management.[19] HIT includes a variety of computer applications, such as billing software, staffing models, and *electronic health records* (EHR).[20] In recent years, there has been a rapid adoption of technological innovations in the U.S., largely due to regulatory and reimbursement changes in healthcare. The now ubiquitous presence of EHR in healthcare has fundamentally changed the way that healthcare is delivered.[21] Namely, EHRs are essential to data collection needed for compliance with the expanding number of initiatives related to value-based care reporting and clinical outcomes analysis,[22] which could financially benefit an MSO depending on the MSO's fee structure.

A *practice management system* (PMS) is software used by healthcare entities that has the ability to automate some of the recurring tasks that burden healthcare providers.[23] PMSs are typically used for administrative and financial tasks and are utilized most by small to medium-sized providers.[24] By automating these time-intensive tasks, physician and provider groups are able to operate more efficiently.[25] As of January 1, 2014, all public and private healthcare providers were required to adopt and demonstrate "*meaningful use*" of EHRs to maintain their existing Medicare reimbursement levels.[26] Of note, financial incentives to utilize EHRs as part of the "*meaningful use*" program was merged into the *Merit-based Incentive Payment System* (MIPS), a value-based reimbursement program implemented under the *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA).[27] Because of the increased use of EHRs and the overlap with PMSs, some providers may integrate the two, which may serve to streamline the workflow, resulting in higher revenues.[28]

With increased administrative burdens within the healthcare industry, more provider groups are opting for *revenue cycle management* (RCM) systems, designed to improve efficiencies and enhance financial performance.[29] RCM systems are more comprehensive than medical billing software in that they also include claim processing, denial management, patient payment, and revenue generation capabilities.[30] RCM systems can either be outsourced to an external vendor, or used in conjunction with an internal EHR system.[31] It is important to note that with the current shift in the reimbursement environment, from *volume-based* to *value-based* payment, RCM systems will now need to track and submit both cost and quality data, as well as accurately administer compensation based on the performance of these metrics.[32]

Valuation Considerations

There are numerous, generally accepted healthcare valuation approaches, methods and procedures that may be utilized in the valuation of MSOs. The choice of approach(es) or method(s) depends primarily upon the purpose of the valuation report and the specific characteristics of the services being appraised. The objective and purpose of the engagement, the standard of value, the premise of value, and the availability and reliability of data must all be

considered by the valuation analyst in the selection of applicable approaches and methods.

In addition to determining the FMV of management services, a valuation engagement may also include the opinion of the *Commercial Reasonableness* of the *Management Services Agreement* (MSA) arrangement. While s*eparate* and *distinct* from the *regulatory* threshold related to the standard of FMV, the threshold of Commercial Reasonableness is *critical* to establish the legal permissibility of a subject healthcare transaction, and may be subject to a similar level of scrutiny by the Internal Revenue Service (IRS) and the OIG. The key components of a Commercial Reasonableness analysis include both a consideration of the *qualitative* factors that affect the Commercial Reasonableness opinion (e.g., the business purpose of the professional medical practice and the necessity of MSA, the experience and expertise of the MSO, various enterprise and organizational elements of the medical practice), as well as a *quantitative* analysis of the elements of the MSA.

Practice Management Industry Outlook

MSOs may face several challenges in the near future. The aging *Baby Boomer* population, and the associated rise in the number of chronic conditions suffered by this cohort, is expected to increase the number of individuals requiring services provided by healthcare providers in subsequent years, which may drive growth within the PM industry.[33] The primary challenge of MSOs may be staying compliant with current laws and regulations. For instance, the fee charged by an MSO to a physician group must be at FMV and be *commercially reasonable*, as to not violate federal and state *Anti-Kickback*, *Stark*, or *Corporate Practice of Medicine* (CPOM) laws.[34] Further, professional physician practices may face an uncertain reimbursement environment, as public payors, notably Medicare and Medicaid, are switching from *volume-based* to *value-based* models of reimbursement.[35] In order to cope with uncertain reimbursement policies, as well as a potential increase in demand, healthcare entities, with the help of MSOs, will likely have to become more efficient, which may be achieved in part through the adoption of HIT.

As evidenced by these trends, the U.S. healthcare environment is complex and rapidly changing; to meet these challenges, successful MSOs must: (1) have expertise in the specialties of the medical practices that they manage; (2) strategically plan for future changes in the industry; (3) regularly assess the practice's performance; and, (4) provide guidance to the practice regarding mergers and acquisitions.[36] In an era of increasing regulatory scrutiny and growing healthcare transaction volume, an FMV and *Commercial Reasonableness* opinion, prepared by an experienced and independent valuation firm, can increase the defensibility, and regulatory compliance, of the proposed MSA arrangement.

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Trade Secrets: Fair Market Value Considerations

[Excerpted from the article published in June 2018.]

Healthcare enterprises are increasingly relying on intangible assets to enhance their ability to provide timely, quality professional medical services to patients. Trade secrets are one such class of intangible asset that may be owned by a healthcare enterprise. A trade secret is any information that has economic value and is not generally known by the public.[1] Technical and specialty research may be considered the "*work-in-progress*" of patents, copyrights, trademarks, or other intangible assets, and this research usually entails the use of *trade secrets*, i.e., special "*know how*" that is often protected (or *padlocked*), in contrast to being *patented*.

The *Uniform Trade Secrets Act* defines trade secret as:

> "*information, including a formula, pattern, compilation, program, device, method, technique, or process, that: (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy*."[2]

Additionally, the definition of a *trade secret*, as set forth in The Merriam Webster Dictionary, is:

> "*something (such as a formula) which has economic value to a business because it is not generally known or easily discoverable by observation and for which efforts have been made to maintain secrecy*."[3]

For information to be called a trade secret, it should meet the following requirements:

(1) The information should not be generally known in the trade;

(2) The information should provide competitive advantage to the owner; and,

(3) Steps are taken to protect the secrecy of the information.[4]

Information that is typically considered to be a trade secret includes, but is not limited to:

(1) Formulas, recipes, ingredients, and methods of combination;

(2) Accounting procedures, personnel practices, marketing strategies, and sales techniques;

(3) Research and development information, experimental designs; and,

(4) Formations and plays of a sports team, or its training regimen.[5]

The benefits to the owners of the trade secret are similar to that of the grantor of a trademark or trade name.[6] The owners of the trade secret have the right to control access to their trade secret, and whether to sell or license it (in full or in part) to another party. Licensing enables the owner of the trade secret to expand their geographic footprint and increase market penetration by allowing the licensor to utilize the licensee's local resources in markets to which the licensor may not have access.[7]

The competitive advantage associated with a trade secret creates economic value for the trade secret by way of:

(1) Increased sales;

(2) The ability to charge a price premium;

(3) Reduced costs; and,

(4) Increased market share.

Trade secrets can be valued within the framework of the following general valuation methods:

(1) Asset or Cost-based approach;

(2) Market-based approach; and,

(3) Income-based approach.

Asset/Cost-based approach methods seek an indication of value by determining the cost of reproducing or replacing an asset. It is difficult to use a cost-based approach to value trade secrets as an analyst might not be able to determine the exact costs to create or replace a trade secret.[8]

A hybrid market and income-based approach *relief from royalty method* can be used to value trade secrets. This method applies a market or income derived royalty rate to the future cash flows of a business entity or business segment and then discounts those projected cash flows to their present value equivalent at an appropriate risk adjusted required rate of return to arrive at an indication of value for a specified date. In some situations, using this method would be challenging given the absence of disclosed information regarding the licensing of comparable trade secrets.

A valuation analyst may also utilize an income-based approach to calculate an indication of value for a trade secret. The following are income-based methods for valuing a trade secret:

(1) *Incremental Earnings Method* – This income-based valuation method seeks to quantify the difference between the: (i) earnings of the business segment or business enterprise *with* the use of the trade secret; and, (ii) earnings of the business segment *without* the use of the trade secret; and,

(2) *Excess Earnings Method* – This income-based valuation method seeks an indication of value by subtracting the required return on all the other assets of the business enterprise (excluding the trade secret) from

the total earnings of the business enterprise to arrive at an indication of the value of the residual earnings attributable to the trade secret.

Trade secret infringement or misappropriation occurs when someone improperly acquires a trade secret or improperly discloses or uses a trade secret without consent or with knowledge that the trade secret was acquired through a mistake or accident.[9] Economic damages in the case of a misappropriation are calculated as a sum of the following elements:

(1) Lost profits;

(2) Disgorgement of the infringer's profits; and,

(3) Future loss in profits.[10]

Examples of trade secrets in the healthcare industry include, but are not limited to:

(1) Patient lists;

(2) Payor and vendor contract rates and contract terms;

(3) Patient care procedures and protocols;

(4) Manufacturing processes, formulas, and development research (especially for pharmaceutical companies); and,

(5) Marketing tactics.

Trade secrets are gaining importance in the healthcare industry as organizations have come to realize the importance of trade secrets and the competitive edge offered by them. Many healthcare companies possess valuable information, which should be protected under strong internal confidentiality policies.

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Valuation of Urgent Care Centers in an Era of Reform

[Excerpted from the article published in September 2018.]

As demand for healthcare services continues to grow, the site at which these services are performed is experiencing a simultaneous transformation from the inpatient (e.g., hospital) setting to the outpatient setting.[1] This transformation is being driven by factors such as: (1) technological advancements; (2) an increasingly *consumer-driven* and *convenience-driven* healthcare delivery environment; (3) pressure from payors; (4) patient demand; and, (5) the entrance and diversification of new and different outpatient enterprises. One such example of a growing subset of outpatient enterprises includes urgent care centers (UCCs) and other retail clinics. UCCs have become vitally important healthcare resources for people across the U.S., with approximately two new walk-in clinics opening up every single day; it is estimated that there are 8,154 UCCs as of 2018.[2] Compared to a hospital emergency department (ED), UCCs offer some advantages, e.g., shorter wait times and lower costs of care, which may make UCCs a convenient alternative for those patients who do not need an ED's services.[3] For hospital EDs, this may be a blessing, as they are often overwhelmed by non-emergency patients who have limited options for access to healthcare services.[4]

While the services offered by UCCs and retail clinics may overlap, the two facilities are typically differentiated by the level and scope of care provided, as well as their location and ownership structure.[5] Urgent care may be characterized as healthcare that is delivered to treat an acute illness on a walk-in basis, while retail clinics, which also offer walk-in services, may be characterized as providing healthcare services for the treatment of non-acute illnesses and conditions. UCCs can be affiliated with a larger hospital or healthcare system, or operated as an independent freestanding facility, and are influenced by certain market forces and value drivers. These unique value drivers impact the typical valuation approaches, methods, and techniques that are often utilized in determining the value of UCCs in the current healthcare delivery system.

Urgent Care Centers Overview

In contrast, UCCs are typically freestanding facilities that may be owned and operated by a group of physicians, and may be eligible for one of two certifications offered by the *Urgent Care Association of America* (UCAOA): (1) *Category 1* – certifies that licensed physicians are on site during the clinic's hours of operation; and, (2) *Category 2* – certifies that licensed providers, i.e., physicians and midlevel providers (NPs and PAs), are on site during the clinic's hours of operation. To qualify as either a *Category 1* or a *Category 2* certified UCC, facilities must meet the following minimum criteria:

(1) Accepting and advertising that "*walk-ins*" of all ages are welcome;

(2) Providing *x-ray* and *phlebotomy* services;

(3) Maintaining, on site, licensed providers who can: (a) obtain and read an electrocardiogram (EKG) and x-ray; (b) administer *per os* (orally), intramuscular (IM), and intravenous (IV) medication/fluids; and, (c) perform minor procedures;

(4) Keeping on site the following equipment: (a) an automated external defibrillator (AED); (b) oxygen; (c) a drug cart; and, (d) a working phone;

(5) Maintaining two or more examination rooms;

(6) Maintaining a separate waiting area and patient specific restrooms;

(7) Staying open seven days a week, for over four hours a day, for a total of 3,000 hours per year;

(8) Maintaining a Medical Director who is a licensed physician; and,

(9) Performing both administrative and medical activities in an ethical manner.[6]

In addition to *certification*, UCCs may also seek facility *accreditation* through survey bodies such as the *Urgent Care Association of America* (UCAOA),[7] the *American Academy of Urgent Care Medicine* (AAUCM),[8] the Accreditation Association for Ambulatory Health Care (AAAHC),[9] the *National Urgent Care Center Accreditation* (NUCCA),[10] and *The Joint Commission*.[11]

Accreditation is awarded to those facilities that are found to be in compliance with AAUCM standards, including, but not limited to:

(1) Having been in operation for at least six months;

(2) Maintaining a supervisory physician who is responsible for the care provided at the practice;

(3) Maintaining compliance with all federal, state, and local regulations; and,

(4) Submitting an accreditation survey every three years that is completed through *documentation* and/or *on-site observations*.[12]

Value Drivers

While the value drivers identified for UCCs are similar to that of other healthcare outpatient enterprises, there are several specific dynamics related to UCCs and other freestanding outpatient enterprises that should be taken into consideration during the appraisal process.

Scope of Services

The scope of services provided by a particular freestanding outpatient enterprise is a key element impacting the overall indication of value attributed to that enterprise. While each UCC differs slightly in terms of the services that they offer, the most common medical needs that a UCC can provide include:

(1) *Non-life threatening illnesses*: The UCC is the prime site of service for patients who are not sure whether they have a cold, the flu, or some

scary-sounding self-diagnosis. UCCs typically have licensed family care physicians or nurse practitioners on site and they can provide the quality treatment similar to what may be found at a traditional physician's office.

(2) *Minor physical injuries*: UCCs are ideal for any injury that is not life-threatening. This may include minor burns, lacerations, sprains, or small fractures.

(3) *Vaccinations*: This includes seasonal flu vaccines to region-specific vaccines for those planning an international trip.

(4) *School and sports physicals*: Most UCCs and other walk in clinics allow patients to schedule these appointments in advance, and there are plenty of family practitioners who can provide physical fitness exams for children and adults.

(5) *STD testing*: UCCs may include a laboratory and can accommodate the testing for sexually transmitted diseases (STDs) or sexually transmitted infections (STIs).

In addition to the added revenue opportunities created by expanding the scope of services, a UCC may be able to create value through economies of scale. As more revenue is produced by the additional services rendered, only the variable portion of each expense would increase, while the fixed portion remains constant, thereby increasing the incremental benefit generated by each additional service. Note that this incremental benefit would only increase up to the point of capacity, where additional capital costs would reduce the benefit generated by the additional services.

Location

Patient convenience and visibility are important factors to the success of a UCC; therefore, its location is vital. Favorable locations include areas where its patient base has the most access, e.g., near home, the office, and schools. Within these areas, UCCs are often in freestanding buildings, but are also located in shopping malls, medical office buildings, and other mixed-use buildings.

Capacity

Capacity is another key element that impacts the value attributable to UCCs. One measure of capacity for UCCs is the amount of physical space utilized in the provision of services. For example, the number of exam rooms available in a UCC, as well as average turnover rate, can be used as measures of capacity. These metrics can be compared to normative industry benchmark survey data related to comparable enterprises and UCCs. UCCs have, on average, seven exam/treatment rooms.[13]

Payor Mix

The typical payor mix in 2016 for UCCs (by percent of overall patient visits), as reported by the UCAOA 2017 Benchmarking Survey, is as follows:

(1) Commercial Payors – 67%

(2) Medicare/Medicaid – 17%

(3) Cash Payments – 12%

(4) Other (including workers' compensation, TRICARE, direct bill employer services) – 4%[14]

Licensing

Most states do not require a license for UCCs. However, as UCCs become more popular, states may impose regulations on UCCs, in order to set a minimum standard of care.[15]

Operating Expenses

Human resources/personnel costs (wages and benefits) associated with the staff required to operate the UCC typically represents the largest operating expense incurred by UCCs. Physician and non-physician provider compensation comprise the majority of a UCC's personnel expense.

Additional considerations regarding the operating expenses incurred by a UCC include:

(1) The *size of the facility*, e.g., the number of examination rooms and the number of cases;

(2) The *ability of the UCC to manage supply costs*;

(3) Whether the center *directly employs* or *contracts* with physician and non-physician providers; and,

(4) Whether the *management of a UCC is performed by a third party*.[16]

In addition to the types of operating expenses incurred by a UCC, the amount of *fixed* and *variable* expense should be considered when performing an appraisal, as each type of expense is projected differently.

Similar to trends impacting other healthcare entities, UCCs may benefit from increased utilization of administrative related technology, e.g., *electronic health record* (EHR) systems, which can reduce the economic operating costs associated with the provision of administrative tasks and duties. Note that the underlying trend of operating expenses for most healthcare enterprises is rising, due to increases in medical care input costs, which are exerting downward pressure on the profit margins of these facilities.

Market Rivalries and Competitors

The UCC industry (and the healthcare industry as a whole) has been, and is forecasted to continue, experiencing significant consolidation, through mergers and acquisition by both hospitals and corporations. This trend toward consolidation decreases the competition and rivalry among UCCs, and has also resulted in an increase in the number of joint ventures between UCCs and hospitals. Affiliation and integration among smaller UCCs may allow these providers to obtain greater negotiating leverage and the potential to gain access to better managed care and commercial contracts, enhancing their profitability

and increasing their indication of value.[17] The typical ownership structure in 2016 for UCCs (by percent of all UCCs) is as follows:

(1) Corporate Entity – 39%
(2) Joint Venture with a Hospital – 16%
(3) Hospital-Owned – 15%
(4) Owned by Two or more Physicians – 14%
(5) Owned by a Single Physician – 10%
(6) Non-Physician Investors – 3%
(7) Physician Investors – 2%
(8) Other – 1%[18]

Subject Specific/Non-Systematic Risk

While an investor in a particular UCC would have additional investment opportunities available to them, e.g., government bonds, equity indexes, the discount rate utilized to present value all of the expected future net economic benefits should consider these opportunity costs, as well as any idiosyncratic risk associated with an investment in the specific subject enterprise. This subject specific/non-systematic (idiosyncratic) risk for freestanding outpatient enterprises would include the various risk factors that are inherent in and specific to the enterprise being valued, as well as the enterprise's operational performance compared to the most probable performance of similar enterprises as reported in normative industry benchmark survey data. Subject specific/non-systematic risk factors for most UCCs include, but are not necessarily limited to:

(1) The *uncertainty related to the continuity of the projected revenue stream* based on the probability of achieving the projected productivity volume and the efficacy of the projected reimbursement yield utilized in the analysis;
(2) The *risk related to the probability of achieving industry indicated operational and financial benchmarks* utilized in the analysis; and,
(3) The *competitive marketplace* within which the UCC operates, including its location; and,
(4) The *historical operations* of the UCC in comparison to the industry benchmarks.

Conclusion

The value of UCCs is significantly tied to the greater U.S. healthcare industry, rapidly evolving in the modern era of healthcare reform. The ability of UCCs to operate in a continuum of care in the new value-based purchasing paradigm

may determine their viability as an ongoing enterprise in the future. The number of healthcare services provided at UCCs continues to increase, due to rapidly evolving technological advances that allow many services and procedures to be performed in a safe, high quality, and, often, less costly environment than at many hospital-based EDs and physician offices. At the same time, the transactional environment of UCCs is also changing, as they are increasingly being acquired by hospitals and health systems. Further, in addition to the increased hospital employment of physicians, the overall healthcare transactional market is likely to continue experiencing increased transactional activity as a result of healthcare reform initiatives, as physician practices, and other outpatient enterprises, participate in such integration activities as accountable care organizations, medical homes, and co-management arrangements. UCCs are well positioned to be a major player in the future model of healthcare delivery as these initiatives continue to develop.

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Sir Thomas Watson, M.D. D.C.L. F.R.S Crehen.(1792–1882).
In 1843 he published his famous
"Lectures on the Principles and Practice of Physic,"
five editions, the chief English textbook of medicine.

II. REIMBURSEMENT TOPICS

CMS Publishes 2018 Payment Rate Updates

[Excerpted from the article published in November 2017.]

The *Centers for Medicare and Medicaid Services* (CMS) recently released their final rules for *fiscal year* (FY) 2018 payment and policy updates for the: (1) *Medicare Physician Fee Schedule* (MPFS);[1] (2) the *Medicare Inpatient Prospective Payment System* (IPPS);[2] (3) the *Hospital Outpatient Prospective Payment System* (OPPS); and, (4) the *Ambulatory Surgical Center* (ASC) *Payment System.*[3] Whereas the IPPS became effective on October 1, 2017,[4] the MPFS, OPPS, and ASC Payment System will become effective on January 1, 2018.[5] In this *Health Capital Topics* article, changes to these final rules will be discussed.

The final changes made to MPFS for FY 2018 include:

(1) *Increases to the Medicare Conversion Factor (CF)*: A positive adjustment of 0.41 percent will be applied to the MPFS CF used to calculate payments for physician services.[6] This positive adjustment is higher than the 2017 CF adjustment of 0.32 percent.[7] Additionally, the CF used to calculate payments for anesthesia services includes additional adjustments for practice expense and malpractice;[8]

(2) *Modifications to Reporting Requirements for the Physician Quality Reporting System (PQRS)*: CMS now only requires six measures to be reported under the PQRS, rather than nine;[9] and,

(3) *Adjustments to the Value-Based Payment Modifier (VM)*: Physician groups of ten or more who do not meet the minimum PQRS criteria will only be penalized with a downward payment adjustment of -2.0 percent, rather than the previously proposed -4.0 percent.[10] Non-physician practitioners, solo physician practitioners, or physician groups of nine or fewer will experience downward payment adjustments of -1.0 percent, rather than the previously proposed -2.0 percent, for unsatisfactory participation.[11] Practices that have successfully participated in the PQRS will not experience any downward payment adjustments, and may even experience a positive payment adjustment for lowering practice costs and providing higher quality care.[12]

Both the reduction in PQRS reporting requirements, as well as the reduced downward payment adjustments for failing to meet minimum PQRS standards, are a part of the "*Patients Over Paperwork*" initiative launched by CMS in an effort to reduce provider burden, increase efficiencies, and improve patient care.[13] As CMS Administrator Seema Verma articulated in a press release on November 2, 2017, "*These rules move the agency in a new direction and begin to ease that burden by strengthening the patient-doctor relationship, empowering patients to realize the value of their care over volume of tests, and encouraging innovation and competition within the American healthcare system.*"[14] Although the *American Medical Association* (AMA) has not commented on the final rule, they responded to the proposed rule stating, "*The*

AMA is encouraged by many of the proposed changes and applauds the Administration for working with the AMA to address physician concerns."[15] Specifically, the AMA affirmed their support for the proposed modifications to the PQRS and the VM requirements.[16]

Additionally, CMS finalized several updates to the IPPS, including:

(1) *Payment Rate Updates:* For FY 2018, CMS is implementing an overall increase of 1.2 percent for hospital payments.[17] CMS also estimates that Medicare payments to inpatient psychiatric facilities will increase by one percent, or $45 million total, for FY 2018;[18]

(2) *Disproportionate Share Hospital (DSH) Payment*[19] *Adjustment Updates*: For FY 2018, Medicare DSH uncompensated care payments to hospitals will increase by $800 million[20] for a total of $6.8 billion in DSH payments.[21] Starting in 2018, there will be a three-year transition to use Worksheet S-10 data (also known as uncompensated care data) to calculate the amount and distribution of DSH payments to hospitals.[22] This three-year transition was implemented after numerous stakeholders voiced concerns regarding the accuracy and consistency of Worksheet S-10 data to calculate uncompensated care payments;[23] and,

(3) *Changes to the Electronic Health Record (EHR) Incentive Program:* The EHR Incentive Program was established by CMS to promote the adoption, implementation, upgrade, and demonstration of *meaningful use* of certified EHR technology by healthcare providers.[24] Currently, the program has three stages, including a Modified Stage 2 that was included to ease reporting requirements for providers.[25] The final rule for 2018 established that hospitals and *critical access hospitals* (CAH) can choose to use either Modified Stage 2 EHR reporting or Stage 3 EHR reporting for the *EHR Incentive Program*, instead of just Stage 3 EHR reporting.[26] CMS finalized this rule as a way to allow for flexibility among providers who may need additional time to implement updated EHR technology.[27] Further, hospitals are now only required to report EHR data for 90 continuous days, rather than a full year.[28]

Overall, for FY 2018, acute care hospitals expect to see a $2.4 billion increase in total Medicare spending on inpatient hospital payments, due to both payment rate increases and other payment adjustments.[29] The Trump Administration is confident that these updates will benefit hospitals, with Verma stating:

> "*This final rule will help provide flexibility for acute and long-term care hospitals as they care for Medicare's sickest patients…Burden reduction and payment rate increases for acute care hospitals and long-term care hospitals will help ensure those suffering from severe injuries and illnesses have access to the care they need*."[30]

While the *American Hospital Association* (AHA) approved of mandates related to the EHR Incentive Program, it expressed concerns regarding certain parts of the final rule, with the AHA Executive Vice President, Tom Nickels, stating, "*[W]e continue to have concerns over the accuracy and consistency of the*

'Worksheet S-10' data [i.e., uncompensated care data] that CMS will use to determine the cost of treating uninsured patients."[31]

Updates made to Medicare OPPS for FY 2018 include:

(1) *Payment Rate Updates*: For FY 2018, ASCs and *hospital outpatient departments* (HOPDs) will receive smaller increases in payment adjustments than originally proposed, with ASCs receiving a payment adjustment increase of 1.2 percent[32] (compared to the proposed 1.9 percent increase),[33] and HOPDs receiving a payment adjustment increase of 1.35 percent[34] (compared to the proposed 1.75 percent increase);[35]

(2) *Total Knee Arthroplasty (TKA) Reimbursement Changes:* TKA surgeries have been removed from the inpatient-only reimbursement list and are now covered under OPPS;[36] however, they were not added to the procedures reimbursable under the ASC Payment System.[37] Further, CMS is currently discussing whether total ankle arthroplasty, total hip arthroplasty, and partial hip arthroplasty surgical procedures should be reimbursable under the ASC Payment System.[38] Despite the fact that several procedures were not removed from the inpatient-only list of reimbursable items, and the fact that TKA is still not reimbursable under the ASC Payment System, the removal of TKA from the inpatient-only list is a crucial step to eventually having TKA and similar procedures covered under the ASC Payment System.[39]

(3) *The Addition of New Procedures Reimbursable to ASCs:* Beginning in 2018, CMS will reimburse ASCs under the ASC Payment System for: (a) total artificial disc arthroplasties; (b) second level total artificial disc arthroplasty; and, (c) total hysterectomy for uterus greater than 250 grams;[40] and,

(4) *Voluntary Participation of the Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery Survey* (*OAS CAHPS) Program:* The OAS CAHPS is a program aimed at gathering data from Medicare beneficiaries regarding their care episodes at ASCs,[41] similar to those surveys conducted at hospitals. CMS originally proposed for this program to have mandatory ASC participation starting in 2018; however, plans to implement this program have been delayed.[42]

While the Trump Administration, including Verma, insist that these final rules can help increase patient access to healthcare services,[43] Bill Prentice, CEO of the *Ambulatory Surgery Center Association* (ASCA), expressed discontent with the changes, stating:

> "*Yet again, ASC payments fall farther behind those of hospital outpatient departments because CMS continues to use an inflation factor — the CPI-U — that doesn't focus on the costs of goods and services in the healthcare market… CMS insists on waiting for a perfect replacement to the CPI-U while a good one, the hospital market basket, is available.*"[44]

However, other final changes have managed to garner support from the ASCA, with Kara Newbury, JD, regulatory counsel for the ASCA, explaining "*The removal of total knee arthroplasty from the inpatient-only list is an important step to seeing this procedure covered in the ASC setting in the future.*"[45] The ASCA also stated support for voluntary OAS CAHPS participation.[46]

Overall, there have been mixed sentiments regarding the 2018 MPFS, IPPS, OPPS, and ASC payment system updates. Stakeholder groups such as the AMA, AHA, and ASCA generally approve of CMS mandates that lessen provider burden,[47] which policy is a main goal of the Trump Administration.[48] However, many healthcare providers have expressed discontent over the amount of the payment rate updates,[49] as increases in payment rates have stagnated over the past several years.[50] As the growth in payment rates may continue to stagnate in subsequent years, providers may need to find ways to reduce costs and increase efficiencies in order to survive and thrive in this changing healthcare reimbursement environment.

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Massive Cuts Made to 340B Prescription Drug Discount Program

[Excerpted from the article published in December 2017.]

On November 1, 2017, the *Centers for Medicare and Medicaid Services* (CMS) published a final rule cutting Medicare Part B and state Medicaid payments under the *340B Drug Discount Program* (340B Program) by an estimated $1.6 billion in 2018.[1] To illustrate the payment reduction, a drug with an average sales price of $1,000 is currently reimbursed at $1,060, but would be reduced to $775 under the final rule.[2] The 340B Program was originally passed in 1992 as a way to decrease the cost of pharmaceuticals reimbursed to hospitals under Medicare Part B and state Medicaid programs by requiring pharmaceutical companies to give rebates to hospitals and clinics with a high volume of low-income patients.[3] Since its passage, the 340B Program has been expanded three times, most recently by the *2010 Patient Protection and Affordable Care Act* (ACA).[4] In 2015, approximately 40 percent of U.S. hospitals purchased pharmaceuticals through the 340B Program.[5] Moreover, these hospitals provided 60 percent of uncompensated care in the U.S.[6] This final rule, cutting 340B reimbursement, came after a 2015 *Government Accountability Office* (GAO) report entitled, "*Medicare Part B Drugs – Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals"* (2015 GAO Report)[7] was published and the House Energy and Commerce Committee held recent hearings.[8] CMS reasoned among other things, that the 2015 GAO Report indicated that 340B hospitals were being incentivized to increase Medicare revenue by prescribing both a *greater number* of drugs and *more expensive* drugs.[9] CMS further acknowledged concerns of advisory panels such as the Hospital Outpatient Payment Panel,[10] but decided to finalize the proposed rule against their recommendation.[11] Additionally, providers have expressed concerns that this change would force some hospitals, especially safety-net and rural hospitals, to close and block patient access to lifesaving care for patients with serious illnesses like cancer.[12]

Much of the controversy surrounding the 340B Program emanates from the fact that the 340B Program does not include any restrictions regarding how hospitals can use the revenue generated through the program. This appears to be CMS's main concern after the 2015 GAO Report suggested that 340B hospitals were incentivized to increase revenues through prescription drugs.[13] *Pharmaceutical Research and Manufacturers of America* (PhRMA), a pharmaceutical company trade association, is an advocate for these changes to the 340B Program and has employed an advertising campaign geared toward changing this program specifically.[14] Further, PhRMA alleged that the criteria to become a "*covered entity*," i.e. a 340B Program participant, are too lax and agreed with CMS that providers exploit the program by using the revenue to supplement profits instead of providing care to patients.[15]

Opponents of the final rule argue that 340B "*covered entities*" provide a necessary service to communities through large-scale indigent care, and if 340B

Program funding is cut, these populations will not be able to receive proper care.[16] The final rule faces strong opposition by trade associations such as: the *American Hospital Association (*AHA); *America's Essential Hospitals*; and, the *Association of American Medical Colleges*, which filed a lawsuit arguing that CMS violated the *Administrative Practices Act*.[17] This argument is supported by the 2015 GAO Report (on which CMS relied to make its decision), which stated that CMS did not have statutory authority to reduce hospitals' reimbursement for 340B drugs.[18] The *Office of Inspector General* (OIG) estimated that, in 2015, providers experienced an average savings of 33.6 percent of the average sales price.[19] These savings are likely a primary reason PhRMA opposed the reimbursement structure of the 340B Program.

The final rule is set to take effect January 1, 2018, but CMS is accepting comments on the rule through December 31, 2017.[20] Additionally, bipartisan legislation (H.R. 4392)[21] has been introduced that would reverse these payment cuts.[22] Further, because this payment reduction is budget neutral, the savings from the reduction of 340B Program payments (estimated $1.6 billion) would be reallocated among all hospitals reimbursed under the OPPS.[23] If neither the pending legislation nor the pending litigation produce a result before January 1, 2018, providers may experience the immediate effects of decreased 340B Program reimbursement.

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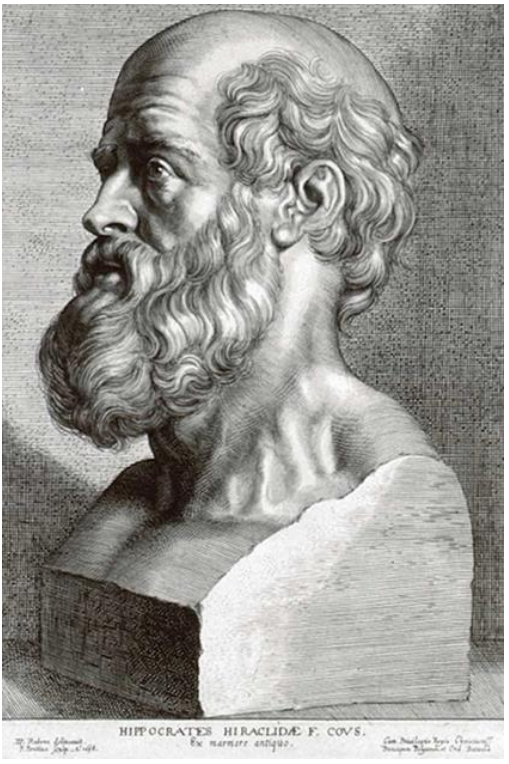

Hippocrates. Engraving by Peter Paul Rubens, (S.L., 1638).

Healthcare Spending Slows in 2016

[Excerpted from the article published in January 2018.]

On December 6, 2017, the *Centers for Medicare and Medicaid Services* (CMS) announced that *fiscal year* (FY) 2016 national health spending was $3.3 trillion ($10,348 per capita), a 4.3 percent increase ($354 per capita) from 2015, a slower pace than the 5.8 percent growth realized in FY 2015.[1] This slowed spending growth was experienced by all major third party payors (e.g., Medicare, Medicaid, and commercial insurers), as well as by several health goods and service categories (e.g., hospital care, physician and clinical services, and retail prescription).[2] Despite the relative deceleration in health spending in 2016, the portion of the U.S. *gross domestic product* (GDP) devoted to healthcare increased 0.2 percent to 17.9 percent overall, in part because healthcare spending grew 1.5 percent faster than the overall economy in 2016.[3]

In regards to spending by major third party insurance payors, private health insurance spending increased 5.1 percent in 2016 to $1.1 trillion, slower than the 6.9 percent growth in 2015.[4] This was, in part, a result of lower health insurance enrollment growth in 2016, after two years of increased enrollment due to the *Patient Protection and Affordable Care Act* (ACA) provisions that increased the number of newly insured individuals under Medicaid and private insurance.[5] Medicare spending grew only 3.6 percent to $672.1 billion in 2016, slower than the 4.8 and 4.9 percent growth in 2015 and 2014, respectively.[6] This also may be attributed to lower health insurance enrollment growth, resulting in decreased spending growth for both Medicare *fee-for-service* (FFS) (1.8 percent in 2016 versus 2.2 percent in 2015) and *Medicare Advantage* (7.4 percent in 2016 versus 11.1 percent in 2015).[7] Medicaid spending increased by 3.9 percent to $565.5 billion, significantly lower in growth than the 2015 and 2014 figures of 9.5 and 11.5 percent, respectively,[8] which may be a result of the initial impact of *Medicaid Expansion* by those states that took advantage of the ACA provision.[9] Notwithstanding the widespread deceleration in healthcare spending among third party payors, it is important to note that *out-of-pocket spending*, including copayments, deductibles, and any direct consumer spending not covered by insurance, had the highest growth rate since 2007.[10] Specifically, the rate grew by 3.9 percent to $352.5 billion in 2016, faster than the 2.8 percent growth in 2015, as well as faster than previous years.[11] This is in part due to a shift toward enrollment in high-deductible health plans, but offset by the decrease in the number of uninsured individuals.[12]

Similar to the decreased growth in spending for all major third party payors, a number of health goods and service sectors experienced decreased growth in expenditures, including hospital care, physician and clinical services, and retail prescription. For example, hospital care comprised 32 percent of healthcare expenditures in 2016, increasing by 4.7 percent to a total of $1.1 trillion, slower than the 5.7 percent increase realized in 2015.[13] Lower patient utilization of healthcare services drove this decrease in spending,[14] following two years of accelerated spending growth.[15] Improved economic conditions, as well as an

increase in the number of newly insured individuals, accounted for the 2014 and 2015 increases in spending growth.[16] In addition to hospital care spending, physician and clinical services, the fastest healthcare spending category, accounted for 20 percent of all healthcare expenditures in 2016, and grew 5.4 percent to $664.9 billion, slightly lower than the 5.9 percent growth experienced in 2015,[17] likely due to the continued growth in clinical services spending for freestanding ambulatory surgical and emergency centers.[18] Further, patient utilization and number of physician and clinical services offered accounted for almost 75 percent of the overall 5.4 percent growth, although this figure was lower than the 2015 figure, primarily because of languishing insurance enrollment growth.[19] Retail prescription drug spending increased by 1.3 percent to $328.6 billion in 2016, slower than the 8.9 percent and 12.4 percent growth in 2015 and 2014, respectively.[20] This relative stagnation may be attributed to fewer new drug approvals, slower growth in brand-name drug spending (especially for hepatitis C drugs), and a decline in spending for generic drugs due to slowed price increases.[21] Significant growth in 2014 and 2015 was in part due to price increases for existing brand name drugs (including hepatitis C drugs), as well as increased spending on new drugs.[22]

Overall, the 2014 and 2015 increases in health expenditures for payors; health goods; and, service categories may be primarily attributed to the health insurance coverage expansion elicited by the ACA, when Medicaid eligibility was expanded in some states and private health insurance options were made available through federal and state marketplaces.[23] However, this initial impact of increased insurance enrollment finally waned in 2016, causing overall health spending to slow.[24] In the past ten years, healthcare spending has decelerated to a historic low, primarily due to slowed growth in medical price inflation[25] as a result of the recent economic recession. During this time, overall economic growth remained low, causing medical price inflation to surpass overall price inflation, which effectively increased the share of the economy devoted to healthcare from 15.9 percent in 2007 to 17.9 percent in 2016.[26] Because medical price inflation stayed low throughout the *Great Recession* due to overall low levels of inflation, and economic growth is a strong predictor of health expenditures,[27] any subsequent growth in the U.S. economy (such as the growth currently being experienced) will likely push healthcare spending growth upward. According to Paul Ginsburg, a health policy professor at the University of Southern California, "*costs remain reasonably under control but are still [rising] at a rate that is too rapid to be affordable for society.*"[28] While the healthcare spending figures for 2016 appear encouraging, this slowed growth is not expected to last, given the surging U.S. economy and the ongoing volatility in the healthcare industry due to repeal of ACA provisions such as the *Individual Mandate*,[29] which forces may serve to drive up costs and incentivize more use of healthcare services by those patients uncertain as to the future of their healthcare insurance coverage.

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Checking up on Healthcare's Hot Trend: Value-Based Reimbursement

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To offset increasing costs and expenditures, healthcare reimbursement has begun shifting from *volume* to *value*, most recently manifested in the *2010 Patient Protection and Affordable Care Act* (ACA) and the *Medicare Access & CHIP Reauthorization Act of 2015* (MACRA).[1] Although *value-based reimbursement* (VBR) programs are relatively new, recently-published preliminary evaluations of the programs have been disappointing, and, in conjunction with the organizational directives of newly-appointed *Centers for Medicare and Medicaid Services* (CMS) leadership, have prompted significant changes to existing VBR programs and the creation of a new VBR program.

The literature published to date has found that VBR programs are not achieving the intended results, and, in fact, indicates that VBR programs did not lead to improved patient care and outcomes.[2] A recent study found that the use of the *Value-Based Payment Modifier*[3] was not associated with better quality of care or lower spending, and did not provide any additional incentive for practices serving a disproportionately higher number of high-risk patients, e.g., complex or low income patients.[4] The findings from this study, and other literature, have suggested that pay-for-performance programs may exacerbate existing healthcare disparities either by financially penalizing, or not providing enough support to, hospitals that serve a greater proportion of these high-risk patients.[5] Additionally, two separate studies from *Health Affairs* and the *U.S. Government Accountability Office* found that the *Hospital Value-Based Purchasing Program*[6] rewards hospitals for maintaining low costs, even if they have low quality scores.[7] These results suggest that CMS's goals of "*Better Care. Smarter Spending. Healthier People*"[8] are not being furthered by some of its current VBR models, and the unintended consequences of these policies may be the sacrifice of higher quality care in the name of cost containment. Perhaps as a result of this research, or due to political ideology, the current administration has developed a new bundled payment model while relaxing the participation requirements for physicians in other VBR programs.

On January 9, 2018, CMS announced the launch of the *Bundled Payments for Care Improved Advanced model* (BPCI Advanced).[9] This new, voluntary payment model was unveiled subsequent to the November 2017 cancellation of the previously mandated hip fracture and cardiac bundled payment models and the reduction of the *Comprehensive Care for Joint Replacement Model* (CJR) program.[10] In the press release related to the hip fracture and cardiac bundled payment models cancellation, CMS expressed its intention to release new voluntary payment bundles in order to "*offer opportunities to improve quality and care coordination while lowering spending…[by] focusing on developing different bundled payment models and engaging more providers…to drive health system change while minimizing burden and maintaining access to care*."[11]

The BPCI Advanced payment program is considered an *Advanced Alternative Payment Model* (Advanced APM) under the *Quality Payment Program* (QPP) established by MACRA.[12] In this program, participating providers can earn incentive payments for 32 different clinical episodes (29 inpatient and 3 outpatient)[13] if all of the beneficiary's expenditures during that episode and the subsequent 90-day period fall below a specified spending target, while concurrently maintaining or improving upon seven specific quality measures.[14] From January 11, 2018 until March 12, 2018,[15] providers may apply for participation in the initial version of the BPCI Advanced payment model, which will run from October 1, 2018 through December 31, 2023.[16]

On January 11, 2018, the *Medicare Payment Advisory Commission* (MedPAC) decided, in a 14 to 2 vote, to recommend that Congress repeal and replace the *Merit-based Incentive Payment System* (MIPS).[17] MIPS is also part of the QPP established under MACRA.[18] MedPAC had previously voiced dissatisfaction with the design of MIPS, stating in a June 2017 report that MIPS "*…is unlikely to succeed in helping beneficiaries choose clinicians, helping clinicians change practice patterns to improve value, or helping the Medicare program reward clinicians based on value*."[19] The report also noted concerns that submission of quality and outcome measures as required under MIPS may become too burdensome for clinicians.[20] MedPAC recommended a replacement program for MIPS, in which providers would be evaluated on a set of population outcome measures as part of a group of physicians, and be compared against other groups to obtain incentive payments.[21] MedPAC will provide further recommendations regarding potential replacement models to Congress in its March 2018 report.[22]

Shortly after being sworn in as the fifteen Administrator of CMS in March 2017, Seema Verma announced in a *Wall Street Journal* op-ed that, "*[t]his administration plans to lead the [CMS] Innovation Center in a new direction,*" which included plans not only to continue the "*shift away from fee-for service…toward a system that holds providers accountable for outcomes…*" but also to "*increase flexibility by providing more waivers from current requirements*."[23] On February 12, 2018, at the *CMS Quality Conference*, Verma reaffirmed this commitment, stating: "*Let me be clear: Moving away from fee-for-service is something that [new Department of Health and Human Services] Secretary [Alex] Azar and I are committed to, and ensuring quality is an essential component of this…We want to support quality, but there have been unintended negative consequences of too many quality measures*."[24] Indications derived from CMS policy changes throughout the first year of Verma's tenure suggest a movement from requiring physicians to participate in programs that include some form of downside risk to voluntary programs with fewer standardized metrics and reporting requirements.

Aside from political motivations, the concern that current VBR models are not appropriately incentivizing provider innovation and quality improvement (potentially due to fundamental flaws in program design) has likely prompted some of the recent (and suggested) changes in the QPP. While VBR programs

will likely continue (at least in the short term) to shift from a mandatory to a voluntary basis under the current administration, it is yet unclear whether this latest VBR iteration will impact provider quality of care and spending levels, which may prompt CMS to continue to adjust, refine, or make wholesale changes to its programs. However, what is clear is that in order to determine the effectiveness of this iteration of VBR models (or any other model which reimbursement is based in part on higher quality care and lower cost), these programs will require significant provider participation. Otherwise, the U.S. healthcare industry may be no closer to the achievement of the "*Triple Aim of Healthcare*" than it was prior to the identification of a need for healthcare reform.

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The Implications of Medicaid Expansion on Hospital Finances and Viability

[Excerpted from the article published in March 2018.]

Four years after the implementation of *Medicaid Expansion* under the *Patient Protection and Affordable Care Act of 2010* (ACA), researchers are now able to utilize available post-expansion data to evaluate its impact on hospitals and patients. Accordingly, several studies have been released over the last few months. One study published in the January 2018 issue of *Health Affairs* found that hospitals in Medicaid Expansion states were 84 percent *less likely* to close and had a significantly better payor mix, i.e., a higher ratio of Medicaid to uncompensated care patients, than hospitals in Non-Expansion states.[1] This same study further found that hospitals in areas with the highest rates of uninsured individuals prior to the ACA, particularly rural hospitals, benefited the most, financially, from the Expansion.[2] Another study, released in January 2018 in *Health Services Research*, found that the proportion of inpatient stays covered by Medicaid significantly *increased*, while the proportion of uninsured visits significantly *decreased*, for both safety net and non-safety net hospitals in nine Medicaid Expansion states.[3]

These findings are particularly relevant given the current healthcare environment. The U.S. has over 4,000 identified medically underserved areas,[4] and 53 rural hospitals across the U.S. have closed since the 2014 implementation of Medicaid Expansion[5] (79 percent of which closures occurred in Non-Expansion states).[6] Rural and safety net hospitals are important links in the healthcare delivery system for those patients that experience difficulty accessing health services, and hospital closures not only reduce access to care, but result in the migration of skilled healthcare labor to urban areas, exacerbating the disparity of physician supply in urban and rural areas.[7] As such, the findings from these recent studies may have far reaching implications for both patients and healthcare providers, regardless of their state's Medicaid Expansion status.

Medicaid was established in 1965 and is jointly funded by federal and state governments as the primary source of health insurance for low-income Americans.[8] While eligibility for Medicaid has traditionally varied by state,[9] the ACA—in an attempt to reduce the number of uninsured Americans—established mandatory Medicaid coverage for all individuals under the age of 65 living in households with an income up to 138 percent of the federal poverty level.[10] However, since the U.S. Supreme Court ruled that Medicaid Expansion would be *optional* for states in June 2012,[11] 33 states, including the District of Columbia, have chosen to expand Medicaid coverage, to varying degrees, in accordance with the ACA.[12] As a result, enrollment in Medicaid and the *Children's Health Insurance Program* (CHIP) has grown to more than 74 million individuals as of October 2017, an increase of almost 20 million since its 2014 implementation (84 percent of which are located in Medicaid Expansion states).[13] While federal funding for Medicaid Expansion has

decreased (from 100 percent coverage from 2014 to 2016, to 90 percent through 2020), the generous allowance has caused some Non-Expansion states to take a serious look at adopting some semblance of Medicaid Expansion measures to take advantage of federal funding while benefiting their underserved patient population.[14] However, despite this allowance, and the recent reprieve for CHIP funding passed by Congress in 2018,[15] continuing uncertainty regarding future federal funding for Medicaid Expansion has caused states to reconsider their stance on eligibility requirements, e.g., increasing the federal poverty limit and adding work restrictions.[16]

These new studies that focus on the impact of Medicaid Expansion have shown that Medicaid Expansion states have a better payor mix, and consequently, increased revenues; higher profit margins; and, decreased costs for uncompensated care.[17] However, some studies have also found drawbacks to the Medicaid Expansion. A January 2018 analysis by *Avalere Health* found that the average Medicaid claims cost has grown by 20 percent over the course of three years.[18] In addition, while a goal of Medicaid Expansion was specifically to increase the number of insured childless young adults, over the 30 months of the study, enrollment by adults aged 19 to 29 years of age decreased by seven percent, while enrollment for adults aged 50 to 64 grew by five percent;[19] this age disparity, and the consequent increase in covered patients with more complex and chronic co-morbidities, is thought to be the underlying reason for the increase in claims cost over time.[20] There are also concerns for providers regarding the potential "*crowding out*" of the more profitable private insurance patients by Medicaid patients; this type of payor mix shift theoretically has the potential to negatively impact a facility's bottom line, though it is estimated that a 70 percent "*crowd out*" would be required to decrease inpatient revenue.[21] It is important to note, however, that although the new Medicaid demographic and claims have shifted in a possibly undesirable financial direction, no studies to date have substantiated a negative impact to hospitals' bottom lines.

At a time when hospitals have been forced to consolidate to acquire the requisite economies of scope and scale to survive; keep pace with rapidly changing regulatory requirements; and, meet the increasing patient demand for services in the communities they serve, these findings should urge hospitals to reconsider both the benefits and potential drawbacks of Medicaid Expansion. It is unknown how the December 2017 repeal of the ACA's *Individual Mandate* (effective as of 2019),[22] and the consequent estimated increase in uninsured individuals,[23] as well as the possible implementation of work requirements for Medicaid eligibility,[24] may have further fiscal impact via altering hospitals' payor mixes. As hospitals are the primary providers of care in a community, they consequently have a responsibility to the community for their continued financial viability. In light of these findings, policymakers in Non-Expansion states may want to reevaluate the efficacy and fiscal responsibility of Medicaid Expansion, and consider strategies for continued success, as well as the impact of their decision on access to care for patients in rural and underserved areas, and the sustainability of hospitals in their state. Hospitals should consider seeking guidance from their legal counsel and business consultants to determine

the appropriate structure and fiscal feasibility of the various strategic financial and business options available to them in the context of both their federal and respective state Medicaid environments.

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The Trump Administration Continues Incremental Efforts to Overhaul U.S. Healthcare

[Excerpted from the article published in April 2018.]

The Trump Administration has shown itself willing, and able, to make numerous policy and regulation modifications throughout its incumbency thus far. U.S. healthcare has been no exception, with a continuing stream of alterations to existing policy and practice in April 2018. On April 9, 2018, the *Centers for Medicare and Medicaid Services* (CMS) released its final 2019 payment notice rule, a lengthy document that makes substantive changes to numerous provisions contained within the *Patient Protection and Affordable Care Act* (ACA).[1] In addition, on April 10, 2018, President Trump signed an executive order entitled "*Reducing Poverty in America by Promoting Opportunity and Economic Mobility*," which imposes work requirements on U.S. beneficiaries of low-income federal aid programs.[2] Both of these actions, consistent with the President's campaign promises, were implemented with little fanfare, but will have a potentially substantial impact on American consumers.

Along with the 2019 final rule, CMS published several guidance letters to clarify many of the provisions contained within the extensive text.[3] Those with the most potential to directly impact consumers include the lifting of several restrictions related to the *Essential Health Benefits* (EHB) requirement of the ACA; under the new rules, states will no longer be limited to the existing ten (10) EHB options, but will have the flexibility to utilize any of the 50 state EHB plans used in 2017, or select their own unique set of EHB requirements, so long as they fall within the scope of federal guidance.[4] In addition, the *Medical Loss Ratio* (MLR) requirements of the ACA, which stated that insurance issuers were required to spend at least 80% of their annual earned premium on *Quality Improvement Activities* (QIA) for the benefit of consumers, were relaxed to make it easier for payors to request a downward adjustment of the standard 80% MLR.[5] Perhaps most significant, the rule expanded the criteria related to "*Hardship Exemptions*" that were originally imposed under the *Individual Mandate* of the ACA. The expanded criteria allowing consumers to opt out of purchasing health insurance will account for those consumers who:

(1) Live in an area where no *qualified health plan* (QHP) is offered through the federal *Health Exchanges*;

(2) Live in an area where there is only one insurer offering coverage through the *Exchanges*;

(3) Only have access to QHPs that provide coverage for abortion services, contrary to one's beliefs; or,

(4) Have other demonstrable "*personal circumstances that create hardship in obtaining health insurance coverage under a QHP*."[6]

This guidance, effective immediately, will allow increased flexibility for U.S. healthcare consumers to avoid purchasing healthcare insurance until the repeal of the *Individual Mandate* becomes effective in 2019.[7]

The multitude of changes in the 2019 final rule are the latest efforts of the current Administration to reduce or otherwise undercut the impact of the ACA, which Congress has (as of yet) failed to repeal.[8] However, while couched as tools with which to "*mitigate the harmful impacts of Obamacare*" (e.g., "*skyrocketing premiums*") and increase flexibility; affordability; integrity; and, stability of marketplace insurance options,[9] the proposed changes may not have the intended effect. For example, with more leniency regarding EHB requirements, insurers may be able to provide decreased premiums, but at the cost of fewer consumer benefits.[10] Additionally, the new changes are not expected to offset the *Congressional Budget Office's* (CBO) estimated 34% increase in premiums for silver-level insurance plans in 2018 (and expected $33 billion increase in the federal deficit by 2028 related to health insurance subsidies) as a result of the Administration's October 12, 2017 decision to stop funding cost-sharing reductions under the ACA.[11] However, note that the deficit would have been an estimated $297 billion more from 2018 to 2027 if the Individual Mandate was still in effect over that time frame.[12]

In a separate (but equally impactful) move, the April 10, 2018 Executive Order signed by President Trump essentially requires implementation of work restrictions for any individuals utilizing low-income assistance (i.e., "*welfare*") programs.[13] This action builds upon the recent guidance by CMS, which permits states to acquire a Section 1115 Medicaid waiver for the purpose of imposing work requirements as a condition of Medicaid eligibility.[14] As of April 9, 2018, ten states have been approved and/or are pending approval of a Section 1115 Medicaid waiver to implement work requirements.[15] The Executive Order, which seeks to address "*the economic stagnation and social harm that can result from long-term Government dependence*," targets any federal assistance program for "*people, households, or families that have low incomes…the unemployed, or those out of the labor force*,"[16] which notably includes not just cash assistance programs, but several safety net programs, e.g., the *Supplemental Nutrition Assistance Program*, f/k/a food stamps, and Medicaid.[17]

In contrast to the arguably more publicized political stalemate that has plagued Republican congressional efforts to "*repeal and replace*" the ACA since 2010,[18] within the past few weeks, the current Administration has clearly illustrated its willingness and capability in making rapid changes to policy and practice within the confines of the Executive branch of U.S. government. The most recent examples of this—the 2019 final rule and the April 10 Executive Order—both demonstrate a principle that continues to underpin the trajectory of the Trump Administration, i.e., "*loosening the reins*" of federal healthcare regulation. However, with a federal budget threatening to break deficit records,[19] it remains to be seen whether the Administration's tactics will be effective at achieving its long term overall goals.

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Thomas Hawkes Tanner (1824-1871)
An English physician and medical writer, who authored such works as "A Manual of the Practice of Medicine" (1854)

MedPAC Outlines Proposed MIPS Replacement Program

[Excerpted from the article published in April 2018.]

As briefly discussed in the previous issue of *Health Capital Topics*,[1] the *Medicare Payment Advisory Commission* (MedPAC) voted to "*repeal and replace*" the *Merit-Based Incentive Payment System* (MIPS).[2] On March 15, 2018, MedPAC released its 2018 annual *Report to the Congress: Medicare Payment Policy*, which includes MedPAC's rationale behind the proposed elimination of MIPS, as well as details regarding a proposed framework for "*moving beyond*" MIPS with the development of an alternative *value-based reimbursement* (VBR) program.[3]

MIPS was originally established, along with *Alternative Payment Models* (APMs), as part of the *Quality Payment Program* (QPP) under the *Medicare Access & CHIP Reauthorization Act of 2015* (MACRA), with the goal of moving physician reimbursement away from a *volume-based* framework toward a *value-based* structure.[4] MIPS was designed as a budget neutral VBR program that incorporated and replaced several predecessor VBR initiatives, including: (1) *Electronic Health Record* (EHR) meaningful use and incentives; (2) the *Physician Quality Reporting Initiative* (PQRI); (3) the *Physician Quality Reporting System* (PQRS); and, (4) the *Value-Based Payment Modifier* (VBPM) program.[5] Clinicians participating in the first MIPS performance period for 2017 were required to submit performance data by March 31, 2018 for payment adjustments in January 2019.[6] The *Centers for Medicare and Medicaid Services* (CMS) has also confirmed plans for provider participation in the 2018 performance period, including continuing improvements and changes to MIPS.[7]

Despite CMS's continuing progress in implementing MIPS, and apparent support of MIPS development and improvement, according to MedPAC, "*…the basic design of MIPS is fundamentally incompatible with the goals of a beneficiary-focused approach to quality measurement…*"[8] for the following reasons:

(1) MIPS is based upon pre-existing Medicare programs that have failed, and will continue to fail, in successfully improving patient outcomes or quality of care;[9]

(2) MIPS evaluates quality using a variety of self-chosen measures that are self-reported on an individual clinician level, and therefore:
   (a) Is burdensome for clinicians;
   (b) Is not directly comparable among clinicians;
   (c) Will not provide enough data for statistically reliable performance scores; and,
   (d) Does not promote the use of coordinated team efforts in quality improvement; and,

(3) MIPS incentives will not promote meaningful performance improvement or a change in practice patterns over time.[10]

Further, MedPAC set forth in its 2018 report an illustrative structure for a potential MIPS replacement program, termed the *Voluntary Value Program* (VVP).[11] The VVP would be (as its name suggests) voluntary for physicians, and allow them to self-organize into sufficiently-sized groups that would be graded on an identical set of performance measures designed to evaluate quality, patient experience, and value.[12] By utilizing this group approach to reporting, the VVP is designed to "*encourage clinicians to address care across time and across settings*" in order to ultimately position physicians to form or join advanced APMs in a movement toward true delivery reform.[13] MedPAC notes that several elements in the VVP design are flexible, including the performance measures; the size and formation of participating groups; the penalty and reward incentive(s); and, the timeline for implementation, and so may be achieved in a number of ways.[14] However, MedPAC recommends that the VVP be designed as a budget neutral program; should not burden physicians with the requirement to report data; and, should utilize uniform, "*scientifically acceptable*" population-based measures to assess performance.[15]

The recommendation for the elimination of MIPS in favor of a voluntary reporting program is consistent with numerous recent changes made by CMS to "*increase flexibility*" for participating providers, as evidenced by alterations to other VBR programs, e.g., cancellation of *mandatory* bundled payment models;[16] decreasing thresholds for MIPS exemption;[17] and, expanding use of *voluntary* VBR programs.[18] On a broader scale, this general shift in thought conforms with statements made by both CMS Administrator Seema Verma, and the Trump Administration, with regard to their intent to *unburden* and *de-regulate* healthcare.[19]

As of yet, Congress has not made any moves to repeal MIPS and adopt the VVP framework laid out by MedPAC. In the meantime, providers and industry stakeholders appear to be divided as to whether MedPAC's proposal will be beneficial or not. The *American Medical Association* (AMA) and physician advocacy groups have actively criticized what they consider to be a premature abandonment of the barely two-year-old MIPS program.[20] In response to widespread dissent over the decision to eliminate MIPS, MedPAC stated in its report that:

> "*If history [e.g., the failure of the sustainable growth rate program] is any guide, once the apparatus for MIPS is…up and running, the process will have its own momentum, and it will become even more difficult to substantially change or improve the program. Furthermore, the longer [MIPS] continues, the signals that MIPS sends will continue. We do not agree with those signals: that clinicians should pick measures to report on which they expect to do well…that quality measures should emphasize processes (instead of outcomes)…and that completing check-the-box activities is a reasonable performance measure…*"[21]

Though the recent MIPS repeal has engendered criticism, not all providers appear to be adamantly in opposition to the change. Seventy-six (76) percent of

respondents in a recent industry survey asserted that their staff does not understand the QPP, and sixty (60) percent stated that they were not prepared for MIPS implementation (even though the program has been in place for almost two years).[22] Additionally, a February 2018 Health Affairs blog post by several industry experts supported the move away from MIPS, for many of the same reasons mentioned by MedPAC.[23] They did not, however endorse replacing it with an alternative VBR program (i.e., the VVP), but instead recommended further expanding and incentivizing provider participation in APMs and other "*well-defined*" and "*high value*" performance improvement activities, e.g., utilizing EHR and submitting data to clinical registries.[24] Thus, while some stakeholders appear to understand the move away from MIPs, the new VVP, considered by some to be an ideological, rashly conceived, and poorly defined "*skeleton-like proposal*" replacement for the unpopular MIPS, has not received much positive feedback from the provider community.[25] Additionally, while there has been no publicized feedback thus far from Congress or CMS, the latter appeared to parrot some of the language from MedPAC's report in its April 24, 2018 press release for the 2019 Inpatient Prospective Payment System Proposed Rule, e.g., by proposing removal of VBR reporting measures that are "*excessively burdensome*" and by "*focusing on…patient-centered outcome measures, rather than process measures*."[26] While many are hopeful that the VVP is the "*silver bullet*" needed to repair the worrying trends of increasing healthcare spending and stagnating quality of care, as the cliché goes, and as history has borne out time and again in healthcare: "*the devil is in the details*."

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Metrodora (c. 200-400 CE)
Greek female physician and author of oldest medical text known to have been written by a woman:
"On the Diseases and Cures of Women."

MedPAC Votes to Lower Urban Freestanding Emergency Department Payments

[Excerpted from the article published in May 2018.]

On April 5, 2018, at the public meeting for the *Medicare Payment and Advisory Commission* (MedPAC), the commissioners passed, via a unanimous vote, the following proposed recommendations related to reimbursement for *freestanding emergency departments* (FSEDs), a/k/a stand-alone emergency departments:

(1) "*Congress should* ***reduce Type A emergency department [ED] payment rates by 30 percent*** *for off-campus stand-alone emergency departments that are* ***within six miles*** *of an on-campus hospital emergency department*"[1] [emphasis added]; and,

(2) "*Congress should allow* ***isolated rural*** *stand-alone emergency departments* ***more than 35 miles*** *from another ED to bill standard outpatient prospective payment system facility fees and provide such emergency departments with annual payments to assist with fixed cost*."[2] [emphasis added]

Currently, Medicare reimburses FSEDs under the *outpatient prospective provider system* (OPPS) by two different methods:

(1) *Type A ED rates* reimburse hospital EDs open 24 hours per day; and,

(2) *Type B ED rates* reimburse hospitals with EDs open fewer than 24 hours per day (note that these payments are approximately *30% lower* than Type A rates).[3]

These recommendations should come as no surprise, given that MedPAC has published findings regarding trends and utilization of stand-alone EDs in both its June 2016 and June 2017 *Reports to the Congress*.[4] In its most recent research, MedPAC found that, of the almost 600 FSEDs currently operating in the U.S., most have been open since 2010, and approximately two-thirds of these can currently bill Medicare for services.[5] Additionally, FSEDs were found to be disproportionately located in areas with higher than average incomes and better (i.e., privately) insured consumers.[6] This is thought to be, in part, due to varying state regulations with regard to FSED required services; ownership structure; and, operational requirements. Thus, in more lenient jurisdictions, FSEDs represent an opportunity for affiliated hospitals to expand their geographic footprint and reduce hospital-based ED overcrowding by increasing access in a nearby FSED. Additionally, FSEDs may allow a hospital system to cut into a competitor's market service area to increase revenue by spending less money,[7] as FSEDs do not maintain operating rooms or trauma teams and do not require on-call specialists, as a hospital-based ED would.[8]

Hospital-affiliated *off-campus emergency departments* (OCEDs) – which comprised 64% of all FSEDs in 2016 – that are located within 35 miles of their affiliated hospital campus are paid the higher Type A rate for Medicare services

(to compensate for the higher acuity patients treated), despite serving patients with acuity levels similar to those paid Type B rates.[9] Should the first of MedPAC's recommendations be passed, approximately 75% of OCEDs will face the recommended 30% payment reduction, saving Medicare anywhere from an estimated $50 to $250 million annually.[10]

This MedPAC recommendation is not the first action focused on reducing outpatient site payments. In the *Bipartisan Budget Act of 2015*, Congress mandated that any medical services provided in an "*off-campus provider-based department*" no longer be reimbursed under the OPPS; the only service exempted from this new rule was ED services.[11] The *Centers for Medicare & Medicaid Services* (CMS) consequently reduced payment for these entities to the applicable (and much lower) non-facility rate under the *Medicare Physician Fee Schedule* (MPFS).[12] These, and subsequent changes by CMS, effectively reduced reimbursement to 25% of the original OPPS reimbursement fee for these outpatient entities, as of 2018.[13] These changes have been met with criticism by the *American Hospital Association* (AHA), which called the previous payment reductions "*arbitrary and capricious*."[14] Similarly, in reaction to the first of MedPAC's most recent recommendations regarding adding FSED reimbursement reductions to the growing list, the AHA called the move "*unfounded and arbitrary*," citing a lack of appropriate analytical data to support the recommendation.[15]

Additionally, in 2016, MedPAC conducted an investigation regarding improving access to emergency care in rural areas, which included reviewing potential scenarios by which financially struggling, isolated hospitals, e.g., *critical access hospitals* (CAH), would be given the option to convert to outpatient-only facilities, e.g., an ED or a clinic with ambulance service, to preserve access and promote efficiency.[16] As noted in this 2016 investigation, should MedPAC's 2018 recommendation be passed by Congress, it would result in a modest increase in spending, but with the benefit of potentially preserving access to emergency care in rural settings.[17]

Many of the MedPAC commissioners commented that these recommendations should be considered just the beginning of a much broader avenue of inquiry regarding the appropriateness of emergency care utilization.[18] The number of ED visits have grown 20% from 2000 to 2010; while more than three quarters of privately insured patients seen in the ED could be more appropriately cared for in a primary care setting, the average ED visit costs $580 more than an outpatient office visit, contributing to unnecessary healthcare spending.[19] While hospital investment in FSEDs may have historically been a smart financial business move, MedPAC appears to be cognizant of the fact that it may not be fiscally advantageous for federal health insurance programs. As Congress has historically agreed with MedPAC's recommendations regarding the reduction of payment for certain outpatient services,[20] investors and health systems should be wary of another imminent reimbursement reduction.

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CMS Inpatient Reimbursement Rate Updates Proposed for 2019

[Excerpted from the article published in June 2018.]

On April 24, 2018, the *Centers for Medicare and Medicaid Services* (CMS) released their proposed rules for payment and policy updates for the Medicare *Inpatient Prospective Payment System* (IPPS) and the *Long-Term Care Hospital* (LTCH) *Prospective Payment System* (PPS) for *fiscal year* (FY) 2019.[1] The proposed rule includes an estimated 1.75% increase in operating payments to general acute care hospitals that successfully participate in the *Hospital Inpatient Quality Reporting* (IQR) *Program* and *electronic health record* (EHR) *Meaningful Use* program,[2] but a projected 0.1% decrease in LTCH PPS payments.[3] Both of these projected increases are less than last year's projections, in which operating payments were estimated to increase by 1.81%, and LTCH PPS payments were projected to decrease by approximately 4.2%.[4] Payments for uncompensated care to *disproportionate share hospitals* (DSH) are expected to increase by $1.5 billion from FY 2018, totaling $8.25 billion for FY 2019.[5] The goal of these proposed rules, according to CMS, is to promote "*greater price transparency, interoperability, and significant burden reduction [to providers]*."[6] In an attempt to achieve this goal, CMS has proposed changes to Medicare's *Meaningful Use* program, as well as several *value-based payment* (VBP) programs.[7] More detailed explanations of these proposed changes are described below.

Increasing Price Transparency

Under current law, hospitals are required to make their list of standard charges public.[8] For FY 2019, CMS is proposing to mandate the public reporting of standard hospital charges via the Internet, effectively increasing price transparency among consumers of healthcare services (i.e., patients).[9] CMS has proposed imposing penalties on hospitals that are not compliant with the requirement, as well as making information regarding hospital non-compliance public.[10] CMS is also seeking comments from the public regarding efforts to improve price transparency overall, given that many patients experience unforeseen hospital bills and the available chargemaster data is not user-friendly or accessible for all patients (e.g., out-of-network bills for physicians, facility fees, and physician fees for emergency room visits).[11]

Promoting Interoperability

In 2011, the Medicare and Medicaid EHR Incentive Programs were established to encourage eligible providers "to *adopt*, *implement*, *upgrade*, and *demonstrate* meaningful use of certified EHR technology (CEHRT)."[12] For FY 2019, CMS is re-naming the Meaningful Use program to "*Promoting Interoperability*" to better reflect their goal of improving the exchange of health data among EHR systems.[13] Further, CMS is considering implementing a new scoring methodology for *electronic clinical quality measures* (CQMs), including the addition of new measures such as those related to the e-

prescribing of opioids.[14] Eligible providers will be required to report at least four self-selected CQMs for a period of at least one quarter of 2019.[15]

Decreasing Provider Burden

In an attempt to lessen provider burden and encourage meaningful reporting, CMS is proposing to reduce the number of measures that acute care hospitals are required to report across five quality and VBP programs:

(1) The Hospital IQR Program;

(2) The Hospital VBP Program;

(3) The *Hospital-Acquired Conditions* (HAC) Reduction Program;

(4) The *Hospital Readmissions Reduction Program* (HRRP); and,

(5) The *PPS-Exempt Cancer Hospital Quality Reporting* (PCHQR) Program.[16]

Measures that show consistently high performance, are duplicative, or are excessively burdensome to providers are being considered for removal.[17] Overall, the proposal removes 18 measures, de-duplicates 21 measures found in one of the other four hospital quality programs, and adds one claims-based readmissions measure.[18] Additionally, the rule proposes implementing measures that would reduce the time that hospitals spend on required paperwork by approximately two million hours.[19]

Through greater price transparency, interoperability, and provider burden reduction, CMS hopes to create a "*patient-centered healthcare system*" in which patients are more informed and proactive healthcare consumers.[20] CMS also expects that these policies will allow hospitals to operate with greater flexibility and increase the time providers can spend with patients, ultimately benefitting the provider-patient relationship.[21] Overall, it is projected that Medicare spending on inpatient hospital services for FY 2019 will increase by $4 billion, in part due to capital payments, uncompensated care payments, and payment adjustments related to several Medicare VBP programs.[22] This increase in spending is offset by the $5 million in savings resulting from the estimated decrease in LTCH PPS payments.[23] Comments related to the proposed rule were due June 25, 2018. The American Hospital Association (AHA) has released a summary of their submitted comments to the proposed rule, which contained comments regarding almost every aspect of the proposed rule. The AHA is generally in favor of the proposed measures, and specifically noted its support related to CMS's use of the "*Meaningful Measures*" framework to reduce unnecessary data collection and prioritize hospital initiatives to improve care.[24] Hospitals have been largely supportive of this proposed rule based generally on "*fewer quality measures, a shorter reporting period for Meaningful Use requirements and an increase in uncompensated rate payments*."[25]

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2019 Physician Payment Proposed Rule – Cutting the Red Tape

[Excerpted from the article published in July 2018.]

On July 12, 2018, the *Centers for Medicare & Medicaid Services* (CMS) proposed historic changes to both fulfill President Trump's promise to "*cut the red tape of regulation*"[1] as it relates to Medicare and restore the doctor-patient relationship while shifting healthcare reimbursement from a *volume*-based to a *value*-based system.[2] The 1,473 page proposed rule, entitled, *Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program*,[3] was posted in the Federal Register on July 27, 2018, and CMS will receive comments on its proposal through September 10, 2018.[4] The rule includes proposed updates to payment policies, payment rates, and quality provisions for services rendered under the *Medicare Physician Fee Schedule* (MPFS).[5]

In 2015, the *Medicare Access and CHIP Reauthorization Act* (MACRA) ended the untenable *sustainable growth rate* (SGR) formula for determining physician payment under Medicare Part B; it then established an incentive program, known as the *Quality Payment Program* (QPP).[6] This program provides two ways for physicians to participate, through: (1) the *Merit-based Incentive Payment System* (MIPS); or, (2) advanced *Alternative Payment Models* (APMs).[7] CMS issued the *2019 Proposed Rule for QPP Year 3* on July 12, 2018 (as part of the 2019 MPFS proposed rule), which is focused on improving quality of care and interoperability, while approaching MIPS and APMs with simplification and burden-reduction initiatives.[8]

The proposed changes to the MIPS policies include: expanding the eligible clinician types who can participate; and, adding physical and occupational therapists, clinical social workers, and clinical psychologists to the Year 2 clinician type list.[9] To be excluded from MIPS based on a *Low-Volume Threshold* (LVT), a third allowable criterion (number of covered professional services provided) was added to the Year 2 list, adding to the two current threshold criteria of: (1) billing less than $90,000 in Part B payments; or, (2) providing care to less than 200 beneficiaries.[10] Of note, this is the second year in a row that these criterion have been changed, resulting in fewer eligible clinicians.[11] Also starting in Year 3, clinicians who meet one or two of the LVT criterion, but not all, will be able to *opt-in* to MIPS; this design furthers CMS's effort to reduce burden and offer flexibilities to aid in successful clinician participation, with a special focus on small practices.[12] Ten new quality measures for MIPS have also been proposed, with four of them being patient reported, seven being high priority; conversely, 34 of the current measures been proposed to be removed.[13]

The proposed changes to the APM policies include: establishing a *Certified Electronic Health Records Technology* (CEHRT) use criterion threshold (previously known as "*advancing care information*") for Advanced APMs, so that it can require 75% of eligible clinicians to use CEHRT to document and coordinate care with patients and other healthcare professionals.[14] Also proposed was:

(1) Extending the 8% revenue-based nominal amount standards for Advanced APMs through 2024;

(2) Increasing flexibility for the *All-Payer Combination Option* and *Other Payer Advanced APMs* for non-Medicare payers in order to be able to participate in QPP; and,

(3) Streamlining definitions and clarifying requirements for assessing performance based on quality measures and cost/utilization.[15]

Regarding the proposed payment updates, a positive adjustment of 0.13% has been proposed to be applied to the MPFS *conversion factor* (CF) used to calculate payments for physician services; this adjustment is lower than the 2018 CF adjustment of 0.31% and like last year, the CF used to calculate payments for anesthesia services includes a separate adjustment based on practice expense and malpractice.[16] The 2019 CF includes a statutory update factor of 0.25% and a Relative Value Unit (RVU) Budget Neutrality Adjustment of -0.12% to the 2018 CF, resulting in the 2019 CF of 36.0463; CMS explains, "*where the aggregate…RVUs within a code family change but the overall actual physician work associated with those services does not change, we make…budget neutrality adjustments to hold the aggregate…RVUs constant within the code family, while maintaining the relativity of values for the individual codes within that set*."[17]

Importantly, and perhaps most controversially, the 2019 MPFS proposed rule contains a provision to radically change the way Medicare pays for an essential physician service – the office visit.[18] This specific proposal would "*level the playing field*" among all physician specialties, making it so that physicians are paid roughly the same amount for an office visit, regardless of a patient's medical need or complications; however, physicians are concerned that this proposal would underpay physicians who treat the sicker, more vulnerable patients.[19] Current Medicare payment rates account for five levels of office visits, with Level 1 being for mostly non-physician services, Level 2 (uncomplicated) office visits awarding $76, and Level 5 office visits, usually involving longer evaluations and chronic conditions, awarding $211; per the proposal, the government would pay $135 per visit for new patients and $93 per visit for established patients.[20] The Administration's goal with this proposal is to simplify physician burdens by requiring minimal documentation requirements and thus, freeing up additional time to be spent with the patient (in fact, CMS estimates those time savings to total 51 hours per physician each year).[21] In another proposed office visit change, CMS proposed the development of new codes for communication technology-based services (e.g.,

telemedicine), allowing for a small reimbursement ($14 per visit in Year 1, and then subsequent payment increases of 0.2%) for e-visits.[22]

In addition to these myriad changes, CMS is seeking review of, and comments related to, a number of other topics. For example, CMS has identified seven procedures they believe to be over-reimbursed (total hip arthroplasty; total knee arthroplasty; esophagogast-roduodenoscopy biopsy single and multiple; colonoscopy with lesion removal; CT imaging of head without contrast; electrocardiogram, complete; and, transthoracic echocardiogram with doppler, complete), and have requested a review of these payment policies.[23] Additionally, CMS seeks ideas regarding how to potentially include *electronic health record* (EHR) utilization performance into the Physician Compare tool.[24]

The U.S. healthcare system's shift from *volume* to *value* has resulted many proposed changes, which are occurring, albeit slowly; to date, current physician compensation levels have felt little impact from this shift (most recently as a result of MACRA), staying relatively flat in 2017 compared to 2016.[25] This indicates that the steady growth in physician compensation, as seen in the past, may have started to slow, with the possible exception of primary care physicians, who are experiencing bigger pay gains (in certain situations) because of their strong demand.[26] Many physicians are preparing "*for the transition to value-based payment models despite uncertainties that still linger around what impact Medicare reimbursement changes will have on their incomes*;"[27] Medicare officials estimate that the 2019 IPPS proposed rule will have a *relatively modest* impact on most physicians, with obstetricians and gynecologists gaining the most, and dermatologists, rheumatologists, and podiatrists losing the most.[28]

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CMS Continued Payment System Overhaul: OPPS Proposed Rule

[Excerpted from the article published in August 2018.]

The *Centers for Medicare & Medicaid Services* (CMS), under the Trump Administration, has proposed numerous changes to various healthcare payment systems in efforts to empower patients and provide more affordable healthcare options.[1] On July 25, 2018, CMS released an advance copy of the proposed rule for the *Calendar Year (CY) 2019 Medicare Hospital Outpatient Prospective Payment System* (OPPS),[2] which includes changes to both OPPS and the *ambulatory surgical center* (ASC) payment system,[3] and drives home the Administration's initiatives through expanding site-neutral payments, increasing transparency, and lowering drug prices.[4] This rule would update Medicare outpatient payment rates by 1.25% in CY 2019, with the total payments to OPPS providers estimated to be $7.4 billion, an increase of $4.9 billion from CY 2018.[5] These proposed changes, and their potential effect on the current healthcare delivery system, as well as relevant stakeholder reactions and predictions for the future, will be discussed below.

Four proposed changes are expected to significantly impact *hospital outpatient provider-based departments* (HOPDs), specifically as regards: (1) off-campus provider-based emergency departments (EDs); (2) site-neutral payments for clinic visits in all off-campus HOPDs; (3) payments for separately payable, covered outpatient drugs and biologicals acquired through the 340B Program; and, (4) expansion of services in excepted off-campus HOPDs.[6] Of note, rural sole community hospitals, children's hospitals, and certain cancer hospitals are exempt from these rules.[7] This proposal's focus on HOPDs integrates Section 603 of the *Bipartisan Budget Act of 2015* (BBA), which provides that, as of January 2017, no off-campus HOPD (i.e., an outpatient department of a hospital located off the hospital's main campus) may bill under OPPS unless: (1) it is a "*dedicated emergency department*"; or, (2) it is *excepted* or *grandfathered*.[8] All non-excepted HOPDs have to bill under a different payment system, i.e., the *Medicare physician fee schedule* (MPFS).[9] Notably, reimbursement rates for HOPD-furnished services are generally much higher under Medicare OPPS than under other payment systems,[10] explaining the desire of healthcare organizations to be eligible to bill under OPPS.

Off-Campus Provider-Based EDs

One of the proposed changes addresses the June 2017 *Medicare Payment Advisory Commission* (MedPAC) recommendation to collect data (for tracking purposes) regarding which OPPS services have shifted to off-campus provider-based EDs.[11] As proposed, a new modifier "*ER*" would be implemented to identify these items and services furnished and would become effective on January 1, 2019.[12]

Site-Neutral Payments for Clinic Visits

CMS also proposes imposing site-neutral payments for clinic visits in *all* off-campus HOPDs.[13] Concerned about the payment incentives that shift services from physician offices to HOPDs, CMS believes that these site-neutral payments will address the beneficiary financial burden caused by this shift, i.e., higher copayments and coinsurance.[14] This CMS proposal aims to extend beyond what is required by the BBA, which currently reduces payments to off-campus HOPDs to the amount paid to physician offices for the same service.[15]

340B Program Payments

Currently, there is a difference between *excepted* off-campus HOPD and *non-excepted* off-campus HOPD receivable payments for furnished 340B-acquired drugs, with services in non-excepted off-campus HOPDs garnering providers a higher payment for these drugs.[16] The 340B Program allows participating hospitals and providers to purchase certain covered outpatient drugs from the manufacturer at discounted prices.[17] However in 2017, CMS finalized a payment policy, for excepted HOPDs, to cover outpatient drugs and biologicals at a rate of the drug's average sales price (ASP) *minus* 22.5%, rather than that under the previous payment system, i.e., ASP *plus* 4.3%, resulting in both large cuts to the 340B Program and significantly higher drug expenditures for hospitals participating in the program.[18] Consequently, CMS proposes to extend the 2017 340B Drug Payment Policy (i.e., ASP minus 22.5%) to non-excepted off-campus HOPDs, to eliminate the incentive for hospitals to move 340B-acquired drug services to non-excepted off-campus HOPDs solely to receive the higher payment amounts for these drugs.[19]

Expansion of Services in Excepted Off-Campus HOPDs

CMS has proposed to require *new* (not furnished between November 2014 and November 2015) types of furnished services provided at *excepted* off-campus HOPDs (i.e., those allowed to bill under OPPS in accordance with the BBA) to be paid at the reduced rate applied to *non-excepted* off-campus HOPDs,[20] specifically at a rate of 40% of the OPPS rate.[21] This proposal is aimed at addressing CMS concern that if excepted off-campus HOPDs are allowed to furnish new services that were not provided prior to the enactment of the BBA, then hospitals will furnish these services with newly purchased physician practices, which will be paid at OPPS rates instead of under the "*MPFS Relativity Adjuster*," a rate of 50% of the OPPS rate.[22] With the clinic visit being the most commonly billed service under OPPS, CMS estimates this proposed change would reduce 2019 Medicare expenditures by $760 million.[23] It is also anticipated that this change would lower clinic visit coinsurance payments for Medicare beneficiaries, from approximately $23, the current average payment, to $9.[24]

Changes to ASC Payment Rates

The CMS 2019 rule also proposes to increase payment rates by 2% for ASCs that meet the quality reporting requirements under the *Ambulatory Surgical Center Quality Reporting* (ASCQR) *Program*, and suggests expanding the

number of procedures payable at ASCs to ensure they remain competitive with HOPDs.[25] CMS is, however, reconsidering whether to pay for spinal surgeries at ASCs, based on an investigation finding that, since 2008, 14 seniors have died from same-day spine operations at ASCs; now, CMS considering whether these procedures "*pose a significant safety risk*" to the patients.[26] Since 2015, CMS has added 38 procedures as payable for ASCs, 25 of them which involve spine surgery.[27]

Stakeholder Reactions

The 2019 OPPS proposed rule has been very controversial among the pertinent stakeholders, with the *American Hospital Association* (AHA) and *America's Essential Hospitals* (AEH) both releasing statements largely disapproving the proposal.[28] AHA Executive Vice President, Tom Nickels, wrote:

> "*CMS has once again showed a lack of understanding about the reality in which hospitals and health systems operate daily…[i]n 2015, Congress clearly intended to provide current off-campus hospital clinics with the existing outpatient payment rate…CMS's proposal runs counter to this and will instead impede access to care for the most vulnerable patients*."[29]

Nickels also made clear that AHA believes that CMS's proposal invokes a legal issue, i.e., that CMS has misconstrued congressional intent as established in the BBA and, thus, lacks statutory authority to propose these rules.[30] Bruce Siegel, President and CEO of AEH, has asserted that these proposals will neither protect nor support America's most vulnerable patient populations, and will severely undermine the foundation of safety net hospitals and those other hospitals that are least able to afford this latest Medicare cost-savings approach.[31] 340B Health, a representative for safety net hospitals, released a statement criticizing CMS for extending the already detrimental cuts to drugs provided in off-campus hospital clinics, which they noted includes, "*facilities providing infusion therapy for cancer patients and other high-cost drug therapies to treat chronic and life threatening conditions*."[32]

Conclusion

Overall, CMS estimates that outpatient hospital payments for 2019 will decrease by $80 million nationwide, or by a net of 0.1%, with teaching hospitals taking the biggest hit – a payment decrease of 0.8%.[33] On average, other hospitals would see a 0.5% increase in payments, and ASCs, gaining the most, would see increases of 2% in 2019 – an estimated payment increase of $32 million.[34] Controversial changes are a constant in the U.S. healthcare industry, and the Trump Administration continues to push forward their agenda to "*empower patients*"[35] and increase the affordability of healthcare; the consequential effect this may have on hospitals and health systems remains to be determined.

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Nonprofit Hospital Executive Salaries Outpace Those of Clinicians

[Excerpted from the article published in September 2018.]

Healthcare management and other nonclinical workers are essential for the efficient functioning of a modern healthcare system, which has become increasingly complex given the growing "*burden*" of nonclinical tasks such as documentation.[1] As healthcare costs continue to rise, the wages and value of nonclinical staff, especially CEOs, have been examined more critically.[2] Over the past decade, nonclinical healthcare workers, including executives, have seen large increases in compensation, outpacing their clinical counterparts.[3] A recent study in *Clinical Orthopaedics and Related Research* compared the wages of nonprofit hospital chief executive officers (CEOs) and chief financial officers (CFOs) to categories of clinical workers over a 10-year period, and found an increasing wage gap between executives and clinical staff at 22 major nonprofit hospitals.[4] Despite this wage gap, the study did not find a similar increase in healthcare utilization, suggesting that the wages paid to these executives did not result in the addition of any significant value to the hospital.[5]

In 2005, nonprofit hospital CEOs made 3 times as much as orthopedic surgeons, 7 times as much as pediatricians, and 23 times as much as registered nurses.[6] By 2015, nonprofit hospital CEOs were making 5 times as much as orthopedic surgeons, 12 times as much as pediatricians, and 44 times as much as registered nurses; the average compensation for nonprofit hospital CEOs increased 93% from 2005 to 2015.[7] In addition to the increased wages of nonclinical executives, the sheer number of nonclinical workers grew during the 10-year period; in 2015, for every physician, a hospital had (on average) one nonclinical management worker and 10 nonclinical workers, a 17% increase from 2005.[8]

From 2005 to 2015, national healthcare expenditures increased from $2.5 trillion to $3.2 trillion, with healthcare wages being accountable for more than 25% of that growth, growing from $633 billion to $865 billion; nonclinicians accounted for 27% of that growth.[9] When comparing the relatively stagnant utilization of healthcare services over this time period to the dramatic increases in the mean compensation for nonprofit hospital executives, it appears that these wage increases "*outpace plausible growth in value*," meaning that it is unlikely that the "*near-doubling of mean compensation to hospital executives is justified by the value added by their work*."[10]

With the affordability of healthcare at the forefront of national healthcare policy debates, the value of each nonclinical healthcare worker, especially hospital executives, is likely being scrutinized closely so as to assure that their compensation is justified by the value of their work.[11] The government already appears to be paying attention, as evidenced by the passage of the *Tax Cuts & Jobs Act of 2017*, which implemented a new 21% excise tax on compensation over $1 million that is paid to a nonprofit organization's five highest-paid employees, bringing nonprofits more in line with their for-profit counterparts.[12] Whether further action will be taken by the federal or state governments in response to the study's findings remains to be seen.

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Clara Barton (1821-1912)
Founder of the American Red Cross

Hygieia, Greek goddess of goddess/personification of health, cleanliness, and hygiene

III. REGULATORY TOPICS

Department of Justice Recovers $3.7 Billion in False Claims Act Cases

[Excerpted from the article published in February 2018.]

On December 21, 2017, the *U.S. Department of Justice* (DOJ) announced their recovery of more than $3.7 billion in settlements and judgments from civil cases involving fraud and false claims for *fiscal year* (FY) 2017.[1] This amount is the fourth largest recovery in thirty years,[2] and the eighth consecutive year in which healthcare fraud settlements exceeded $2 billion.[3] Approximately $2.4 billion was recouped from the healthcare industry for federal losses alone, and included recoveries from drug companies, hospitals, pharmacies, laboratories, and physicians.[4] This figure, almost 65 percent of the total recovery amount, is much higher than the $220 million recovered from defense contractor companies and the $1 billion obtained from other industries such as banking, higher education, and energy.[5] In addition to the $2.4 billion recovered for federal losses, the DOJ recovered millions of dollars for state and Medicaid programs for FY 2017.[6]

Over $900 million of the settlements and judgments were obtained from the drug and medical device industry (approximately 37.5 percent of all healthcare-related recoupments), making this the sector with the largest amount of recoveries.[7] One of the largest settlements within this sector involved Shire Pharmaceuticals LLC, which, in conjunction with Advanced BioHealing, paid $350 million to resolve kickback and fraud allegations that the companies were bribing physicians and clinics to overuse their bioengineered human skin substitute.[8] Additionally, drug manufacturer Mylan Inc. paid approximately $465 million to resolve allegations that it had misclassified their brand name drug, the *EpiPen*, as a generic to avoid paying higher rebates under the *Medicaid Drug Rebate Program*.[9] Despite the price of the EpiPen increasing by approximately 400 percent between the years 2010 and 2016, Mylan only paid a fixed 13 percent rebate to Medicaid.[10]

Additional legal actions were brought by the DOJ against several other sectors within the healthcare industry during FY 2017, including the *skilled nursing facility* (SNF) and the *health information technology* (HIT) industries, resulting in large recoupments. For example, Life Care Centers of American Inc., a company that owns and operates over 220 SNFs, paid $145 million to settle allegations that it had submitted false claims for medically unnecessary services performed in their affiliated SNFs.[11] This was the largest civil settlement involving a SNF in the 154-year history of the *False Claims Act* (FCA).[12] In another instance, eClinicalWorks, one of the nation's largest *electronic health records* (EHR) software vendors, paid $155 million to resolve allegations that it had misrepresented the capabilities of its software to a certifying entity to gain certification, when in fact the software did not meet the requirements for EHR certification.[13]

Money recovered by the DOJ through healthcare fraud enforcement is crucial in returning assets back to federally funded programs such as Medicare, Medicaid, and TRICARE.[14] According to the DOJ's press release, the recoveries made in 2017 are "*a message to those who do business with the government that fraud and dishonesty will not be tolerated.*"[15] Further, Daniel R. Levinson, Inspector General of the *U.S. Department of Health and Human Services* (HHS), noted that "*[l]arge health care recoveries benefit vulnerable Medicare and Medicaid beneficiaries as well as the taxpayers who support these programs.*"[16] Since 1986, recoveries made under civil FCA suits total more than $56 billion.[17] Over the past five years, there has been a significant number of FCA suits brought on by both *whistleblowers* (also known as *qui tam* lawsuits) and the DOJ, with 674 qui tam cases and 125 non qui tam cases initiated in FY 2017 alone.[18] Despite the Trump Administration's actions to deregulate the healthcare industry throughout 2017,[19] the number of new cases in 2017 enforcing healthcare fraud and abuse laws appears to be on par, if not greater than, figures from previous years, suggesting that FCA enforcement will remain high in subsequent years.[20]

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William Senhouse Kirkes, M.D. (1822 – 1864)
British physiologist known for his work entitled, "Kirkes' Physiology"

Healthcare Reform Update

[Excerpted from the article published in June 2018.]

In the first six months of 2018, healthcare reform has returned once again to the forefront of public and political discourse, as: the constitutionality of the *Individual Mandate* is currently being decided in federal court; more states are expanding Medicaid, using Section 1115 Waivers to establish work requirements; and, *Association Health Plans* are being more widely offered in an effort to cut costs. Recent developments relating to each of these three features will be discussed in this article.

Since its 2010 passage, the *Patient Protection and Affordable Care Act* (ACA) has been highly contested, and debate has only escalated since the *Tax Cuts and Jobs Act of 2017* was signed into law by President Donald Trump in December 2017.[1] This new legislation, to become effective in 2019, eliminates the ACA's *Individual Mandate* tax penalty, bringing the constitutional validity of the mandate into question, as its previous authority was established as a constitutional exercise of Congress's taxing power.[2]

In the 2012 case, *NFIB v. Sebelius*, the U.S. Supreme Court established that Congress can constitutionally impose the minimum essential coverage requirement of the *Individual Mandate* by making the penalty a "*tax*;" it was further held that the essential feature of any tax is that it "*produces at least some revenue for the Government*."[3] With the *Tax Cuts and Jobs Act* reducing this tax penalty to $0, it is "*[not] fairly possible*",[4] as Chief Justice Roberts explained in the 2012 majority opinion, to classify this mandate as a tax because it no longer meets this "*essential feature*" threshold, i.e., the ability to raise revenue.[5]

This is the argument that Texas, along with 19 other state plaintiffs, used in its lawsuit against the U.S. in the U.S. District Court for the Northern District of Texas, in an attempt to completely dismantle the ACA. The plaintiffs argue that this dismantlement is necessary because the requirements of the ACA are unlawful and nonseverable from the now unconstitutional *Individual Mandate*.[6] Specifically, the plaintiffs claim that the new tax law invalidates the *Individual Mandate* and thus, the entirety of the ACA.[7]

Subsequently, on June 7, 2018, the Office of the U.S. Attorney General released a letter asserting that, while the *Department of Justice* (DOJ) acknowledges and accepts that the *Individual Mandate* can no longer be held as constitutional, unlike Texas, it plans to argue that the *Individual Mandate* is severable from the ACA, meaning that the ACA can still function without the *Individual Mandate* in place.[8] The DOJ did, however, state that they do not believe that the "*guaranteed issue*" provision (requiring health insurance companies to accept all applicants regardless of pre-existing conditions); the "*community rating*" provision (banning health insurance companies from charging individuals higher premiums based on their health status); or, the requirement of providing the "*10 Essential Health Benefits*" within every plan, are

severable, and do not plan to argue in support of their continuance.[9] As of June 22, 2018, a group of nine governors have responded to this letter with a request that Attorney General Jeff Sessions reconsider defending these provisions, and work toward bipartisan solutions to ensuring coverage and lowering healthcare costs, while still protecting those with preexisting conditions.[10]

If the argument of the 20 state plaintiffs is accepted by the federal court, and the entire ACA is eliminated, the number of uninsured Americans by 2019 would increase by 50%, or 17.1 million people, according to an *Urban Institute* analysis.[11] This analysis also found that in 2019, Medicaid and *Children's Health Insurance Program* (CHIP) would see an enrollment decrease of 15.1 million, individuals with private, non-group insurance would fall by 3.6 million, and those who remain insured "*would likely have fewer benefits and pay more out of pocket*."[12]

If the DOJ argument is accepted by the court, and these aforementioned provisions are not continued, health insurance companies will, once again, be able to implement underwriting techniques and deny people coverage or charge them higher premiums based solely on their medical history or current conditions.[13] This creates the potential of leaving yet more individuals uninsured, and consequently risks significantly increasing already high healthcare costs and health insurance premiums, which are the exact outcomes the ACA was enacted to avoid.[14] Pre-existing conditions may include cancer, diabetes, epilepsy, heart disease, arthritis, and even pregnancy (potentially reopening the door for gender-based health insurance discrimination).[15] Based on past use of pre-existing conditions and government surveys, the *Kaiser Family Foundation* estimated that, as of 2016, approximately 52 million Americans under the age of 65 had pre-existing conditions; without these preventative provisions in place, one out of every four Americans would have difficulty obtaining insurance coverage.[16] Further, a recent analysis completed by *Avalere Health*, found that the premiums for the popular silver-level health insurance plans are expected to increase by 15% in 2019,[17] perhaps as a response to this uncertainty in the healthcare industry.

In contrast to the push for the complete dismantlement of the ACA, final regulations for an ACA "*work around*" to current health insurance marketplace plans were released in June 2018 by the *U.S. Department of Labor* to expand eligibility for *Association Health Plans* (AHPs), in an effort to increase affordability of health insurance for Americans.[18] AHPs can be created and sold within a region or state by small businesses or trade groups.[19] The controversy behind these regulations is that while AHP insurance may be more affordable, the plans are expected to be exempt from ACA requirements, including the "*10 Essential Health Benefits*" and "*guaranteed issue*" provisions (described above), leaving individuals with less coverage.[20]

In contrast to the curtailing of many ACA provisions, the ACA *Medicaid Expansion* provision (through which states may increase Medicaid coverage to up to 138% of the federal poverty level) is experiencing a renaissance of sorts, with several states reevaluating their expansion options. Although originally a

mandatory ACA provision, compliance to *Medicaid Expansion* was found by the U.S. Supreme Court in 2012 to be optional for the states.[21] As of June 2018, 17 states had yet to adopt *Medicaid Expansion*, with 3 of those states (Idaho, Utah, and Nebraska) currently considering expansion.[22]

In January 2018, *Centers for Medicare and Medicaid Services* (CMS) released a policy announcement supporting those states that seek to implement work or community engagement requirements (Section 1115 Waivers) for Medicaid enrollees.[23] This development has spurred multiple states to reconsider expanding Medicaid, with Virginia, Maine, and Idaho considering or passing legislation to bring *Medicaid Expansion* to their respective states.[24]

In May 2018, the State of Virginia, with its Republican-controlled Senate, voted to expand Medicaid to cover "*an additional 400,000 low-income adults*" starting in 2019,[25] but will be seeking a requirement that non-disabled adults must either work or volunteer to be eligible for the expanded program.[26] In the fall of 2017, Maine voters became the first state in the nation to approve *Medicaid Expansion* through a public referendum, but Maine's Governor, Paul LePage, refused to move ahead with the expansion.[27] In April 2018, advocates sued the LePage administration based on his refusal to comply, and in the judge's most recent ruling, she ordered the administration to submit a state expansion plan to the *Department of Health and Human Services* (HHS) by June 11, 2018.[28] On June 7, 2018, however, Maine Insurance Commissioner, Ricker Hamilton, filed an appeal arguing a separation of powers violation and requested the judge's order be stayed until the appeal is decided.[29] Maine's actual timeframe for submitting a state plan will likely become clearer following this litigation. Maine submitted a Section 1115 Waiver in 2017 to impose Medicaid eligibility work requirements for individuals up to age 64,[30] so it is probable that a variation of these requirements will be incorporated into their new state plan. In Idaho (a Republican majority state), expanding Medicaid coverage has become more favorable among residents, and petitions have been circulated to include the initiative on the upcoming November ballot.[31] If Idaho expands, an estimated additional 78,000 residents would be covered.[32]

Even states that have already expanded Medicaid are submitting Section 1115 Waivers to increase eligibility requirements; as of June 22, 2018, there are eight pending Section 1115 Waivers containing work requirements.[33] These pending waivers were submitted by Arizona, Kansas, Maine, Mississippi, Ohio, Utah, Wisconsin, and Michigan.[34] If approved, these eight states will join the four states that have already received approval for their work requirements: Arkansas, Indiana, Kentucky, and New Hampshire.[35]

The state of U.S. healthcare is constantly changing, and the ACA may be significantly revamped once again, pending: the outcome of the court's decision in *Texas v. U.S.* as to the status of the ACA; the ramifications of the expansion of AHPs; and, renewed state interest in expanding Medicaid, with the caveat of work requirements. Each of these developments is highly contested, and healthcare generally is expected to be one of the top voter issues

in the 2018 midterm elections,[36] as Democrats seek to regain control in the U.S. House of Representatives and lessen the Republican majority in the U.S. Senate.

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Elizabeth Blackwell (1821-1910)
First woman to receive a U.S. medical degree

CMS to Review Stark Law Relevance Once Again

[Excerpted from the article published in July 2018.]

On June 25, 2018, the *Centers for Medicare & Medicaid Services* (CMS) issued a Request for Information (RFI) related to the regulatory burden of the *physician self-referral law* (known as the *Stark Law*), on both providers and the overall healthcare industry.[1] The aim of this request is to determine whether revision(s) of healthcare fraud and abuse laws is needed in order to remove any regulatory impediments to the accelerating shift toward *value-based reimbursement* (VBR) and coordinated care, and further innovation in the U.S. healthcare delivery system.

Government regulators perceive many types of healthcare business arrangements, which in other industries are often seen as typical motivations in commercial relationships, as exhibiting the potential for a significant risk of fraud. For example, referral relationships, which in other industries are lawful and exhibit the potential for increased profit, may violate federal fraud and abuse laws, such as the Stark Law, when existing between healthcare providers. However, there is an inherent conflict between fraud and abuse laws and VBR, as the pursuit of VBR and coordinated care by providers has driven the pursuit of closer relationships between hospitals (that are seeking to amass the various specialties needed to provide a full continuum of care in a cost-effective manner) and physicians (who are experiencing tightening reimbursement at the same time that they are being required to heavily invest in healthcare information technology for quality reporting purposes), through various alignment strategies, e.g., practice acquisitions, direct employment, *provider services agreements* (PSAs), co-management, and joint venture arrangements.[2]

One result of provider alignment in pursuit of VBR goals, particularly when aligning through employment arrangements with hospitals and health systems, may be that hospitals or health systems sustain *practice losses*.[3] This may be due to a number of reasons, including: (1) encountering a more adverse payor mix in a hospital setting; (2) needing to pay more competitive salaries to employed providers; and, (3) the treatment of ancillary services by the hospital or health system (i.e., treating vertically integrated physician practices as stand-alone economic enterprises, which, when stripped of their ancillary service and technical component (ASTC) revenue, and relying solely on professional services, i.e., *work relative value unit* [wRVU] related revenue, and paying physicians at FMV, are almost certain to generate "*book financial losses*").[4] Corresponding with this increased provider alignment, there has been enhanced federal, state, and local regulatory oversight regarding the legal permissibility of these arrangements.[5] Most notably, there has been more intense regulatory scrutiny related to the Anti-Kickback Statute and the Stark Law, especially as these fraud and abuse laws relate to potential liability under the *False Claims Act* (FCA).[6]

The 2018 CMS RFI specifically seeks input on the undue regulatory impact that the Stark Law has placed on VBR and coordinated care, and strategies to

reduce this burden.[7] This request is part of the *U.S. Department of Health and Human Services* (HHS) initiative, *Regulatory Sprint to Coordinated Care*, which is in line with their goal to transform the U.S. healthcare industry from a *volume-based* to a *value-based* reimbursement system, with care coordination being a key aspect of this shift.[8] The list of information sought from healthcare industry stakeholders is extensive, but it includes requests on topics involving *alternative payment models* (APMs), additional exceptions to the Stark Law to facilitate innovation, changes to the current provisions of Stark Law, changes to existing compensation formulas, and exceptions necessary to protect *accountable care organizations* (ACOs) and bundled payment models.[9]

On July 17, 2018, the House Committee on Ways and Means hosted a hearing to gain insight from relevant stakeholders on modernizing the Stark Law to ensure a successful transition from *volume* to *value*-based Medicare reimbursement.[10] Of note, HHS Deputy Secretary, Eric Hagan, emphasized during the hearing the agency's interest in regulatory reforms for *both* Stark Law and the *Anti-Kickback Statute* (AKS); Hagan stated both laws could be stifling innovative arrangements, and thus, hindering better patient outcomes.[11] To address this, HHS plans to issue a separate RFI on AKS reforms imminently.[12]

The hearing also made apparent that HHS plans to make these modifications to Stark Law administratively (i.e., not through Congress), which it will seek to accomplish by creating a proposal to address the comments that CMS receives and other efforts to streamline coordination of care.[13] Also, as discernable from the comments of the panel of healthcare professionals, the Stark Law acts as a barrier to innovation, specifically in implementing APMs; the professionals note their desire to have the fraud and abuse waivers enjoyed by ACOs (which are a type of APM) be extended to all APMs.[14] Regarding the panelists' comments, panelist Michael Lappin, Chief Integration Officer for Advocate Aurora Health, stated his desire to have Congress involved in any reforms, specifically to define key terms such as *Fair Market Value* and other terms that would offer physicians bright-line guidance to ensure proper compliance.[15] However, panelist Claire Sylvia, a healthcare attorney, advised lawmakers to proceed with caution, because paying for value and/or coordinated care does not completely eliminate the financial motive for physicians to "*overlook*" a patient's best interests.[16] Ms. Sylvia's concern is in line with that of Representative Sander Levin (D-MI9), who argued that this move to VBR may potentially weaken "*important tools for protecting Medicare beneficiaries from inappropriate referrals and overutilization of care*."[17]

This is not the first time that Congress has sought information regarding the inherent conflict between the shift toward VBR and the enforcement of the Stark Law. In December 2015,[18] the U.S. Senate Finance Committee, along with the House Committee on Ways and Means, invited federal prosecutors, former CMS officials, and healthcare attorneys to take part in a roundtable discussion regarding significant potential changes to the Stark Law.[19] These participants were asked to identify two main issues: "*(1) changes to the Stark*

Law to implement health care reform, specifically [the Medicare Access and CHIP Reauthorization Act of 2015] MACRA, and (2) the distinction between technical and substantive violations."[20] Beyond these two main categories, the comments received by the Finance Committee addressed other "*non-MACRA*" issues; most notable among these topics were changes to Stark Law definitions, such as *fair market value*, taking into account the volume or value of referrals, and *commercial reasonableness*.[21] On June 30, 2016, the Committee published a white paper recapping the meeting, which included discussions of the two issues specifically identified by the Finance Committee, as well as the other "*non-MACRA*" issues identified by the roundtable participants and outside commenters.[22]

In addition to the white paper, in July 2016, the Committee listened to testimony from healthcare attorneys and hospital executives suggesting desired changes to the Stark Law.[23] Similar to the December 2015 roundtable discussion, the hearing offered industry stakeholders an opportunity to:

> "*[G]ive members of the Committee the opportunity to hear how the Stark Law works in practice for today's healthcare providers and what reforms are needed to streamline the law to make it work for providers, patients and taxpayers*."[24]

At the end of the July 2016 hearing, Senator Orrin Hatch (R-UT), chairman of the Committee, noted that the Committee would "*try to do something about this before the end of the year*,"[25] but nothing ever came of the hearings.

This 2018 CMS RFI and hearing could be an important opportunity for providers and the healthcare industry to again express their experiences and challenges with the Stark Law to CMS, and has the potential to shape how the Stark Law (as well as the Anti-Kickback Statute) is implemented in the future.[26] As CMS Administrator, Seema Verma, stated, "*We are looking for information and bold ideas on how to change the existing regulations to reduce provider burden and put patients in the driver's seat*."[27] The public examinations into the scope and utility of the Stark Law over the past few years demonstrate an increased focus on reforming this regulatory scheme in light of the healthcare industry's continued transition from *volume* to *value*.[28] With the Stark Law not only serving as a significant driver of spending of healthcare compliance, but also as a potential impediment to the implementation of VBR strategies such as APMs,[29] many industry stakeholders have urged for some type of modification to this scheme.[30]

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Louis Pasteur (1822-1895)
Known for discoveries related to pasteurization and vaccinations

CMS Seeks Comments on Anti-Kickback Statute Reform

[Excerpted from the article published in September 2018.]

The Trump Administration has continued to identify potential barriers to care coordination and value-based care incentives through changes to current regulation, as part of the Administration's "*regulatory sprint towards coordinated care*."[1] These changes have been primarily focused on modernizing fraud and abuse laws, as noted by the June 25, 2018 *Request For Information* (RFI) seeking public comments on reforming the physician self-referral law, commonly known as the *Stark Law*.[2] On August 24, 2018, the same day that comments were due for the Stark Law RFI, the *Office of Inspector General* (OIG) of the *Department of Health and Human Services* (HHS) published another RFI seeking public input on changes to the *Anti-Kickback Statute* (AKS) and beneficiary inducements in the *Civil Monetary Penalty* (CMP) *Law*.[3]

HHS has stated that updating fraud and abuse laws is key to facilitating innovation in coordination of care arrangements that ultimately underlie the healthcare industry's shift toward *value-based reimbursement* (VBR).[4] As part of the most recently released RFI, HHS is seeking comments on ways that the agency could improve the safe harbors to AKS and the exceptions to the beneficiary inducements CMP definition of "*remuneration*."[5] AKS "*provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration to induce or reward the referral of business reimbursable under Federal health care programs*."[6] AKS safe harbors are available for providers who comply with their components in order to avoid criminal prosecution under AKS and the imposition of civil monetary penalties.[7] The CMP Law, specifically the beneficiary inducement prohibition, authorizes imposing civil monetary penalties for offering or paying any remuneration to Medicare or Medicaid beneficiaries in efforts to influence the beneficiary's provider or supplier selection.[8]

The OIG states in the RFI that it is soliciting comments specific to four categories. One category on which the agency is seeking feedback is the promotion of care coordination and value-based care, including potential care and payment models which they are interested in pursuing, and how those models promote care coordination or value-based care, while preventing potential harms, e.g., increased costs.[9] Additionally, the OIG requests commenters to identify any AKS safe harbors or CMP exceptions that should be added or modified related to coordinated care.[10] The RFI also asks how "*'value' could be defined and used in a safe harbor or exception such that OIG could evaluate 'value' within an arrangement to determine compliance*."[11] Lastly, commenters are encouraged to provide thoughts on the potential definitions for a number of terms, as well as on where the OIG might "*clarify its position through guidance as opposed to regulation*."[12]

The second category for which information is requested is beneficiary engagement, including beneficiary incentives (e.g., the types of incentives in

which providers and suppliers are interested, how they can affect quality of care and care coordination) and cost-sharing obligations (e.g., situations in which cost-sharing obligations are challenging, any financial or fraud and abuse risks to waiving cost-sharing amounts, and any potential risks to reducing/eliminating cost-sharing).[13]

The third category requests feedback regarding other regulatory topics, including information on current fraud and abuse waivers, cybersecurity-related items and services (including the donation or subsidization of same), and new exceptions required by the *Bipartisan Budget Act of 2018*.[14]

The fourth category for which the OIG seeks information from commentators is the intersection of the Stark Law and AKS.[15] The agency is asking for feedback related to specific circumstances where Stark Law exceptions and AKS safe harbors should align to achieve the aforementioned goals of the RFI, as well as whether any Stark Law exceptions should not have a corresponding AKS safe harbor.[16]

Because many VBR models potentially implicate fraud and abuse laws, the OIG has recognized that they are significant hurdles for arrangements that may otherwise advance coordinated care efforts.[17] Over the past few years, the OIG has received "*an increasing number of comments*" from industry stakeholders to its yearly safe harbor and special fraud alert solicitation.[18] Perhaps in response to this increasing input from the healthcare industry, HHS has already issued this year an RFI on the Stark Law (as noted above) and a proposed rule (which is currently being reviewed by the Office of Management) entitled, "*Removal of Safe Harbor Protection for Rebates to Plans or PBMs Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection.*"[19] However, whether these RFIs on the "*modernization*" of fraud and abuse laws in the shift to VBR will ultimately result in any agency action remains to be seen.

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202018/August%2024%202018/HHS-Asks-for-Stakeholder-Input-on-Reforming-Anti-Kickback-Statute-.aspx (Accessed 8/31/18).
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6 Federal Register, August 27, 2018, p. 43608.
7 *Ibid.*
8 Hooper, August 27, 2018.
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13 *Ibid*, p. 43609-43610.
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15 *Ibid*, p. 43611.
16 *Ibid.*
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19 *Ibid.*

William Cullen, MD (1710-1790)
A Scottish physician, chemist and, agriculturalist, and a central figure in the Scottish Enlightenment.

SCOTUS Nominee Brett Kavanaugh's Paper Trail & Potential Influence on U.S. Healthcare Laws

[Excerpted from the article published in July 2018.]

The future of healthcare policy could be significantly affected by the appointment of President Donald Trump's nominee, Judge Brett M. Kavanaugh, to the Supreme Court of the United States (SCOTUS). SCOTUS has been highly influential in U.S. healthcare policy in the past, and going forward, it has the power to drastically change the healthcare system, perhaps most severely by declaring laws or past executive action to be unlawful or unconstitutional.

On July 9, 2018, President Trump nominated Judge Kavanaugh to replace retiring Justice Anthony Kennedy, who often served as the swing vote of the 9-justice SCOTUS during his 30 years on the bench.[1]

In the wake of Judge Kavanaugh's appointment, reviewing his past opinions, especially as relates to the myriad laws and regulations that govern the U.S. healthcare system, may provide insight into how SCOTUS, with Judge Kavanaugh on the bench, may rule in future cases.

Judge Kavanaugh, in his current position as U.S. Circuit Judge of the U.S. Court of Appeals for the District of Columbia (to which he was appointed by President George W. Bush in 2006[2]), has rendered an opinion in a case specifically concerning the *Patient Protection and Affordable Care Act* (ACA). In 2011, Judge Kavanaugh was selected at random to rule on whether the ACA was constitutional before any of its provisions were imposed.[3] Judge Kavanaugh faced a career-altering decision, which decision would likely put him at odds with either the Republican Party, who nominated him to the D.C. circuit back in 2006, or the American people and their elected representatives, who shared generally positive views of efforts to increase health insurance coverage.[4] He managed to avoid discussing or ruling on the merits of the case; when the other two judges on the D.C. Circuit upheld the ACA, Kavanaugh dissented, stating that the suit should have been dismissed for lack of standing until after the tax penalty in the *Individual Mandate* took effect.[5] Specifically, Kavanaugh argued that he could not rule on the case because doing so would not adhere to the text of the *Anti-Injunction Act* of 1867, acting as a statutory bar on jurisdiction: "*The Anti-Injunction Act, when applicable, bars any suit seeking relief that would necessarily preclude the assessment or collection of taxes under the Internal Revenue Code, regardless of the plaintiff's professed motivation for the suit*."[6] It was originally held that regulatory taxes are covered by the *Anti-Injunction Act* (i.e., the suit is not barred) "*as long as they raise some revenue*"; but the majority opinion suggested that the ACA tax penalties were not designed to *raise revenue* for the Government, and thus may not qualify as taxes under the *Anti-Injunction Act* (thus barring the suit).[7] In essence, Kavanaugh argued that the court could not rule on the case because the *Anti-Injunction Act* did not allow courts to rule on the legality of a tax before

it had been imposed.[8] Of note, Judge Kavanaugh's "*raise revenue*" argument subsequently became the Obama Administration's legality argument in defending the law, and was ultimately the reasoning used by Chief Justice Roberts in upholding the ACA as a constitutional exercise of Congress's power to tax.[9]

In June 2018 (just days before his nomination), Judge Kavanaugh ruled against the *U.S. Department of Health and Human Services* (HHS) in a case brought by hospitals claiming that Medicare has been using flawed data since 1983, to which claim HHS responded that factual determinations made so many years ago cannot be challenged.[10] Judge Kavanaugh rejected this argument and wrote, "*[i]t would seem to be the very definition of arbitrary and capricious for H.H.S. to knowingly use false facts when calculating hospital reimbursements…[s]aving money is a laudable goal, but not one that may be pursued by using phony facts to shift costs onto the backs of hospitals*."[11] The court stated that when an agency's interpretation is plainly erroneous or inconsistent with the regulation, the court will not defer; this opinion is consistent with Judge Kavanaugh's ostensible skepticism of the *Chevron* doctrine (regarding the level of judicial deference given to agency decisions),[12] as indicated by his decisions.[13]

This theme is also apparent in the 2017 case, *Americans for Clean Energy v. Environmental Protection Agency (EPA)*, where Kavanaugh held that the EPA exceeded its authority because its interpretation of "*supply*" was too broad within the relevant provision, and did not defer to the EPA's interpretation of the provision.[14] In a second 2017 case, *Allina Health Services v. Price*, Kavanaugh held that the HHS calculation of *disproportionate share* (DSH) payments under Medicare was procedurally and substantively invalid because they did not provide an opportunity for notice and comment, which the *text* of the Medicare Act *expressly requires*.[15] Kavanaugh also found HHS's argument, that the *Administrative Procedural Act* (APA) interpretative-rule exception exempts them from notice-and-comment requirements, to be unpersuasive.[16]

Another Kavanaugh opinion dealing with an HHS statutory interpretation was in the 2011 case, *University of Texas M.D. Anderson Cancer Center v. Sebelius*, in which Kavanaugh held that the HHS interpretation of the term "*reasonable cost*" in calculating outpatient reimbursement under Medicare was reasonable, and thus unambiguous.[17] Although Judge Kavanaugh sided with the agency interpretation in this case (in contrast to the other three cases), the main takeaway from his four opinions is that he has textualist, originalist, and formalistic tendencies, all of which are common characteristics of a conservative judge. Kavanaugh's opinions are often narrow in the sense that they are decided by applying uncontroversial constitutional principles to the facts; he cites statutory text throughout his opinions and relies strongly on constitutional principles and doctrines, such as procedural and substantive due process.[18]

Justice Neil Gorsuch, another President Trump nominee who replaced the deceased Justice Scalia in 2017, has also written powerfully about the *Chevron*

doctrine, suggesting that it may violate the constitutional separation-of powers doctrine; with two Supreme Court Justices having this view, agencies may generally experience tighter restrictions on their federal regulatory powers.[19]

Judge Kavanaugh, whose confirmation hearing is expected to be set for fall 2018, has the potential to significantly influence future decisions of SCOTUS. The paper trail left by his previous opinions as U.S. Circuit Judge, which sheds some light as to how he could rule in future cases before SCOTUS – particularly those that relate to federal healthcare laws, may serve as a double-edged sword in his (likely to be contentious) judicial nomination, as the 2018 midterm elections heat up.

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6 "Seven-Sky v. Holder" 661 F.3d 1, 44 (U.S. App. D.C., 2011).

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8 "Everyone is panicking about what Trump's selection of Brett Kavanaugh means for the future of Obamacare" By Bob Bryan, Business Insider, July 10, 2018, http://www.businessinsider.com/brett-kavanaugh-nomination-impact-on-obamacare-healthcare-2018-7 (Accessed 7/20/18).

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14 "Americans for Clean Energy v. Environmental Protection Agency" 864 F.3d 691, 703 (U.S. App. D.C., 2017).

15 "Allina Health Services v. Price" 863 F.3d 937, 944 (U.S. App. D.C., 2017).

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17 "University of Texas M.D. Anderson Cancer Center v. Sebelius" 650 F.3d 685, 687-91 (U.S. App. D.C., 2011); "Coalition for Mercury-Free Drugs v. Sebelius" 671 F.3d 1275, 1278-9 (U.S. App. D.C., 2012); "Allina Health Services v. Price" 863 F.3d 937, 944 (U.S. App. D.C., 2017).

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Susan B. Anthony (1820-1906)
American social reformer and activist.

CMS Proposes Revamp of Federal ACO Program

[Excerpted from the article published in August 2018.]

On August 9, 2018, the *Centers for Medicare & Medicaid Services* (CMS) announced their plan to overhaul the *Medicare Shared Savings Program* (MSSP) by removing the Track 1 and Track 2 financial models for *accountable care organizations* (ACOs), effectively eliminating the program's zero and low-risk tracks.[1] The *Patient Protection and Affordable Care Act* (ACA) established the MSSP to encourage groups of doctors, hospitals, and other healthcare providers to join together as an ACO to promote coordination of care under Medicare Parts A and B, ultimately in efforts to lower healthcare expenditures and improve the quality and efficiency of healthcare delivery.[2] The MSSP began in 2012, and as of January 2018, was comprised of 561 participating ACOs serving over 10.5 million Medicare *fee-for-service* (FFS) beneficiaries.[3] All ACOs that participate in MSSP agree "*to be held accountable for the quality, cost, and experience of care of an assigned Medicare FFS beneficiary population*," and all ACOs that successfully meet the quality and savings requirements are eligible to share a percentage of Medicare's achieved savings.[4]

Currently, the MSSP includes three financials models (Tracks 1, 2 and 3), plus one additional option implemented in January 2018 (Track 1+); ACOs are allowed to select the arrangement that best suits their organization.[5] There is relatively high participation in Track 1, the one-sided, shared savings-only model; also called the "*upside-only*" track, 82% of MSSP ACOs participating in this model as of 2018, cumulatively assigned to 8,147,234 beneficiaries.[6] In this track, eligible ACOs receive a share of any savings under the benchmark, but are not required to share losses when spending goes over the benchmark.[7] Track 2 is the program's two-sided, shared savings and losses model, wherein eligible ACOs share in a larger portion of any savings, but are also required to share losses, and, thus, endure more financial (downside) risk.[8] Participation in Track 2 has decreased over the years (only 8 ACOs currently participate),[9] especially after the 2016 introduction of Track 3, "*the program's highest-risk track*"[10] (which also has the highest level of potential reward), with 38 ACOs currently participating.[11] Lastly, Track 1+ was introduced in January 2018 to accelerate the progress of Track 1 ACOs undertaking performance-based risk. Track 1+ is a two-sided model, but with lower downside risk, and as of January 2018, 55 ACOs were participating.[12]

The MPPS proposed rule states CMS's plan to launch a "*BASIC*" track in replacement of Track 1 and 2, which BASIC track has the same maximum level of risk as the Track 1+ model.[13] CMS plans to keep the high-risk Track 3 option, to be renamed the "*ENHANCED*" track.[14] Prior to this proposed rule, ACOs were allowed to participate in Track 1, without assuming any responsibility for potential losses, for up to 6 years before having to transition to a two-sided model; the proposed rule changes the low-risk participation limit to 2 years for first-time ACOs,[15] and 1 year for returning ACOs.[16] Additional proposed

policies to strengthen the MSSP include; (1) terminating ACOs with repeated poor financial performance; (2) ensuring ACOs are meeting local growth rates and spending levels; (3) providing ACO spending targets for accountability purposes; and, (4) requiring risk-based ACOs to offer financial incentives to patients to encourage healthy behavior.[17] CMS believes that the BASIC track will be a successful intervention, because their data indicates that two-sided models perform better over time and are more capable of lowering growth in expenditures and improving quality, when compared to one-sided model ACOs.[18]

ACOs were among the fundamental initiatives of the ACA, designed to address Medicare's exponential costs; the non-partisan *Congressional Budget Office* (CBO) estimated that ACOs would save the government nearly $5 billion in Medicare spending by 2019.[19] But as of the date of publication, the program is far from that estimate; the *Department of Health and Human Services* (HHS) *Office of Inspector General* (OIG) 2017 Report found that MSSP ACOs reduced Medicare spending by approximately $1 billion from 2013 to 2016, but Track 1 ACOs cost CMS $384 million over that same 3 year period.[20] In a statement released by CMS Administrator Seema Verma, the Administration believes that "*Medicare cannot afford to support programs with weak incentives that do not deliver value. ACOs can be an important component of a system that increases the quality of care while decreasing costs; however, most Medicare ACOs do not currently face any financial consequences when costs go up, and this has to change*" [emphasis added].[21] Further, CMS worries that the "*upside-only*" track (Track 1) models are encouraging marketplace consolidation, reducing competition, and consequently, reducing choice for Medicare FFS beneficiaries.[22]

CMS estimates that these proposed changes will save Medicare $2.2 billion over the course of the next decade,[23] while simultaneously improving interoperability and coordination of care.[24] However, nearly 300 of the participating ACOs have already been using the Track 1 model for a period of over 2 years, so next year, after a 6-month grace period, these ACOs will need to decide if they are switching models or dropping out of the MSSP entirely.[25] A spring 2018 survey conducted by the National Association of ACOs found that 71% of the surveyed ACOs would likely drop out of the MSSP if forced to take on more financial risk.[26] Additionally, CMS has predicted that, within a decade, 109 fewer ACOs will participate in MSSP (resulting in 452 participating ACOs).[27] Industry experts have predicted even greater implications than CMS, i.e., that fewer than 100 ACOs will continue participating in the MSSP because of the required financial risk.[28]

Andy Slavitt, who previously headed CMS under the Obama Administration, stated, "*[a]t first look, they [the contents of the proposed rule] look positive to me*;"[29] however, his opinion is in the minority. Clif Gaus, CEO of the National Association of ACOs, believes the "*likely outcome will be that many ACOs quit the program, divest their care coordination resources and return to payment models that emphasize volume over value*."[30] Critics at large have asserted that

this proposal is undermining the task of building a successful ACO, and that it is naïve to assume that ACOs are ready to take on large financial risk before they have voluntarily chosen to do so.[31]

MSSP ACOs are an important payment innovation designed to assist in the move away from volume-based reimbursement, and toward paying for value and outcomes.[32] While taking this into account, the Administration believes that requiring ACOs to accept the negative side of the risk model is necessary in keeping these organizations *accountable*.[33] But the Administration's eagerness to require ACOs to abruptly take on financial risk cannot outweigh the economic realities faced by ACOs; the requirement of potentially having to pay back millions to Medicare, if costs exceed projections, is not feasible for many organizations.[34] Moreover, because MSSP ACOs (all but Track 1) are classified as Advanced *Alternative Payment Models* (APM) under the *Medicare Access and CHIP Reauthorization Act* (MACRA),[35] the potential unintended effects that may trickle down to MACRA will remain to be seen. Stakeholder comments on the proposed rule are due to CMS by October 16, 2018.[36]

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Claudius Galen, a prominent Greek physician.
Lithograph by Pierre Roche Vigneron
(Paris: Lith de Gregoire et Deneux, ca. 1865)

340B's Uphill Legal Battle for Hospital Associations

[Excerpted from the article published in August 2018.]

As discussed in the December 2017 *Health Capital Topics* article entitled, "*Massive Cuts Made to 340B Prescription Drug Discount Program*," the 2018 Hospital *Outpatient Prospective Payment System* (OPPS) final rule cut Medicare Part B and state Medicaid payments under the *340B Drug Discount Program* (340B Program) by an estimated $1.6 billion.[1] These cuts faced fierce opposition prior to their January 2018 implementation, and several hospital groups, including the *American Hospital Association* (AHA), *Association of American Medical Colleges* (AAMC), and *America's Essential Hospitals* (AEH), filed legal action to block these cuts from taking effect.[2] On July 17, 2018, the D.C. Circuit Court of Appeals, affirming the decision of the District Court, dismissed the lawsuit for failure to satisfy the presentment requirement for judicial review;[3] the hospital group plaintiffs plan to refile the suit in hopes of obtaining a binding decision by the end of 2018.[4]

The 340B Program was created by Congress in 1992 in an effort to provide the vulnerable and uninsured with access to prescription medications at safety-net facilities, i.e., those serving a high number of the vulnerable or uninsured patient population (termed "*covered entities*").[5] In 1994, the *Health Resources and Services Administration* (HRSA) released guidance allowing the off-campus outpatient sites of 340B hospitals to be included as covered entities, and in 1996, HRSA released guidance that allowed covered entities without an on-site pharmacy to contract with one off-site pharmacy.[6] In 2010, HRSA released guidance allowing all covered entities to have an unlimited number of contract pharmacies, and with the passage of the *Patient Protection and Affordable Care Act* (ACA) that same year, 340B eligibility was extended to: (1) critical access hospitals; (2) sole community hospitals; (3) rural referral centers; and, (4) cancer centers.[7] When enacted, the 340B Program required pharmaceutical manufacturers to enter into *pharmaceutical pricing agreements* (PPA) with the *Department of Health and Human Services* (HHS) to ensure discounts for hospitals and clinics serving the most vulnerable patient populations.[8] In 2016, the median amount of uncompensated care provided by hospitals participating in the 340B Program was higher than their non-340B counterparts; between 2011 and 2016, the number of hospitals participating in the 340B Program increased by more than 60%, largely due to the ACA broadening program eligibility.[9]

The ACA eligibility expansion led to the 2014 statement by Kathleen Sebelius (then Secretary of HHS), during testimony before the Senate Finance Committee, that the 340B Program "*has expanded beyond its bounds*" (i.e., the number of 340B Program participants had increased to an unsustainable amount).[10] Further, according to the *Government Accountability Office* (GAO), the number of unique contract pharmacies in 2010 was 1,300, but by 2017, that number had jumped up to 18,700, a more than 1,300% increase.[11] The HHS *Office of Inspector General* (OIG) believes that these "*contract pharmacy*

arrangements complicate efforts to prevent diversion and duplicate discounts," both of which would (allegedly) be in violation of 340B Program requirements.[12] Hospital lobbyists have argued that the 340B Program is vital to safety-net providers serving low-income populations, while drugmakers have differing opinions on the program's scope and reach.[13]

In July 2017, the *Centers for Medicare and Medicaid* (CMS) proposed changes to the 2018 OPPS that significantly impacted the 340B Program.[14] As discussed in the August 2018 *Health Capital Topics* article, "*CMS Continued Payment System Overhaul: OPPS Proposed Rule*," the finalized 2018 OPPS covered outpatient drugs and biologicals at a rate of the drug's *average sales price* (ASP) *minus* 22.5%, compared to the original payment system rate, i.e., ASP *plus* 4.3%; this resulted in both large payment reductions to the 340B Program and significantly higher drug expenditures for those hospitals participating in the program.[15]

The 2018 OPPS proposed rule was finalized on November 13, 2017, and on the same day, AHA, AAMC, and AEH filed the aforementioned lawsuit against HHS in the D.C. District Court, in an effort to prevent the 340B payment cuts from taking effect.[16] These hospital associations argued that the HHS Secretary lacked authority to establish an average-price metric, and that a 30% payment reduction cannot qualify as a mere "*payment adjustment*."[17] HHS stated that these 340B payment reductions were justified based on developments in the market and the program's overexpansion;[18] ultimately, the District Court dismissed the case for lack of subject-matter jurisdiction, specifically for the associations' failure to present claims for reimbursement to the HHS Secretary, as required for judicial review under Medicare.[19] The hospital associations appealed the case to the D.C. Circuit Court of Appeals, and on May 4, 2018, the AHA, alongside 34 state and regional hospital associations, asserted during oral arguments that they satisfied the presentment requirement by filing comments opposing the new OPPS rule during the informal rulemaking process.[20] But on July 17, 2018, the Court of Appeals affirmed the District Court's ruling and dismissed the case on the same subject-matter jurisdiction grounds.[21]

CMS Administrator, Seema Verma, stated, "*The court's ruling is a big win for patients, who this year alone are expected to save $320 million in out-of-pocket expenses for medicines in their doctors' offices....[t]his policy is providing relief every day from the rising costs of drugs, a top priority for President Trump*."[22] The hospital associations released a statement shortly after the ruling expressing their disappointment over the courts "*once again fail[ing] to rule on the merits of [the] case*."[23] The associations also stated that they plan to continue their fight to reverse these "*unwarranted*" 340B payment cuts and protect access for patients; they expect to refile "*promptly*" in district court.[24]

The straining effects of the 340B payment cuts have been further exacerbated in the 2019 OPPS proposed rule, by extending these cuts to drugs provided in non-excepted off-campus *hospital outpatient provider-based departments* (HOPDs) (i.e., a hospital-affiliated provider-based facility located off of the

hospital's main campus).[25] On July 25, 2018, AHA released a condemnatory statement in regards to the proposal to expand the 340B cuts to a significant number of additional HOPDs and life-saving drugs. AHA stated, "*…like the previous cuts…[this proposal] requires no federal contributions…but instead relies on discounts required of drug companies, [which] exceed[s] CMS's statutory authority and remain subject to legal challenge*."[26]

Despite CMS cuts to the program through OPPS rulemaking, Congress is seeking information on how to improve upon the 340B Program. On August 1, 2018, the Energy and Commerce Committee of the U.S. House of Representatives sent letters to nine 340B contract pharmacy participants, seeking information related to their 340B Program participation.[27] These letters were sent in response to a June 2018 GAO report that found weaknesses in contract pharmacies' compliance with 340B Program requirements.[28]

Because prescription drug affordability is such a prevalent and predominant problem in the U.S. healthcare industry, it is debatable as to whether making significant cuts to the 340B Program is the most effective way to address it. The AHA asserts that the 340B Program represents a very small portion of national drug expenditures, and 340B Health states that the 340B presence in the overall drug market "*cannot plausibly be causing manufacturers to increase drug prices*."[29] According to HRSA data, in 2016, the 340B Program accounted for only 3.6% of the total U.S. drug market.[30] Time will tell if the current administration's efforts to lower drug prices will actually increase access and affordability for the patient, or if drug manufacturers will remain the sole market beneficiaries in the pharmaceutical industry

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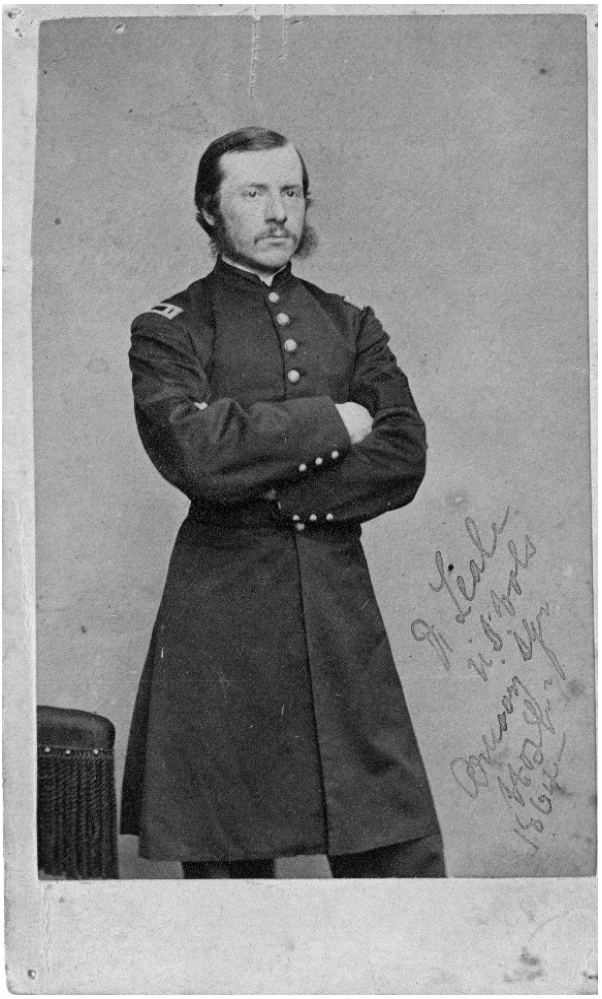
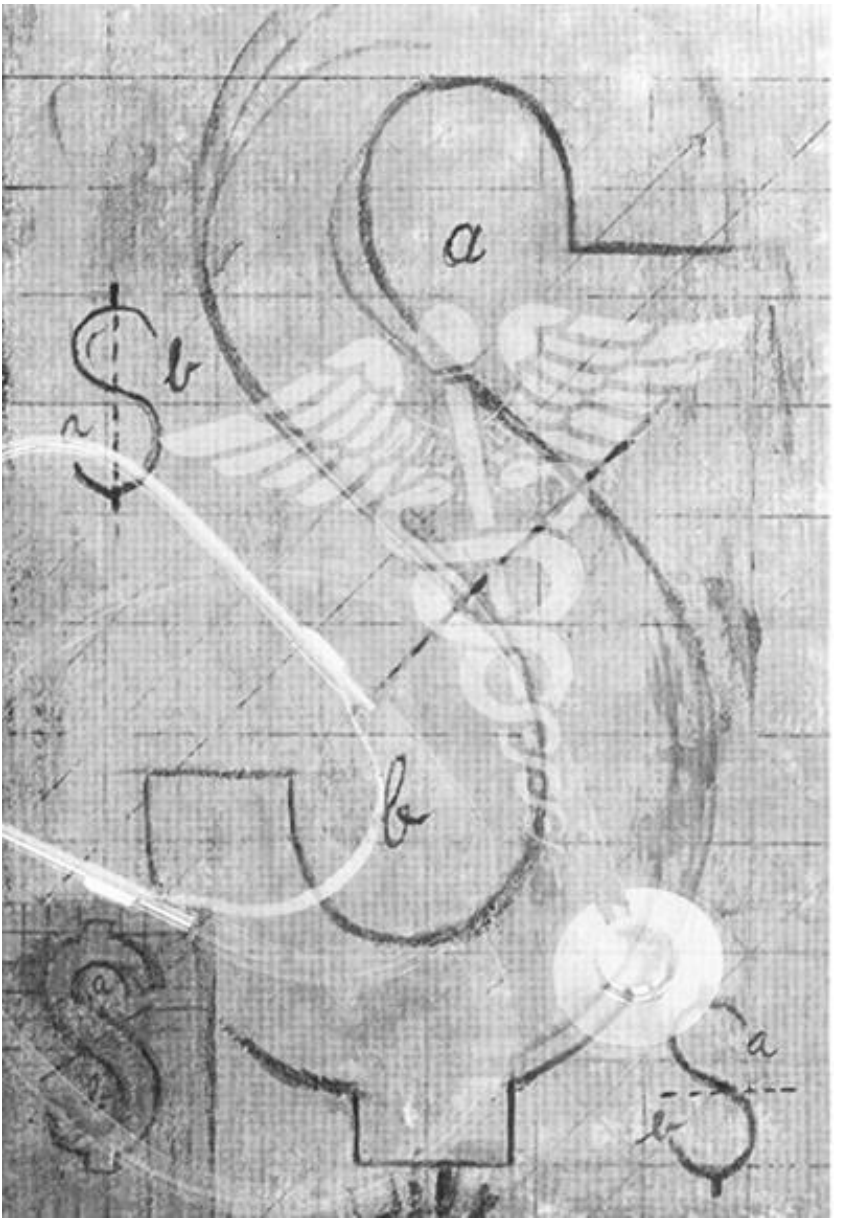


Charles Leale (1842-1932)
Union doctor who was the first to arrive on the scene when President Abraham Lincoln was assassinated.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IV. COMPETITION TOPICS

CVS Announces Potential Acquisition of Aetna

[Excerpted from the article published in November 2017.]

As of October 26, 2017, the *Wall Street Journal* announced that CVS Health Corporation is in discussions with Aetna Inc. regarding a prospective acquisition.[1] This transaction would potentially give CVS a strategic marketplace advantage over one of its main competitors, Amazon,[2] which is expected to enter the pharmacy business after having acquired licenses in several states to operate as a pharmacy wholesaler.[3] The acquisition would join Aetna's insurance division with CVS's *pharmacy benefit management* (PBM) division,[4] allowing CVS to expand on and secure the number of members for its PBM,[5] as well as providing the entity with more leverage over pharmaceutical manufacturers when negotiating the cost of drugs.[6] The consolidation could happen as early as December 2017,[7] and would be the largest business transaction of the year,[8] totaling more than $70 billion.[9] However, the *Department of Justice* (DOJ) may challenge this acquisition, given the large market shares held by both Aetna and CVS, and the acquisition's potential negative effects on consumers.[10] The acquisition may also significantly impact the healthcare industry, and may pose a direct threat to competitors of CVS and Aetna, including: Amazon, Anthem, Express Scripts, Centene, WellCare, and Humana.[11] In this *Health Capital Topics* article, the potential effects of consolidation between Aetna and CVS on both consumers and the healthcare industry will be discussed.

It remains to be seen whether this proposed consolidation will elicit attention from the DOJ, which could ultimately lead to the abandonment of acquisition plans.[12] In the past, several proposed consolidations failed to advance after encountering legal scrutiny from the DOJ and federal judges, such as the proposed 2017 Cigna-Anthem merger and the proposed 2017 Aetna-Humana merger,[13] because they had the potential to harm consumers.[14] However, unlike the proposed Cigna-Anthem or Aetna-Humana mergers, which were examples of *horizontal* integration, i.e., integration between two similar types of entities, the CVS-Aetna proposed merger is an example of *vertical* integration, or integration between a buyer and supplier, making the effects of the acquisition more unclear due to the lack of legal precedence for these types of antitrust cases.[15] The DOJ may argue that the CVS-Aetna merger is more harmful to consumers than the Cigna-Anthem or Aetna-Humana mergers because of an effect termed the *double margins puzzle*.[16] With vertical integration, at least two types of organizations with different profit-earning motives consolidate to form two profit centers along a supply chain, unlike horizontal integration, in which at least two types of organizations with similar profit-earning motives consolidate to form one profit center.[17] Vertical integration may be more harmful to consumers because the formation of two profit centers along a supply chain may give the companies more leverage to negotiate for higher prices, increasing the price of goods and services more so than if the companies only had one profit center.[18] Conversely, CVS and Aetna may argue that the

integration of CVS's PBM division and Aetna's insurance division facilitates cost savings that will ultimately lower the cost of services for consumers.[19] Such efficiencies may primarily arise from the increased leverage that the joined companies would have over pharmaceutical companies when negotiating drug prices.[20] However, the DOJ may argue that CVS and Aetna will have little incentive to allocate some of the cost savings to consumers, and will instead retain the profits for themselves.[21]

The acquisition of Aetna by CVS will likely alter the dynamic of the healthcare industry. For example, consolidation is likely to make CVS and Aetna a competitor to Amazon, which, as noted above, is seeking to enter the pharmaceutical wholesaler business after receiving licenses to do so in several states.[22] Further, vertical integration between CVS's PBM arm and Aetna's health insurance arm allows for the elimination of a separate PBM middle-man, increasing organizational efficiencies, and posing a threat to stand-alone PBMs such as Express Scripts, as well as insurers, such as WellCare, Centene, Anthem, and Humana, who are all direct competitors.[23] Anthem, which recently terminated its partnership with Express Scripts,[24] is now partnering with CVS to form its own PBM.[25] An acquisition of Aetna by CVS may generate a conflict of interest, in which CVS may have to terminate its relationship with Anthem, requiring Anthem to find a new PBM with which to partner.[26] Overall, the acquisition is likely to spur change within the healthcare industry, with not only horizontal integration continuing to occur, but with vertical integration becoming increasingly common as well.

If the acquisition of Aetna by CVS is allowed to proceed, it would be one of the largest transactions in the U.S. healthcare industry, as CVS currently holds 25 percent of the U.S. market share for prescription drug sales,[27] and Aetna holds 6 percent of the market share for health insurance plans.[28] An acquisition of this size may give rise to regulatory scrutiny from the DOJ due to concerns over the potential negative effects that the consolidation may have on consumers.[29] If the DOJ determines that the acquisition is in fact harmful to consumers, then acquisition plans are likely to come to a halt, and a legal precedent is likely to be set for future vertical integration cases among other healthcare organizations.[30] However, CVS and Aetna may argue that vertical integration between the two companies will help lower the cost of providing healthcare services through increased efficiencies, effectively benefitting consumers.[31] Consolidation among the two entities may also bring significant change to the healthcare industry, and may pose a threat to their competitors, such as other health insurers and PBMs.[32] In recent years, consolidation has become a more common practice among healthcare entities, as the cost of providing healthcare services is becoming increasingly unaffordable for these organizations, due to the rising costs of medical supplies and pharmaceuticals,[33] as well as declining reimbursement rates from payors.[34] Consolidation may help these organizations persevere in an increasingly competitive healthcare environment.

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Physician Manpower Utilization & The Role of Non-Physician Providers

[Excerpted from the article published in Chicago Medicine in February 2018.]

Concerns related to the availability and adequacy of the physician workforce have been debated in the healthcare industry for decades. Although often centered on physician supply and demand, these discussions realize the multifactorial nature of patient utilization of the physician workforce for providing care within the current healthcare delivery system. As stated in a 2002 *Health Affairs* editorial, "…*a larger health care workforce has hardly been synonymous with a better one*."[1] In this article, the current status of the physician workforce, and how the use of *non-physician providers* (NPPs) could affect potential future physician utilization, will be discussed.

Overview of Workforce Planning

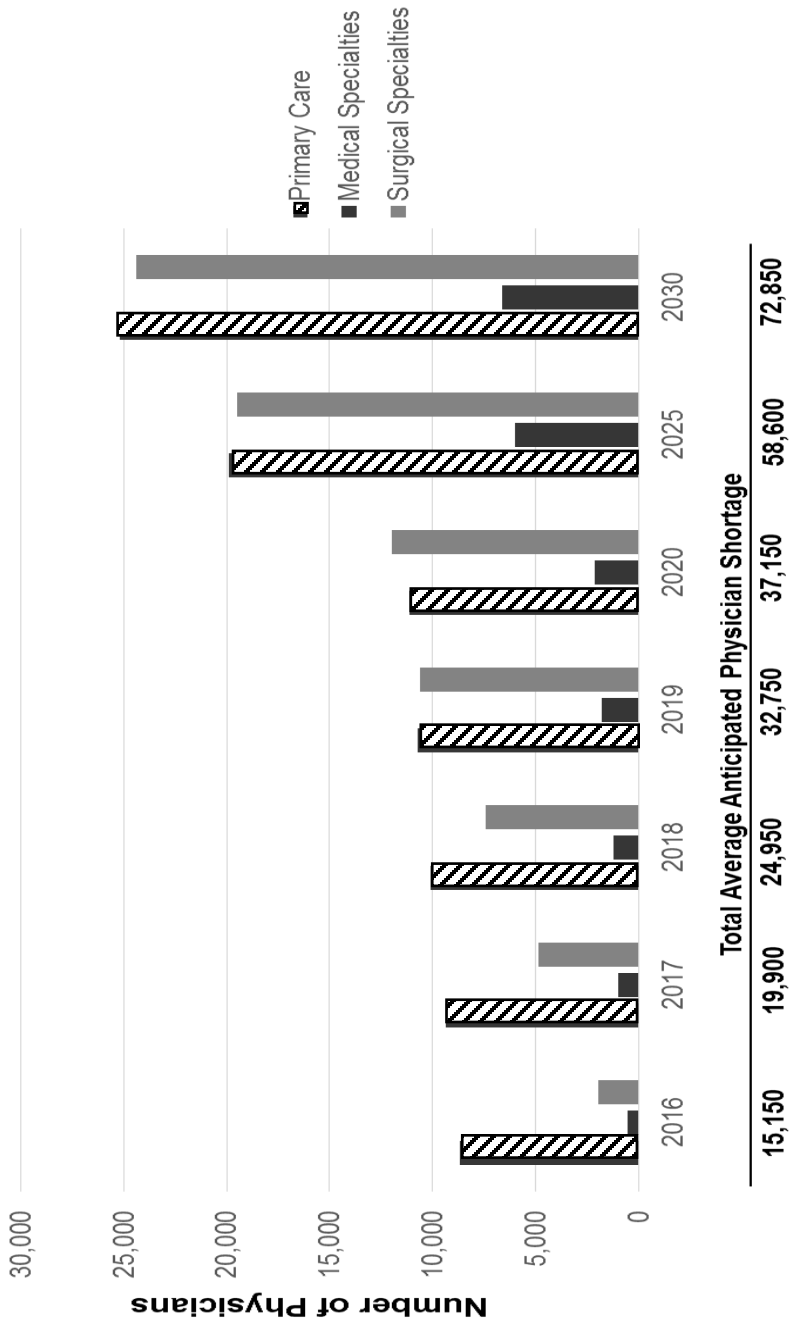
Healthcare workforce planning has become much more complex than a simple numbers game related to supply and demand, due not only to budget constraints, but also to the changing healthcare environment. Planning now requires that both *cyclical factors*, e.g., short-term changes in economic cycles and the current healthcare environment, and *structural factors*, e.g., long-term factors such as population and disease trends and healthcare infrastructure, be addressed.[2] Additionally, traditional models often evaluated providers within separate "*silos*", e.g., physicians and nurses.[3] More recent models have begun to consider the "*plasticity*" of healthcare workers, both in terms of *horizontal integration* among different physician specialties, e.g., the provision of obstetrics care by both physicians trained in obstetrics/gynecology and family practice, and, more recently, *vertical integration*, i.e., task sharing across different occupational groups such as physicians and NPPs.[4]

The Current Healthcare Workforce: Supply & Demand

Recent studies by the *Association for American Medical Colleges* (AAMC) and the *Health Resources and Services Administration* (HRSA) have both predicted that physician demand is, and will continue to, grow faster than supply, leading to a future shortfall of total physicians.[5] The AAMC has estimated that by 2030, there will be a total physician shortage of 40,800 to 104,900 physicians (see Figure 1).[6]

See Next Page for

Figure 1: Anticipated Physician Shortage by Specialty Category[7]


Primary Care
Medical Specialties
Surgical Specialties
Number of Physicians
30,000
25,000
20,000
15,000
10,000
5,000
0
2016
2017
2018
2019
2020
2025
2030
Total Average Anticipated Physician Shortage
15,150
19,900
24,950
32,750
37,150
58,600
72,850

Current Trends in Physician Supply

As of 2016, there were approximately 272 active physicians, 92 active primary care physicians, and 7.8 active general surgeons per 100,000 population in the U.S.[8] This might be considered adequate if the workforce was appropriately distributed; however, estimated shortages in physician supply fluctuate based on geographic area. As of December 2017, HRSA identified 7,118 *Health Professional Shortage Areas* (HPSA) in primary care.[9] A number of the provisions in the 2010 *Patient Protection and Affordable Care Act* (ACA) have attempted to address this disproportionality by providing funds to underrepresented minorities from rural areas to pursue careers in healthcare (in hopes that they might return to these locations to practice); supporting physician recruitment and retention in underserved areas; and, encouraging medical students to pursue focused training and experiences in rural and urban HPSAs.[10]

There is also growing concern regarding the number of active physicians nearing retirement age, particularly with the aging "*baby boomer"* population.[11] As of 2016, more than 30% of physicians were over the age of 60.[12] Compounding this concern, data have shown that physicians under the age of 35 are working approximately 13% fewer hours than their older colleagues.[13] These trends, in addition to the stagnant number of new physicians entering the workforce due to the "*cap*" on *graduate medical education* (GME) funding by Medicare,[14] further curtails the supply of physician services.

Current Trends in Physician Demand

The primary driver of increasing healthcare demand continues to be the growth and aging of the general population. While the U.S. population is projected to grow 12% from 2015 to 2030, the percentage of the population aged 65 and older is projected to grow by 55%.[15] Given that the elderly population comprises only 14% of the total population, but accounts for more than 30% of inpatient procedures and diagnostic treatments,[16] the demand on the healthcare workforce is predicted to concurrently increase with the aging of the population.[17] Additionally, the expansion of health insurance coverage under the ACA, which has increased the number of insured non-elderly people by approximately 19 million from 2010 to 2015,[18] has amplified the demand for physician services. Although the non-partisan *Congressional Budget Office* has estimated that the number of uninsured will rise due to the recent repeal of the financial penalties related to the *Individual Mandate*,[19] it is unknown how this repeal will impact physician demand estimates.

Utilization of NPPS

The expansion of NPP services has been viewed as a strategy to improve access to care, contain healthcare costs, and relieve anticipated physician shortages.[20] Since the concept of *nurse practitioners* (NP) was first introduced in the 1960s,[21] the role has evolved and is now part of the larger umbrella term of

NPPs, otherwise known as "*mid-level*" providers; *advanced practice registered nurses* (APRN); or, advanced practice providers. Examples of NPP roles include: NPs; *physician assistants* (PA); *certified registered nurse anesthetists* (CRNA); and, *certified nurse midwives* (CNM). Most recently, in 2017, Missouri became the first state to create a new NPP role – the a*ssistant physician* (AP) – for those individuals who have completed medical school but not a post-graduate residency program.[22]

The role of the NPP was originally created to expand a primary care physician's workload capacity and allow more patients to access primary care services, particularly in underserved or rural areas. Additionally, health systems could (ideally) improve access to primary care by relieving physicians from performing many basic and necessary, but time consuming, tasks common within primary care, including counseling on lifestyle issues and management of routine screening and preventive care. Delegating these tasks could reduce costs to health systems while allowing for advancement opportunities for nurses and increasing the quality of patient care.

In recent years, the role of NPPs within the healthcare industry has expanded. There has been much debate regarding the appropriate scope of care for NPPs, including autonomy regarding prescriptive abilities and supervision of services, which scope remains highly varied by title, state legislation, and even institutional policy. One of the primary concerns regarding the increasing use and autonomy of NPPs is whether the care provided is as safe and efficient as care provided by physicians. Multiple studies have addressed this issue, particularly in the realm of primary care, and found that nurse-led care is equivalent to physician care with regard to patient clinical outcomes, safety, and satisfaction.[23]

Estimates predict that the growth rates of NPPs will outpace that of physicians in the coming years. From 2015 to 2030, the projected Physician-to-PA ratio is expected to fall from approximately 7:1 to 4:1, and the Physician-to-APRN ratio from approximately 4:1 to 2:1.[24] This will impact multiple medical specialties, but most significantly those of anesthesiology; obstetrics and gynecology; and, primary care.[25] Data have shown that NPPs are more likely than physicians to pursue primary care.[26] For instance, a 2013 *Health Affairs* study showed that NPs practicing in states with fewer restrictive regulations were 2.5 times more likely to provide primary care to Medicare patients than their counterparts in the most restrictive states.[27]

What Does This Mean for Physicians?

Job openings for NPPs are growing at an annual rate of approximately 160%, and it appears unlikely that the growth in the healthcare market for NPPs will decrease any time soon.[28] While physician organizations have historically voiced unease about the potential supplanting of physicians with NPPs, thus far, NPPs have served an important role in caring for underserved communities with unmet needs,[29] and in the future, NPPs likely will be needed to offset the

increasing demand for healthcare services, as evidenced by the ongoing (and growing) physician shortage.

The rising number of retail clinics[30] (often staffed by NPPs), and increased utilization of NPPs in general, are expected to supplement unmet demand for physician services, especially in primary care.[31] A growing number of hospitals and health systems are developing partnerships with retail clinics to increase their patient outreach and provide care for many routine medical situations.[32] The NPPs staffing those clinics may be able to unburden physicians, who can delegate the more routine medical treatments to NPPs and focus on higher acuity patients.[33] Further, physicians are being sought out to serve in managerial positions for hospitals, health systems, and commercial payors (e.g., medical and service line directors, executive leadership), and provide clinical input for the purposes of *evidence-based medicine* in this era of value-based, quality-driven reimbursement.[34]

It has also been shown that physician practices that utilize NPPs typically perform better financially and have higher physician compensation.[35] This may be due in part to increased practice efficiency, allowing physicians to concentrate on more complex patients or procedures.[36] In addition, NPPs who are directly supervised by physicians can bill for 100% (as *incident-to* billing) of the physician fee schedule, while unsupervised NPPs are typically reimbursed at only 85%, thereby directly increasing practice revenue.[37] As such, it appears that NPP utilization has the ability to augment a physician's practice without supplanting physician services.

Future Workforce Planning Efforts

Of the myriad factors that affect physician workforce planning, the utilization of NPPs remains a valid strategy to positively impact both the supply and demand of healthcare practitioners within the ever-changing healthcare environment. In particular, given the aging of the "*baby boomer*" population and an increased focus on the management of chronic diseases (an area in which NPPs have been shown to be effective providers, as discussed above), NPPs have the potential to greatly alleviate the growing demands on the physician workforce. Challenges remain with regard to NPP scope of practice, as well as the impact on patient care and costs that require continued assessment and evaluation.[38] Notwithstanding this uncertainty, NPPs will likely serve an important role in the healthcare delivery system going forward, providing an already stretched physician workforce the availability to care for higher acuity patients and the time to assume a leadership role and take a meaningful "*seat at the table*" in directing the future of the U.S. healthcare delivery system.

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Hospitals Form Pharmaceutical Company to Combat Rising Drug Prices

[Excerpted from the article published in March 2018.]

On January 18, 2018, four health systems – *Intermountain Healthcare*, *Ascension*, *SSM Health*, and *Trinity Health*, along with the *U.S. Veterans Affairs Department* (VA) – announced their intention to establish a non-profit, generic pharmaceutical company, with the goal of developing cheaper, more accessible drugs.[1] In the years preceding this announcement, hospitals experienced artificially-induced drug shortages, which led to exceedingly high drug prices.[2] In fact, between the years of 2006 and 2016, total prescription drug expenditures increased by nearly 50 percent.[3] Further, drugs such as morphine and *Nitropress*, an essential heart medication, have encountered persistent shortages and abrupt price increases in the recent past.[4] Over time, these price increases have created enough of a financial burden on health systems so as to prompt them to finally take action against the pharmaceutical industry.[5] The creation of a new drug manufacturing company may pose a direct threat to the pharmaceutical industry, which has ignored repeated requests from hospitals to lower their prices.[6] The partner health systems consist of at least 450 hospitals, and more than 100 hospitals joined the initiative within a few weeks of the announcement, with an expectation of over 1,000 hospital participants in the future.[7] It is believed that up to a third of all U.S. hospital operators may become members of the new nonprofit venture, which is expected to become operational later this year.[8]

The announced plans highlight an emerging healthcare industry trend in which buyers are consolidating with their suppliers, otherwise known as *vertical integration*.[9] This trend toward vertical integration includes hospitals as well as other sectors within the healthcare industry, such as health insurance companies and *pharmaceutical benefit management* (PBM) companies.[10] For example, on December 3, 2017, *CVS Health* announced that it will acquire *Aetna* for $69 billion in order to combine CVS's PBM division with Aetna's insurance division.[11] Additionally, in 2017, *Optum*, a subsidiary of health insurer *United Health Group*, announced that it would consolidate with both *Surgical Care Affiliates*, a walk-in surgical practice chain,[12] and *DaVita Medical Group*, one of the largest independent medical groups in the U.S.[13] Most recently, in March 2018, *Cigna* announced acquisition of *Express Scripts* (the last major independent PBM) for $52 billion.[14] These transactions are a departure from past instances of *horizontal integration*, or a type of integration in which two similar types of entities consolidate.[15] In recent years, several horizontal mergers have been blocked by antitrust authorities, such as the case with the failed *Humana-Aetna* merger, as well as the failed *Cigna-Anthem* merger.[16] Whether future instances of vertically integrated transactions will experience this level of regulatory scrutiny still remains in question.

News of consolidation within other sectors of the healthcare industry, e.g., health insurance and PBMs, comes in the wake of the financial hardship

experienced by many hospitals struggling to navigate declining growth in Medicare reimbursement rates.[17] Therefore, hospitals have taken it upon themselves to vertically integrate with other healthcare organizations along the supply chain.[18] However, this current plan to create a hospital-based drug manufacturing company is not without its challenges, as taking on such a project requires significant financial capital, as well as a considerable amount of time for FDA drug approvals and facility inspections.[19] There is still discussion among the health systems as to whether they will manufacture the drugs themselves, or if the drugs will be developed by subcontracted companies.[20] Acquiring or contracting with a drug manufacturer may be a more efficient way to carry out the initiative, and building a new infrastructure may trigger regulatory and financial concerns.[21] Uncertainty remains as to whether this proposal will be effective at alleviating drug shortages and lowering drug prices, as previous attempts to form a specialty-pharmacy network among hospitals failed.[22] Nonetheless, some industry leaders are still optimistic, such as Michael Rea, CEO of *Rx Savings Solutions*, a company that sells software to help health insurers lower drug costs, who stated:

> "*There are no new entrants to the [pharmaceutical] market because it is so difficult to get into…But having the capital source of hospitals is a great start—now they need to execute on the plan.*"[23]

With drug spending expected to increase by 8 percent in 2018, health systems are proactively seeking solutions to combat rising drug costs, such as the proposal to establish a hospital-based drug manufacturing company.[24] According to Laura Kaiser, President and CEO of SSM Health,

> "*The best way to control the rising cost of healthcare in the U.S. is for payers, providers and pharmaceutical companies to work together and share responsibility in making care affordable…Until that time, initiatives such as this will foster our ability to protect patients from drug shortages and price increases that limit their ability to access the care they need.*"[25]

Although this initiative attempts to confront the problem of rising drug prices directly, the health systems involved may still face many challenges, including issues of limited capital funding as well as regulatory scrutiny from the FDA, *Federal Trade Commission* (FTC), and *Department of Justice* (DOJ). Further, previous instances of blocked horizontal mergers may foreshadow potential regulatory scrutiny toward vertical mergers. Whether the health systems are successful in their attempts to implement this solution depends on their ability to overcome these forces.

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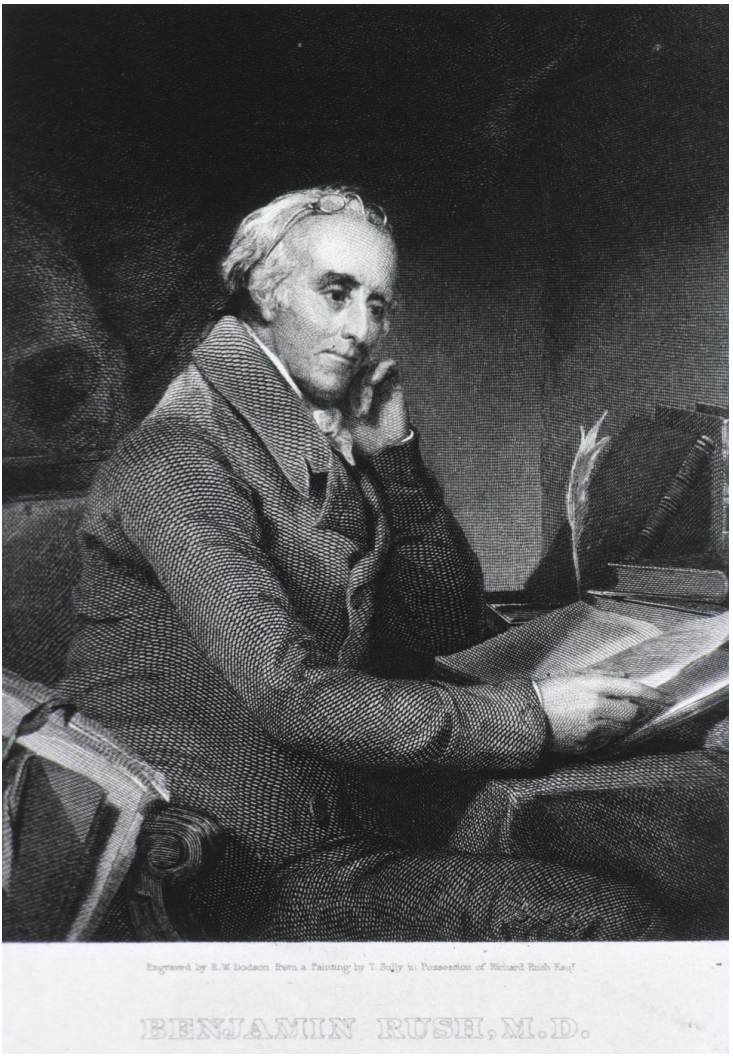

Benjamin Rush (1746-1813)
Founding Father of the United States, and Surgeon General of the Continental Army, as well as a physician, social reformer, educator, and humanitarian.

Capitalism in U.S. Healthcare: The Case of Walmart

[Excerpted from the article published in April 2018.]

The 2010 *Patient Protection and Affordable Care Act* (ACA), a/k/a Obamacare,[1] passed in response to untenable rising costs in the healthcare industry, commenced the latest iteration of U.S. healthcare reform. Although the ACA substantially decreased the number of uninsured Americans,[2] and instituted myriad value-based reimbursement programs (e.g., accountable care organizations),[3] it has not been the panacea for the continuously rising cost of U.S. healthcare (projected to comprise almost 20% of the *gross domestic product* [GDP] by 2026) that was expected.[4] As a result, the private sector, e.g., retail giants such as Amazon and Walmart, has taken up the mantle to solve what has been described as "*the single-most pressing American economic issue*" of the 21st century.[5] In addition, with the recent repeal of the ACA's *Individual Mandate* penalty[6] and general efforts toward "*de-regulation*" of U.S. healthcare under the Trump Administration,[7] new opportunities for alternative, non-traditional players in the healthcare market have expanded exponentially. Indeed, healthcare innovation has become a field now described by industry stakeholders as "*an emerging market in plain sight*."[8]

Most recently, integration and consolidation among healthcare providers; payors; pharmacy benefit management companies; and, private retail have proliferated.[9] On March 29, 2018, the latest in this merger/acquisition series—the commencement of preliminary talks regarding the potential acquisition of Humana by Walmart—was announced.[10] Unlike Amazon's January 30, 2018 announcement of a new joint venture, which is its first foray into the field of healthcare (see further discussion on this joint venture in the March 2018 issue of *Health Capital Topics*),[11] Walmart has been a long-time player in the healthcare market, with footholds most notably in pharmacies and retail clinics.[12] In 2014, Walmart implemented the "*Healthcare Begins Here*" initiative, which provided consumers with free health screenings; access to immunizations; and, assistance with the (then new) ACA health insurance exchanges.[13] At that time, it announced its intentions "*to be the number one healthcare provider in the industry*."[14]

Currently, Walmart operates pharmacies in most of its more than 5,300 U.S. stores, as well as several retail clinics in select states.[15] Additionally, the retail giant has pioneered and supported innovative and successful programs that have resulted in cost savings for their bottom line, as well as consumers' pocketbooks, such as Walmart's $4 Prescription Program (which has purportedly saved consumers more than $3 billion over the last decade),[16] and participation in the *Employers Centers of Excellence Network* (ECEN).[17] The ECEN, wherein employers directly contract with select hospital systems that provide bundled services to their employees at a 10 to 15 percent discount compared to standard *fee-for-service* (FFS) arrangements, has been shown to decrease out-of-pocket and overall healthcare costs; result in better quality

outcomes; decrease the performance of unnecessary procedures; and, increase employee satisfaction.[18]

In its most recent expedition into healthcare, Walmart's potential acquisition of Humana would not only be the largest acquisition in Walmart's history thus far (estimated at approximately $37 billion), it would instantly make Walmart one of the largest insurers in the U.S.[19] Further, given Humana's significant market share of Medicare Advantage programs,[20] and acquisition of a minority stake in Kindred Healthcare (one of the largest home healthcare providers in the U.S.),[21] this deal is poised to particularly impact the aging *Baby Boomer* population.[22] This type of vertical integration is primarily pursued to help control costs, but can also serve to diversify revenue streams and improve care coordination, as has been demonstrated by United Healthcare's success with pharmaceutical benefit manager Optum, which it acquired in 2015.[23] While this move may be potentially transformative for Walmart consumers, it will ultimately depend on the determination of the legality of other vertical integration plans (e.g., CVS and Aetna, Cigna and Express Scripts) by the *Department of Justice* (DOJ), *Federal Trade Commission* (FTC), and other lawmakers, with respect to the potential anti-competitive effects of such relationships.[24]

The Walmart-Humana deal, although just the latest in a string of recent consolidation talks, has drawn a significant amount of attention, in large part due to Walmart's consumer footprint as the largest retailer in the world (with 2.3 million employees serving almost 270 million consumers each week worldwide);[25] with "*employees and customers [that] come from all demographic groups…Walmart has access to…Americans from all social classes, and not just the [one] 1 percent.*"[26] However, unlike the traditional healthcare delivery system, Walmart's investment in healthcare has not been based upon the ethics of the Hippocratic Oath (a required oath to uphold professional medical ethical standards),[27] but rather on the concept of "*marketing 10. Go to where the people are*."[28] In continuing to broaden its reach into current healthcare delivery infrastructure, Walmart aspires to "*build an 'ecosystem' [of]…referrals*"[29] that can become a "*one-stop shop*"[30] for consumers' healthcare needs. As lawmakers consider the possible anti-competitive effects of recent proposals for vertical acquisition, Walmart's newest venture into healthcare has the potential to provide an innovative view as to what the U.S. healthcare system could look like if it embraced the principles of capitalism.

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V. TECHNOLOGY TOPICS

FDA Announces Approval of a Digital Pill that Tracks Pill Consumption

[Excerpted from the article published in December 2017.]

On November 13, 2017, the *Food and Drug Administration* (FDA) announced the approval of the first "*digital pill*" – a drug that will track medication ingestion by a patient.[1] Specifically, this pill is a digital version of *Abilify*, an antipsychotic used to treat conditions such as schizophrenia, bipolar and depression, otherwise known as *Abilify MyCite*.[2] Patients can sign a consent waiver allowing a physician and up to four other people to view electronic data on a smartphone application related to the date and time the pill was taken, and viewing permissions can be revoked by the patient at any time.[3] The pill was designed to address the issue of nonadherence to medication regimens, which is an issue for many diseases, including psychiatric disorders that Abilify treats, e.g., schizophrenia and bipolar, as well as chronic conditions such as hypertension and high cholesterol.[4] Many patients, such as the elderly, may find the digital pill consumption tracking useful, as they may be prone to forget to take their medication.[5] However, the emergence of the pill is not without controversy, as both physicians and patients have concerns related to the potentially coercive nature of medication-consumption tracking.[6]

The digital pill is embedded with a sensor that is the size of a grain of sand and is made of copper, silicon, and magnesium; the pill is activated when it comes into contact with stomach fluid.[7] Once activated, the sensor transmits a signal to a Band-Aid-like patch, which is worn on the left side of the patient's torso and must be replaced every seven days.[8] The patch then sends the date and time that the pill was ingested to a smartphone application that is viewable by anyone to whom the patient designates access.[9] This is the first approved drug to have a sensor embedded in the pill itself; prior to the creation of this pill, sensors could only be placed inside capsules.[10] Although the digital pill was designed to address the issue of patient non-compliance, the effects on health outcomes, due to increased prescription adherence, has not yet been determined.[11] However, encapsulated ingestible sensors previously have been proven to be effective at increasing medication regimen adherence for patients experiencing uncontrolled hypertension.[12] The use of other pharmaceutical technologies to track medication ingestion showed promising results when used to promote treatment adherence for schizophrenia and tuberculosis patients, such as AiCure, a smartphone-based visual recognition system that documents patients' medication consumption.[13]

The pill prompts discussion over ethical issues surrounding patient autonomy. Both experts and patients have expressed concerns that the digital pill could become coercive in nature, e.g., the government could use the pill as a condition for parole, or for the release of a patient committed to a psychiatric facility.[14] *Otsuka*, the manufacturer of Abilify, asserts that the assumptions underlying this concern are flawed because the pill's consumption-tracking technology

only works if the patient is compliant with wearing the associated patch.[15] However, some patients who participated in the drug's clinical trials stated that the idea of pill-consumption tracking was "*overbearing*" and "*unnecessary*."[16] Despite apprehensive attitudes toward drug consumption-tracking, the FDA affirms that this technology may benefit some patients,[17] such as those who tend to forget to take their medication, or those wanting to be held accountable for taking their medications.[18] Further, caregivers and family members may benefit from consumption-tracking technology if they are concerned as to whether the patient has taken their medication.[19]

Many health experts have expressed surprise that the first digital pill was created for a drug that treats disorders like schizophrenia, given that many schizophrenia patients have delusions and paranoia about being watched.[20] It is worth noting, however, that this technology can be applicable to the treatment of other diseases, especially those requiring strict medication regimens, such as heart disease, stroke, and *human immunodeficiency virus* (H.I.V.).[21] Medication consumption-tracking technologies are still limited in their commercial use, but this may change in subsequent years due to the fact that several pharmaceutical companies are investing in and manufacturing their own digital pills, including etectRx, a Florida company that designed the ID-Cap, an ingestible sensor that is currently being tested with opioids and other drugs.[22] Before the use of these technologies becomes widespread, more research may be needed to determine their ability to improve health outcomes, and concerns may need to be addressed related to patient privacy, convenience, and cost.[23]

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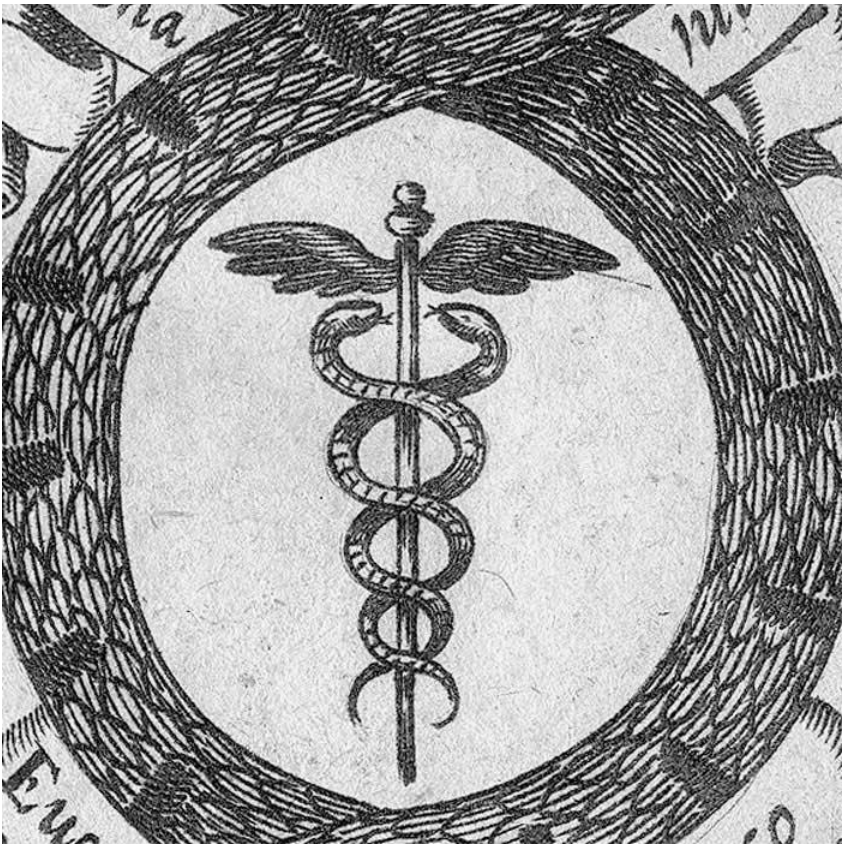

Detail from t.p. of Marco Amelio Severino. Viper Pythia. (Patavii: Typis Pauli Frambotti, 1651)

Amazon Joint Venture to Create Healthcare Company

[Excerpted from the article published in March 2018.]

On January 30, 2018, Amazon, Berkshire Hathaway, and JPMorgan Chase & Co. announced a new partnership dedicated to developing an independent, not-for-profit healthcare company for their respective employees.[1] The project's goals include creating simpler, higher quality, and transparent healthcare for the companies' more than one million employees at lower costs, by using innovative technological solutions to address current problems seen in healthcare.[2] The announcement created consternation among various healthcare industry giants, and was accompanied by an estimated $30 billion decrease in market shares for the top ten health insurance and pharmaceutical companies within two hours of its publication.[3] This venture denotes Amazon's first serious foray into the healthcare industry, though not its first effort to expand its innovative approaches across industry lines, e.g., the acquisition of Whole Foods in August 2017.[4]

Amazon's fledgling healthcare venture has stimulated robust debate; the move has been characterized as "*disruptive*," viewed with skepticism, and lauded as an opportunity for market diversification.[5] Nonetheless, it appears that Amazon has no intention of curtailing its incursion into the healthcare marketplace. In February 2018, *The Wall Street Journal* reported that Amazon was piloting an expansion of its burgeoning medical supply business, with the goal of revolutionizing the traditional model of hospital purchasing.[6]

While this new partnership has garnered much attention, both good and bad, it is not the first of its kind. The *Health Transformation Alliance* (HTA), established in 2016, is a nonprofit cooperative comprised of 46 large self-funded companies, e.g., American Express, IBM, Johnson & Johnson, that have joined together to offer employees and their families an alliance by which to negotiate healthcare contracts and change care delivery.[7] Currently, HTA is piloting structured group contracts with United Healthcare and Cigna to provide care for common and costly healthcare conditions, whereby providers are paid based on performance targets instead of volume.[8] While HTA anticipates a savings of more than $600 million over three years based on this scheme, they acknowledge that this strategy simply takes advantage of their greater leveraging power, is not truly "*transformative*," and probably will not last in the long term.[9] HTA's exploitation of the current healthcare marketplace, where size equates to power, simply emphasizes the systemic flaws that have allowed for the continued corporatization and commoditization of healthcare services and providers, and builds upon the pay-for-performance models that have not yet been proven to increase quality or decrease cost. In contrast, during an interview with CNBC, Warren Buffet of Berkshire Hathaway stated that this new joint venture plans to do more than "*simply squeezing middlemen for better prices*,"[10] but also acknowledges that "*it's gonna be difficult to…really make fundamental change. But we're committed to it*."[11] However, critics remain skeptical about the feasibility of cutting out the healthcare industry "*middlemen*," e.g., insurers, pharmaceutical benefit managers, and drug distributors, without adequate existing infrastructure, as well as the likelihood of successfully tackling the often contradictory goals of reducing spending and increasing quality.[12]

The trio has not yet released much detail regarding the new venture or plans for implementing potential change. However, speculation has run rampant since the announcement. In a March 2018 webinar by the Polsinelli law firm, industry experts discussed the "*Potential Amazon Effect*," whereby they posited that Amazon may revolutionize the healthcare market by applying past successes in their ability to change consumers' purchasing behaviors and creating simpler and more efficient distribution models that create value in high quality providers.[13] Although Warren Buffett, in a recent interview with CNBC, did not allude to any particular plans for the venture, he did state that their first step will be to find the right CEO to head this new project within the next year.[14]

The healthcare industry has largely maintained the "*status quo*" over the past several decades with regard to the continued and growing inefficiencies that defy efforts of cost containment, driven by the stagnant policy of polarized political parties and the continued fiduciary incentives for stakeholders to maintain that status quo.[15] The government, while able to set goals and provide a regulatory framework to facilitate solutions to healthcare's overarching problems, often relies on private sector involvement to create and pilot the innovative and transformative tools to implement real change.[16] This is done by utilizing an "*assess-expand-or-end*" pilot approach to evaluating potential breakthrough innovations,[17] such as that pursued by *Centers for Medicare & Medicaid Services* (CMS) Administrator, Seema Verma, who stated in a *Wall Street Journal* op-ed that, "*[w]e are analyzing all [CMS] Innovation Center models to determine what is working and should continue, and what isn't and shouldn't…We will move away from the assumption that Washington can engineer a more efficient healthcare system from afar*."[18]

Amazon and its partners are pursuing a company that is "*free from profit-making incentives and constraints*."[19] This approach will not only spur additional support and investment, and ideally rally bipartisan support for larger scale changes, but, if effective, will also collectively reduce healthcare costs, potentially saving these partner companies billions of annual dollars spent on healthcare.[20] While this undertaking is still in its infancy, it has the potential to introduce a new, innovative view of how quality healthcare can be provided while simultaneously reducing costs, a feat that has been unachievable thus far in the U.S. healthcare system. At the very least, it will help determine how much of the country's continually growing healthcare costs are due to greed of "*middlemen*" versus flaws in systemic infrastructure.[21] Jeff Bezos, Amazon founder and CEO, stated that the partners are aware of the complexities and difficulties associated with these goals, and intimates that "*success is going to require talented experts, a beginner's mind, and a long-term orientation.*"[22] While some view this venture as foolhardy, and others with burgeoning hope, U.S. history is testimony to a litany of failed efforts in the realm of healthcare innovation and reform, and it remains to be seen whether Amazon and its new partners can succeed where others have not.

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Sir William Fergusson, FRCS, FRS, FRSE (1808-1877)
Practical surgeon of Edinburgh

Renewed Public & Private Efforts to Increase Access to Patient Data

[Excerpted from the article published in May 2018.]

On May 8, 2018, Change Healthcare, a healthcare technology company, announced that it plans to partner with Adobe and Microsoft to develop a cloud-based tool that can collect, aggregate, and activate consumer data from various healthcare *information technology* (IT) sources, such as *electronic health records* (EHRs), registration, scheduling, and billing.[1] Specifically, the tool will bring together three different platforms, including *Adobe Experience Cloud*, *Microsoft Azure*, and the *Change Healthcare Intelligent Healthcare Network*, to streamline the online experiences of patients within a healthcare organization.[2] The tool will also help organizations gain a competitive advantage within the healthcare industry by assisting with revenue cycle and *patient relationship management* (PRM) initiatives, similar to the way retailers currently engage customers.[3] According to Matt Thompson, Adobe executive vice president of field operations, "*Patients today expect the same seamless, personalized experiences with healthcare providers they already know from other consumer brands…By collaborating with Microsoft and Change Healthcare, a pioneer in healthcare IT, we'll be able to help transform the way healthcare organizations engage with patients across all channels, from follow-up care coordination and caregiver personalization to cost transparency.*"[4] The partnership between Change Healthcare, Adobe, and Microsoft is just one of the many examples of technology companies attempting to transform EHRs into *Comprehensive Health Records* CHRs[5] – a step that will increase patient engagement, interoperability, and transparency within the healthcare industry.[6]

In addition to this announced partnership, other tech companies such as *Apple*, *Amazon*, and *Google* have begun their own initiatives to enter the health IT industry.[7] Apple is working in conjunction with various hospitals and EHR vendors (including *AthenaHealth*, *Cerner*, and *Epic*) to implement *Apple Health Records*, a program that aggregates EHR data and allows patients to view their medical records on an iPhone application.[8] Further, Google and Amazon are in the process of developing their own EHR platforms, otherwise known as *Google Cloud Healthcare* and *Amazon Web Services* (AWS), respectively.[9] Such technologies are examples of public *application programming interfaces* (APIs)[10] – software intermediaries that allow two applications to talk to each other – which have become increasingly reliant on *Fast Healthcare Interoperability Resources* (FHIR), a new and simple standard for exchanging healthcare data electronically.[11] Unlike the current standard for transferring healthcare data (i.e., C-CDA), which can only transfer entire documents, FHIR enables the sharing of specific data fields, such as sex or eye color, making information exchanges more interoperable, more efficient, and faster.[12] Given that these new EHR systems may be viewed as "*data repositories on which workflow and other applications can be built*,"[13] the use of public APIs and FHIR standards will likely pave the way for a "*true app*

store approach" to healthcare data,[14] subsequently leading to the "*deconstruction of monolithic EHRs*" by forcing existing EHR vendors to provide open access to patients' digital records.[15] As stated by Charles Jaffee, Chief Executive Officer of *Health Level Seven International* (HL7), the organization that created FHIR, the use of interoperable and public APIs is "*a significant step toward enabling patient engagement at a level that we hadn't appreciated in the past.*"[16]

In addition to the technology industry's efforts to facilitate the seamless exchange of healthcare information, the Trump Administration has listed the interoperability of, and access to, patient data as a top administration priority.[17] On March 6, 2018, the *Centers for Medicare and Medicaid Services* (CMS) announced *MyHealthEData*, a new initiative aimed at giving patients control over their healthcare information.[18] This government-wide initiative will be led by the *White House Office of American Innovation* in conjunction with the *Department of Health and Human Services* (HHS), CMS, the *Office of the National Coordinator for Health Information Technology* (ONC), the *National Institutes of Health* (NIH), and the *Department of Veterans Affairs* (VA), and will serve to allow patients to access their medical history electronically through a device or application.[19] Along with *MyHealthEData*, CMS also announced the launch of *Medicare's Blue Button 2.0*, in which Medicare beneficiaries can safely access and share their healthcare information, such as previous prescriptions, treatments, and procedures.[20] Both initiatives are an attempt to align with the October 2017 Executive Order to "*Promote Healthcare Choice and Competition Across the United States*," which mandates the improved access to and quality of data related to healthcare prices and outcomes.[21] According to Jared Kushner, leader of the White House Office of American Innovation, and Seema Verma, CMS Administrator, closed data systems can "*lead to duplicative testing, possibly missed opportunities to improve outcomes and an inability for doctors to coordinate patient care.*"[22] Kushner goes on to state that "*unleashing data will unleash innovation*" and that it is the Trump Administration's goal to put "*more decision making in [the] hands of customers*."[23]

After the successful conversion of physical health data into an electronic format by healthcare providers, in response to various EHR Incentive Programs, the Trump Administration is now spearheading efforts to make clinical information more interoperable and accessible to consumers.[24] At the same time, as noted above, several technology companies have begun initiating their own projects to increase patient engagement with their own medical records. The push for open access of health information through public APIs and FHIR standards presents a direct threat to existing EHR vendors, such as Cerner and Epic, who currently benefit from limiting data access and interoperability.[25] However, this threat may be offset by the fact that well-funded tech giants have historically struggled to enter the healthcare industry, suggesting that there may be future challenges in penetrating the market.[26] This was the case when Google attempted to create *Google Health*, an open API that was later discontinued after the service failed to gain widespread adoption.[27] Nonetheless, the Trump

Administration has stated its commitment to continuing its efforts to "*create a health care ecosystem that allows and encourages the health care market to tailor its products and services to compete for patients on the basis of value convenience, customization and quality*," so that the healthcare delivery system (and consequently, patients) can benefit from greater efficiencies and lower costs.[28]

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Anita Newcomb McGee, MD (1864-1940)
First Female Acting U.S. Assistant Surgeon General

VI. About
Health Capital Consultants

FIRM PROFILE

HCC HEALTH CAPITAL CONSULTANTS

HEALTH CAPITAL CONSULTANTS (HCC) is a nationally recognized healthcare economic and financial consulting firm specializing in valuation consulting; financial analysis, forecasting and modeling; litigation support & expert testimony; mergers and acquisitions; certified intermediary services; provider integration, consolidation & divestiture; certificate-of-need and other regulatory consulting; and, industry research services for healthcare providers and their advisors.

Founded in 1993, HCC has developed significant research resources; a staff of experienced professionals with strong credentials; a dedication to the discipline of process and planning; and, an organizational commitment to quality client service as the core ingredients for the cost-effective delivery of professional consulting services. HCC has served a diverse range of healthcare industry & medical professional clients in 49 states including hospitals & health systems (both tax exempt & for profit); outpatient & ambulatory facilities; management services organizations; clinics, solo & group private practices in a full range of medical specialties, subspecialties & allied health professions; managed care organizations; ancillary service providers; Federal and State agencies; public health and safety agencies; other related healthcare enterprises and agencies; and, these clients' advisory professionals.

The HCC project team's exclusive focus on the healthcare industry has provided a unique advantage for our clients. Over the years, our industry specialization has allowed HCC to maintain instantaneous access to a comprehensive library collection of healthcare industry-focused literature and data comprised of both historically-significant resources, as well as the most recent information available. HCC's information resources and network of healthcare industry resources, enhanced by our professional library and research staff, ensures that the HCC project team maintains the highest level of knowledge of the profession regarding the current and future trends of the specific industry or specialty market related to the project, as well as the U.S. healthcare industry overall.

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Clients have recognized HCC as setting the gold standard for the valuation of healthcare enterprises, assets, and services, in providing professional services such as:

- Valuation in all healthcare sectors & specialties, including:
  - Acute care hospitals, rehabilitation facilities, skilled nursing facilities, and other inpatient facilities;
  - Ambulatory surgery centers, diagnostic imaging centers, urgent care, and other outpatient facilities;
  - Compensation for professional clinical services, including physician administrative services, executive administrative services, board positions, and other healthcare related services;
  - Tangible and intangible assets, including covenants not to compete, rights to first refusal, and intellectual property;
- Commercial Reasonableness opinions;
- Accountable Care Organization (ACO) value metrics, capital formation, and development and integration;
- Financial feasibility analyses, including the development of forecasts, budgets and income distribution plans;
- Healthcare provider related merger and acquisition services, including integration, affiliation, acquisition and divestiture;
- Certificate of Need (CON) and related regulatory consulting;
- Litigation support and expert witness services; and,
- Industry research services.

The accredited healthcare professionals at HCC are supported by an experienced research and library support staff to maintain a thorough and extensive knowledge of the healthcare reimbursement, regulatory, technological and competitive environments.

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LEADERSHIP

TODD A. ZIGRANG, MBA, MHA, ASA, FACHE, is President of HCC, where he focuses on the areas of valuation and financial analysis for hospitals and other healthcare enterprises. Mr. Zigrang has over 20 years of experience providing valuation, financial, transaction, and strategic advisory services nationwide. Mr. Zigrang holds a Master of Science in Health Administration and a Master in Business Administration from the University of Missouri at Columbia. Mr. Zigrang is the co-author of *"The Adviser's Guide to Healthcare – 2nd Edition"* [AICPA – 2015], and has taught before IBA; HFMA; ACHE; NACVA; AHLA; the American Bar Association; and, Physician Hospitals of America.

John R. Chwarzinski, MSF, MAE, is Senior Vice President of HCC, where he focuses on the areas of valuation and financial analysis of healthcare enterprises, assets and services.

Mr. Chwarzinski holds a Master's Degree in Economics from the University of Missouri – St. Louis, as well as, a Master's of Science in Finance Degree from the John M. Olin School of Business at Washington University in St. Louis. He has presented before associations such as the National Association of Certified Valuators and Analysts; the Virginia Medical Group Management Association; and, the Missouri Society of CPAs. Mr. Chwarzinski's areas of expertise include advanced statistical analysis, econometric modeling, and economic and quantitative financial analysis.

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LEADERSHIP

Jessica L. Bailey-Wheaton, Esq. is Vice President & General Counsel of HCC, where she focuses on project management and consulting services related to the impact of both federal and state regulations on healthcare exempt organization transactions, and 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. She has presented before associations such as the American Bar Association and NACVA.

Ms. Bailey-Wheaton holds her Juris Doctor, with a health law concentration, from the Saint Louis University School of Law.

Daniel J. Chen, MSF, CVA, is a Senior Financial Analyst at Health Capital Consultants (HCC), where he develop fair market value and commercial reasonableness opinions related to healthcare enterprises, assets, and services. In addition he 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 and ancillary services and technical component (ASTC) revenue streams. Mr. Chen has a M.S. in Finance from Washington University St. Louis and he holds the Certified Valuation Analyst (CVA) designation from the National Association of Certified Valuators and Analysts.

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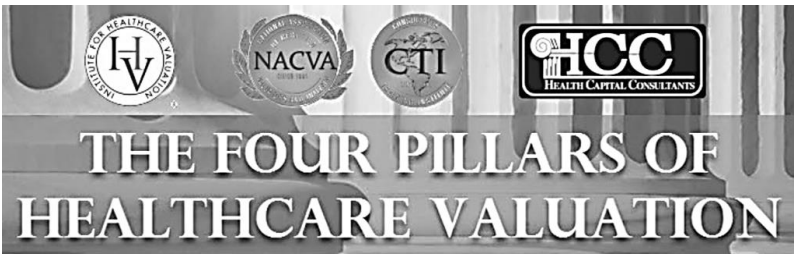
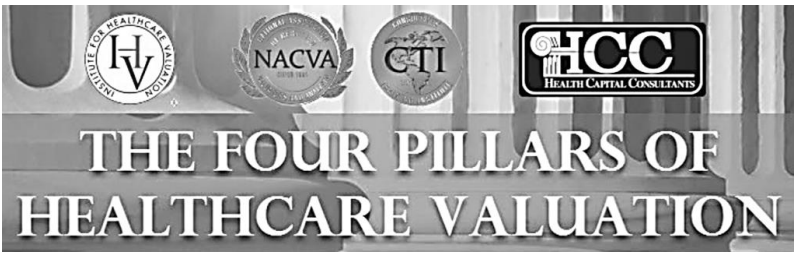


The Four Pillars of Healthcare Valuation -
Advanced Distance Education to Launch in 2019

The *Institute for Healthcare Valuation* (IHV) and *Consultants' Training Institute* (CTI) are pleased to announce premier healthcare valuation training through a distance education program, the *Certificate of Educational Achievement* (CEA) for *Advanced Education in Healthcare Valuation*. The program will launch in 2019 and will bridge the interdisciplinary nature of healthcare valuation to include: the Four Pillars of Healthcare (regulatory, reimbursement, competition, and technology); the market forces shaping the U.S. healthcare industry; and the valuation of healthcare enterprises, assets, and services. Legal professionals and healthcare providers, as well as those wishing to expand their scope of activities in healthcare valuation engagements and those seeking to enhance their current healthcare valuation service lines, will gain comprehensive knowledge through the expansive program.

"*In the current volatile regulatory environment, with the consolidation of hospitals, physicians, and other providers, the determination that the arrangements do not exceed Fair Market Value and are commercially reasonable are essential safeguards for the parties entering into these vertical integration transactions. It is critical that experienced, well-trained valuation professionals consult and collaborate with regulators and legal professionals before establishing and promoting so-called accepted methodologies and approaches*," states nationally-known healthcare attorney, David W. Grauer, Esq., of Jones Day. "*Valuation is a branch of financial economics, and it can be short-sighted and dangerous to develop an appraisal that does not reflect the economic foundations of the transactional elements to which statutes, regulations, and case law apply*," he continues.

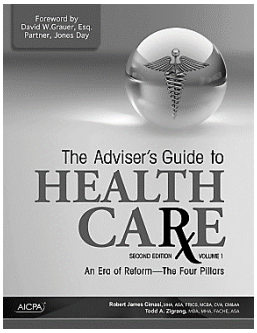
The program has been developed and is being presented by industry thought leaders **HEALTH CAPITAL CONSULTANTS** (HCC), alongside a blockbuster faculty made up of healthcare subject matter experts from the legal, federal regulatory, and valuation professions. According to Todd Zigrang:

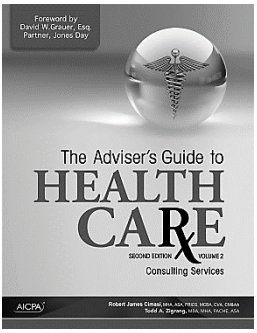


> "*With the rapid sea change resulting from the most recent iteration of healthcare reform and environmental drivers, the once well-defined, relatively stable business landscape of U.S. healthcare delivery now presents an unpredictable milieu of new provider consolidations and configurations, reimbursement strategies, and tactics to which the healthcare industry must adapt, and which impacts how those healthcare enterprises, assets, and services are appraised.*"

The training is comprised of eight core modules covering basic valuation tenets, competitive forces in healthcare, an overview of the regulatory environment, technological advancements in the industry, changes in reimbursement, development of a commercial reasonableness opinion, inpatient and outpatient enterprises, valuing intangible assets and tangible personal property, and the classification and valuation of healthcare services. Attendees will be able to customize their training by selecting from elective courses complimented by a robust series of topical webinars. Attendees who successfully complete the course requirements, assessment quizzes, and interactive case study will earn a CEA. As noted by HCC:

> *"The significant amount of time devoted to the discussion of healthcare during the 2016 U.S. Presidential Election is indicative of the importance of the U.S. healthcare industry, which is now approaching one-fifth of the U.S. gross domestic product. Regardless of the outcome of the election, healthcare industry valuation experts will remain in demand during this turbulent period in the healthcare industry, and specialized training for these experts will become more important to equip themselves to appraise healthcare enterprises, assets, and services."*





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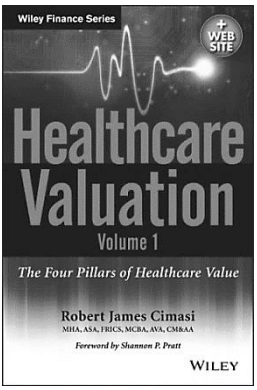

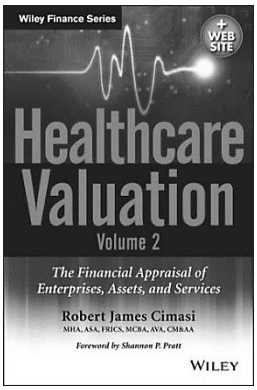

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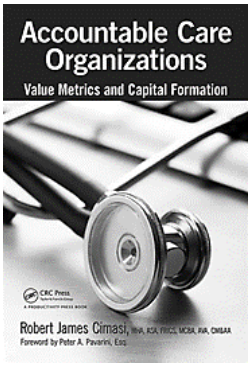

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